

GENERAL PRESCRIBED DOSE LIMIT RECOMMENDATIONS

1. The following is a list of the routine dose limit recommendations for adult studies. These are based on package insert information or on recognized standard practices.
2. Physicians may request higher (or lower) doses than normal if in his/her opinion the benefit of using this dose outweighs the risks involved.
3. Each radiopharmaceutical has a package insert section titled "Dosage and Administration". This section specifies a recommended dose and route of administration. Consult the package insert if questions arise regarding dose limits or for newly approved radiopharmaceuticals which are not listed.
4. This list does not include procedures that require a written directive. Each procedure requiring a written directive must have the dose prescribed by an authorized user prior to each administration.

Radionuclide	Chemical Form	Procedure	Range for Adult Dose	Recommended Dose
Carbon-14	¹⁴ C-urea capsule	Urea Breath Test	1 mCi	1 mCi
Technetium-99m	Pertechnetate	Brain Scan/Ceretec	15-30 mCi	25 mCi
GA-68 Dotatate Fluorine-18	GA-68 Dotatate 18F-PSMA	PET/Skull to thigh PET/Skull to thigh	4.32-6.4 mCi 7.2-10.8 mCi	5.4mCi 9 mCi
Fluorine-18	¹⁸ F FDG	PET/CT Brain	6.4-9.6 mCi 8mCi	
Fluorine-18	¹⁸ F FDG	PET/CT Heart Glucose Loading	8-12 mCi 10mCi	
Fluorine-18	¹⁸ F FDG	PET/CT Skull/Thigh	4-18 mCi Weight based	
Fluorine-18	¹⁸ F Axumin	PET/CT Prostate CA	9-13 mCi 10mCi	
Fluorine-18	¹⁸ F FDG	PET/CT Thyroid CA	4-18 mCi Weight based	
Fluorine-18	¹⁸ F FDG	PET/CT Wholebody	4-18 mCi Weight based	
Technetium-99m	Pertechnetate	G.I. Scan/Meckels	20-25 mCi (0.2 mCi per kg)	20 mCi <i>Adults</i> 3 mCi <i>Peds</i>
Technetium-99m	Pertechnetate	Thyroid Scan	2-10 mCi	10 mCi
Technetium-99m	Pertechnetate	Testicular	10-30 mCi	20 mCi <i>Adults</i> 15 mCi <i>Peds</i>

Radionuclide	Chemical Form	Procedure	Range for Adult Dose	Recommended Dose
Technetium-99m	Sulfur colloid	Peritoneal cavity	1-5mCi	2 mCi
Technetium-99m	Certec Blue (HMPAO) or DTPA	Brain Death	15-30 mCi	25 mCi
Technetium-99m	Bicisate (Neurolite)	Brain Scan	20-25 mCi	20 mCi
Technetium-99m	Sulfur Colloid	Liver/Spleen Scan	1-12 mCi	8 mCi
Technetium-99m	Sulfur Colloid	Bone Marrow Scan	5-12 mCi	10 mCi
Technetium-99m	Sulfur Colloid	Gastric Emptying (solid) 2-5 y / 6-14 y / 14 y>	0.8-1.2 mCi	1 mCi
Technetium-99m	Sulfur Colloid	Retro-Peritoneal/ LeVein Shunt	8-12 mCi	10 mCi
Technetium-99m	Sulfur Colloid Lymphoseek	Melanoma	113-145 μ Ci x 4 injections 125uCi	
Technetium-99m	Sulfur Colloid Filtered	Sentinel Node Detection / Lymphoscintigraphy	0.8-1.2mCi	1 mCi
Technetium-99m	Lymphoseek	Sentinel Node Detection / Lymphoscintigraphy	0.4-1.2 mCi	1 mCi
Technetium-99m	DMSA	acute pyelonephritis	2-6 mCi	5 mCi
Technetium-99m	Pentetate (DTPA)	Brain Scan	20-25 mCi	20 mCi
Technetium-99m	Glucaptate	Renal Scan	5-12 mCi	
Technetium-99m	Pentetate (DTPA)	Renal Transplant	15-20 mCi	
Technetium-99m	Pentetate (DTPA)	Renal Scan-Vascular Flow	15-20 mCi	15 mCi
Technetium-99m	Pentetate (DTPA)	Renal Scan-GFR Flow	2-10mCi	5mCi
Technetium-99m	Pentetate (DTPA)	Aerosolized DTPA	15-40 mCi	30 mCi
Technetium-99m	Macroaggregated	Lung Perfusion	3-6 mCi	4 mCi
Technetium-99m	Macroaggregated	Liver Mapping	3-6 mCi/2-3 mls	4 mCi
Technetium-99m	MAA	Venogram	1-2 mCi	2 mCi/limb
Technetium-99m	Pyrophosphate- In-vivo or Cold Kit	Myocardial Imaging- MUGA	15-25 mCi	20 mCi
Technetium-99m	Pyrophosphate- In-vivo or Cold Kit	Cardiac Amyloidosis	10-20 mCi	

Radionuclide	Chemical Form	Procedure	Range for Adult Dose	Recommended Dose
Technetium-99m	Tagged Red Blood Cells	Myocardial Imaging-MUGA	20-30 mCi	20 mCi
Technetium-99m	Tagged Red Blood Cells	G.I. Blood Loss	20-30 mCi	25 mCi
Technetium-99m	HDP	Bone Scan	10-30 mCi	25 mCi
Technetium-99m	Medronate (MDP)	Bone Scan	10-30 mCi	25 mCi
Technetium-99m	Medronate (MDP)	3 Phase	10-30 mCi	25 mCi
Technetium-99m	Medronate (MDP)	SPECT	10-30 mCi	25 mCi
Technetium-99m	Medronate (MDP)	Total Body	10-30 mCi	25 mCi
Technetium-99m	Disofenin	Hepatobiliary EF Kinevac / Fatty Meal / Morphine / Oddi.	2-8 mCi	6 mCi
Technetium-99m	Mebrofenin	Hepatobiliary EF Kinevac / Fatty Meal / Morphine / Oddi.	2-8 mCi	6 mCi
Technetium-99m	Succimer/MAG3	Renal Scan	5-12 mCi	5 mCi
Technetium-99m	Succimer/MAG3	Renal Scan / Diuretic	5-12 mCi	
Technetium-99m	Sestamibi/ Myoview	Myocardial- Rest Imaging	8-16 mCi	10 mCi
Technetium-99m	Sestamibi/ Myoview	Myocardial- Stress Imaging	24-36 mCi	30mCi
Technetium-99m	Sestamibi/ Myoview	Myocardial Imaging (two day protocol)	24-36 mCi/each dose	30 mCi
Technetium-99m	Sestamibi	Breast Imaging	10-30 mCi	25 mCi
Technetium-99m	Sestamibi	Parathyroid	20-30 mCi	25 mCi
Technetium-99m	HMPAO (Ceretek)	White Cell Label	20-30 mCi	25 mCi
Technetium-99m	Pertechnetate (Ultra-Tag Kit)	Red Blood Cell Label	20-30 mCi	20 mCi
Technetium-99m	Pertechnetate (Ultra-Tag Kit)	RBC Label – Liver	20-30 mCi	
Iodine-123	Sodium Iodide	Thyroid	200-400 μ Ci	200 μ Ci
Iodine-123	MIBG		3-12mCi	10 mCi

Radionuclide	Chemical Form	Procedure	Range for Adult Dose	Recommended Dose
		Brain Tumor/Adrenal Gland		
Iodine-123	Ioflupane	DaTscan	2.5-6 mCi	3-5 mCi
Iodine-131	Sodium Iodide	Uptake & Scan	50-100 μ Ci	100 μ Ci
Xenon-133	Elemental Gas	Liver	6-40 mCi	20 mCi
Xenon-133	Elemental Gas	Lung Ventilation	6-40 mCi	20 mCi
Indium-111	Oxine	White Cell Label	0.3-0.8 mCi	0.5 mCi
Indium-111	Pentetreotide	Brain (Octreoscan)	4-7 mCi	5 mCi
Indium-111	Pentetate (D.T.P.A.)	Cisternography	1-1.5 mCi	1 mCi
Thallium-201	Thallous Chloride	Myocardial-Stress	1-4 mCi	3 mCi
Thallium-201	Tl-201 Thallous Chloride	Myocardial-Rest	2-4 mCi	3 mCi
Thallium-201	Thallous Chloride	Myocardial Viability	2-4 mCi 1-2 mCi	3 mCi <i>Baseline</i> 1 mCi <i>4-hour</i>

* Patient dose can vary depending on age and weight.

Chart of Minimum Doses of Nuclear Medicine Agents	
Procedure/Radioimaging/Nuclear Medicine Agent	DOSE
Biliary Atresia / Tc99m MBF	2.0 mCi
Bladder – Cystogram / Tc99m Sulfur Colloid	1.0 mCi.
Bone / Tc99m MDP	5.0 mCi
Brain Death / Tc99m Ceretec	10.0 mCi
Gastric Empty / Tc99m Sulfur Colloid	0.5 mCi
Meckel's / Tc99m Pertechnetate	3 mCi
Renal / Tc99m MAG3	2 mCi
Thyroid Uptake / Image – Iodine-123	100 μ Ci
Tumor / MIBG – Iodine-123	2 mCi
PET / F-18 FDG	1.0 mCi

Radionuclide Dose Calculations for Pediatrics			
Weight		Surface Area Metus ²	Percentage of Adult Dose
Kg	lb		
2	4.4	0.15	9
4	8.8	0.25	14
6	13.2	0.33	19
8	17.6	0.40	23
10	22.0	0.46	27
15	33.0	0.63	36
20	44.0	0.83	48
25	55.0	0.95	55
30	66.0	1.08	62
35	77.0	1.20	69
40	88.0	1.30	75
45	99.0	1.40	81
50	110.0	1.51	87
55	121.0	1.58	91

From “Drugs for Children,” Dove, Alan K., in Modell, W. (Editor), Drugs of Choice, 1970-1971, St. Louis, C.V. Mosby Co., 1970.

If the weight of the child is not known, use the child’s age and apply Young’s rule:

$$\left(\frac{\text{Age of the Child (years)}}{\text{Age of the Child (years)} + 12} \right) \times (\text{Average Adult Dose}) \text{ OR}$$

$$\frac{X}{X+12} * \text{Adult dose, where } X = \text{child's age in years}$$

Authorized User

Date

Testing Methodologies Statement for Nuclear Medicine

All in-vivo, non-imaging studies use a radiometric methodology. The patient is given a radio-labeled compound such as urea and a specimen is collected. The specimen is analyzed and compared to a standard or known normal value. The analysis is then interpreted by a radiologist.

All in-vivo imaging studies use emission planar acquisition or single photon emission computerized tomography (SPECT). To conduct these procedures a radio-labelled compound is administered to the patient. The compound or agent is given an opportunity to localize within the body and then images of the photon (gamma ray) emission pattern are acquired with a scintillation camera. (Some studies include a CT to measure attenuation or give anatomical detail). The acquisition may be in rapid, short time frames or longer acquisition times to allow collection of higher levels of data. Analysis programs may be used to generate regions of interest, graphs, curves, and numerical comparisons. The data is digitally stored and displayed for physician interpretation. All data is displayed and stored on a Picture Archiving Computer.

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Revised : 11/2018

Approved by: S. Sheridan

**METHODIST MEDICAL CENTER
UNITY POINT HEALTH
NUCLEAR MEDICINE**

Review of Results:

Results and reports of Nuclear Medicine studies and procedures are reviewed routinely to detect clerical and significant analytical errors and unusual outcomes.

This review is performed by the radiologist or cardiologist prior to signature of the report. When errors are detected a correction addendum is made.

Image and Report Availability:

All Nuclear Medicine studies, procedure outcomes and reports are put on the Radiology Picture Archiving Computer System (PACS) for indefinite storage. This complies with Iowa Codes.

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NUCLEAR MEDICINE**

Proper Image Labeling:

Patient demographic information will include middle initial if one is provided.

Prior to verification of the image file in the PACS:

1. label the view/orientation and left/right side indicators
2. label all anatomical markers
3. describe any special technique that was used to accomplish the image
4. annotate the radioagent used and the amount
5. annotate the use of interventional drugs; amount, route of administration and time in relationship to the administration of the radioagent
6. annotate any unusual events during the acquisition
7. annotate artifacts and possible causes
8. on dynamic images annotate number of frames and time per frame

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Administration of Radioagents to Humans

Guidelines Adopted from the U.S. Nuclear Regulatory Commission circular No. 79-01

1. Immediately after removing a radioagent from the shipping container, confirm that the compound is the correct agent as per the order request. Enter all radioactive agents in the Radiopharmacy ("hot lab") inventory records. If the product received is not the same as ordered, return it to the shipping container and notify the vendor.
2. Confirm that the radio-agent is intended for human use.
3. Verify that the radioisotope, chemical form and quantity of agent received are the same as described in the testing protocol and prescribed by the nuclear medicine physician. Refer to the Nuclear Medicine Manual to review the agents and supplies needed for each test protocol.
4. The radio-agent must be manufactured and distributed under a license issued by the Nuclear Regulatory Commission or an agreement state. This can be verified by referring to labels and other product information supplied with the products.
5. Follow all guidelines and policies in the Nuclear Medicine Manual to assure that the correct agent and substances are administered to the correct patient.
6. Procedures to administer testing agents and the procurement of blood from patients **must follow aseptic technique**. A minimum requirement is the preparation of the injection site, skin or port, with 70% isopropyl alcohol. **Maintain sterility of all items after removal from packaging.**
7. Administration of a unit dose radiopharmaceutical may be only attempted on one person. After the first attempt the integrity of the unit is lost and may not be used on another individual.

Procedure for Requesting Nuclear Medicine Studies

1. The Nuclear Medicine diagnostic modalities offered on site are enumerated in the table of diagnostic procedures in this section of the procedure manual. These procedures may be ordered by a member of the medical staff, a member of the house staff, and licensed independent practitioners who are not members of the medical staff, but whom the Medical Center has authorized to request such services.
2. Nuclear imaging studies may be requested in two ways.
 - A. Verbally:
 1. A physician may request a study by coming to Nuclear Medicine and personally requesting the type of study desired. (The written order will subsequently be written in the medical chart.)
 2. A telephone order to Nuclear Medicine may also be used to request the procedure. (The test order will subsequently be written on the medical chart.)
 - B. Written:
 1. An order for testing must be placed in the patient's chart. The order will be noted by nursing personnel and put into Epic/Radiant order/entry.
3. Qualified physicians or their representatives may order and schedule diagnostic Nuclear Medicine tests for outpatients via telephone by contacting Outpatient Registration Services at 241-6111.

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Please see Department Safety Management Plan Radiology/Nuclear Medicine-Iowa Methodist Med Ctr on the HUB

Please see Isolation Standard Precaution on the HUB

Central Iowa Health System Nuclear Medicine Emergent Studies Policy

There are several Nuclear Medicine diagnostic procedures, which may need to be performed as emergent studies outside of the department's routine hours of service. A nuclear medicine technologist is "on call" each day to respond to these requests. A call schedule is on file in Nuclear Medicine and at the Radiology front desk. A pager is provided to the individual on call in or the use of their cell phone is used in order to assist in locating and communication when a "call-back" to the Department is needed. Emergent studies are to be performed in an efficient manner. A satisfactory on-site response time is considered to be 30-minutes.

Emergent studies performed after hours will be read by the radiologist on call from the PACS system and ordering physician will be notified of the results within the EPIC patient chart.

1. Emergent radiopharmaceutical doses are obtained from Cardinal Radiopharmacy.
2. After all the images in the study have been acquired, transfer the files to PACS.
3. The emergent study is considered complete after each step is performed in accordance with the test protocol and the regulations and conditions of radioactive materials license.

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Timelines for Documentation of in-vivo Radionuclide Doses

1. Every patient dose that leaves the Radiopharmacy will have an identification label with the following data: radionuclide and chemical form, amount (millicuries or microcuries) time and date of preparation, and initials of technologist who assayed the dose. Peaking sources and other in vitro radionuclides will be labeled with the radionuclide, amount, and date. Proper shielding will be used. Doses to be administered in Nuclear Medicine will be taken to injection areas only. These areas are Cardiac Stress room, Rooms 1, 2, 3 and injection room.
2. When red blood cell labeling is carried out the patient's name and medical record number will be fixed to all containers (vials, syringes) that receive the blood.
3. Syringes and other intravenous puncture apparatus will be disposed of properly and immediately after the injection has been completed. This is an important step to prevent accidental assumption that the syringe still contains a newly prepared dose.
4. After the doses have been entered in the synTRAC, the dose ID label will be affixed to the patient's Nuclear Medicine request form.
6. The imaging agent and amount of radiation will be noted on the PACs images so the radiologist will have that information readily available during interpretation. When this is done the test request does not need to be in the possession of the radiologist. This is very helpful in callback situations.

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Iowa Lutheran Hospital, Iowa Methodist Medical Center and Methodist West Nuclear Medicine Imaging Overview

Warnings:

Nuclear Medicine studies should never be performed on pregnant patients when other diagnostic alternatives are available. Radio-imaging agents should not be administered to patients who are pregnant or who may become pregnant or during lactation unless the information to be gained outweighs the possible potential risks from the radiation exposure. The referring physician must consult with a radiologist to make this determination.

If a radiologist approves a nuclear medicine test on a pregnant patient, the nuclear medicine technologist must receive a verbal approval from the radiologist before the procedure can be initiated. **The name of the radiologist must be documented in the patient's PACS record.** The Radiation Safety Policy requires an "Informed Consent" form (Department of Radiology, 2.Appendix A) must be completed with the patient's signature. This form is also included in the PACS record.

Ideally, examinations using radioactive agents, especially those elective in nature on a woman of childbearing capability, should be performed during the first few (approximately 10) days following the onset of menses. All female patients in the childbearing age of 12-50 years inclusive must be asked if they could be pregnant. If the patient cannot answer "no" with certainty, the patient may elect to have a laboratory pregnancy test performed or reschedule the testing.

No administration of agents containing Iodine 131 or Iodine 125 will be made to women of childbearing capability in the 12-50 age group unless there is a recent (24-72 hours) negative HCG (blood) test. (See the Radioiodine Quality Management Program) Administration of Iodine 131 above 30 microcuries must follow the Iodine QMP. This includes the completion of the Physician's Written Directive.

Handling of Radionuclides:

Nuclear Medicine agents should be used only by persons who are qualified by specific training in the safe use and handling of radionuclides.

Precautions:

Care should be taken to ensure minimum radiation exposure to patients consistent with proper patient management, and to ensure minimum radiation exposure to Nuclear Medicine employees, other employees and visitors. Portable shielding boxes, syringe shields and fixed workstation shields are provided in the work areas.

Breast Feeding:

Breast feeding should be interrupted for an amount of time appropriate for the radiopharmaceutical used. For a few diagnostic studies (e.g., ^{131}I whole body imaging), breast-feeding must be stopped for 1-2 months; therefore, it is impractical to resume breast-feeding for that child.

Current Nuclear Regulatory Commission regulations require that written instruction be given to breast feeding women if the potential radiation dose to the infant is likely to exceed 5mSv (500 mrem); oral instructions are required if the potential radiation dose to the infant is likely to exceed 1 mSv (100 mrem). Pathways for exposure include ingestion of contaminated breast milk and external exposure due to close contact during breast-feeding. There is considerable uncertainty about the actual dose to the infant since little data is available for excretion into breast milk for most radiopharmaceuticals.

Patient Identification:

Verification of patient identification (ID) is a required first step in any Nuclear Medicine procedure. To verify identity with the double method, check the wrist ID bracelet. This data must match the information on the test requisition and medical chart. Ask the patient to state name and birth date.

Administration of Blood Products:

Dual identification checks are required prior to administration of radio-labeled blood products such as Technetium $^{99\text{m}}$ RBC, $^{99\text{m}}$ Tc WBC and Indium 111 WBC. This means that two individuals will double identify the patient and match the radio-labeled blood product to the patient.

Radio-imaging Agents:

Each patient radio-imaging agent dose must be measured by a suitable radioactivity calibration system within 30 minutes prior to administration and be within established dose ranges given by the supervising radiologist.

Test Orders:

The information included on the electronic (EPIC) order is sufficient to verify valid indications. Any changes/modifications to the order should be discussed with the ordering provider.

Documentation:

The technologist who performs administration (LV.oral etc) of the radio-imaging agent shall be responsible for entering the necessary documentation of patient and agent data into the SynTRAC system or downtime forms.

References:

1. Iowa Bureau of Environmental Health Memorandum, June 12, 1987.
2. Operator's Manual SynTRAC Nuclear Medicine Data Manager.
3. Product inserts for all imaging agents.
4. SNM Procedure Guideline for General Imaging.
5. UPHDM Radiology Radiation Safety Policy.
6. The British Journal of Radiology, May 2002
7. Neonatal Lactation and Radioactivity, AMA-Texas Tech University Health Science Center, Table 3; January 2003.

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NM Imaging Overview

Nmpro

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R: 10/2005; 05/2011;
12/2013; 11/2018

Peritoneal Cavity Imaging

Principle:

Peritoneal cavity scintigraphy is indicated for assessing whether there is direct communication between the peritoneal cavity and an extraperitoneal fluid collection (e.g. pleural effusion, hydrocele). Sulfur colloid is injection into the peritoneal cavity will normally distribute throughout this space. Abnormal connection of the peritoneal cavity with the pleural space or the scrotum are demonstrated by the presence of the tracer in these regions.

In patients who are being evaluated for abnormal fluid collection associated with peritoneal dialysis, it is desirable to evaluate the patient during the normal dialysis procedure. The sulfur colloid should be injected into the dialysis catheter and should be flushed into the peritoneal cavity with the usual volume of the dialysate. Images of abdomen should be obtained 2-4 hours after the infusion of the dialysate has been completed and again after the dialysate has been drained. The drained dialysate can be disposed of in the usual manner.

Patient Preparation: None

Patient Scheduling:

This study should be scheduled only after consultation with radiologist. The indication for this study needs to be clearly understood since the indication with affect how the study is performed. At the time that the study is schedule, the physician who will provide access to the peritoneal space needs to be present. CPT code and IMG code.

Equipment:

1. Gamma camera: LFOV camera in adults or 1.4 zoomed in small children.
2. Low energy all purpose, 140keV with 20% window. 256x256 matrix, 5min images.
3. Dose range: 1-5mCi Tc99m Sulfur colloid.

Supplies for physician:

1. Alcohol prep, and drape for the catheter needed. Radiologist to inject Tc99m Sulfur colloid.

Procedure:

1. Place the patient supine for injection and imaging on camera table.
2. Immediate images, and 30-minute images:
 - a. Anterior abdomen and chest.
 - b. Anterior abdomen and chest with xyphoid marker or transmission source.
3. Possible addition images as needed at 2 & 4 hours post-injection.
 - a. Anterior abdomen and chest
 - b. Anterior abdomen and chest with xyphoid marker or transmission source.

Result: This is a physician interpreted study.

References: University Health Shreveport protocol. Revision: 10/2014

Red Blood Cell Labelling with Technetium-99m Pertechnetate Using Ultratag

Principle:

Technetium-99m (Tc-99m) Pertechnetate-labeled red blood cells (RBCs) have become the agent of choice for blood pool scinti-imaging. This technique is utilized in gastrointestinal bleeding detection and in multigated acquisition of information from the heart. From detailed studies of in vitro labeling kinetics, it has been shown that Pertechnetate distribution artifacts can be reduced significantly by incubating the desired Pertechnetate radioactivity with a volume of in vitro-tinned patient (autologous) blood. The incubation takes place in a closed system before reinjection. This in vitro method of labeling RBCs does not tin the entire red cell volume of the patient and, as a result, does not affect subsequent Nuclear Medicine studies which use Pertechnetate. This method uses materials and supplies common to Nuclear Medicine laboratories and an FDA-approved kit.

Patient Preparation:

None. The patient does supply 1-5 ml of whole blood obtained during a phlebotomy.

Equipment, Reagents, and Supplies:

1. Reaction vial, syringe I, and syringe, I of FDA-approved (Mallinckrodt Medical, Inc., catalog #068) Ultratag RBC kit.
2. One large bore (19-21 gauge) needle.
3. One lead vial shield (minimum wall thickness of 1/8 inch) with a lead cap.
4. Dose of Tc-99m Pertechnetate, 20-30 millicuries (740-1,110 MBq) in a volume up to 3 ml.
5. Heparin (1000:1), 10-15 units per ml of whole blood to be drawn.
6. Dose calibrator.
7. Face/body splash shield and gloves.
8. Yellow isolation gown or other impermeable outer barrier.
9. Syringe shield and dose carrier designated for use with blood products to comply with USP 797.
10. Test tube rocker/agitator, optional.

Notes:

1. Sterile technique must be used in all steps of this procedure.
2. USP 797 requires that blood manipulations be clearly separated from routine procedures and that they be controlled by specific standard operating procedures avoid cross-contamination. Position the RBC-tagging work area as far from routine procedures as possible.
3. The implementation of universal precautions is required when handling and manipulating blood. See section 7I of this Nuclear Medicine Manual.

Red Blood Cell Labelling with Technetium-99m Pertechnetate Using Ultratag - 2

4. To maintain sterility of the patient's blood specimen, the syringe needle may be recapped but only with the use of a needle guard holder such as the Syringe-Mate or the "one hand" technique.
5. All syringes, vials, and tubes which will contain the patient's blood during this procedure will be identified with the patient's name, birthdate, medical record number, and date.

Procedure:

1. Collect 3-5 ml of the patient's blood into a syringe which contains enough heparin to make a ratio of 10-15 units of heparin per ml of blood. During processing/labeling of the blood specimen, the technologist must use face/body splash shields at the work station and wear gloves and a yellow isolation gown or other impermeable outer barrier.
2. Gently mix the blood with the heparin by inverting the syringe 4-5 times. Do not use EDTA or oxalate as an anticoagulant. Using a large bore needle (19-21 gauge), transfer 1.0 to 3.0 ml of anticoagulated whole blood to the reaction vial and gently mix to dissolve the lyophilized material. Allow to react for five minutes.
3. Add contents of syringe I; mix by gently inverting 4-5 times.
4. Add the contents of syringe II to the reaction vial; mix by gently inverting 4-5 times.
5. Place the vial in the lead shield and add the dose of 20-30 millicuries (mCi) of Tc-99m Pertechnetate in a volume of up to 3 ml to the reaction vial. Cover the shield with a lead cap. The use of fresh Sodium Pertechnetate is recommended.
6. Mix by gently inverting the reaction vial 4-5 times. Allow to react (incubate) for 20 minutes with occasional mixing or positioned on a gentle mechanical rocker/ agitator.
7. Use the only syringe shields and dose carrier that are identified for use with "Blood Products."
8. Withdraw all the labeled RBC solution and assay in a dose calibrator. The activity should be between 15-25 mCi. Technetium 99m-labelled red blood cells should be re-injected within 30 minutes of preparation.
9. To prevent misadministration and the risk of patient exposure to bloodborne pathogens, the administration of biologic products (labeled red cells) will be handled similarly to the administration of blood products. This system requires that two persons will cross-check the identification of labeled RBCs (dose) to be injected and patient identification.
10. The only exception to this system will be when only one patient and one Nuclear Medicine person are in Nuclear Medicine the entire time of preparation.

Red Blood Cell Labelling with Technetium-99m Pertechnetate Using Ultratag - 3

References:

1. "Seminars in Nuclear Medicine," August 1984.
2. Journal of Nuclear Medicine, 25:881-886, 1984.
3. Product insert for Ultratag RBC kit, Mallinckrodt Medical, Inc.
4. Operator's manual for Capintec CRC-12R dose calibrator.
5. MMWR, Vol. 41, No. 31, pp. 575-578.
6. Bloodborne Pathogens program in Section II of this manual, (based on requirements of the Occupational Safety and Health Administration, 29 CFR 1910.1030).
7. USP 797.org website.
8. "Frequently Asked Questions (FAQs) about USP 797", prepared by Joseph C. Hung, Division of Nuclear Medicine, Department of Radiology, Mayo Clinic, Rochester, Minnesota and James A. Ponto-Section of Nuclear Medicine, Department of Radiology, University of Iowa Hospitals and Clinics.

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Updated by: Stephen A. Kuhn, October 1992; January 2006; February 2010; May 2014, 11/2018

Approved by: S.Sheridan



TECHNICAL BULLETIN UltraTag RBC Kit

The package insert for UltraTag RBC (kit for the preparation of Tc-99m red blood cells) recommends that heparin or Anticoagulant Citrate Dextrose solution (ACD) be used to collect the blood sample. Since market introduction of the UltraTag RBC Kit in June 1991, Mallinckrodt Medical has received a number of requests for guidance on the quantity of anticoagulant which should be used to draw the blood sample. This technical bulletin provides information on the appropriate amounts of each anticoagulant to use during blood collection. An update on the relationship between the anticoagulant used and RBC labeling efficiency is also provided.

Quantity of Anticoagulant

Heparin:	10-15 units/mL of blood
ACD Solutions:	0.15 mL ACD/mL of blood

Excellent *in vitro* Tc-99m RBC labeling efficiency has been obtained using each of the ACO formulations listed below:

- USP ACD, Solution A
- USP ACO, Solution 8
- Squibb's Modified ACO
- Mallinckrodt Medical's Modified ACD

Anticoagulant Selection Labeling Efficiency

Some technical issues need to be considered when selecting an anticoagulant for collection of the blood for Tc-99m tagging using the UltraTag RBC Kit. When Tc-99m solutions contain appreciable amounts of Tc-99 carrier, it has been reported that heparin provides more effective, reliable labeling efficiency than ACO¹. Whenever a technetium generator is eluted for the first time, following several days of no elution, the presence of Tc-99 carrier in the eluate will be significant. This situation commonly occurs upon first elution of a generator as it is received on Monday morning. Appreciable Tc-99 carrier levels may also be present in situations where "instant technetium" is used.

The reported difference in performance between ACD and heparin in the presence of appreciable Tc-99 carrier has been confirmed by Mallinckrodt Medical, Inc. In addition, the original inventors of the UltraTag RBC chemistry, at Brookhaven National Laboratory, have compared the effectiveness of ACD and heparin during "tinning" of the RBC's². During this initial "tinning" step, stannous ions enter the RBC's. It was found that higher intracellular stannous levels were obtained

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using heparin. The higher intracellular stannous levels obtained with heparin "tinning" are consistent with the observation that heparin preparations better tolerate high concentrations of Tc-99 carrier.

Mallinckrodt Medical, Inc. also showed less than optimal Tc-99m labeling results when excess ACD was used to collect the blood (i.e., above 0.15 ml ACD/ml of blood). In similar studies, Tc-99m RBC labeling efficiency was not affected by using excess quantities of heparin during blood collection.

Based on these findings, heparin is the preferred anticoagulant. ACD may still be used, but must be used with certain restrictions. ACD must not be used above a ratio of 0.15 ml ACD/ml of blood and should not be used with Tc-99m solutions that contain appreciable amounts of Tc-99 carrier, such as technetium eluate obtained from a generator that was not eluted any time during the 3 previous days.

In order to assure the Tc-99m labeling efficiency of the red blood cells, labeling efficiency may be determined prior to injection using the procedure described in the UltraTag RBC package insert. For further information or technical assistance regarding the kit, please contact Mallinckrodt Medical's Professional Services Department at 800-325-3688.

(Please see full prescribing information)

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1. Wilson, M.E. and Hung, J.C., letter to the Editor, J Nucl Med, 1991 (in press).
 2. Srivastava, S.C. and Straub, R.F., Reply to Letter to the Editor, J Nucl Med, 1991 (in press).
 3. Masouredis, S.P. Preservation and Clinical Use of Erythrocytes and Whole Blood, In: Hematology, 4th edition, V.I. Williams, A.J. Ersler, M.A. Lichtman, Editors, McGraw Hill, New York, 1990, pp. 1628-1647.

Arteriogram with Radionuclide

Principle:

The radionuclide tracer imaging modality can be used to visualize arteries to the level of the popliteal artery in the legs and to the level of the ulnar and radial arteries in the arm. A rapid, unimpeded flow is interpreted as absence of significant disease. Total occlusions are readily apparent. Aneurysms are seen as a widened lumen, which represents the aneurysmal sac, or as a narrowed tortuous lumen surrounded by an area of relatively decreased activity which represents clot within the aneurysm. The radionuclide arteriogram is useful in the postoperative evaluation of surgical bypass graft patency. It is also a much more acceptable follow-up examination than contrast angiography because it can be repeated frequently and is better tolerated.

Equipment, Supplies and Reagents:

1. Radioisotope camera and imaging computer with LEAP or GAP collimator.
2. Dose range of 20-30 millicuries of Technetium-99m (Tc-99m) agent, which can be Pertechnetate, Glucoptate, DTPA, or Technetium-labelled autologous red blood cells (RBC's). The radiologist may have a preference. Adjust the dosage for pediatric patients by using the weight/dose chart.
3. Blood pressure cuff and intravenous administration items including 0.9% NaCl for irrigation and flushing.
4. PACS image review and archiving system.

Patient Preparation:

None

Procedure:

1. Verify patient identity using two methods and verify inpatient orders.
2. Explain the test procedure to the patient and answer appropriate questions.
3. Set up the radioisotope camera to detect the 140 keV photons of Tc-99m with a 15% window. Use the camera/computer protocol to set the other parameters such as time/frame and format.
4. Obtain directions from the radiologist to determine which artery is of interest and what will be the best view to use.
5. Position the patient and place an intravenous administration set with a NaCl flush in an appropriate location. Inject the Tc-99m imaging agent with a bolus technique. Start the camera/computer early enough to record the very first appearance of the tracer in the field of view. Acquire other images as needed. Produce screen captures and transfer images files to the PACS.
6. Dismiss the patient and prepare the equipment and room for the next examination.

Interpretation:

This is a physician-interpreted study.

Arteriogram with Radionuclide – Page 2

References:

1. Operator's Manual, radioisotope camera/computer.
2. Operator's Manual, PACS.
3. Nuclear Medicine, William H. Blahd, M.D., 2nd Edition.
4. Seminars in Nuclear Medicine, Vol. VI, No. 2, April 1976.
5. Textbook of Nuclear Medicine, Vol. II, Clinical Applications, J. Harbert, M.D. and A. F. G. DaRocha, M.D., 2nd Edition, 1984.

Written by: Stephen A. Kuhn, December 1987

Updated by: S. Sheridan 4/2019

Abscess Imaging With Indium-III Tropolone Autologous Leukocytes

Principle:

1. Leukocytes function primarily in the localization, destruction, and removal of microorganisms and damaged cells. The leukocyte chemotactic, phagocytic, and microbial destruction functions all play a role in the body's defense mechanisms. Using Indium-III Tropolone as a radio-labelling agent, it is possible to image the whole body distribution of leukocytes. The Tropolone carries the Indium-111 across the leukocyte (white blood cell) cell membrane. The labeled cells retain viability and function. The labeled leukocytes are administered intravenously to the patient and normally distribute to the liver, spleen, and functioning bone marrow. Some cells will continue to circulate in the blood. Any collection of labeled leukocytes outside of these areas indicates an area of abnormality to which the patient's white blood cells are being attracted.
2. Leukocyte imaging is useful in a spectrum of inflammatory diseases including abscess localization, acute and chronic osteomyelitis, and evaluation of the activity of inflammatory bowel disease.
3. If symptoms do not point to a specific location, then a radionuclide leukocyte examination, which will encompass the entire body, is performed. Labeled white cells will effectively demonstrate pyelonephritis and cystitis.

Patient Preparation:

No preparation required. A patient phlebotomy is performed to obtain whole blood for white cell labeling by the Cardinal Radiopharmacy.

Equipment, Reagents, and Supplies:

1. Blood collection items: 60 cc syringe and needle or butterfly set, Typenex green, identification bracelet for specimen/patient/dose identification, biohazard plastic bag, test worksheet, and Indium WBC information forms. Cardinal Radiopharmacy supplies the Typenex green bracelets, biohazard plastic bag, and the WBC information forms in a kit. Call for replacement deliveries of these items when inventories become low.
2. Heparin: two, 2ml vials.
3. Butterfly infusion set, 16g-23g.
4. Antiseptic swabs
5. Radioisotope camera/computer, medium collimator.
6. PACS image review and archiving system
7. Geiger-Muller radiation-detection instrument

Notes:

1. Pregnancy is not an absolute contraindication. All fetal radiation should be avoided where possible. The radiation dose to the fetus from labeled white cells will be equivalent to the radiation from a single abdominal x-ray. Consult with a radiologist.
2. Sterile technique must be used in all steps. To maintain sterility of the patient's blood specimen, the syringe needle may be recapped but only with the use of a needle guard holder, such as the Syringe-Mate, or the "one hand" technique.

4. The patient's labeled-white cells must be re-injected within 5 hours of the

phlebotomy. **Procedure:**

1. Verify patient identity using two methods and verify inpatient chart orders. Obtain the most recent WBC and neutrophil count report. If the WBC is less than 1,000 and the calculated absolute neutrophil count is below 1,000, the patient will not have enough leukocytes to provide for labeling. (If the WBC and neutrophil counts are over 1,000, proceed to step 6 to label autologous white blood cells.) When the patient's own number of WBCs is not adequate, the study can only be performed by obtaining a donor unit of blood from which WBCs can be provided for radio-labelling. The unit must be fresh (less than 24 hours old). Fresh blood cannot be refrigerated because leukocyte labeling will not occur. Donor blood for labeling must be drawn during the daytime. The donor blood must be typed and cross-matched to the patient. No fresh blood is available on Sundays or Mondays.
2. The ordering physician should be consulted by the radiologist before proceeding with labeling of donor white cells. A physician must write a cross-match order. Contact the Immunohematology section to determine the type of blood needed. Immunohematology will contact The Blood Center to search for a unit of fresh blood. When a unit is located, Immunohematology will do the crossmatch and notify Nuclear Medicine.
3. Withdraw 50 cc of blood from the donor bag into the 60-cc syringe. Do not use heparin. In cases when the whole blood donor units do not sediment well, it may be necessary to have Immunohematology take off theuffy coat and use this fraction of the donor unit for radio-labelling.
4. Use a Typenex green identification label to comply with specimen identification requirements. Write the patient's name and medical record and "Nuclear Medicine" on the label portion of the band. Affix this pressure-sensitive label to the syringe/blood specimen and place the bracelet on the patient's wrist. Cut off the excess length of strap, which contains small, green alphanumeric 1D labels. Affix one small label to the patient's test requisition and one on the "WBC information form", and send the remainder to Cardinal Radiopharmacy to be used during the WBC processing.
5. If the syringe has a needle, remove it (approved exception to the "no removal" rule) and position a clean, red syringe cap on the opening. Put the capped syringe in a biohazard plastic bag, seal the bag shut, and place the sealed-side up in the syringe carrying case provided by Cardinal. Attach a security tag. Keep the syringe and the carrying case in an upright position so the blood can begin to settle properly. Store the case in an upright position to facilitate sedimentation. The Cardinal transporter will bring a replacement transport case.
6. If the patient has adequate WBCs for labeling, verify the patient's identity and verify inpatient test orders. Explain the test procedure to the patient and answer appropriate questions. Perform a phlebotomy to obtain autologous leukocytes.
 - a. Preparation of the syringe: to perform Indium-111 leukocyte imaging, aseptically transfer the heparin into the 60-ml syringe. For adult testing, obtain approximately 50 ml of the patient's blood. This can be taken from PIC lines or Ports with a nurse's permission. A triple antiseptic scrub should be used before performing an intravenous puncture on leukocyte patients. Using three consecutive swabs, apply the antiseptic solution in a spiral pattern with an increasing diameter starting at the intended

- puncture site. During collection, provide periodic, gentle agitation of the heparin solution and blood.
- b. Immediately after completing the phlebotomy, the syringe must be inverted gently several times to mix the blood and heparin. Use a Typenex green identification bracelet to comply with specimen identification requirements. (In addition to the patient's name, medical record number, and date, include the name of the hospital, so Cardinal will know the origin of the specimen.) Write the patient's name and medical record number and "Nuclear Medicine" on the label portion of the band. Affix this pressure-sensitive label to the syringe/blood specimen and place the bracelet on the patient's wrist. Cut off the excess length of strap, which contains small, green alphanumeric ID labels. Affix one small label to the patient's test requisition and one on the "WBC information form", and send the remainder to Cardinal Radiopharmacy to be used during the WBC processing. Complete a test worksheet and a Cardinal Indium111 Tropolone leukocyte information form.
 - c. For pediatric testing, draw 20 ml of the patient's blood into about 2 milliliters of heparin. This can be taken from PIC lines or Ports with a nurse's permission. The triple scrub should be used before doing an intravenous puncture. Using three consecutive swabs, apply the antiseptic solution in a spiral pattern with an increasing diameter starting at the intended puncture site. Immediately after completing the phlebotomy, the syringe must be inverted gently several times to mix the blood and heparin. Use a Typenex identification bracelet as described above. Send the remainder to Cardinal to be used during the WBC processing. Keep the syringe and the carrying case in an upright position so the blood can begin to settle properly. If no transport case is available, processing time may be saved by starting the RBC sedimentation with the syringe at about a 90-degree angle with the capped end up.
(If a huffy coat fraction is used, sedimentation will usually be achieved at Cardinal's laboratory.) The Cardinal transporter will bring a replacement transport case. Complete the test worksheet and the Cardinal Indium leukocyte information form.
7. The Indium-III labeled leukocytes will be returned about two and one-half hours later. Verify the amount of Indium-III radioactivity before injecting it. To assure no incidences of misadministration and the risk of patient exposure to blood-borne pathogens, in addition to the green Typenex system, the administration of biologic products (labeled cells) will be handled similarly to the administration of blood. This system requires that two persons be present for crosschecking the identification of labeled WBCs (dose) to be injected and the patient identification.
 8. If a PIC catheter or Port are not available, reinject with a butterfly setup. Indium WBC doses are very expensive and difficult to replace, and care must be exercised to completely administer the entire dose to ensure the best quality images.
 9. To assure complete infusion without significant infiltration of the Indium-III-WBCs, obtain radiation readings with a Geiger-Muller detection instrument over the injection site and the anterior chest. The chest reading should be the higher value. A planar image of the reinjection site and anterior chest may be used as an alternate method to check for a high quality re-injection. This quality control may be performed 1-2 minutes after completion of the reinjection.
 10. The quality and diagnostic value of the images will be optimized if imaging is performed on the day after injection of the labeled cells (18-24 hours).

11. Set up a radioisotope camera (whole body imaging systems are preferred) to detect the 171 and 245 keV photons of Indium-111 with a 20% window and a medium-energy collimator. Follow the individual camera charts or protocols for other parameters such as speed, total counts, and intensity.
12. Anterior and posterior whole body images are routinely performed. Additional spot views of the upper and lower abdomen as well as extremity images are performed as indicated.
13. Produce screen capture files of all images and transfer them to the PACS for review by the radiologist. Perform other imaging as directed.

Results:

This is a physician-interpreted study.

Limitations:

1. False-negative examinations may result when the chemotactic function of the white blood cell has been altered. A number of causes for this have been reported including hemodialysis, hyperglycemia, hyperalimentation, and steroid therapy. Patients on long-term antibiotic therapy may fail to attract white cells to indolent abscesses.
2. False-positive studies of the abdomen may occur in patients with gastrointestinal bleeding and in patients with upper respiratory infections or pneumonitis who swallow purulent sputum. In these instances, repeat images to monitor movement of radioactivity through the gut will differentiate between an abdominal abscess and white cells, which have entered the gut through bleeding or swallowing.

References:

1. Operator's Manual, radioisotope camera/computer.
2. Operator's Manual, PACS system
3. Product literature supplied with Indium 111 Tropolone.
4. Blood borne Pathogens Program as published on December 6, 1991 (based on requirements of the Occupational Safety and Health Administration, 29 CFR 1910.1030).
5. Journal of Nuclear Medicine, 1:122-125, 1980.
6. Journal of Nuclear Medicine Technology, Volume 32, No.2, June 2004.
7. "Clinical Nuclear Medicine Updates," Central Chapter, Society of Nuclear Medicine, #0016, March 1985.
8. Seminars in Nuclear Medicine, Vol43, No 2, March 2013.

Written by: Stephen A. Kuhn, December 2003

Updated: February 2005; October 2006; May 2007; November 2014, 11/2018

Approved by: S.Sheridan 4/2019

Technetium-99m Ceretec (HMPAO) Autologous Leukocyte Imaging

Principle:

Leukocytes function primarily in the localization, destruction, and removal of microorganisms and damaged cells. The leukocyte chemotactic, phagocytic, and microbial destruction functions all play a role in the body defense mechanisms. Using Technetium-99m (Tc-99m) Ceretec (HMPAO) as a radiolabeling agent, it is possible to image the whole body distribution of leukocytes. The radioactive Ceretec crosses the leukocyte (white blood cell) membrane where it preferentially binds to cytoplasmic proteins. The radiolabeled cells retain viability and function. The labeled leukocytes are administered intravenously (I.V.) to the patient and normally distribute to the liver, spleen, and functioning bone marrow. Nonspecific bowel accumulation appears mainly after two hours following re-injection. Some cells will continue to circulate in the blood. Any collection of labeled leukocytes outside of these areas indicates an area of abnormality to which the patient's white blood cells are being attracted. Ceretec WBC in the gut is a normal finding therefore, it is usually reserved for indications involving the extremities. Indium-111 Tropolone WBCs are used for whole body imaging indications such as inflammatory diseases (including abscess localization), acute and chronic osteomyelitis, and evaluation of the activity of inflammatory bowel disease. Labeled white cells will effectively demonstrate pyelonephritis and cystitis.

Patient Preparation:

No preparation required. A patient phlebotomy is performed to obtain whole blood for white cell labeling by the Cardinal Health Radiopharmacy. Note that the patient's labeled-white cells must be re-injected within 5 hours of the phlebotomy.

Equipment, Reagents, and Supplies:

1. Blood collection items: 60 cc syringe, Typenex identification bracelet for specimen/patient/dose identification, one biohazard plastic bag, test worksheet, 2,000 units of heparin, and Tc 99m Ceretec WBC information sheet. Cardinal Health supplies these in kit form and replacements are provided when blood is picked up.
2. Butterfly infusion sets, 16-23 gauge; hypodermic needles.
3. Antiseptic Chloraprep applicators.
4. TB or 3 cc syringe with needle.
5. Radioisotope camera system with imaging computer; low-energy, high-resolution, or LEAP collimator.
6. PACS image review and archiving system.
7. Cardinal Health will supply the Tc 99m Pertechnetate and Ceretec (HMPAO).
8. Ceretec is performed at Cardinal Health. The labeling efficiency is 40%-50%.
The Tc-99m Ceretec WBC dose will be in the range of 20-30 millicuries.

Procedure:

1. *If* available, obtain the most recent WBC and neutrophil count report. **If** the WBC is less than 1,000 and the calculated absolute neutrophil count is below 1,000, the patient will not have enough leukocytes to provide for labeling.

2. Use a Typenex identification system on the specimen to comply with specimen identification requirements. (Include "IMMC" so Cardinal Health can tell which institution the blood came from.)
Affix a Typenex label to the patient's test requisition, and send the remaining labels from the bracelet for identification of the specimen throughout the labeling process. Cardinal Health radiopharmacy will perform the Tc 99m Ceretec labeling. Call them to pick up the specimen for processing.
3. Verify the patient's identity using two methods. Verify inpatient test orders. Explain the test procedure to the patient and answer appropriate questions. (Patient teaching guides are available for patients who want to read about the use of WBC imaging in infections and inflammations. Provide them as needed.)
4. Perform a phlebotomy to obtain autologous leukocytes.
 - a. Preparation of the syringe for adults: Upon receiving a request to perform labeled leukocyte imaging, aseptically draw 2,000 units of heparin from a 2ml, 1,000 unity/ml vial. A 3 cc syringe is most accurate to make this measurement. Transfer the heparin into the 60 ml syringe. Obtain approximately 50 ml of the patient's blood. This can be taken from subclavian or Hickman lines, with a nurse's permission; or from blood transfusion units that may be infusing when the patient presents to start this exam. Antiseptic applicators will be used to triple scrub before doing an intravenous puncture on leukocyte patients. Using three consecutive applicators, apply the antiseptic solution in a spiral pattern with an increasing diameter starting at the intended puncture site. During the collection, provide periodic gentle agitation of the syringe contents. Right after completing the phlebotomy, invert the syringe several times in order to mix the heparin with the blood. Use a Typenex identification bracelet to comply with Cardinal Health and Laboratory specimen identification requirements. After affixing the pressure-sensitive label to the specimen, place the bracelet on the patient's wrist. Advise the patient that only Nuclear Medicine personnel may remove this bracelet. Cut off the excess length of "strap" which contains small alphanumeric and color-coded ID labels. Affix one label to the patient's test requisition and send the remainder to Cardinal Health to be used during the WBC processing.
 - b. Preparation of the syringe for pediatric (under 100 pounds) patients: Aseptically draw a volume of heparin that contains 2,000 units. A TB or 3 cc syringe is most accurate to make this measurement. Transfer the heparin into the 60 ml syringe. Using the syringe with the heparin, draw 20 ml of the patient's blood. This can be taken from subclavian or Hickman lines with a nurse's permission. The triple antiseptic scrub will be used before doing an intravenous puncture (described previously in adult procedure).
 - c. During collection of the blood, provide periodic gentle agitation to mix the blood and heparin. Immediately after completing the phlebotomy, the syringe must be inverted gently for about a minute to mix the blood and heparin. Use a Typenex identification bracelet to comply with Cardinal Health and Laboratory specimen labeling requirements. After affixing the pressure-sensitive label to the specimen, place the bracelet on the patient's wrist. Cut off the excess length of strap which contains small alphanumeric and color-coded ID labels. Affix one label to the patient's test requisition, and send the remainder to Cardinal Health to be used during the WBC processing. Call Cardinal Health to pick up the specimen for the radiolabeling process.

- d. Remove the needle (approved exception to the "no removal" rule) and position a clean syringe cap on the opening. Put the capped syringe in a biohazard plastic bag, seal the bag shut, and place it in the syringe carrying case provided by Cardinal Health. Always keep the syringe and the carrying case in an upright position so the blood sample can begin to settle properly. Store the case in an upright position to facilitate sedimentation. If no transport case is available, sometime may be saved by starting the RBC sedimentation with the syringe in a clamp and ringstand assembly. Position the syringe in the clamp at about a 30-degree angle with the capped end up. The Cardinal Health transporter will bring a new kit and transport case. The Cardinal Health transport person will require 20-30 minutes to arrive. During this time, the RBC portion will settle toward the plunger. Complete the test worksheet and the Ceretec WBC information sheet. Include the patient's name, IMMC medical record number, date, time, initial of technologist, and identify IMMC as the institution sending the specimen to Cardinal Health.
 - c. The Tc-99m Ceretec leukocytes will be returned about two and one-half hours later. Verify the amount of radioactivity before reinjecting it. To prevent misadministration and the risk of patient exposure to blood borne pathogens, in addition to the Typenex system, the administration of biologic products (labeled cells) will be handled similarly to the administration of blood. This system requires that two persons be present to cross-check the identification of the labeled WBCs (dose) to be injected and the patient identification. (Personnel from other work areas may be used to perform this cross-check.) Do not use direct IV method to re-inject Tc-99m WBC doses. Use a butterfly setup, PIC line or other existing, functioning IV accesses. Ceretec WBC doses are very expensive and care must be exercised to ensure a successful I.V. administration of the dose.
5. To assure complete infusion without significant infiltration of the Tc99m-WBCs, obtain radiation readings with a Geiger-Muller detection instrument over the injection site and the anterior chest. The chest reading should be the higher value. A planar image of the reinjection site and anterior chest may be used as an alternate method to check for a high quality re-injection. This quality control may be performed 1-2 minutes after completion of the reinjection. After successful administration of the dose, remove the Typenex ID bracelet from the patient's wrist.
 6. The majority of white blood cell localization will occur within the first one hour following re-injection. Imaging is usually started 2 hours after re-injection of the WBC's.
 7. Set up a radioisotope camera/computer to detect the 140 keV photons of Tc-99m with a 20% window and a low-energy, high-resolution collimator. Follow the individual camera charts or protocols for other parameters such as total counts.
 8. Anterior, posterior and lateral planar acquisitions of the extremities are routine views. Produce screen capture files and transfer images to the PACS system. Allow a radiologist to review and direct additional imaging.
 9. When the procedure is complete, prepare the equipment and room for another patient.

Results:

This is a physician-interpreted study.

Notes:

1. If a patient has had a Gallium scan, the background Gallium activity will preclude a white cell study for several weeks.
2. Pregnancy is not an absolute contraindication. All fetal radiation should be avoided where possible. The radiation dose to the fetus from labeled white cells will be equivalent to the radiation from a single abdominal x-ray. The radiologist should consult with the ordering physician.
3. Sterile technique must be used in all steps.
4. To maintain sterility of the patient's blood specimen, the used needle may be recapped but only with the use of a needle guard holder, such as the Syringe-Mate, or the "one hand" technique.

Limitation:

False-negative examinations may result when the chemotactic function of the white blood cell has been altered. A number of causes for this have been reported including hemodialysis, hyperglycemia, hyperalimentation, and steroid therapy. Patients on long-term antibiotic therapy may fail to attract white cells to indolent

abscesses. References:

1. Operator's Manual, radioisotope camera/computer.
2. Operator's Manual, PACS system.
3. Technetium 99m Ceretec product literature.
4. "Radionuclide Imaging of Infection", Journal of Nuclear Medicine Technology, Vol. 32, No. 2, June 2004.
5. MMWR, Vol. 41, No. 31, pp. 575-578.
6. Iowa Methodist Medical Center Bloodborne Pathogens Program as published on December 6, 1991 (based on requirements of the Occupational Safety and Health Administration, 29 CFR 1910.1030).
7. "Procedures for Labeled Leukocyte Studies," Cardinal Health Radiopharmacy, 12/92.
8. Seminars in Nuclear Medicine, Vol43, No 2, March 2013.

Written by: Stephen A. Kuhn, November 1991

Reviewed: S.Sheridan 4/2019

Updated by: Stephen A. Kuhn, October 1992; January 1993; October 1993; October 1 1995; September 2002; February 2007; December 2014, 11/2018

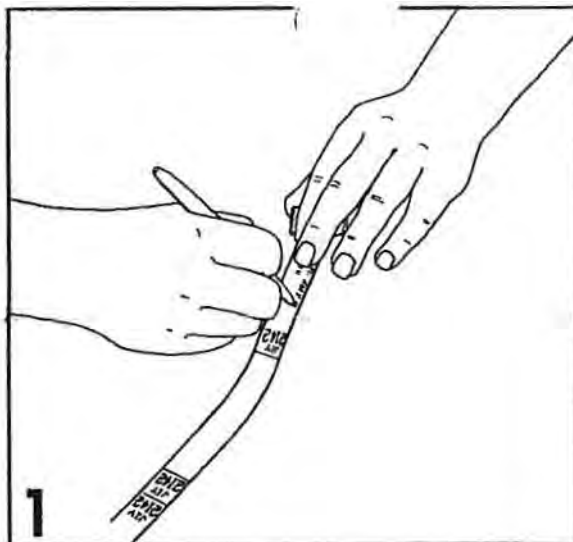
How can I provide proper identification of patient blood samples?

The Typenex® Blood Recipient Identification System

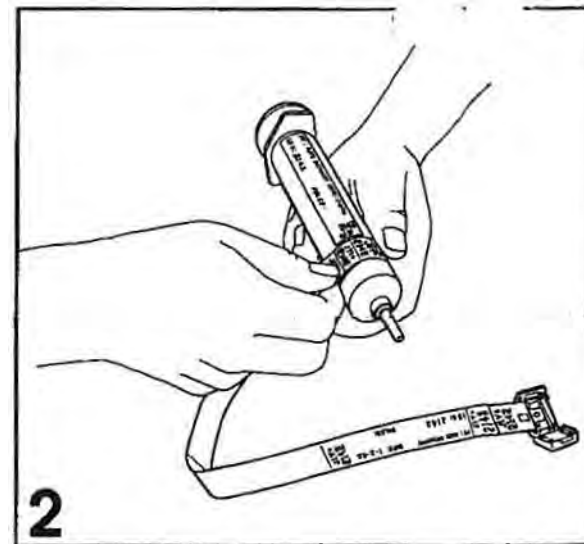


Syncor International Corporation

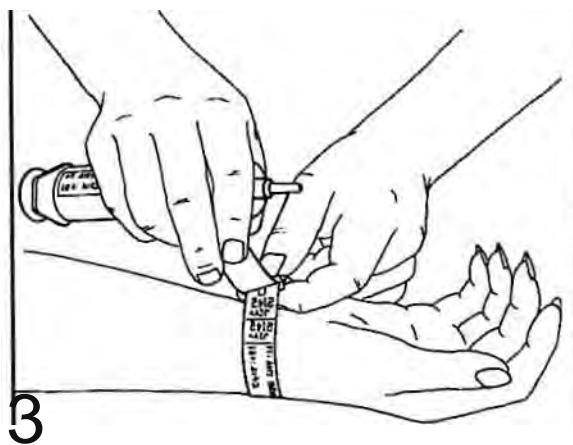
The Service DifferenceSM



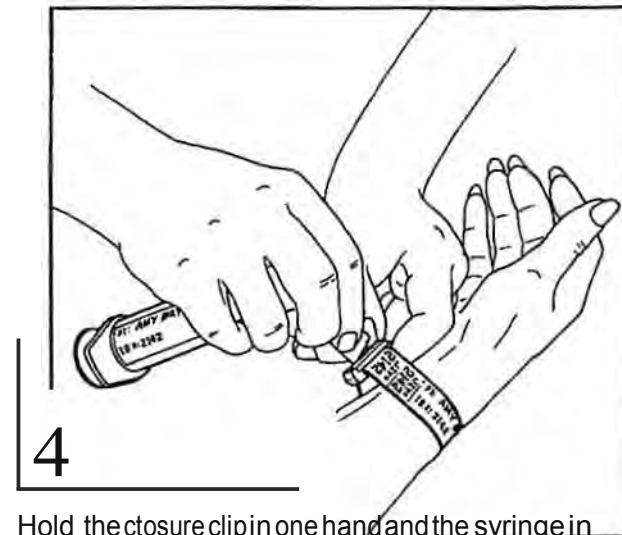
Write the date, patient name, identification number and hospital name on the long label near the closure clip of the bracelet.



Remove the plastic backing from the end of the bracelet opposite the closure clip. Press this end of the bracelet to the syringe. Remove the handwritten label from the bracelet and attach it to the syringe.



Wrap the bracelet around the patient's wrist or ankle with the name and identification numbers facing outward. Position the white part of the bracelet in the closure clip and snap the clip shut.



Hold the closure clip in one hand and the syringe in the other, and tear the strip of labels away from the bracelet. Draw the patient sample with the syringe. If additional syringes are used to obtain a blood sample, label each additional syringe with complete patient information, and one of the numbered tags.

ALWAYS:

Use proper safety precautions when handling blood products.

Verify all information at each step:

- Patient name
- Medical record number
- Hospital name
- Typenex® number.

Contact your Syncor pharmacist if you have any questions.

5

In the Syncor pharmacy, the numbered tags are used to identify all paperwork, sample tubes and syringes. When the dose is returned from the Syncor pharmacy, verify that the patient name, hospital ID and tag number on the syringe all match the data on the Syncor prescription form.

7

Remove one of the labels remaining on the patient bracelet, and attach it to the Syncor prescription form sent to you by the pharmacy. When the prescription form is put into your record book, this becomes a permanent record that the samples were identified.

6

Verify that the patient name, hospital identification and tag number on the syringe all match the patient bracelet. IF THERE IS ANY DISCREPANCY, DO NOT INJECT THE DOSE.

Bone Marrow Imaging

Principle:

Visualization of the distribution of active bone marrow depends on its function as an important site of reticuloendothelial activity. Phagocytosis of colloidal particles by reticuloendothelial cells of the bone marrow correlates well with hematopoietic activity and forms the basis for this approach to bone marrow imaging.

Marrow imaging is indicated to delineate areas of active marrow, to detect abnormal bone marrow expansion into the extremities, and to detect compensatory marrow activity in sites normally occupied by fat. Defects in active marrow, contraction of marrow, and marrow neoplasms can also be detected with this method.

Patient Preparation:

None

Equipment, Reagents, and Supplies:

1. Radioisotope camera with low energy, high resolution or low energy ultra high-resolution collimators. A dual detector camera is preferred.
2. Dose of 5-12 millicuries Technetium-99m sulfur colloid (Tc-99m S.C.), microfiltered. Use the weight/dose chart for pediatric doses.
3. Intravenous administration supplies.
4. PACS image review and archiving system.

Procedure:

1. Verify patient identity using two methods and verify inpatient orders.
2. Explain the procedure and answer appropriate questions.
3. Inject the dose of Tc-99m microfiltered sulfur colloid intravenously and start first image 10-15 minutes later.
4. Set up the radioisotope camera to accept the 140 keV gamma ray with 15% window.
5. Any suitable imaging table may be used. Images are should be performed in a planar format.
6. Acquire a posterior view of the pelvis for 1,000 K counts and note the imaging time. All other views are images using this time as a preset time.
7. Other views are taken to include the spine, lateral skull, and extremities. Use an anatomical marker to indicate the right side.
8. Produce image screen capture files and transfer them to the PACS. Review the images with the radiologist before dismissing the patient.
9. When imaging is completed, dismiss the patient and prepare the equipment and room for the next test.

Results:

This is a physician-interpreted study.

References:

1. Operator's Manual, radioisotope camera.
2. Operator's Manual, PACS image review and archiving system.
3. Operator's Manual, Park Medical Isocam II radioisotope camera/computer.
4. Nuclear Medicine, William H. Blahl, M.D., 2nd Edition, 1971.
5. Product literature supplied with sulfur colloid kit.

Written by: Stephen A. Kuhn, December 1980 Reviewed by: S.Sheridan

Updated by: Stephen A. Kuhn, February 1987;
November 2002; May 2007, 4/2019 -

Bone marrow/pro/sale

1211418

R: 11/91, 06/99, 11/2002; 05/2007, 11/2018

Brain SPECT Imaging with Neurolite OR Ceretec

Principle:

Brain SPECT imaging with Technetium-99m Neurolite (BICISATE) or Ceretec (HMPAO) enables clinicians to more completely evaluate patients with suspected non-lacunar stroke which may be underappreciated with morphologic imaging modalities. These agents are neurotransmitter analogs that rapidly cross the intact blood-brain barrier allowing them to be taken up by metabolically active neurons, predominately in the gray matter. Images reveal regional changes in brain physiology, indicating impaired brain function.

First-pass extraction of the agent is high, washout is slow, and brain-blood ratios are high. The initial distribution of the tracer agent is maintained for at least one hour despite slow washout.

Equipment, Supplies and Reagents:

1. Radioisotope camera/computer that is capable of SPECT acquisition and reconstruction; low energy, high or ultra high collimators for the camera. The first choice should be the Siemens Symbia camera/computer.
2. PACS image review and archiving system.
3. Dose of Technetium-99m Neurolite is preferred (use Technetium Ceretec if necessary, 20-25 millicuries).
4. Intravenous injection items.
5. Head and body immobilizers.

Patient Preparation:

1. Before ordering the imaging dose, the patient should be evaluated to assure capability to cooperate and remain in position for the acquisition of images. Arrange for sedative(s) if necessary to be given after administration of the imaging dose.
2. To minimize the radiation dose to the bladder, the patient should be encouraged to drink fluids and void frequently after the imaging has been completed.

Procedure:

1. Verify the identity of the patient using two methods and verify all inpatient imaging orders.
2. Explain the procedure and answer appropriate questions. The cooperation of the patient to remain motionless during the rotation of the camera should be stressed. It is very critical that the patient's head remain straight up and motionless during

Brain SPECT Imaging with Ceretec or Neurolite-

the acquisition. Talking by the patient or to the patient should be avoided during the imaging.

3. Attach the low energy, high or ultra high resolution collimators to the camera detectors. Use the proper commands to set up the acquisition protocol. Refer to the computer manual for details. The time per stop should be 30 seconds if the patient can cooperate that long. A minimum of 25 seconds is recommended. The program will allow the time per stop to be manually entered.
4. It is important to have a quiet environment during this examination. Eliminate extraneous noise by keeping the imaging room door closed. Inactivate the overhead speaker so pages and messages are not heard in the room. Position the patient supine on the SPECT table. Secure the patient's head with a positioning device to prevent motion. Provide safety straps around the patient's body to prevent falls. Make table and camera positioning adjustments so that the rotation is ready to be started before the imaging dose is given.
5. Use the "cold start" technique using a butterfly and a saline flush to assure that the venipuncture is successful before the imaging agent is introduced into the patient. Intravenously administer 20-25 millicuries of Technetium 99m Neurolite or Ceretec. Wait 10-15 minutes before beginning the SPECT acquisitions. During this time, the patient should remain quiet but awake. The computer program may be set up at this time.
6. After SPECT data acquisition has been completed, create a sinogram and review it as a quality control step. Assure that no motion of the head occurred during the acquisition.
7. Reconstruction of the raw data is performed according to the current protocol or workflow. Send all processed images to PACS. The radiologist will review and direct any additional imaging.
8. After the examination has been completed, prepare the room for the next patient.

Results:

This is a physician-interpreted study.

References:

1. Operator's Manual, Siemens Symbia camera/CT/computer.
2. Operator's Manual Picker 2000 SX/451 FX radioisotope camera/computer.
3. Operator's Manual PACS image review and archiving system.
4. Product literature supplied with Technetium 99m Neurolite agent.
5. Product literature supplied with Technetium 99m Ceretec.
6. Neurodiagnostic Update, M. A. Flitter, M.D. and W. Smoak, M.D. • Editors, Mount Sinai Medical Center, 1987.
7. Journal of Nuclear Medicine, Vol. 39, No.9, Sept. 1998.
8. Journal of Nuclear Medicine, Vol. 39, No. 10, Oct. 1998.
9. Seminars in Nuclear Medicine, Vol. 37, No. 1, January 2007

Brain SPECT Imaging with Ceretec or Neurolite- 3

Written by: Stephen A. Kuhn, March 1988

Updated by: Stephen A. Kuhn, 8/1989; 9/1989; 5/1999; 2/2007, 11/2018

Approved by: S.Sheridan 4/2019

Brain SPECT imaging/nmpro/sak/ss
03/02/88
R:08/89;09/89;05/99:0212007, 11/2018

Brain Imaging with Thallium-201 Chloride

Principle:

Soon after the introduction of Thallium-201 (Thallous Chloride) for myocardial perfusion imaging, it was noted that Thallium also is concentrated in some neoplasms. Thallium has been found to be taken up by a number of tumors including thyroid carcinomas, soft tissue sarcomas, and some lung cancers. Uptake also has been seen in brain tumors, both in primary and metastatic lesions. This uptake has been seen even after treatment when there is viable tumor tissue remaining or regrowth of the primary tumor. This observation can be extremely useful in evaluating these patients, since prior surgery or radiation therapy causes extreme abnormalities on both CT and NMR images, making them difficult to evaluate.

Thallium-201 Chloride is thought to localize in brain tumors as a result of blood flow to living, metabolically active tumor cells. The Thallium is probably handled by the sodium-potassium pump in this situation as well, being concentrated in areas where this pump is active. There is more uptake in tumor cells than in surrounding normal tissue.

Equipment, Reagents, and Supplies:

1. Radioisotope camera/computer capable of SPECT acquisition and processing, preferable dual detectors; high-resolution parallel collimators are required.
2. Dose of Thallium-201 as Thallous Chloride; 2-5 millicuries.
3. Intravenous administration supplies; syringe, assortment of sterile needles, winged infusion sets, aseptic pads, and stopcock.
4. PACS image review and archiving system

Patient Preparation:

1. The patient must be fasting for a minimum of four hours.
2. If the patient is diabetic and needs other nutritional considerations or if questions exist about this aspect of the test consult with the referring physician.

Procedure:

1. Verify the identity of the patient using two methods and verify inpatient chart orders.
2. Explain the procedure to the patient and answer appropriate questions. Patient cooperation is very important to eliminate motion during the imaging time.
3. Administer the Thallous Chloride dose (2-5 millicuries) intravenously. Begin imaging after 15-20 minutes.
4. Set up the camera to acquire the 77 keV photon of Thallium-201 at 20% window during a 360 degree brain SPECT acquisition. Acquire 64 frames at 20-30 seconds each into a 64 x 64 matrix. Take extra care during positioning so the distance from the patient's head to the detector (collimator) is minimized.
5. After the acquisition is completed, produce a sinogram and evaluate the quality of the data applying the usual criteria.
6. Allow the radiologist to review the study to determine if other techniques are indicated. Planar views in limited form are an option in each case to supplement SPECT data. When planar images are required, follow the computer protocol and/or the specific instructions of the radiologist. Dismiss the patient when all imaging data has been obtained.

Brain Imaging with Thallium-201 Chloride- 2

7. Perform SPECT processing to produce tomographic images in three planes following the reconstruction program parameters or referring to the SPECT data and processing parameters table near the front of this section of the manual.
8. Produce screen captures and transfer the image files to the PACS for review/interpretation by the radiologist.
9. Prepare the equipment and imaging room for the next examination.

Results:

This is a physician-interpreted study.

References:

1. Operator's Manual, radioisotope camera/computer.
2. Product literature supplied with Thallium-201 Chloride.
3. "201-Tl Imaging of Brain Tumors," Gary L. Dillehay, M.D., Applied Radiology, February 1993, pp. 55-60.
4. Operator's Manual, PACS system

Written by: Stephen A. Kuhn, May 1993

Updated by: Stephen A. Kuhn, 11/2002, 11/2018

Review by: S.Sheridan 4/2019

DaTscan Ioflupane I-123 (injection) scan and protocol

Principle:

DaTscan is a radiopharmaceutical indicated for striatal domain transporter (DaT) visualization using SPECT brain imaging to assist in the evaluation of adult patients with suspected parkinsonian syndrome (PS). The density of DaT is the stratum progressive decreases in specific patterns in PS (including idiopathic Parkinson's disease, multiple system atrophy, and progressive supranuclear palsy). Following intravenous injection of DaTscan, the active substance I-123 Ioflupane, distributes to the striata in the brain, where it binds with high affinity to the presynaptic DaT protein. In adult patient with suspected PS, DaTscan may be used to help differentiate essential tremor (ET) from tremor due to PS.

Preparation: Well hydrated patient and comfortable clothing. Instruct to take Lugol's solution 1 hour prior to appointment. Lugol's supplied in omni-cell, draw 1.0ml of lugols, in 4 oz juice or equivalent to 100mg.

Common medication or drugs that may interfere with ioflupane binding.	
Consider stopping such medication for at least 5 half-lives.	
5 half-lives:	
ephedrine, ketamine, isoflurane	1 day
cocaine, methylphenidate	2 days
methamphetamine, mazindol, modafinil	3 days
benztropine, fentanyl	5 days
amphetamine, dextroamphetamine	7 days
bupropion, cannabidiol	8 days
phentermine, phencyclidine	14 days

Contraindications: Allergy to Ioflupane I-123. Please see drugs that are listed above. Iodine is not a contraindication.

Equipment and Supplies:

1. Scintillation camera (LEHR) collimators. A dual camera head is required.
2. PACs image review and archiving system.
3. Dose range of 3-5 mCi I-123 DaTscan
4. Intravenous administration items.

Procedure:

1. Verify the identity of the patient two methods and verify inpatient orders.
2. Explain the test procedure and answer appropriate questions.
3. Inject the patient with the correct dose of I-123 DaTscan.

4. One hour prior to injection, patient ingest Lugol's solution to block thyroid gland.
5. Scan 3-6 hours post injection using LEHR collimators.
6. Position the patient supine with the head on an off-the-table headrest. A flexible head restraint such as a strip of tape across the chin or forehead can also be used to help avoid movement.
7. Set a circular orbit for the detector heads with the radius as small as possible (11 to a maximum of 15cm)
8. Position patient with no tilt. A lateral tilt may make a normal image appear abnormal.
9. Minimal patient motion, decrease excess motion with head, arm, and leg straps.
10. Acquisition type: step and shoot, 3 degree per step, 30 second per step.
11. Matrix 128x128 sufficient for 3.5mm to 4.5 mm pixel size and zoom 1.23. At least 15million total counts should be acquired for optimal image. +/-10% (20% total window width) Centered on 159keV.
12. Process SPECT images. Filter back projection (FBP or iterative reconstruction OSEM) Butterworth or another low-pass linear filter. Filter power factor set at 8-10 system dependent.
13. Send to McKesson PACs for interpretation.

Interpretation: This is a physician-interpreted study.

Imaging

2.1 Imaging Guidelines for DaTscan¹

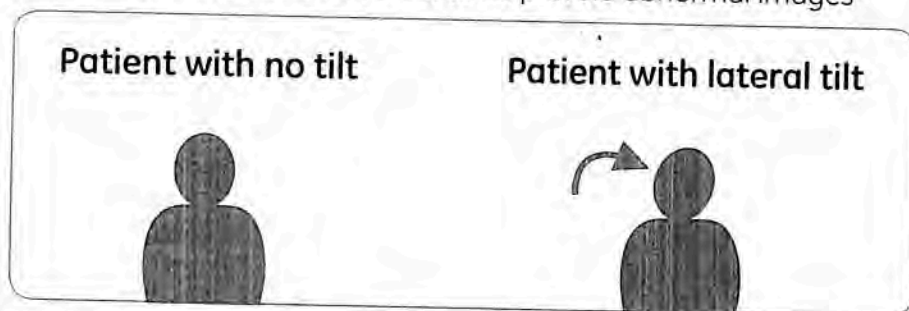
Begin SPECT imaging three to six hours following DaTscan administration. Acquire images using a gamma camera fitted with low-energy, high-resolution (LEHR) collimators and set to a photopeak of 159 keV with a $\pm 10\%$ energy window. Angular sampling should not be less than 120 views over 360 degrees. Position the patient supine with the head on an off-the-table headrest. A flexible head restraint such as a strip of tape across the chin or forehead can also be used to help avoid movement. Set a circular orbit for the detector heads with the radius as small as possible (11 to a maximum of 15 cm).

Experimental studies with a striatal phantom suggest that optimal images are obtained with matrix size and zoom factors selected to give a pixel size of 3.5 to 4.5 mm. Collect a minimum of 1.5 million counts for optimal images.

2.2 Patient Positioning

The following factors in patient positioning are critical to acquiring interpretable images with DaTscan.

- **Proper head tilt:** A lateral head tilt may make a normal image appear abnormal. Always use an off-the-table headrest to help avoid abnormal images¹



- **Small acquisition radius:** Place the camera detectors as close to the patient's head as physically possible without touching. The best image resolution occurs with a circular orbit and radius of rotation of 11 to a maximum of 15 cm.¹
- **Minimal patient motion:** Decrease excess motion with head, arm, and leg straps

Best practices for patient positioning can help avoid imaging problems:

- Communicate clearly with the patient, emphasizing the need to remain still and reassuring the patient during the test
- Always use an off-the-table headrest, and consider using head, arm, or leg straps to minimize patient motion
- For additional patient support and comfort, you may want to use a pillow or foam block placed under the knees and a blanket tucked around the upper body. Do not use a standard pillow under the head
- **If you do not have an off-the-table headrest, do not perform imaging with DaTscan**

Prior to administration, please see Important Risk and Safety Information on page 24 and enclosed Full Prescribing Information.

2.3 Recommended Image Acquisition Parameters

Gamma camera	Double- or triple-headed SPECT gamma camera system
Collimators	Only low-energy, high-resolution (LEHR) collimators (parallel hole or fanbeam) or ultra-high-resolution (UHR) fanbeam collimators have been tested for use with this guide. Use of UHR parallel hole or any type of medium energy or general-purpose collimator is not recommended with DaTscan
Patient positioning	Supine with the head off the imaging table in a suitable off-the-table headrest with restraint to minimize radius of rotation and prevent patient motion. Middle of the ear must be in the field of view
Orbit	Circular, 360°
Radius of rotation of detector heads	As close as possible, with a maximum radius of rotation of 15 cm
Acquisition type	Step and shoot, 3° per step, 30 seconds per step (dual-headed cameras) or 45 seconds per step (triple-headed cameras)
Acquisition start time	Three to six hours postinjection
Matrix	128 x 128
Zoom	Sufficient for 3.5 mm to 4.5 mm pixel size
Total counts	At least 1.5 million total counts should be acquired for optimal images
Energy window	±10% (20% total window width)
Photopeak	Centered on 159 keV

2.4 Image Processing Parameters

Reconstruction algorithm	Filtered back projection (FBP) or iterative reconstruction (eg, OSEM)
Filtering (pre-2D or post-3D)	Butterworth (or other low-pass linear filter)
Filter power factor	8 to 10 (system-dependent)
Cutoff	Changing the filter cutoff will affect image resolution. 0.5 to 0.6 cycles per cm nominally (or as appropriate to achieve approximately the same level of smoothing as the images shown throughout this guide)
Attenuation correction	Not necessary. If desired, can use Chang (also known as linear or zero-order)
Attenuation correction coefficient (if used)	A locally calculated attenuation correction coefficient from a phantom measurement should be used if available. Otherwise, use nominal value of 0.11 cm^{-1}
Background subtraction	No background subtraction
Pixel (voxel) size	3.5 mm to 4.5 mm isotropic
Presentation	Transaxial (transverse) slices parallel to the anterior commissure-posterior commissure (AC-PC) line with single-pixel thickness
Color scale	The preferred option for displaying images is the “cool” color scale shown below



B/W, Linear



GE Color, Rainbow, Cool

Prior to administration, please see Important Risk and Safety Information on page 24 and enclosed Full Prescribing Information.

Siemens ECAM Dual Head

- Radius of rotation – 13 cm
- Collimation – LEHR
- Energy window – 159 keV, 15%
- Projection angles – 120 over 360°
- Image matrix – 128 x 128, zoom 1.23 (~3.89 mm)
- Time per projection – 30 sec
- FBP, 2-D Butterworth prefilter, power factor 8, cutoff 0.6



Phantom Image



Normal Image



Abnormal Image

Siemens Symbia Dual Head

- Radius of rotation – 13.0 cm (14-cm CT headrest)
- Collimation – LEHR
- Energy window – 159keV, 15%
- Projection angles – 120 over 360°
- Image matrix – 128x128, zoom 1.23 (~3.89 mm)
- Time per projection – 30 sec
- FBP, 2-D Butterworth prefilter, power factor 8, cutoff 0.6



Phantom Image



Normal Image



Abnormal Image

SMV Dual Head

- Radius of rotation – 12.5-13.5 cm
- Collimation – LEHR, parallel hole
- Energy window – 159 keV, 20%
- Projection angles – 128 over 360°
- Image matrix – 128 x 128 (~3.8 mm), zoom 1.12 or 1.33 (~3.3 mm)
- Time per projection – 30 sec
- FBP, 2-D prefilter, Butterworth 8-10, 0.5



Phantom Image



Normal Image



Abnormal Image

DaTscan™
Ioflupane I 123 Injection

Important Risk and Safety Information About DaTscan™ (Ioflupane I 123 Injection)

INDICATIONS AND USAGE: DaTscan is a radiopharmaceutical indicated for striatal dopamine transporter visualization using single-photon emission computed tomography (SPECT) brain imaging to assist in the evaluation of adult patients with suspected parkinsonian syndromes (PSs). DaTscan may be used to help differentiate essential tremor from tremor due to PS (idiopathic Parkinson's disease [PD], multiple system atrophy [MSA], and progressive supranuclear palsy [PSP]). DaTscan is an adjunct to other diagnostic evaluations. DaTscan was not designed to distinguish among PD, MSA, and PSP. The effectiveness of DaTscan as a screening or confirmatory test and for monitoring disease progression or response to therapy has not been established. **CONTRAINDICATIONS:** DaTscan is contraindicated in patients with known hypersensitivity to the active substance, any of the excipients, or iodine. **WARNINGS AND PRECAUTIONS — Hypersensitivity Reactions:** Hypersensitivity reactions, generally consisting of skin erythema and pruritus, have been reported following DaTscan administration. **Thyroid Accumulation:** The DaTscan injection may contain up to 6% of free iodide (iodine 123 or I-123). To decrease thyroid accumulation of I-123, block the thyroid gland at least one hour before administration of DaTscan; failure to do so may increase the long-term risk for thyroid neoplasia. **ADVERSE REACTIONS:** In clinical trials, headache, nausea, vertigo, dry mouth, or dizziness of mild to moderate severity were reported. In postmarketing experience, hypersensitivity reactions and injection-site pain have been reported. **DRUG INTERACTIONS:** Drugs that bind to the dopamine transporter with high affinity may interfere with the DaTscan image. The impact of dopamine agonists and antagonists on DaTscan imaging results has not been established. **SPECIFIC POPULATIONS — Pregnancy:** It is unknown whether DaTscan can cause fetal harm or increase the risk of pregnancy loss in pregnant women. DaTscan should be given to pregnant women only if clearly needed. Like all radiopharmaceuticals, DaTscan may cause fetal harm, depending on the stage of fetal development and the magnitude of the radionuclide dose. Radioactive iodine products cross the placenta and can permanently impair fetal thyroid function. **Nursing Mothers:** It is not known whether DaTscan is excreted into human milk; however, I-123 is excreted into human milk. Because many drugs are excreted into human milk and because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to interrupt nursing after administration of DaTscan or not to administer DaTscan at all. Nursing women may consider interrupting nursing and pumping and discarding breast milk for six days after DaTscan administration to minimize risks to a nursing infant. **Pediatric Use:** The safety and efficacy of DaTscan have not been established in pediatric patients. **Geriatric Use:** There were no differences in responses between the elderly and younger patients that would require a dose adjustment. **Renal and Hepatic Impairment:** The effect of renal or hepatic impairment on DaTscan imaging has not been established. The kidney excretes DaTscan; patients with severe renal impairment may have increased radiation exposure and altered DaTscan images. **OVERDOSAGE:** It is unknown whether or not ioflupane is dialyzable. The major risks of overdose relate to increased radiation exposure and long-term risk for neoplasia. In case of radioactivity overdose, frequent urination and defecation should be encouraged to minimize radiation exposure to the patient. **PROCEDURE — Radiation Safety:** DaTscan emits radiation and must be handled with safety measures to minimize radiation exposure to clinical personnel and patients.

Prior to DaTscan administration, please read the enclosed Full Prescribing Information.

Breast Sentinel Node Radiotracer Administration Without Nuclear Images

Principle:

The lymphatic system is a partially closed circulatory system that conducts water, electrolytes, proteins, enzymes, and migrating cells from the interstitial space back into the vascular system. Identification of lymph drainage is a challenge that may be very difficult when based only on clinical anatomical localization. Early metastatic spread from breast disease may occur via the lymphatics. Radiotracers and a hand-held Geiger Mueuer-type probe is an effective method to assist in location of breast sentinel nodes. Currently, the sentinel node biopsy procedure is recognized as the standard treatment for stages I and II. No images of distribution are acquired.

Equipment, Supplies and Reagents:

1. Obtain a dose of radiotracer per the provider order: in the range of 0.8-1.2 millicurie of either Tc99m Lymphoseek or Tc99m Sulfur Colloid.
2. Lidocaine is used/needed only with the use of Tc99m Sulfur Colloid. Other required items are aseptic pads, plastic-lined absorbent pads, disposable gloves, hypodermic needles (22 x 1.5 inch) and radiation safety devices.
3. PACS data review and archiving system.

Patient Preparation:

These studies will be performed primary on outpatient surgery patients. Surgery will call the patient and discuss preparation requirements. Patients will register at Outpatient Surgery. Some patients will have a needle localization procedure prior to the administration of the radiotracer. Radionuclide administrations are always performed in a Nuclear Medicine examination/imaging room. Call surgery for patient transportation following the administration of radiotracer.

Physician Preparation:

Authorized Users and approved physicians who have been granted annual, permission by the Radiation Safety Committee, may administer Tc99m Lymphoseek and Sulfur Colloid doses for sentinel node detection. (See the current posted listing.)

Procedure:

1. When the patient arrives in Nuclear Medicine, verify identity by two methods and verify that there is a written chart order. Verify the physician is on the Radioactive Materials License (RAM) license or has obtained permission to perform this administration.
2. Contact the Authorized User or approved surgeon when the patient and room are ready for the injection of the radiotracer. The procedure will be explained to the patient by the physician.

- Direct the patient to an examination/imaging room and bring the assayed dose of Tc-99m radiotracer to the room in proper shielding.
3. When the physician has completed the administration of the radiotracer, notify the Surgery Department and a surgery transporter will return to take the patient to the Operating Room where the sentinel node will be identified.
 4. Check for radioactive contamination with G-M survey meter and dry wipe test. Sanitize the room and prepare for the next patient. Enter required documentation in Syntrac.
 5. Since this exam has no image files, send a one-view dummy image from one of the cameras to PACS. Scan the test requisition and dose information into the PACS.

Interpretation:

The radiologist will generate a report to document the administration of radionuclide to the patient.

References:

1. Seminars in Nuclear Medicine, L. M. Freeman, M.D. and M. D. Blaufox, M.D., Ph.D., Editors, Vol. XIII, No. I, January 1983.
2. Textbook of Nuclear Medicine, Volume II, Clinical Applications, J. Harbert, M.D. and A. F. G. DaRocha, M.D., 2nd Edition, 1984.
3. Product literature supplied with Sulfur Colloid.
4. Product literature supplied with Lymphoseek (tilmanocept)
5. Seminars in Nuclear Medicine, January 1999, Vol. XXIX, No. 1.
6. Seminars in Nuclear Medicine, April 2005, Vol. XXXV, No. 2.
7. Journal of Oncology, Volume 2012 (2012), Article ID 361341, 7 pages

Written by: Stephen A. Kuhn, September 22, 2001 Reviewed: S. Sheridan

Updated by: Stephen A. Kuhn, 9-2003; 4- 2006; 7- 2014, 11-2018, 4/2019 ·

Carbon M14 (CM14) Urea Breath Test for Detection of Helicobacter Pylori

Principle:

Helicobacter Pylori is an important causative agent in the pathogenesis of gastritis/peptic Ulcer disease. The diagnosis of this disease is made when the bacteria is present in a gastric mucosal biopsy obtained during endoscopy. Helicobacter pylori (H. pylori) can be effectively treated and eradicated with appropriate antibiotic therapy. The recommended standard of care in the treatment includes confirmatory testing to demonstrate the eradication of the bacteria following appropriate antibiotic therapy. The C-14 Urea Breath test is the most reliable non-invasive method available to confirm the presence or absence of Helicobacter pylori. The test sensitivity is 97% and specificity is 100% in the detection of H. pylori. Normal human cells do not contain the urease enzyme needed to split urea into HCO_3 and NH_4 . H. pylori bacteria do have the urease enzyme. HCO_3 enter the bloodstream and is rapidly expired in the lungs as CO_2 . Carbon (CM 14) indicates the presence of H. pylori.

Equipment and supplies:

1. Stopwatch or clock.
2. The Carbon 14 urea capsule (1mCi capsule dose) and balloon are obtained from Cardinal Health radio-pharmacy in a testing kit. Order 2-4 days prior to the test day.
3. Gloves
4. The analysis of the breath specimen collected in step 3 below, is performed by Cardinal Health radio-pharmacy.

Patient Preparation and Screening:

1. NPO for food or drink is required for 6 hours prior to the study.
2. Patient must not take carafate or prolosec one week prior to the test. Preparation of Pepcid, Tagamet, acid, and Zantac maybe taken up to 24 hours prior to the test.
3. Antibiotic or drugs containing bismuth (pepo bismol) should not be taken for 30 days prior to the study.
4. Women of childbearing age 12-50years must be asked if they could be pregnant. A pregnancy test is not required. Pregnant patient should not have the test performed.

Procedure:

1. Verify the patient and verify patients test orders.
2. Assure that the proper patient preparation has been followed as listed above. Explain the procedure to the patient and answer questions.
3. Fill the measuring/portion cup with 20mL of warm tap water.
4. With gloves on, open the package containing the C-14 capsule should not be directly handled. Give the capsule to the patient into a clean, dry portion cup. Hand the patient the portion cup containing 20mL of warm water. Ask the patient to tip the capsule directly into his/her mouth, then swallow it with the 20mL of warm water.
5. Start the stopwatch. After 3 minutes of elapsed time ask the patient to drink an additional 20mL of water to ensure that the capsule enters the stomach and has not lodged in the esophagus. Document the administration of the dose, time, date, and capsule number.
6. Collect a breath sample at 10minutes after administration of the dose to have the patient exhale into a mylar balloon via a cylindrical breath transfer device (Straw) **Note:** that is

necessary to collect at least breath of carbon dioxide in each breath sample. The patient should inhale and hold their breath for 10-20 seconds prior to filling the Mylar balloons.

Put a knot in the neck of the balloon so air cannot leak out.

7. Call cardinal radio-pharmacy for pickup of the balloon/breath specimen.

Results:

The results of the analysis will be reported in disintegration per minute (DPM). The use of DPM instead of CPM removes instrument variability. The count analysis and data worksheets will be returned with the patient's name, date and initials of the technologist who performed the calculation. These are then submitted to the radiologist for review and interpretation.

Note:

Radiation exposure during this test is small.

Normals:

1. This test requires physician interpretation.
2. The approximate diagnostic criteria is as follows:

DPM < 100 is negative (the great majority of test results should be <30 DPM)

DPM 100-199 is borderline, repeat test, values between 100 and 200 should be rare.

DPM >200 is positive with a sensitivity of 95%.

References:

1. Product literature supplied with Carbon C-14 Urea Breath Test.
2. The Journal of Nuclear Medicine Vol. 36, No. 5, May 1995 P. 227.

Written by: Stephen Kuhn Review by: Sharon Sheridan

GASTROESOPHAGEAL REFLUX STUDY (GER) AND COMBINED LIQUID GASTRIC EMPTYING TIME FOR PEDIATRIC (0-2 Years of Age) PATIENT

Principle:

1. To detect and evaluate gastroesophageal reflux.
2. To detect and evaluate prolonged gastric emptying time.
3. To detect and evaluate pulmonary aspiration of stomach contents.

Patient Preparation:

1. Fasting time equal to the patient's feeding interval (usually 3-5 hours).
2. Infants may need NG placement and/or X-ray to verify NG placement.

Equipment and Supplies:

1. Scintillation camera and imaging computer and high-resolution collimator.
2. Anatomical radiospot marker and Cobalt 57 camera flood sheet source.
3. Dose of Technetium 99m (Tc-99m) Sulfur colloid (S.C.), 500 microcuries.
4. For infants or young children still on formula diet the test meal is 2-4oz of milk or formula or their usual feeding volume.
5. Baby bottle, cups or N-G for oral administration of the liquid test meal.
6. One sheet of linear graph paper and one copy of time, activity, and residual worksheet.
7. PACS image review and archiving system.

Special Note:

Prior to giving the test meal (feeding) via naso-gastric (N-G) tubes, the placement of the N-G must be checked with X-ray. If the N-G has been in place less than 24 hours, check for a placement image on PACS. If there is no PACS record or if the N-G was placed more than 24 hours ago, the patient will be sent to Radiology for an X-Ray to check proper placement. Proceed only with the approval of the radiologist.

Procedure:

1. Identify the patient using two methods and verify inpatient orders. Explain the procedure and answer appropriate questions.
2. a. Place a plastic-line absorptive barrier over the chest and abdomen of the patient and use caution to prevent radioactivity from spilling onto the patient. Contamination will cause artifacts in the acquired data. For infants and young children still on a formula diet, mix 500 microcuries of Tc-99m S. C. in 5 mL fraction of the formula. Administer this portion to the patient. (If parents or a nurse accompany the patient, they may be helpful to assist the patient to drink

GASTROESOPHAGEAL REFLUX STUDY (GER) AND COMBINED LIQUID GASTRIC EMPTYING TIME FOR PEDIATRIC PATIENTS –2

- the mixture/formula.) Follow this with 5-50 mL of formula without radiotracer.
- b. Nasogastric and gastric tubes may be used to administer the test meal. If a nasogastric tube is used (see Special Note above) to deliver the test meal into the stomach, the tube must be removed before imaging begins. Only personnel with N-G competencies, (usually nurse or physician) may infuse and remove N-G tubes.
 3. Set up the scintillation camera/computer to optimize detection of the 140 keV photons of Tc-99m. After ingestion of the test "meal", delay no more than 10 minutes before beginning the data acquisition.
 4. Position the patient supine and acquire images posteriorly. Acquire sequential (dynamic) images of 20 seconds each for a total 180 frame in one hour. This will allow the radiologist to view the acquired data in a cine loop.
 5. Imaging must continue until 50% stomach emptying is reached. This may require extra images in a static format.
 6. If delayed aspiration imaging is included in the referring physician's order, begin this planar image about 4 hours after ingesting of the tracer meal. Image the patient's chest in the anterior projection for 5 minutes. Use an anatomical marker and/or a Cobalt 57 camera flood source to outline the borders of the patient's body. Produce screen captures of image data and transfer to PACS. Scan the test requisition into PACS to provide information about the type, volume and method of ingestion of the test meal.

Analysis and Calculations:

1. Apply proper gastric ROIs on the images and obtain count data in order to manually generate an emptying curve. Plot the count data on the vertical side of logarithmic graph paper and the time post-test meal (e.g. 15 minute-image) on the horizontal. **Note: Time zero is always graphed at 100%.** Draw a best-fit, regression line. Draw intersecting lines to denote the point of emptying intercept with the 50% count. Find the time on the horizontal axis. This is the emptying half-time. Write this value on the graph paper. Label the graph paper with patient identification and scan this into the PACS.
2. Place a ROI around the stomach in the first and last image acquisition. Determine the counts in each and decay correct if needed. Calculate the percent of test meal remaining (residual) and the percent emptying. Produce a screen capture showing this work and transfer to PACS.
3. Transfer the sequence of raw image frames to PACS.

GASTROESOPHAGEAL REFLUX STUDY (GER) AND COMBINED LIQUID GASTRIC EMPTYING TIME FOR PEDIATRIC PATIENTS –3

Optional Manual Calculations:

1. Compute gastric reflux using this formula:

$RI = E(1) - E(b) / G(o)$ this is quantity multiplied by 100.

RI represents GE reflux index as a percent of gastric count;
E(1) esophageal counts: E(B), esophageal background counts; and
G(o) maximal gastric count. Use areas of interest to obtain counts in areas needed.

NOTE: In interpretation of the tubeless gastroesophageal nuclear study, care must be taken that the ingested radionuclide solution empties completely from the esophagus to the stomach in order to avoid false readings of GE reflux. If an abnormality of esophageal emptying is suspected, the test should be performed after placement of NG or G-tube, allowing the labeled solution to be instilled directly into the stomach.

Results:

This is a physician-interpreted study.

Exposure:

500 microcuries Tc-99m Sulfur Colloid gives an estimated total body exposure of 100 millirads.

References:

1. Journal of Gastroenterology, 70:301-308, 1976.
2. Operator's Manual, Radioisotope Camera/Computer.
3. Literature supplied with Sulfur Colloid agent.
4. Operator's Manual, PACS system, 2007
5. Seminars in Nuclear Medicine, Pediatric Nuclear Medicine, Part I, Vol37, No 4, July 2007

Written by: Stephen A. Kuhn, February 1985

Updated by: S.Sheridan

Approved by: Dr. Walker DO.

Gastric Emptying

Ages 2-5years, 5-14years, and 14years to adult

Principle:

Gastric emptying time studies are useful in the evaluation of patient with complaints of satiety, bloating, pain, gastric regurgitation, suspected gastroparesis, poor diabetic control, or heartburn in untreated patients; patient on cholinergic or anticholinergic medication; and postoperative gastric surgery patients.

Patients are given a portion of milk, or scrambled eggs that have been labeled with a radioactive isotope. The clearing or emptying of this food from the stomach is directly observed with a nuclear medicine camera and processing protocol. Qualitative as well as quantitative data is obtained. This procedure is useful in evaluating either organic or functional delays in gastric emptying in conditions such as gastric, duodenal, or pyloric ulcers; hypertrophic pyloric stenosis; post vagotomy and pyloroplasty; diabetic gastroparesis; and Zollinger-Ellison syndrome.

Patient Preparation:

The patient must be fasting a minimum of 8 hours prior to the test. The study will require imaging up to 4-hours.

Equipment, Reagents, and Supplies:

1. Radioisotope camera with high resolution collimator interfaced to an imaging computer.
2. The test meal for 2-5 years is 4oz of milk and possible toast with butter. 5-14 years old one scrambled egg/toast with butter meal. 14 years and older two scrambled egg/toast with butter meal. (With the permission of the radiologist, oatmeal may substitute.)
3. 4oz milk meal: Container (sippy cup) to mix isotope with the milk, toaster, slice of bread with butter. 5-14-year-old: one egg, slice of bread, butter, toaster, skillet, and burner to cook the eggs, cup of 4oz of water. 14 years and older: two eggs, slice of bread, toaster, skillet, and burner to cook the eggs. All ages use disposable dishware.
4. Dose range of 0.8-1.2mCi of Tc99m Sulfur colloid or MAA if sulfur colloid is not available. **Please see chart for dose calculations and minimum doses on form 130-1 for pediatric patients.**
5. McPACs for imaging review and archiving.
6. On sheet of linear graph paper, and one copy of time, activity, and residual worksheet.

Procedure:

1. Verify and identity of the patient using two methods. Verify the physician's test orders
2. Explain the test and answer appropriate questions.
3. Set up the radioisotope camera for the 140 KeV, 15-20% window, and high-resolution collimator. There are protocols set up on e-cam, Symbia S and T.
4. Obtain a carton of milk, or eggs, slice of bread with butter from the main kitchen at IMMC or ILH. If oatmeal is used as an alternate, request a packet of ready to eat oatmeal from the kitchen.

FOR 2-5 years:

1. Mix range of 0.8-1.2mCi of Tc99m S.C. in a 1oz (approximately) fraction of the milk. For this age group a sippy cup might be the most practical device of confine the milk with the isotope to reduce contamination. One slice of bread to toast and butter it.
2. Administer the 1 oz portion of milk orally to the patient. (If the parent or nurse accompany the patient, they may be helpful to assist the patient to drink the milk.)
3. A plastic-lined absorptive barrier over the chest and abdomen of the patient may be necessary. Use caution to prevent radioactivity from spilling onto the patient. Contamination will cause artifacts in the acquired data.
4. After drinking the 1-oz portion, give with the remaining 3-oz of milk that has no radiotracer. The slice of toast with butter maybe consumed with the portions of milk.
5. Encourage the patient to consume the meal within 5-10mins, with 10minutes being the maximum. Begin images within completion of the meal. Position the patient either standing or laying supine with stomach in the mid-upper part of the image field in the anterior projection. The stomach should be completely within the field of view. Obtain one 60-second acquisition immediately, 1-hour, 2-hour, and 4-hour. The patient is not required to remain on the imaging table during image intervals.

FOR 5-14 years:

1. Obtain a raw egg from the main kitchen at IMMC or ILH. If oatmeal is used as an alternate, please order an oatmeal packet from main kitchen and heat up oatmeal and add isotope. Prepare the radio-labeled eggs by cracking and placing the whole egg in a frying pan. Inject the dose of Tc99m SC in the egg. Stir as needed during cooking. The egg should be cooked until it has firm consistency.
2. Toast the slice of bread and butter. Serve the toast on side with the egg meal and 4 oz of water.
3. Encourage the patient to consume the meal within 5-10mins, with 10minutes being the maximum. Begin images within completion of the meal. Position the patient standing in front of the camera. The stomach should be completely within the field of view. Obtain one 60-second anterior acquisition immediately, 1-hour, 2-hour, and 4-hour.

FOR 14 years to adult:

1. Obtain two raw eggs from the main kitchen at IMMC or ILH. If oatmeal is used as an alternate, please order an oatmeal packet from main kitchen and heat up oatmeal and add isotope. Prepare the radio-labeled eggs by cracking and placing the eggs in a frying pan. Inject the dose of Tc99m SC in the egg. Stir as needed during cooking. The egg should be cooked until it has firm consistency.
2. Toast the slice of bread and butter. Serve the toast on side with the egg meal and 4 oz of water.
3. Encourage the patient to consume the meal within 5-10mins, with 10minutes being the maximum. Begin images within completion of the meal. Position the patient standing in front of the camera. The stomach should be completely within the field of view. Obtain one 60-second anterior acquisition immediately, 1 hour, 2 hour, and 4-hour.

Analysis and Calculations:

1. Apply proper gastric ROIs on the images and obtain count data to manually generate an emptying curve. Decay-correct the data. Plot the count data on the vertical side of semi-logarithmic graph paper (single cycle) and the time post-test meal (e.g., 1 hour image) on the horizontal. Draw the best-fit, regression line. The place where this line intersects the best-fit regression curve is the half-emptying time. Draw a vertical line and find the time value on the x-axis. Write this value on the graph paper. Label the graph paper with date and patient identification and scan this in the McPACs.
2. Place the ROIs around the stomach and whole abdomen on the all the images acquired. Determine the count in each and decay-correct counts in each image. Calculate the percent of test meal remaining or residual in the stomach and the percent emptying. Produce a screen capture showing this work and transfer to McPACs.
3. Generate a screen capture showing this work and transfer to McPACs.
4. Complete clinical note in EPIC and McPACs.

Results:

This is a physician-interpreted study.

References:

1. JNMT Consensus Recommendations for Gastric Emptying Scintigraphy: A Joint Report of the American Neurogastroenterology and Motility Society and the Society of Nuclear Medicine. March 2008.
2. Society of Nuclear Medicine Procedure Guideline for Gastric Emptying and Motility. Internet www.misnm.org

Gastrointestinal Bleeding Detection

Principle:

Gastrointestinal bleeding is a common diagnostic problem. The radionuclide imaging technique has greatly helped the management of patients with gastrointestinal (G.I.) bleeding. Localization of the bleeding site depends upon detecting the pooling of extravagated radiolabeled blood. Labeling of the red blood cell portion of the blood is achieved in vitro with Technetium 99m Pertechnetate and Ultratag. Imaging is performed over the abdomen to detect extravascular accumulations of the tracer. Bleeding rates of approximately 2 ml/minute can be detected. Upper abdominal bleeding around the liver and spleen as well as intermittent bleeding can be detected. Blood is an irritant in the bowel and causes active peristalsis, rapid antegrade and retrograde movement away from the bleeding site can occur. The use of continuous computer imaging and reviewing the dynamic images in a cinematic display results in a more accurate localization of the site of GI bleeding.

Patient Preparation:

The patient provides a small specimen of whole blood during a phlebotomy; patient should be free of barium in the GI tract.

Equipment, Supplies, and Reagents:

1. Radioisotope imaging camera/computer with high-resolution collimator
2. Dose of Technetium 99m Pertechnetate for red blood cell labeling, 20-30m Ci (Pediatric doses are adjusted by weight.) One Ultratag kit
3. PACS image review and archiving system
4. Intravenous administration items

Note:

If the gastrointestinal bleeding scan order is received after 3pm and before 6pm, Monday-Friday, notify the interventional radiologist (IR) on-call or call the radiologists' coordinator (Renee, 515-210-3969) and she will alert their on duty.

Procedure:

1. Verify the identity of the patient using two methods. Verify proper patient orders including physician signature.
2. Explain the procedure and answer appropriate questions.
3. Perform a venipuncture to obtain a 2-5 mL specimen of blood. If the patient has a blood transfusion in progress, 2-5mL of the may be taken from the donor bag or delivery line. If the donor blood is used, it is not necessary to add heparin to the syringe since the donor blood already contains an anticoagulant. Follow the in-vitro labeling procedure provided in the Ultratag RBC labeling kit. This process labels the red blood cells in the whole blood specimen with Technetium 99m. The labeling procedure requires about 25 minutes.
4. Set up the radioisotope camera with the appropriate GI Bleed dynamic imaging protocol. Optimize detection of 140 keV photons with a 15-20% window.
5. Position the patient in the anterior view with the abdomen and pelvis in the field.

6. The administration of biologic products (labeled red cells) will be handled similarly to the transfusion of blood and blood products. This system requires that two persons be present to crosscheck the identification of labeled RBCs (dose) to be re-injected and the patient identification. The only exception to this system will be when only one patient and only one nuclear medicine technologist are in the section at the time the test is conducted. Other patient care personnel may perform this review/certification step.
7. Re-administer the Technetium-labeled RBCs intravenously. Start image acquisition immediately. Obtain 5-second dynamic frames for 1-2 minutes. Then acquire at a rate of one frame per minute and in sets of 15. After image 15, evaluate for any positive frames. If all are normal, continue on with another set of 15 images. Continue until a positive image is seen or until 60 minutes have elapsed.
8. Obtain right and left lateral images: routinely. Produce screen captures of all images. Transfer raw images and screen captures to PACS. Scan history sheets and the requisition into the patient's PACS file. Compose a PACS clinical note describing the study and tracer dose administered.
9. Review the images with the radiologist to determine the need for more images. Patients with normal images can be re-imaged later (up to 24 hours), without relabeling of RBCs, if bleeding symptoms reoccur.

Interpretation:

This is a physician-interpreted study.

References:

1. Operator's Manual, radioisotope camera/computer.
2. Operator's Manual, Picture Archiving Computer system (PACS).
2. Literature supplied with Mallinckrodt Ultratag kit.
3. Nuclear Medicine Technology, Imaging and Function Studies, Lyle Goodin, www.webhome.idirect.com
4. Diagnostic Nuclear Medicine 3rd Edition, Williams and Wilkins, Baltimore, 1996, pp. 801-821.
5. Seminars in Nuclear Medicine, 1996, 28:43-50
6. Seminars in Nuclear Medicine, Vol 37, No.4, July 2007
7. Nuclear Medicine Technology: Procedures and Quick Reference, 2nd Edition, Pete Shackett, 2009.

Reviewed by: S.Sheridan 4/2019

Revised: 05/89; 05/90; 10/92; 12/95; 05/96; 12/2003; 12/2006; 5/2009; 7/2012; 11/2012; 11/2018

GI Bleeding RBC/nmp/ro IMMC/ss

R: 05/89; 05/90; 10/92; 12/95; 05/96; 12/2003; 12/2006; 05/2009; 07/2012; 11/2012; 11/2018

Lutathera Lu-177 Dotatate Treatment

(Peptide Receptor Radionuclide Therapy)

PRINCIPLE:

Lutathera is indicated for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults.

EQUIPMENT AND SUPPLIES:

1. Infusion pump and pole.
2. 2.5cm, 18-gauge needle (short needle).
3. 9cm, 18-gauge needle (long needle, spinal).
4. Two 10ml syringes.
5. Two IV pump infusion sets with clamp and Y-connector to regulate flow.
6. Male to male (m/m) patient line with clamp.
7. 3 or 4-way stopcock.
8. Sterile gloves
9. Towel/gauze/alcohol wipes.
10. Waste container for contaminated items.
11. Green Emesis bags.
12. Saline 500 mL
13. Antiemetic medications
14. Amino acid solution
15. Long acting octreotide if being administered post Lutathera.
16. Lutathera dose Batch paperwork phone number: 844-367-3222
17. Rescue Sandostatin Injection/SQ 200 mcg for Carcinoid Crisis.
Call Pharmacy (North 2nd floor) at 1-5811 if needed.

PATIENT DOSE:

200mCi Lu-177, beta-emitting, 6.7 day half-life.

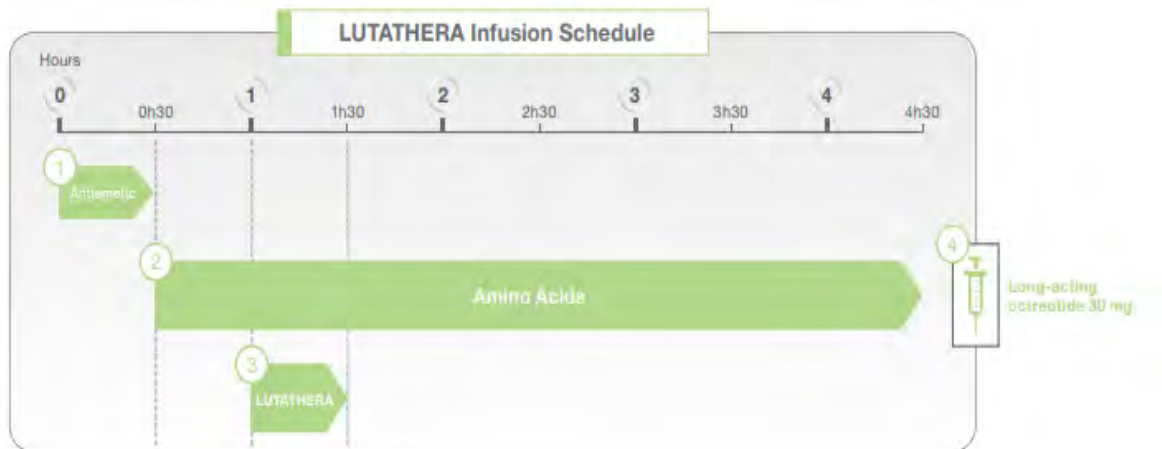
1. The recommended Lutathera dosage is 7.4 GBq (200mCi) IV, every 8 weeks, for a total of 4 doses.
2. Lutathera dosage should be modified based on hematologic, renal, hepatic, or other adverse reactions.

TREATMENT SITE PREPARATION:

1. Lutathera is primarily eliminated renally. Because urine and vomit are radioactive after Lutathera administration, room preparation is essential to reduce potential contamination.
2. Absorbent drapes should be used to cover vulnerable areas in the patient room and bathroom. This includes the floors and toilet.
3. A nearby dedicated toilet is needed. (Room # 2 and Room #7 in Radiation Oncology are designated treatment rooms with dedicated bathrooms)

TIMING OF LUTATHERA:

1. *Pretreatment antiemetic (Nurse):* Administer an antiemetic to help avoid treatment-related nausea and vomiting before the start of the amino acid solution infusion.
2. *Concomitant amino acid infusion (Nurse):* For renal protection, initiate an IV amino acids infusion containing L-lysine and L-arginine 30 minutes before administering Lutathera. Continue amino acids during and for at least 3 hours after the Lutathera administration. *Do not decrease the dose of the amino acid solution if the Lutathera dose is reduced.
3. *Lutathera infusion (Nuclear Medicine Technician):* Lutathera must be administered as an IV infusion over 30 to 40 minutes.
4. *Long-acting octreotide (Nurse):* Administer long-acting octreotide 30mg intramuscularly between 4-24 hours after each Lutathera dose. Patients may wait an hour after infusion to receive dose or come in the following day to be injected. Another long-acting octreotide may be administered 4 weeks after Lutathera infusion if the Medical Oncologist and Radiation Oncologist so choose.

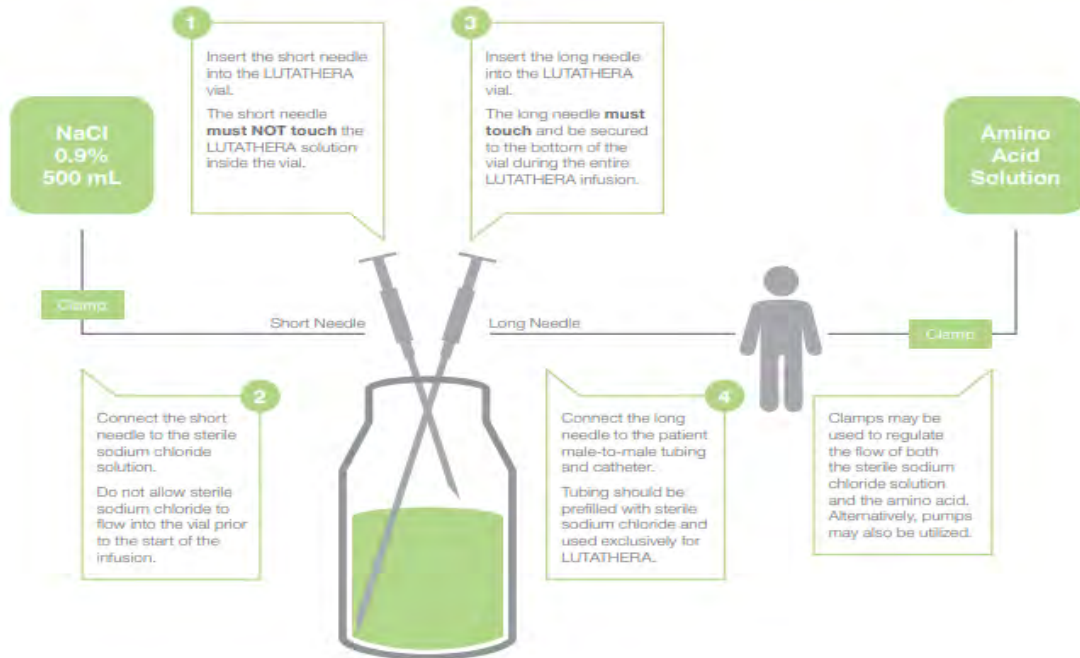


PATIENT PREPARATION:

1. Patients may arrive in street clothes and change into hospital gown to avoid possible contamination of personal belongings.
2. Patients should be advised to hydrate and urinate frequently during and after administration of Lutathera to reduce renal toxicity.
3. Patients should be instructed regarding procedures to avoid contamination of the bathroom. All patients, including men, should sit on the toilet to urinate. Patients should close the toilet lid prior to flushing and double-flush the toilet after use.
4. Somatostatin and its analogs competitively bind to somatostatin receptors and may interfere with the efficacy of Lutathera. Discontinue long-acting somatostatin analogs at least 4 weeks and short-acting octreotide at least 24 hours prior to each Lutathera administration. (Please see somatostatin medication list for reference.)

DOSE PREPARATION AND DELIVERY (Nuclear Medicine):

LUTATHERA administration setup (gravity method)



• Do not inject LUTATHERA directly into any other IV solution!

IV Intravenous

1. Confirm Batch Release certificate has been received prior to Lutathera administration. The certificate will be emailed from AAA/Novartis customer service to Kendy, Shashi and Sharon. Please save this record with QMP paperwork.
2. If the paperwork does not arrive, call 844-367-3222.
3. Use aseptic technique and radiation shielding when administering the Lutathera solution. Use tongs when handling the vial to minimize radiation exposure.
4. Confirm the amount of radioactivity of Lutathera in the radiopharmaceutical vial with an appropriate dose calibrator prior to the Lutathera administration.
5. Inspect the product visually for particulate matter and discoloration prior to administration under a shielded screen. Solution should be clear and colorless to slightly yellow. Make a visual line on the vial with a Sharpie where the top of the solution is. Place vial back in the shielded container with a wedge under it so that the line is visible.
6. Verify patient's identity and set up as per above diagram for Lutathera administration (gravity method).
7. Lutathera must be administered as an IV infusion over 30 to 40 minutes. The pump will be adjusted by the nurse. Do not administer as an IV bolus.
8. Prevention of infiltration is critical. Check the IV line patency prior to administration.
9. During infusion place GM meter over the IV tubing, checking for isotope infusion flow. After the first 15 minutes, the GM meter should start to move to background.

50mL/hour for 10minutes.

200mL/hour to 300mL/hour for following 25 to 30minutes.

During infusion, ensure that the fluid level in the Lutathera vial does not go above the black sharpie line mark. If it does, stop the pump and inject air (around 5 mL) into the line, or change out the long needle.

10. Once the reading is stable for at least 5 minutes, stop the flow from the saline bag and close the saline line.
11. Follow the infusion with an IV flush of 25 mL of 0.9% sterile sodium chloride.

DISASSEMBLY AND DISPOSAL

1. Clamp patient line.
2. Disconnect tubing from the patient catheter, cap the line and the patient catheter to prevent radioactive contamination.
3. Disconnect saline tubing from the short needle.
4. Use GM survey meter to check for contamination.
5. Place in plastic container and transport back to Nuclear Medicine. Assay the vial for residual activity in the dose calibrator. Use tongs when handing the vial to minimize radiation exposure.
6. Carefully remove the long needle with tubing attached and place in a sharp's container for radioactive waste. Remove short needle and place it in sharps/radioactive waste container.
7. Store vial in Decay closet until disposal. Some vials may have a long half-life impurity in which case they would need to be disposed of by a vendor.
8. When patient is ready to be discharged, survey patient at 1 meter and record reading.
9. Perform and record surveys and wipe tests after patient has vacated the treatment room.

RADIATION ONCOLOGY PROCEDURES:

At Consult

1. Patient to sign consent form after consulting with Radiation Oncologist.
2. Have patient stop long acting somatostatin analogs > 4 weeks before treatment date and short acting somatostatin analog for 24 hours before Lutathera dose.
3. Start preauthorization process.
4. Order Lutathera dose and other supplies for procedure, notify Nuclear Medicine and reserve treatment room.
5. Patient to have labs drawn. See table below for recommended threshold values

NANETS/SNMMI Recommended Laboratory Thresholds for LUTATHERA Treatment ¹	
Laboratory	Acceptable value before first treatment
Hemoglobin	>8 g/dL
WBC count	>2,000/mm ³
Platelet count	>70,000/mm ³
eGFR	>50 mL/min
Total bilirubin	≤3 x ULN
Serum albumin	>3.0 g/dL

These values should be considered general guidelines only.

This research was originally published in JNM. Hope TA, et al. *J Nucl Med*. 2019;60(7):937-943. © SNMMI.

2 -3 Days Before Treatment

1. Physician to assess the patient
2. Patient to get Labs for standard blood tests including pregnancy test if female of childbearing potential. Go over treatment procedures and radiation safety guidelines with patient.
3. Verify presence of all supplies, signed consent form, discontinuation of somatostatin analogs. See Somatostatin medication list for reference.

Day of Treatment

1. Have patient change into hospital gown and take vitals.
2. Verify pregnancy test results and check that patient has been off somatostatin analog for appropriate amount of time.
3. Start two IVs, one for Amino Acids and the other for Lutathera. (18 – 20 gauge IV set).
4. Open 500 mL, 0.9% sterile sodium chloride, prime IV pump infusion set and program to 30 mL/hour.
5. Administer antiemetics (e.g. Ondansetron).
6. Open one of the sterile tubing sets and spike the bag containing the amino acid solution. Prime tubing set.
7. Contact Nuclear Medicine department to let them know that administration has started and the projected time for Lutathera administration. Also inform Radiation Oncologist (AU for the procedure). If a family member is present, have them leave the room during the Lutathera infusion.

8. Just prior to Lutathera administration, have the patient use the bathroom to empty bladder.
9. Have Nuclear Medicine start Lutathera infusion after 1/8th of the amino acid solution has been infused (at least 30 minutes). The Radiation Oncologist (AU) is available for the Lutathera infusion.
10. Assist Nuclear Medicine technologists with adjusting IV pump infusion rates. Lutathera is administered at a rate of 50mL/hour to 100mL/hour for 5 to 10 minutes and then 200mL/hour to 300mL/hour for the next 25 to 30 minutes. The infusion is started at a slower rate to assess the patient.
11. Monitor patient for signs of neuroendocrine hormonal crisis.
12. Take vitals when the Lutathera treatment is complete.
13. Continue the amino acid infusion until done. This will take around three additional hours. Encourage patient to hydrate and urinate frequently.
14. Patient can have a meal during infusion on disposable plates and utensils.
15. Patient may wait another hour for the octreotide intramuscular injection or come back for it within 24 hours.
16. Ensure patient has copies of Radiation Safety guidelines, discharge instructions, and future appointment schedule for labs and subsequent treatments as needed.
17. Inform Nuclear Medicine personnel before patient leaves. Nuclear Medicine will take a reading at one meter from the patient and record on form.
18. The treatment room and attached bathroom will be surveyed by Nuclear Medicine for contamination before being released for general use.
19. Note: With the pharmacy prepared amino acids, the nausea rate can be higher. To decrease this side effect, increase the flow rate slowly such as 50mL every 15 minutes until reaching 250-300mL/hour. Administer the Lutathera after 1/8th of amino acid solution (125mL) has been infused. This means amino acids will run longer (1-1.5 hours before the Lutathera is given) and will still need to run 3 hours post-Lutathera.

List of somatostatin analogs:

lanreotide	<i>Long-acting (doses last ~ 4 weeks)</i>
lanreotide acetate (Somatuline)	<i>Long-acting (doses last ~ 4 weeks)</i>
octreotide	<i>Short-acting (doses last ~ 8 hours)</i>
octreotide acetate (Sandostatin)	<i>Short-acting (doses last ~ 8 hours)</i>
octreotide acetate (Sandostatin LAR Depot, Bynfezia Pen)	<i>Long-acting (doses last ~ 4 weeks)</i>
pasireotide (Signifor LAR)	<i>Long-acting (doses last ~ 4 weeks)</i>
pasireotide diaspargate (Signifor)	<i>Short-acting (doses last ~ 12 hours)</i>

Radiation Safety Guidelines for Patients treated with Lutathera

Please follow the guidelines below to minimize radiation exposure to others.

For the first 3 days after each treatment:

- Sleep in a separate bedroom and avoid intimate contact.
- Maintain a distance of 6 feet from others. Use a general guideline of being no closer than 3 feet for not more than 1 hour per day.
- Minimize public transportation and use of public facilities. Avoid extended time in public places.
- Drink plenty of fluids and urinate frequently. Sit down while urinating to avoid splashing. If you have a Nephrostomy tube, empty the bag as often as possible and keep the bag away from yourself while sleeping.
- Close the lid and double flush the toilet after each use. Wash hands with soap every time. Use separate towels and washcloths.
- If a caregiver provides assistance, have them wear disposable gloves.
- Return to work after 3 days if desired and only if able to meet guidelines regarding distance to others.

For the first 7 days after each treatment:

- Maintain a distance of 6 feet from infants, children, and pregnant women.
- Refrain from sexual activity.

For the first 15 days after each treatment:

- Sleep in a separate bedroom from infants, children, and pregnant women.

Breastfeeding:

Do not breastfeed during treatment, and for 2.5 months after the final Lutathera infusion.

Birth Control:

Use effective birth control during Lutathera treatment and for:

- 7 months after the final dose if female
- 4 months after the final dose if male with a female partner that can become pregnant.

If you have any questions regarding these guidelines, please feel free to contact your Radiation Oncologist at 515-241-4330.

I have read (or had them read to me) and understand these guidelines:

Signature

Date

Lutathera Written Directive

Patient Name: _____ DOB: _____ MR# _____

Radiopharmaceutical: Lutathera (lutetium Lu-177 Dotatate) Dose Sequence: # _____

Prescribed Dose: _____ mCi; Route: IV infusion; Date of administration: _____

AU Name: _____ AU Signature _____ Date: _____

Therapy Administration Record

Patient Verification by name and DOB: _____ Yes _____ No

Verification of Radiopharmaceutical: _____ Yes _____ No

Expected Dose from Batch Release Certificate: _____ MBq / 37 = _____ mCi

Assayed Dose in Vial (A): _____ mCi on Date: _____ at Time: _____

Residual Dose in Vial (B): _____ mCi; Delivered Dose to Patient (A – B): _____ mCi

Dose rate at 1 m from patient after infusion: _____ mR/hr (should be < 8.6 mR/hr)

Survey and Wipe Results

Survey Meter: _____ Model: _____ S/N: _____ Last Cal: _____ Bkg: _____ mR/hr

 Well Counter: _____ Model: _____ S/N: _____ Last Cal: _____ Bkg: _____ cpm
 Efficiency: _____; Wipe Results in dpm = (Wipe in cpm – Bkg in cpm) / Efficiency factor

Area	Room Floor	Infusion Chair	Bathroom Floor	Sink	Toilet at 30 cm from seat
Survey (mR/hr)					
Wipe (cpm)					
Wipe (dpm)					

Room outline
Modification of Written Directive:

_____ No Exceptions. AU signature not required.

_____ Yes, Reason: _____ AU signature: _____ Date: _____

NM Technologist: _____ Signature: _____ Date: _____

Medical Physicist: _____ Signature: _____ Date: _____

Hepatobiliary Imaging

Principle:

1. Following intravenous administration in normal subjects, Technetium 99m Mebrofenin (MBF) is rapidly cleared from the circulation. The mean percent injected dose remaining in the blood at ten minutes is 17%. The injected activity is cleared through the hepatobiliary system with visualization of the liver by five minutes and maximum liver uptake occurring at 11 minutes post-injection. Hepatic duct and gallbladder visualization occurs by 10-15 minutes and intestinal activity is visualized by 30-60 minutes in subjects with normal hepatobiliary function.
2. In Jaundiced patient, the percent injected dose remaining in the blood at ten minutes may be twice as high or more than the level in normals. Hepatobiliary transit may be delayed, and visualization times increased. Therefore, the quality of the images obtained frequently diminished.
3. Mebrofenin (choletec) is an iminodiacetic acid (HIDA) derivative with no known pharmacologic action at the recommended doses. When labelled with Tc99m, it is used to image the polygonal cells of the liver. The gallbladder is also imaged to evaluate for the chronic and acute cholecystitis. As the imaging agent moves through the biliary system, the biliary tract is evaluated for the normal drainage or suspected bile leak.
4. To detect biliary atresia a dose of phenobarbital is ordered 5 days prior.

Equipment, Reagent, and Supplies:

1. Radioisotope camera/computer system with high-resolution or general-purpose collimator.
2. Dose of Tc99m Mebrofenin 2-8mCi for adult for non-jaundiced patient 4-8mCi of adults with serum bilirubin levels greater than 1.5mg/dl. These doses are adjusted lower for pediatric patient based on weight.
3. Syringe shield and supplies for intravenous administration.

Patient Preparation:

When the test is performed to detect bile leak or demonstrate biliary atresia, no preparation is necessary. For other indication, the patient should be in a fasting state. Although eight hours is preferable, four hours may be adequate. False positives (non-visualization) may result if the gallbladder has been emptied by ingestion of food.

Procedure:

1. Verify the patient's identity using two methods and verify test orders.
2. Explain the procedure to the patient and answer questions.
3. Set up the radioisotope camera to detect the 140 keV photon of Tc99m at 20% window. Follow the workflow/protocol for other parameters.
4. The computer acquisition is usually performed as a one-hour series of dynamic images but static may be substituted to meet the need of the patient. In studies performed to demonstrate atresia, image may be needed at 4-6 hours, approximately 24 hours and 48 hours at the direction of the radiologist.
5. Aseptically administer the proper dose of MBF intravenously.
6. Position the patient so the liver and abdomen are in the anterior projection to the detector. If the movement of radiolabeled bile is delayed (no visualization of gallbladder

or intestinal tract) additional imaging time and/or other projection maybe necessary- Consult radiologist.

7. Produce screen captures of the image and transfer them to PACs, scan in the paper document and compose addition notes that will be helpful to generate the report.
8. After the examination is completed, change the linens on the imaging table and prepare the room for the next patient study.

Results:

This is a physician-interpreted study.

References:

1. Operator Manual, radioisotope central computer.
2. Operator Manual, PACs system
3. Nuclear Medicine William H. Bland MD 2nd edition 1971
4. Seminars in Nuclear Medicine, "Pediatric Nuclear Medicine Update Vol 37, No 4, July 2007.

Written by: Stephen Kuhn, Updated: Sharon Sheridan

Hepatobiliary Imaging with Interventional Gallbladder Ejection Fraction

Principle:

Following intravenous administration in normal subjects, Technetium 99m Mebroferun (MBF), packaged as Choletec, is rapidly cleared from the circulation. The mean percent-injected dose remaining in the blood at ten minutes is 17%. The injected activity is cleared through the hepatobiliary system with visualization of the liver by five minutes and maximum liver uptake occurring at 11 minutes post-injection. Hepatic duct and gallbladder visualization occurs by 10-15 minutes, and intestinal activity is visualized by 30-60 minutes in subjects with normal hepatobiliary function.

In jaundiced patients, the percent-injected dose remaining in the blood at ten minutes may be twice as high or more than the level in normal patients. Hepatobiliary transit may be delayed and visualization times increased. As a consequence, the quality of the images obtained frequently diminishes. Mebrofenin (Choletec) is an aminodiacetic acid derivative with no known pharmacological action at the recommended doses. When labeled with Technetium 99m, it is used to image the polygonal cells of the liver. The gallbladder is also imaged to evaluate for chronic and acute cholecystitis and to determine percent of bile ejected when it is stimulated to contract. As the imaging agent moves through the biliary system, the biliary tract is evaluated for normal drainage or to evaluate suspected bile leaks.

A threshold of cholecystikinin (CCK) is required to induce gallbladder contraction. Using a biologic preparation, the minimum dose was found to be 0.010 Crick-Harper-Raper units/kg/minute at a constant infusion. Increasing the infusion rate augments the rate of gallbladder emptying. When the dose is too high, incomplete contractions may be induced, perhaps as a result of premature infundibular spasm.

Kinevac (Sincalide) is the synthetic C-terminal octapeptide of cholecystikinin. When injected intravenously, Kinevac produces a substantial reduction in gallbladder size by causing this organ to contract. The evacuation of bile that results is similar to that which occurs physiologically in response to endogenous cholecystikinin. Kinevac causes a prompt contraction of the gallbladder that becomes maximal in 5-15 minutes, as compared with the stimulus of a fatty meal, which causes a progressive contraction that becomes maximal after approximately 40 minutes.

Equipment, Reagents, and Supplies:

1. Radioisotope camera/computer with high-resolution or general-purpose collimator.
2. Dose of Tc 99m Mebrofenin (Choletec); 2-8 millicuries. This dose is adjusted lower for pediatric patients based on weight.
3. Kinevac (Sincalide for injection), lyophilized, 5 micrograms/vial. Must be reconstituted with 5 ml of sterile water for injection U.S.P. Kinevac is obtained from the PXYIS.
4. Sterile water for injection, U.S.P.; 5 milliliters.
5. Microbore tubing and other supplies for intravenous administrations.
6. PACS image review and archiving system.

Special Note:

All patients scheduled for hepatobiliary imaging must have a prior gallbladder ultrasound within 6 months of the Nuclear Medicine appointment. The ultrasound report must be available at the time of hepatobiliary scheduling.

Hepatobiliary Imaging with Interventional Gallbladder Ejection Fraction - 2

Patient Preparation:

The patient must be in a fasting state; eight hours is preferred and four hours is usually the minimum. The radiologist should be consulted when in doubt about adequate patient preparation. False positives (nonvisualization) may result if the gallbladder has been emptied by prior ingestion of food.

In patients who have been fasting more than 24 hours prior to this test or have parenteral hyperalimentation and severe intercurrent illness should be pretreated with Kinevac to prevent interpretational pitfalls. The preparation of Kinevac is accomplished the same process as Kinevac administered for GBEF. Pretreatment can be done between 15-60 minutes prior to starting the mebrofenin imaging. The pre-mebrofenin administration of Kinevac augments gallbladder filling and can reduce false interpretations without changing GBEF during the same evaluation. Consult the radiologist as needed.

Preparation of Kinevac:

Reconstitution of a vial of Kinevac containing 5 micrograms of CCK, is accomplished by adding 5 ml of water for injection, U.S.P. One milliliter of this solution contains 1.0 meg of Sinclade. The usual adult dosage for prompt gallbladder contraction is 2.5 meg. The formula, 0.02 meg of Kinevac per kilogram of patient body weight, may be used. Pull 2.5 mL (2.5 meg) into a syringe and QS to 10 mL with normal saline. Administer intravenously at a rate of 0.5 mL per minute for 20 minutes. To achieve this set the pump rate to 30 ml/hr.

Procedure:

1. Verify the patient's identity using two methods and verify inpatient test orders.
2. Explain the procedure to the patient and answer appropriate questions. Ensure that the patient has met the minimum fasting time for adequate preparation. Obtain the patient's body weight for calculation of the Kinevac dose.
3. Set up the radioisotope camera and computer with the optimum parameters to detect the 140 keV photon of Tc 99m.
4. Aseptically administer the proper dose of mebrofenin (Choletec) intravenously.
5. Acquire images over the liver and abdomen at one frame per minute for a total of 60 minutes in the anterior projection. (Following the 45 minutes image if gallbladder and intestinal filling is seen, Kinevac may be administered prior to the end of the 60 minutes.) If these anatomical areas are not visualized at 60 minutes do not administer Kinevac. Begin an additional 30 minutes of acquisition at one minute per frame. If these areas are not visualized on this series, consult the radiologist.
6. The radiologist's protocol for the dosage of Kinevac for each patient is given above in the preparation section.
7. During Kinevac infusion acquire a set of 30 anterior images at 60-second per image ending at 10 minutes post-Kinevac infusion. After all images have been acquired, the patient may be dismissed. Use the gallbladder ejection fraction analysis software to determine gallbladder response to Kinevac.

Hepatobiliary Imaging with Interventional
Gallbladder Ejection Fraction - 3

8. Transfer all image and analyses screen-capture files to PACS. Scan-to-PACS the test requisition, patient questionnaire, US report and other documents pertinent to the examination. Edit-into PACS any additional information useful to the radiologist.
9. Sanitize and prepare the room for the next study.

Notes:

1. Kinevac (Sincalide) may be stored at room temperature prior to reconstitution. If refrigerated, allow the lyophilized Kinevac to reach room temperature before adding sterile water.
2. Reconstituted Kinevac solution is for single dose use.
3. Narcotic pain medications may cause false abnormal results. Most of these medications must be discontinued for 6 hours.

Results:

1. Gallbladder ejection fraction values of 35% and greater is considered normal.
2. This is a physician-interpreted study.

References:

1. Operator's Manual, radioisotope camera computer.
2. Journal of Nuclear Medicine Technology, Hepatobiliary imaging update, Chester M. Glowinski, 20:3-7; 1992.
3. Product literature supplied with Kinevac, Bracco Diagnostics, Inc., May 2002.
4. Product literature supplied with Choletec (Mebrofenin), Bracco Diagnostics, Inc., September 2002.
5. Operator's Manual, PACS system
6. "Hepatobiliary Scintigraphy, Case Review of Sincalide (Kinevac) Applications", Mark Tulchinsky, MD; October 2008
7. Seminars in Nuclear Medicine, Functional Studies of the Gastrointestinal Tract; Vol. 42, No. 2; March 2012.

Written by: Stephen A. Kuhn, October 1992

Reviewed by: S. Sheridan 4/2019

Updated by: Stephen A. Kuhn, October 1995; October 2003; February 2005; November 2006;
June 2009; August 2013, 11/2018

OPIOID ANALGESICS			
GENERIC	BRAND	GENERIC	BRAND
alfentanil	Alfenta	hydromorphone	Dilaudid
buprenorphine	Buprenex		Palladone
	Temgesic	levorphanol	Levo-Dromoran
	Subutex	methadone	Dolophine
butorphanol	Stadol		Methadose
codeine	Tylenol with Codeine	meperidine	Demerol
	Empirin with Codeine		Mepergan
	Fiorinal with Codeine	morphine	MS Contin
	Capital with Codeine		Roxanol
	Phenaphen with Codeine		Oramorph
	Cheracol		Avinza
	Robitussin AC		Kadian
dihydrocodeine	Synalogs-DC		Duramorph
diQuenoxylate	Lomotil		Astromorph
	Logen		Depo-Our
fentanyl	Duragesic	nalbuphine	Nubain
	Sublimaze	opium	Paregoric
	Actiq		Laudanum
	Oralet	OXYcodone	Oxycontin
	Innovar		Percocet
hydrocodone	Lortab		Percodan
	Vicodin		Endocet
	Vicoprofen		Oxicodone
	Lorcet	oxycodone	Numorphan
	Zydene	pentazocine	Talwin
	Bancap HC	propoxyphene	Darvon
	Panacet		Darvocet
	Duocet		Propacet
	Cogesic	sufentanil	Sufenta
	Hydrocet	tramadol	Ultram
	Hyphen		Ultracet
	Stagesic		
	T-Gesic		
	Anexsia		
	Norco		1-4-06 KK

Valium is ok to have.

Fentanyl patch 1/2 life is 24-27°

Nuclear Medicine

Radiologists Standing Order

For Kinevac Preparation and Administration

Within Hepatobiliary Imaging Protocol

To one vial of Kinevac, add 5 milliliters of sterile water. Invert the vial several times; visually check for complete solution. Technologist preparing solution will attach label to the vial with the date and initials. The concentration is 1 microgram/milliliter.

For adult patients undergoing Nuclear hepatobiliary imaging with Tc99m mebrofenin (MBF), draw 2.5 milliliters (2.5 micrograms) of reconstituted Kinevac solution and qs. to 10.4 milliliters volume with 0.9% preservative-free NaCl solution.

For patients less than 18 years old undergoing Nuclear hepatobiliary imaging with Tc99m MBF, draw a volume of Kinevac solution equal to 0.02 micrograms per kilogram body weight; qs. to 10.4 milliliters with 0.9% preservative-free NaCl solution.

Use a syringe pump to infuse diluted Kinevac (10ml) solution intravenously at a rate of 0.5 milliliter per minute for a total of 20 minutes. (Set the pump to deliver 30 milliliters per hour.) Use mini-bore tubing to connect syringe with Kinevac to the patient's IV cannula. Expel the air in the tubing (priming volume is 0.4 ml) prior to connection and administration of Kinevac preparation.

Print Name of Radiologist: Dr. Marvin Walker D.O.

Reviewed by: S. Sheridan 11/2018

Hepatobiliary Imaging with Fatty-Meal Stimulated - Gallbladder Ejection Fraction

Principle:

Following intravenous administration in normal subjects, Technetium 99m Mebrofenin (MBF), packaged as Choletec, is rapidly cleared from the circulation. The mean percent-injected dose remaining in the blood at ten minutes is 17%. The injected activity is cleared through the hepatobiliary system with visualization of the liver by five minutes and maximum liver uptake occurring at 11 minutes post-injection. Hepatic duct and gallbladder visualization occurs by 10-15 minutes, and intestinal activity is visualized by 30-60 minutes in subjects with normal hepatobiliary function.

In jaundiced patients, the percent-injected dose remaining in the blood at ten minutes may be twice as high or more than the level in normal patients. Hepatobiliary transit may be delayed and visualization times increased. As a consequence, the quality of the images obtained frequently diminishes. Mebrofenin (Choletec) is an aminodiacetic acid derivative with no known pharmacological action at the recommended doses. When labeled with Technetium 99m, it is used to image the polygonal cells of the liver. The gallbladder is also imaged to evaluate for chronic and acute cholecystitis and to determine percent of bile ejected when it is stimulated to contract. As the imaging agent moves through the biliary system, the biliary tract is evaluated for normal drainage or to evaluate suspected bile leaks.

Oral consumption of a lactose-free, fatty meal supplement, causes a progressive gallbladder contraction that becomes maximal after approximately 40 minutes and estimates bile ejection fraction.

Equipment, Reagents, and Supplies:

1. Radioisotope camera/computer with high-resolution or general-purpose collimator.
2. Dose of Tc 99m Mebrofenin (Choletec); 2-8 millicuries. This dose is adjusted lower for pediatric patients based on weight.
3. One container Ensure Plus, lactose-free nutrition supplement, any flavor; 8 oz (240mL).
4. PACS image review and archiving system.

Note:

All patients scheduled for hepatobiliary imaging must have prior gallbladder ultrasound, within 6 months of the Nuclear Medicine appointment. The ultrasound report must be available at the time of hepatobiliary scheduling.

Patient Preparation:

The patient must be in a fasting state; eight hours is preferred and four hours is usually the minimum. The radiologist should be consulted when in doubt about adequate patient preparation. False positives (non-visualization) may result if the gallbladder has been emptied by prior ingestion of food.

Procedure:

1. Verify the patient's identity using two methods and verify inpatient test orders.

Hepatobiliary Imaging with Fatty-Meal Stimulated Gallbladder Ejection Fraction - 2

2. Explain the procedure to the patient and answer appropriate questions. Verify that the patient has met the minimum fasting time for adequate preparation. Obtain the patient's body weight.
3. Set up the radioisotope camera and computer with the optimum parameters to detect the 140 keV photon of Tc 99m.
4. Aseptically administer the proper dose of MBF (Choletec) intravenously.
5. Acquire images over the liver and abdomen at one frame per minute for a total of 60 minutes in the anterior projection. If gallbladder filling is seen after 45 minutes, this imaging series may be stopped and the fatty-meal stimulation may be started. If gallbladder and intestinal filling are not seen at 60 minutes, do not give the Ensure Plus. Begin an additional 30 minutes of acquisition at one minute per frame. If these areas are not visualized on this series, consult the radiologist.
6. Prior to giving the fatty-meal stimulation, the patient should void to assure comfort and cooperation during the post-stimulation imaging.
7. The patient will then ingest 8oz (240 ml) of Ensure Plus, nutrition supplement in chocolate, strawberry or vanilla flavor. After consumption of the nutrition supplement, acquire images over the liver and abdomen at a rate of 1 per minute for an additional 60 minutes.
8. After all images have been acquired, the patient may be dismissed. Use the gallbladder ejection fraction analysis software to determine gallbladder response to the fatty-meal.
9. Transfer all image and analyses screen-capture files to PACS. Scan-to-PACS the test requisition, patient questionnaire, US report and other documents pertinent to the examination. Edit-into PACS any additional information useful to the radiologist.
10. Sanitize and prepare the room for the next study.

Notes:

1. Narcotic pain medications may cause false abnormal results. Most of these medications must be discontinued for 6 hours.

Results:

1. Gallbladder ejection fraction values of 33% and greater is considered normal.
2. This is a physician-interpreted study.

References:

1. Operator's Manual, radioisotope camera computer.
2. Journal of Nuclear Medicine Technology, Hepatobiliary imaging update, Chester M. Glowniak, 1992; 20:3-7.
3. Journal of Nuclear Medicine Technology, Choleystokinin Cholescintigraphy: Methodology and Normal Values Using a Lactose-Free Fatty-Meal Food Supplement, Harvey A. Ziessman, 2003; 44:1263-1266.
4. Seminars in Nuclear Medicine, Functional Studies of the Gastrointestinal Tract; Vol42, No. 2; March 2012.

Hepatobiliary Imaging with Fatty-Meal
Stimulated Gallbladder Ejection Fraction - 3

4. Product literature supplied with Choletec (Mebrofenin), Bracco Diagnostics, Inc., September 2002.
5. Operator's Manual, PACS system

Written by: StephenA.Kuhn; 8/2013

Updated by: S. Sheridan 10/2020

HEPATOBILIARY IMAGING WITH MORPHINE

PRINCIPLE:

Following intravenous administration in normal subjects, Technetium 99m Mebrofenin (Tc 99m .MBF) is rapidly cleared from the circulation. The mean percent injected dose remaining in the blood at ten minutes is 17%. The injected activity is cleared through the hepatobiliary system with visualization of the liver by five minutes and maximum liver uptake occurring at 11 minutes post injection. Hepatic duct and gallbladder visualization occurs by 10-15 minutes and intestinal activity

Is visualized at 30-60 minutes in subjects with normal hepatobiliary function.

In jaundiced patients, the percent injected dose remaining in the blood at ten minutes may be twice as high or more than the level in normal. Hepatobiliary transit may be delayed and visualization times increased. As a consequence, the quality of the images obtained frequently diminishes.

Mebrofenin is an aminodiacetic acid derivative with no known pharmacologic action at the recommended doses. When labeled with Tc99m, it is used to image the polygonal cells of the liver. The gallbladder is also imaged to evaluate for chronic and acute cholecystitis. As the imaging agent moves through the biliary system, the biliary tract is evaluated for normal drainage or suspected bile leaks.

By using morphine, the sphincter of Oddi contracts, thus forcing the Mebrofenin into the gallbladder, ruling out acute cholecystitis.

EQUIPMENT, REAGENTS, AND SUPPLIES:

1. Radioisotope camera/computer system with high-resolution or general purpose collimator.
2. Amount of morphine to be given is usually calculated with the following formula: **.04 mg/kg** body weight; infused over 1-3 minutes. Follow amount ordered by referring physician or radiologist.
3. Dose of Tc99m Mebrofenin (Choletec); 2-8 millicuries. This dose is adjusted lower for pediatric patients based on weight.
4. Syringe shield and supplies for intravenous administration.
5. PACS image review and archiving system.

PATIENT PREPARATION:

1. The patient should be in a fasting state. Although eight hours is preferable, four hours may be adequate. Consult the radiologist as needed about the preparation.
2. The patient should have no radiological contrast within the last 72 hours.
3. Confirm with patient that they are not allergic to morphine. If outpatient status, patient must have a driver.

PROCEDURE:

1. Verify the identity of the patient using two methods and verify inpatient orders. Explain the procedure and obtain the patient's allergy history.
2. Set up camera and use the hepatobiliary imaging protocol.

HEPATOBIILIARY IMAGING WITH MORPHINE – Page 2 of 2

3. Establish an intravenous access. The proper amount of morphine will be determined and administered IV by qualified personnel (RN or physician) over 1-3 minutes. Retain the IV access to give the Choletec. Assure that the morphine administration is recorded on the "Other" line of the "Contrast Media, Assessment/Administration Checklist".
4. About 15 minutes after the morphine, administer the IV Choletec. Within 5 minutes position the patient supine on an imaging table and position the camera detector over the anterior abdomen to include the liver near top of the field.
5. Start the camera/computer to acquire a dynamic series at 60 seconds for 60 frames or alternatively static views can be taken immediately, 5, 10, 15, 20, 25, 30, 45, and 60 minutes for 1000k counts.
6. If at 60 minutes the gallbladder is not visualized, transfer the image files to the PACS. Review this series with the radiologist and then release patient.
7. Produce screen captures of all images and transfer to PACS. Scan the test requisition and history sheet(s) into PACS. Scan the "Contrast Media, Assessment/Administration Checklist" into the PACS. Compose a clinical note to include doses of agents and names of personnel involved in the procedure.

Results:

1. This is a physician-interpreted study.

References:

1. Operator's Manual, radioisotope camera computer.
2. Journal of Nuclear Medicine Technology, Hepatobiliary imaging update, Chester M. Glowniak, 20:3-7; 1992.
3. Product literature supplied with morphine.
4. Product literature supplied with Choletec (Mebrofenin), Bracco Diagnostics, Inc., September 2002.
5. Operator's Manual, PACS system
6. Seminars in Nuclear Medicine, Pharmacologic Interventions and Monitoring, Vol 39, No 3, May 2009.

Written by: Stephen A Kuhn; 1/2007

Reviewed by S. Sheridan ; 4/2019

1
NARCOTIC DRUGS UNDER INTERNATIONAL CONTROL
Section 1
Drugs Included in Schedule I of the 1961 Convention

<i>Narcotic drugs</i>	<i>Description/Chemical name</i>
Acetorphine	3-O-acetyltetrahydro-7a-(1-hydroxy-1-methylbutyl)-6,14-endo-ethenooripavine
Acetyl- α -methylfentanyl	N-[1-(α -methylphenethyl)-4-piperidyl]acelanilide
Acetyl- α -methyl-4-(4-phenylheptan-3-yl)-piperidine	3-ecetoxy -dimethylamino-4,4-diphenylheptane
Alfentanil	N-[1-[2-(4-ethyl-4,5-dihydro-5-oxo-1H-tetrazol-1-yl)ethyl]-4-(methoxymethyl)-4-phenylpropanamido]
Allylprodine	3-allyl-1-methyl-4-phenyl-4-propionoxypiperidine
Alphacetylmethadol	α -3-ecetoxy-O-dimethylamino-4,4-diphenylheptane
Alphameprodine	α -3-ethyl-1-methyl-4-phenyl-4-propionoxypiperidine
Alphamethadol	α -dimethylamino-4,4-diphenyl-3-l'leptanol
α -methylfentanyl	N-[1-(α -methylphenethyl)-4-piperidyl]propionanilide
α -methyl-4-(4-phenylheptan-3-yl)-piperidine	N-[1-[1-methyl-2-(2-thienyl)ethyl]-4-piperidyl]propionanilide
Alphaprodine	piperidyl]propionanilide α -1,3-dimethyl-4-phenyl-4-propionoxypiperidine
Anileridine	propionoxypiperidine
Benzethidine	1-p-ethylphenethyl-4-phenylpiperidine-4-carboxylic acid ethylester
Benzylmorphine	1-(2-benzyloxyethyl)-4-phenylpiperidine-4-carboxylic acid ethylester
Betacetylmethadol	3-benzylmorphine
Beta-l'hydroxyfentanyl	11-3-ecetoxy -dimethylamino-4,4-diphenylheptane
Beta-l'hydroxy-3-methylfentanyl	N-[1-(11-l'hydroxyphenethyl)-4-piperidyl]propionanilide
Betameprodine	N-[1-(11-l'hydroxyphenethyl)-3-methyl-4-piperidyl]propionanilide
Betanmethadol	11-3-ethyl-1-methyl-4-phenyl-4-propionoxypiperidine
Betaprodine	11 -dimethylamino-4,4-diphenyl-3-l'leptanol
Betaprodine	B-1,3-dimethyl-4-phenyl-4-propionoxypiperidine
Bezitramide	1-(3-cyano-3,3-diphenylpropyl)-4-(2-oxo-3-propionyl-1-benzimidazolyl)piperidine
Cannabis and cannabis resin and extracts and tinctures of cannabis	Indian hemp and resin of Indian hemp
Chlortalazine	2-(chlorobenzyl)-1-diethylaminoethyl-5-oxobenzimidazole
Coca leaf	
Cocaine	methylester of benzoylecgonine
Codoxime	dihydrocodeinone-3-O-carboxymethylolme
Concentrate of poppy straw	the material arising when poppy straw has entered into a process for the concentration of its alkaloids when such material is made available in trade
Desomorphine	dihydrodeoxymorphine
Dextromoramide	(+)-4-[2-methyl-4-oxo-3,3-diphenyl-4-(1-pyrrolidinyl)butyl]morpholine
Diampromide	N-[2-(methylphenethylamino)propyl]propionanilide
Diethylthambutene	3-diethylamino-1,1-di(2-thienyl)-1-butene

For the calculation of estimates and statistics in accordance with the terms of the 1961 Convention, coca leaf preparations containing more than 0.1 per cent of cocaine and made direct from coca leaf should be considered to be *coca leaf* (preparations).

4

<i>Narcotic drugs</i>	<i>Description/Chemical name</i>
Morphine-N-oxide	
MPPP	1-methyl-4-phenyl-4-piperidinol propionate (ester)
Dextromethorphan ((+)-3-methoxy-N-methylmorphinan) and dextrorphan ((+)-3-hydroxy-N-methylmorphinan) are isomers specifically excluded from this Schedule.	
Myrophine	myristyl benzytmorphine
Nicomorphine	3,6-dimethylmorphine
Noracymethadol	(p)-3-acetoxy-6-methylamino-4,4-diphenylheptane
Norlevorphanol	(-)-3-hydroxymorphinan
Normethadone	6-dimethylamino-4,4-diphenyl-3-hexanone
Nonmorphine	demethylmorphine
Norpinane	4,4-diphenyl-6-piperidino-3-hexanone
Opium -	
Oxycodone	14-hydroxydihydrocodeinone
Oxymorphone	14-hydroxydihydromorphinone
Paral. fluoro fentanyl	4-fluoro-N-(1-phenethyl-4-piperidyl)propanamide
PEPAP	1-phenethyl-4-phenyl-4-piperidinolacetate (ester)
Pethidine	1-methyl-4-phenylpiperidine-4-(carboxylic acid ethyl ester)
Pethidine Intermediate A	4-(4-oxo-1-methyl-4-phenylpiperidine)
Pethidine Intermediate B	4-phenylpiperidine-4-(carboxylic acid ethylester)
Pethidine intermediate C	1-methyl-4-phenylpiperidine-4-(carboxylic acid)
Phenadoxone	6-morpholino-4,4-diphenyl-3-heptanone
Phenampromide	N-(1-methyl-2-piperidinoethyl)propanamide
Phenazocine	2'-hydroxy-5,9-dimethyl-2-phenethyl-6,7-benzomorphan
Phenomorphane	3-hydroxy-N-phenethylmorphinan
Phenopiridine	1-(3-hydroxy-3-phenylpropyl)-4-phenylpiperidine-4-(carboxylic acid ethylester)
Piminodine	4-phenyl-1-(3-phenylaminopropyl)piperidine-4-(carboxylic acid ethyl ester)
Pirrolamide	1-(3-(4-oxo-3,3-diphenylpropyl)-4-(1-piperidino)piperidine-4-(carboxylic acid amide)
Proheptazine	1,3-dimethyl-4-phenyl-4-propionoxyazacycloheptane
Propiridine	1-methyl-4-phenylpiperidine-4-(carboxylic acid isopropylester)
Racemathorphan	(p)-3-methoxy-N-methylmorphinan
Racemoramide	(p)-4-(2-methyl-4-oxo-3,3-diphenyl-4-(1-pyrrolidinyl)butyl)morphine
Racemorphan	(p)-3-hydroxy-N-methylmorphinan
Remifentanyl	1-(2-methoxy carbonyl-ethyl)-4-(phenylpropylamino)piperidine-4-(carboxylic acid methylester)
Sufentanyl	N-(4-(methoxymethyl)-1-(2-(2-thienyl)ethyl)-4-piperidyl)propanamide
Thebacon	acetyl dihydrocodeinone
Thebaine	
Thiofentanyl	N-(1-(2-(2-thienyl)ethyl)-4-piperidyl)propanamide

• For the calculation of estimates and statistics in accordance with the terms of the 1961 Convention, all preparations made direct from opium are considered to be opium (preparations). If the preparations are not made direct from opium itself but are obtained by a mixture of opium alkaloids (as is the case, for example, with pantopon, omnopon and papaveretum) they should be considered as morphine (preparations).

<i>Narcotic drugs</i>	<i>Description/Chemical name</i>
Trilidone	(p)-ethyl-trans-2-(dimethylamino)-1-phenyl-3-cyclohexene-1-carboxylate
Trimeperidine	1,2,5-trimethyl-4-phenyl-4-propionoxypiperidine
AND the isomers, unless specifically excepted, of the drugs in this Schedule whenever the existence of such isomers is possible within the specific chemical designation; the esters and ethers, unless appearing in another Schedule, of the drugs in this Schedule whenever the existence of such esters or ethers is possible; the salts of the drugs listed in this Schedule, including the salts of esters, ethers and isomers as provided above whenever the existence of such salts is possible.	

Section 2

Drugs Included in Schedule II of the 1961 Convention

<i>Narcotic drugs</i>	<i>Description/Chemical names</i>
Acetyldihydrocodeine	
Codeine	3-methylmorphine
Dextropropoxyphene	a-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-butanolpropionate
Dihydrocodeine	
Ethylmorphine	3-ethylmorphine
Nicodoline	6-nicotinylcodeine
Nicodoline	6-nicotinyldihydrocodeine
Norcodeine	N-demethylcodeine
Pholcodine	morpholinylethylmorphine
Propiram	N-(1-methyl-2-piperidinoethyl)-N-2-pyrrolidonepropionamide

AND the isomers, unless specifically excepted, of the drugs in this Schedule whenever the existence of such isomers is possible within the specific chemical designation;
 the salts of the drugs listed in this Schedule, including the salts of the isomers as provided above whenever the existence of such salts is possible.

Section 3

Drugs Included in Schedule IV of the 1961 Convention

<i>Narcotic drugs</i>	<i>Description/Chemical names</i>
Acetorphine	3-O-acetyltetrahydro-7a-(1-hydroxy-1-phenylethyl)-6,14-endo-ethenopropine
Acetyl-alpha-methylfentanyl	N-(1-(alpha-methylphenethyl)-4-piperidyl)acetanilide
Alpha-phenethylfentanyl	N-(1-(alpha-methylphenethyl)-4-piperidyl)propionanilide
Alpha-phenethylthiofentanyl	N-(1-(1-methyl-2-(2-phenyl)ethyl)-4-piperidyl)propionanilide
Beta-hydroxy-3-methylfentanyl	N-(1-(beta-hydroxyphenethyl)-3-methyl-4-piperidyl)propionanilide
Beta-hydroxyfentanyl	N-(1-(beta-hydroxyphenethyl)-4-piperidyl)propionanilide
Cannabis and Cannabis resin	
Desomorphine	dihydrodeoxymorphine
Etorphine	tetrahydro-7a-(1-hydroxy-1-methylbutyl)-6,14-endo-ethenopropine
Heroin	diacetylmorphine
Ketobemidone	4-methoxyphenyl-1-methyl-4-propionylpiperidine

Section 3

Drugs Included in Schedule I of the 1961 Convention

<i>Narcotic drugs</i>	<i>Description/Chemical names</i>
3-methylfentanyl	N-(3-methyl-1-phenethyl-4-piperidyl)propionanilide
3-methylthiofentanyl	N-(3-methyl-1-(2-(2-thienyl)ethyl)-4-piperidyl)propionanilide
MPPP	1-methyl-4-phenyl-4-piperidinol propionate (ester)
Para-fluorofentanyl	4'-fluoro-N-(1-phenethyl-4-piperidyl)propionanilide
PEPAP	1-phenethyl-4-phenyl-4-piperidinolacetate (ester)
Thiofentanyl	N-(1-(2-(thienyl)ethyl)-4-piperidyl)propionanilide

AND the salts of the drugs listed in this Schedule whenever the formation of such salts is possible.

Hepatobiliary Imaging for Sphincter of Oddi function In a Post-cholecystectomy Patient

Principle:

Following intravenous administration in normal subjects, Technetium 99m Mebrofenin (MBF), packaged as Choletec, is rapidly cleared from the circulation. The mean percent-injected dose remaining in the blood at ten minutes is 17%. The injected activity is cleared through the hepatobiliary system with visualization of the liver by five minutes and maximum liver uptake occurring at 11 minutes post-injection. Hepatic duct visualization occurs by 10-15 minutes, and intestinal activity is visualized by 30-60 minutes in subjects with normal hepatobiliary function.

In jaundiced patients, the percent-injected dose remaining in the blood at ten minutes may be twice as high or more than the level in normal patients. Hepatobiliary transit may be delayed and visualization times increased. As a consequence, the quality of the images (scintigrams) obtained frequently diminishes. Mebrofenin (Choletec) is an aminodiacetic acid derivative with no known pharmacological action at the recommended doses. When labeled with Technetium 99m, it is used to image the polygonal cells of the liver and visualize the movement of bile into the small intestine.

After a cholecystectomy, the normal biliary tree is transformed into a single-outlet system where intrahepatic ductal bile can flow only through the common duct into the duodenum. The alternate flow pathway into the gallbladder no longer exists. During contraction of the sphincter of Oddi in a normal patient, intraductal pressure remains normal because the biliary system can decompress by draining into the gallbladder. This organ acts as a pressure reservoir. However, sphincter contraction in a post-cholecystectomy patient usually results in elevation of intraductal pressure because the reservoir effect of the gallbladder is no longer present. High intraductal pressure may cause pain and together with a tight sphincter may lead to biliary stasis, ductal dilatation, and to delayed hepatobiliary radionuclide transit.

One concern of all dynamic radionuclide tracer studies is the potential of false-positive studies caused by low flow states. This is common in radionuclide kidney studies where delayed transit and tracer retention may be seen in dehydrated patients due to decreased urine flow. This could potentially occur also on hepatobiliary scans during states of decreased bile flow. In an attempt to prevent false-positive results, patients are pretreated with Kinevac (Sincalide). Kinevac is the synthetic C-terminal octapeptide of cholecystokinin (CCK). In the post-cholecystectomy patient CCK is believed to stimulate bile production. CCK may lower sphincter pressure and improve test specificity by enhancing biliary drainage in normal patients.

Sphincter of Oddi dysfunction (SOD) is a disorder which creates an obstacle to bile drainage from the common bile duct (CBD). Usually presenting with recurrent pain after a cholecystectomy, the obstacle is often caused by stenosis or dyskinesia of the sphincter of Oddi. This hepatobiliary protocol utilizes a scoring system of cholecystokinin-stimulated hepatobiliary scintigrams that combine visual and quantitative criteria for the diagnosis of SOD.

Equipment, Reagents, and Supplies:

1. Radioisotope camera/computer with high-resolution collimator.
2. Dose of Tc 99m Mebrofenin (Choletec); Adults receive 2-8 millicuries.
3. Kinevac (Sincalide for injection), lyophilized, 5 micrograms/vial. **Must** be reconstituted with 5 mls of sterile water for injection U.S.P. Kinevac is obtained from the Omnicell.
4. Sterile water for injection, U.S.P.; 5 milliliters.
5. Microbore tubing and other supplies for intravenous administrations.
6. PACS image review and archiving system.

Preparation of Kinevac:

Reconstitution of a vial of Kinevac containing 5 micrograms of CCK, is accomplished by adding 5ml of water for injection, U.S.P. One milliliter of this solution contains 10 microgram of CCK. Calculate volume of CCK solution to equal 0.02 micrograms of Kinevac per kilogram patient body weight. Remove that volume of CCK solution and add NaCl quantity sufficient to make 5 mL plus the volume of "dead space" in IV tubing.

Patient Preparation:

The patient must be in a fasting state at least 3 hours. The dose of Kinevac solution for pretreatment is 0.02 microgram/kilogram body weight. Administer the Kinevac intravenously in a three-minute infusion. Fifteen minutes later administer intravenously 5 millicuries Tc99m mebrofenin. Patient should not have narcotic pain medications for 4-6 hours prior to this exam. The radiologist should be consulted when in doubt about adequate patient preparation.

Procedure:

1. Verify the patient's identity using two methods and review the provider's test order.
2. Explain the procedure to the patient and answer appropriate questions. Ensure that the patient has met the preparation rule for fasting and pain medication. Obtain the patient's body weight for calculation of the Kinevac dose.
3. Set up the radioisotope camera and computer with the optimum parameters to detect the 140 keV photon of Tc 99m, framing rate of 1 image/minute for a total of 60, using a 128 x 128 matrix size.
4. Manually administer the 5 mL Kinevac solution intravenously over a period of 3-minutes Using a 10ml syringe and place in syringe pump set for 100 mL/hr. Wait 15 minutes.
5. After the patient is positioned for supine, anterior liver imaging, administer the Tc99m MBF (Choletec) intravenously. Upon completion of the radiotracer administration, begin imaging immediately.
6. At the completion of the exam dismiss the patient and process the images/data. Sanitize and prepare the room for the next patient.

Hepatobiliary Imaging for Sphincter of Oddi Function Page 3 of 5

Data/Image Processing:

1. Place a region of interest over the liver parenchyma and another ROI over the common bile duct (CBD) to generate time-activity curves. The liver ROI is chosen in the right lobe excluding visible bile intrahepatic ducts; the CBD ROI is placed in the lowest portion of the CBD not affected by superimposed bowel activity.
2. From these curves derive:

a.) From the liver curve determine Time of hepatic peak (t-peak) (example: 30 minutes)

b.) percent CBD emptying, which is calculated by the equation:

$$100 \times (\text{Peak CBD counts} - \text{at 60 min} / \text{Peak CBD counts})$$

(Example: $100 \times (900 - 300 = 600 / 900 = 0.67) = 67\%$)

When a continuously raising curve is obtained, the 30-minute value is taken as the peak CBD counts.

3. Transfer all images and analyses screen-capture files to PACS. Scan-to-PACS the test requisition, patient questionnaire, U/S reports and other documents pertinent to the examination. Enter PACS comments and additional information useful to the radiologist.

Notes:

1. Kinevac (Siocalide) may be stored at room temperature prior to reconstitution. **If** refrigerated, allow the lyophilized Kinevac to reach room temperature before adding sterile water.
2. Reconstituted Kinevac solution is for single dose use.
3. Narcotic pain medications may cause false abnormal results. Discontinue these medications 4-6 hours prior to the study.

Results:

1. This is a physician-interpreted study that includes analysis of images and curves to score six parameters. The parameters evaluated are:
 - a.) Time of peak liver activity, as obtained from the right lobe time-activity curve.
 - b.) Time at which intrahepatic biliary tree was first visualized determined from the series of Tc99m MBF images.
 - c.) Prominence or dilatation of the biliary tree as determined from the images as a subjective evaluation similar to that described by Zeman (see reference 8) and Lee (see reference 9).
 - d.) Time at which bowel was first visualized as determined from the series of Tc99m MBF images.

- e.) Percent CBD emptying as calculated from the CBD curve using the equation described in Data Processing, 2b, above.
- f.) CBD-to-Liver ratio. This parameter was obtained from the static images by visually comparing the CBD at 60 minutes (CBD60) to the liver parenchyma at 60 minutes (Liver60) and liver parenchyma at 15 minutes (Liver15). This ratio represents activity retained in the CBD at the end of the study.

Criteria for Scoring Images:

1. Peak Time:
 - a.) Less than 10 minutes 0
 - b.) 10 or more minutes
2. Time of Biliary Visualization:
 - a.) Less than 15 minutes 0
 - b.) 15 or more minutes
3. Prominence of Biliary Tree:
 - a.) Not prominent 0
 - b.) Prominent major intrahepatic ducts 1
 - c.) Prominent small intrahepatic ducts 2
4. Bowel Visualization:
 - a.) Less than 15 minutes 0
 - b.) 15-30 minutes
 - c.) More than 30 minutes 2
5. CBD Emptying:
 - a.) By more than 50% 0
 - b.) Less than 50% 1
 - c.) No change 2
 - d.) Shows increasing activity 3
6. CBD-to-Liver Ratio
 - a.) CBD60 Less than
or equal Liver60 0
 - b.) CBD60 higher than Liver60
but lower than Liver15
 - c.) CBD60 higher than Liver60
and equal to Liver15 2
 - d.) CBD60 higher than
both Liver60 and Liver15 3

The range of the final score is 0 to a maximum of 12; the higher numbers correspond to slower kinetics.

Normal Patients scores = 0-4

Patients with SOD scores = 5-12.

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A Noninvasive Test of Sphincter of Oddi Dysfunction in Postcholecystectomy Patients: The Scintigraphic Score

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The ideal noninvasive test of sphincter of Oddi dysfunction (SOD) does not exist and the diagnosis of patients with postcholecystectomy pain often relies on invasive procedures. In this paper we describe a scintigraphic test for SOD: the scintigraphic score. This score combines quantitative and visual criteria for interpretation of hepatobiliary scans. Twenty-six consecutive postcholecystectomy patients underwent hepatobiliary imaging, ERCP, and sphincter manometry. Twelve patients had SOD and 14 had normal sphincters determined by clinical findings, ERCP, and manometric studies. All patients with normal sphincter had scores of 0–4, while patients with SOD had values of 5–12 for a perfect sensitivity and specificity of 100%. Hepatobiliary scans scored in this fashion may become the noninvasive test of choice to screen postcholecystectomy patients with suspected SOD.

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Sphincter of Oddi dysfunction (SOD) is a poorly defined disorder which creates an obstacle to bile drainage from the common bile duct (CBD). Usually presenting with recurrent pain after a cholecystectomy, the obstacle is often caused by stenosis or dyskinesia of the sphincter of Oddi, conditions best identified and characterized by manometry (1).

According to estimates by Steinberg and Bar-Meir (1, 2), at least 45,000 patients in the U.S. develop postcholecystectomy pain every year. In approximately 6200, the pain is due to SOD. If manometry were employed to screen patients with postcholecystectomy pain, 7.2 studies would be performed for every case of SOD detected. This efficacy ratio may be unacceptable for a procedure that is invasive, difficult to perform and associated with significant complications, such as pancreatitis (1,3).

A need exists for a reliable noninvasive screening test to identify patients likely to have SOD and who may benefit from the more invasive manometric test.

Several techniques have been proposed for this purpose, but quantitative cholescintigraphy is probably the one most often utilized (4–7). It can identify patients with SOD by demonstrating and quantifying a significant delay in hepatic uptake and washout (Fig. 1). This ability to quantify is helpful because it allows assignment of a concrete numerical value to a physiologic function. This value can be used to compare patients, to estimate statistical significance between groups and to compare follow-up studies in the same subject. Unfortunately, quantitative cholescintigraphy has not yielded a high sensitivity consistently and is therefore not a good screening test (8). It also suffers from lack of specificity. Patients with liver dysfunction and cholestasis show results indistinguishable from those of SOD (1,4,5).

Recently, in an attempt to improve sensitivity and specificity, we amplified work done by other authors (9,10) and described a modified scintigraphic technique utilizing cholecystokinin (CCK) pretreatment and visual interpretation of hepatobiliary scintigrams (11). By using visual rather than quantitative criteria, we achieved perfect sensitivity and specificity in a small group of postcholecystectomy patients with recurrent pain and suspected SOD. In spite of the good results, visual interpretation fails to provide measurable parameters amenable to quantification.

In this paper, we propose a scoring system of CCK-stimulated hepatobiliary scintigrams that combines visual and quantitative criteria for the diagnosis of SOD. This strategy is expected to maintain the high sensitivity and specificity of visual analysis, while adding the advantages of quantification. Moreover, the presence of quantitative data to support the visual interpretation should increase the diagnostic certainty of the interpreters.

MATERIALS AND METHODS

Patient Population

Between December 1988 and December 1990, 26 consecutive postcholecystectomy patients were referred by a single gastroenterologist (ANK) for disofenin CCK-stimulated biliary imaging to search for possible SOD. Some patients had biliary pain, some had nonbiliary pain and still others were asymptomatic. Endo-

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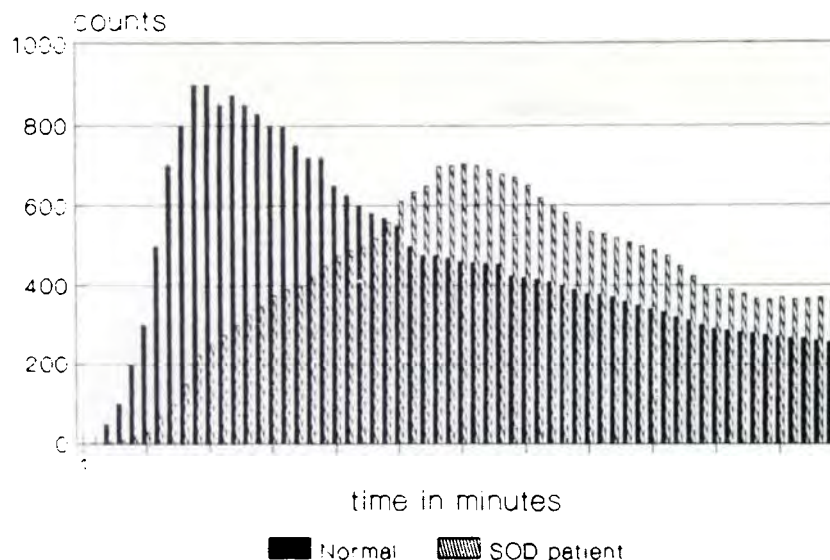


FIGURE 1. Quantitative scintigraphy in a normal subject and in a patient with SOD. Note delayed hepatic peak and washout in the SOD patient.

scopic retrograde cholangiopancreatography (ERCP) and sphincter manometry were performed in all within 48 hr of the scintigraphic study. This was designed as a prospective, double-blind study and no clinical, ERCP or manometric information were available at the time of hepatobiliary scintigraphy.

Scintigraphic Method

After a fasting period of at least 3 hr, each patient received 0.02 $\mu\text{g/kg}$ cholecystinin-8 (CCK) (Kinevac, Squibb Diagnostics, Princeton, NJ) in a 3-min intravenous infusion. Fifteen minutes later, 5 mCi (185 MBq) $^{99\text{m}}\text{Tc}$ -DISIDA (Disofenin) were administered intravenously.

Imaging was performed in the anterior projection with a large field of view gamma camera centered on the 140-keV photopeak. Timed static images were obtained in a 256×256 matrix at 3, 5, 10, 15, 30, 45 and 60 min. Simultaneously, a dynamic study was acquired at a rate of 1 frame/min and stored on computer in a 128×128 matrix.

Regions of interest (ROIs) were placed over the liver parenchyma and CBD to generate time-activity curves. From these curves we derived: (a) time of hepatic peak (T-peak) and (b) % CBD emptying, which was calculated by the equation (Fig. 2A):

$$100 \times (\text{Peak CBD counts} - \text{CBD counts at 60 min} / \text{Peak CBD counts})$$

When a continuously raising curve was obtained, the 30-min value was taken as peak CBD counts.

The liver ROI was chosen in the right lobe excluding visible bile ducts; the CBD ROI was placed in the lowest portion of the CBD not affected by superimposed bowel activity (Fig. 2B).

The static images were recorded on film for subsequent visual interpretation.

Image Interpretation

Two independent observers interpreted the images and curves without knowledge of the clinical or endoscopic findings. They

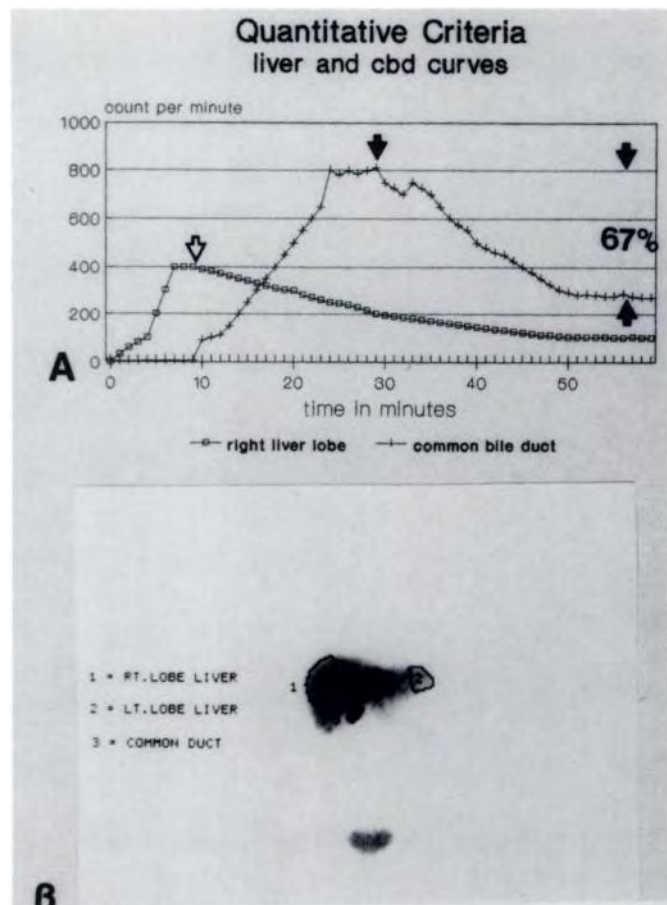


FIGURE 2. (A) Time-activity curves from liver and CBD used to calculate T-max (open arrow) and percent CBD emptying (solid arrows). (B) Placement of hepatic and CBD ROIs. Occasionally, a third ROI was placed in the left hepatic lobe, but the curve was not used in the interpretation.

TABLE 1
Criteria for Scoring Scintigrams

Criteria	Score
1. Peak Time	
a. Less than 10 min	0
b. 10 or more min	1
2. Time of Biliary Visualization	
a. Less than 15 min	0
b. 15 or more min	1
3. Prominence of Biliary Tree	
a. Not prominent	0
b. Prominent major intrahepatic ducts	1
c. Prominent small intrahepatic ducts	2
4. Bowel Visualization	
a. Less than 15 min	0
b. 15–30 min	1
c. More than 30 min	2
5. CBD Emptying	
a. By more than 50%	0
b. Less than 50%	1
c. No change	2
d. Shows increasing activity	3
6. CBD-to-Liver Ratio	
a. $CBD_{60} \leq Liver_{60}$	0
b. CBD_{60} higher than $Liver_{60}$ but lower than $Liver_{15}$	1
c. CBD_{60} higher than $Liver_{60}$ and equal to $Liver_{15}$	2
d. CBD_{60} higher than both $Liver_{60}$ and $Liver_{15}$	3

were asked to score six parameters in each study as described in Table 1. The following parameters were evaluated:

1. Time of peak liver activity. Obtained from the right lobe time-activity curve as in Figure 2A.

2. Time at which intrahepatic biliary tree was first visualized, determined from the static images (Fig. 3).
3. Prominence or dilatation of the biliary tree as determined from the static images as a subjective evaluation similar to that described by Zeman (9) and Lee (10) (Figs. 4 and 5).
4. Time at which bowel was first visualized as determined from the static images (Figs. 3–5).
5. Percent CBD emptying as calculated from the CBD curve using the equation described above (Fig. 6).
6. CBD-to-Liver ratio. This parameter was obtained from the static images by visually comparing the CBD at 60 min (CBD_{60}) to the liver parenchyma at 60 ($Liver_{60}$), and liver parenchyma at 15 min ($Liver_{15}$). This ratio represents activity retained in the CBD at the end of the study (Figs. 4 and 5).

The range of the final score varied from a minimum of 0 to a maximum of 12, the higher numbers corresponding to the slower kinetics.

Interobserver Variability

Two nuclear physicians served as observers. We accepted concurrence between the observers when the scores were identical or varied by no more than 1 point. Sensitivity, specificity and accuracy were calculated for each individual observer.

Manometric and ERCP Methods

Endoscopic biliary manometry was done with a standard triple lumen catheter (Arndorfer Medical Specialties Inc, Greendale, WI) as described by Arndorfer (12). Manometric studies were carried out in the fasting state at the time of ERCP under light sedation with diazepam. With the patient in the prone position, the catheter was introduced into the CBD and then withdrawn at 2-mm increments until active sphincter pressures were observed. Sphincter pressures were then recorded for approximately 2–3

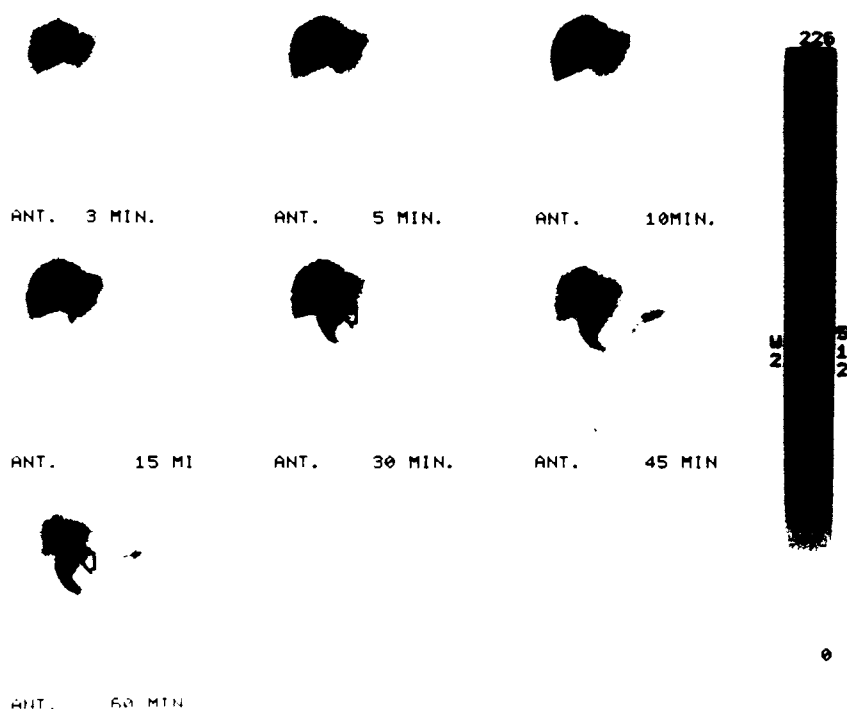


FIGURE 3. Hepatobiliary scintigram in a patient with SOD. Basal sphincter pressure: 60 mmHg. (1) Biliary tree is first visualized at 15 min. (2) CBD and intrahepatic biliary tree appear prominent in the 30-min image (this prominence is either due to true dilatation or to stasis of active bile in the ducts). The prominence persists at 45 and 60 min. (3) Bowel is first visualized at 30 min. (4) The activity in the CBD at 60 min is higher than in liver at 15 min. Notice also that activity in the CBD does not decrease between 30 and 60 min.

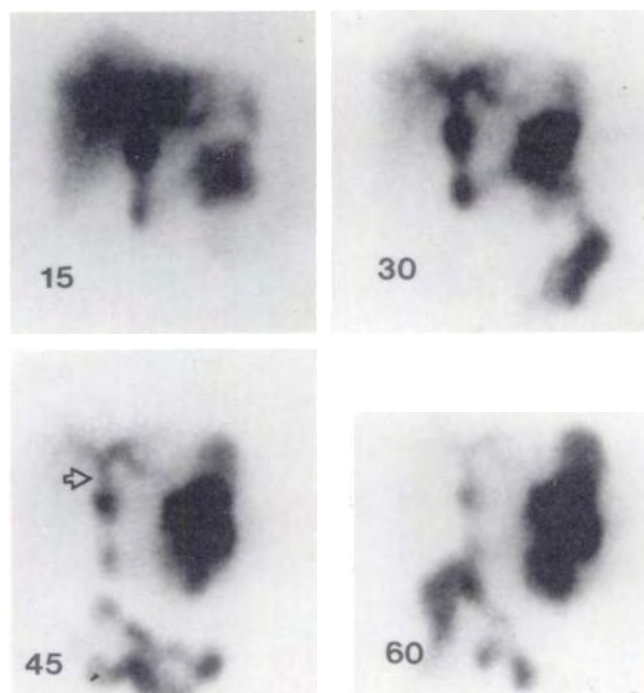


FIGURE 4. Hepatobiliary scintigram in a normal postcholecystectomy patient (sphincter pressure: 15 mmHg). (1) There is marked activity in the bowel by 15 min. Bile ducts and bowel were actually visualized in earlier images (not shown). (2) By 45–60 min, the biliary tree does not appear prominent. After 30 min, the CBD becomes progressively thinner and fainter. (3) The CBD at 60 min is slightly more active than the liver at 60 min, but much less than liver at 15 min.

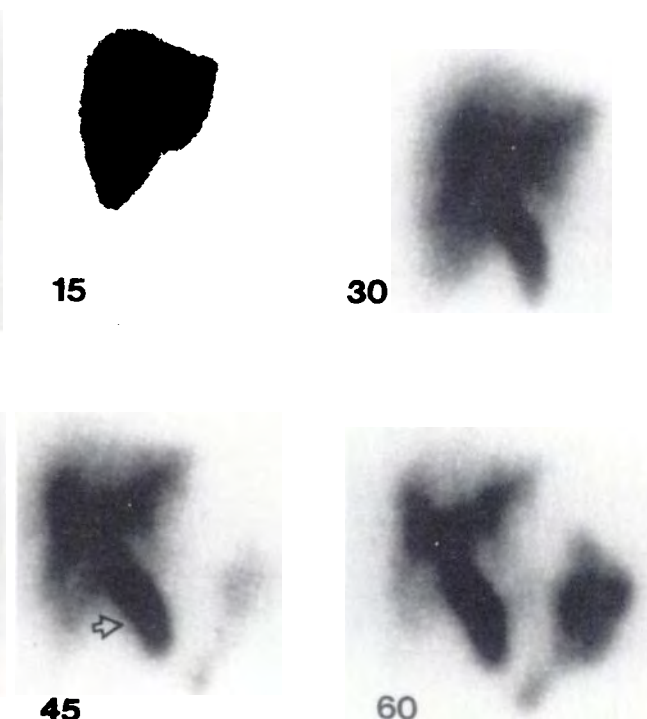


FIGURE 5. Scintigram in patient with SOD (sphincter pressure: 65 mmHg). (1) Biliary tree activity initially seen at 30 min and bowel activity at 45. (2) Biliary tree appears dilated in the 45–60-min images. (3) There is no drop in CBD activity between 30 and 60 min and CBD is more intense than the liver at 15 min.

min. The duodenal lumen pressure was used as a reference and the patient was considered abnormal if the basal pressure was equal or higher than 40 mmHg above the duodenum, or if a paradoxical response to CCK could be demonstrated.

The ERCP studies were performed using standard techniques, and criteria for diagnosis of SOD required: (a) CBD dilatation (>1.2 cm) and (b) delayed emptying of contrast from the CBD (>45 min). Another role of ERCP was to exclude structural biliary diseases such as CBD stones and strictures. Patients with such structural lesions were excluded from the study.

The diagnosis of SOD was made when at least one of the following criteria was met: (1) basal sphincter pressure of 40 mmHg or higher, (b) paradoxical pressure response to CCK or (c) abnormal ERCP showing both CBD dilatation and contrast retention for more than 45 min.

Informed consent was obtained from all patients after the nature of the procedures were fully explained. The protocol was approved by the Joint Committee of Clinical Investigations.

Data Analysis

Sensitivity, specificity and accuracy were calculated using standard equations (13). We used the Student's *t*-test to compare group means.

RESULTS

Patients with SOD

A final diagnosis of SOD was established in 12 patients. Seven had elevated basal pressure (range: 40–65 mmHg).

Another three had normal basal pressure (15, 14 and 16 mmHg) but demonstrated a paradoxical response to CCK with elevation of sphincter pressure to 60, 52 and 30 mmHg, respectively.

The remaining two patients had normal basal pressures (23 and 30 mmHg) but showed both CBD dilatation and delayed contrast emptying on ERCP. Thus, the diagnosis of SOD was made without a CCK challenge. One of them had a previous sphincterotomy and presented with recurrent symptoms. Sphincter pressure may be difficult to interpret under these conditions. A papillary stricture was seen during the procedure and a second sphincterotomy was performed with excellent relief of symptoms. The second patient had been scheduled to receive somatostatin during manometry and a CCK challenge could not be given. Sphincterotomy in this patient also yielded excellent symptomatic response.

The CBD was normal in size in three patients (0.5, 0.5 and 0.8 cm), mildly dilated in another three (1.4, 1.5 and 1.5 cm) and significantly dilated in six (2–2.5 cm). These measurements were based on ERCP findings.

There were four males and eight females in the group of patients with SOD. Ages ranged from 20 to 80 yr (mean: 52) and time from cholecystectomy ranged from 1–34 yr. All had biliary-type pain.

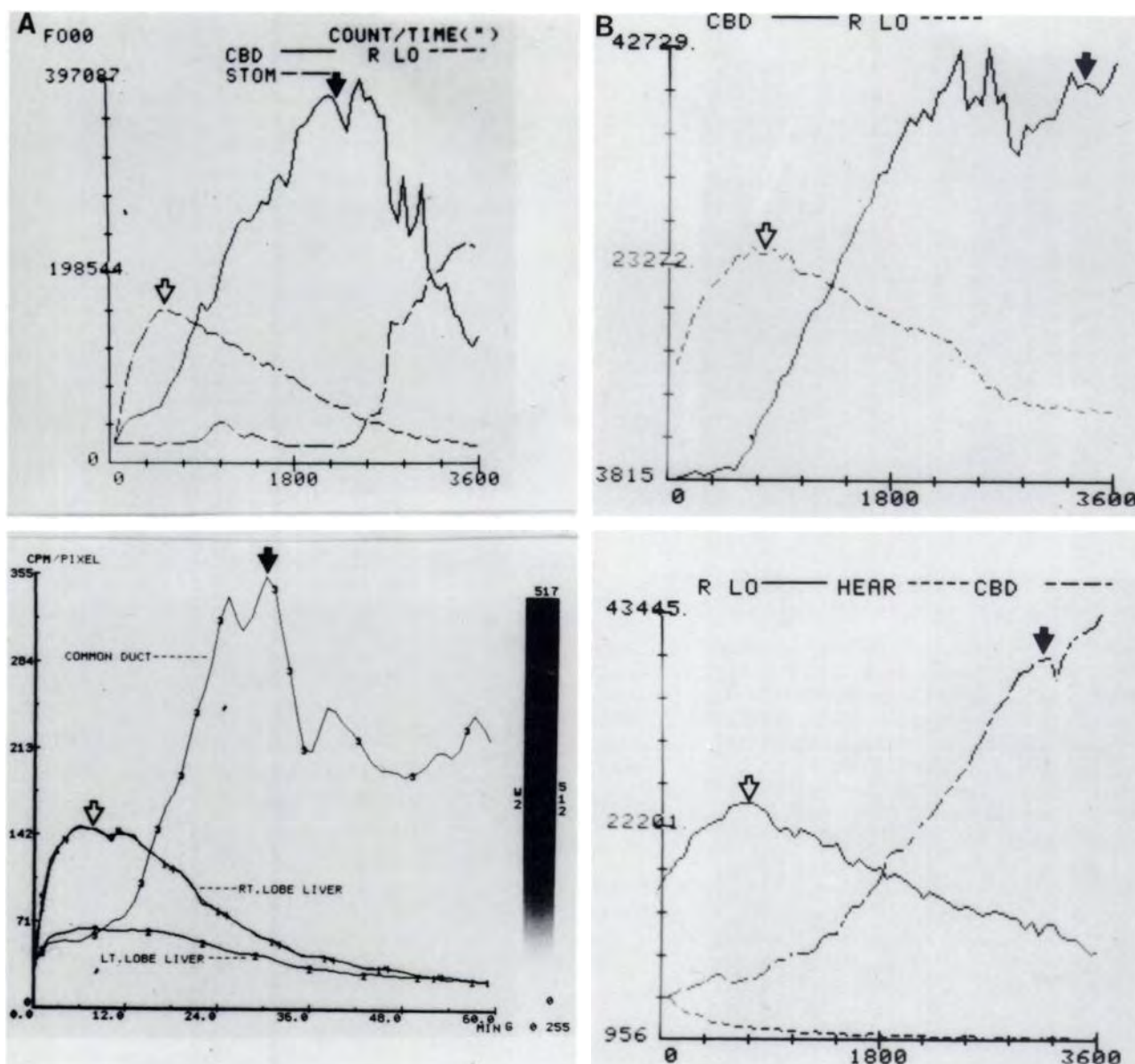


FIGURE 6. (A) CBD curves for calculation of CBD emptying. Solid arrows identify the CBD curve. (Upper) Normal curve. Notice a marked drop of CBD activity (70%) after the peak. (Lower) Abnormal curve in patient with SOD. CBD empties less than 50% after the peak. (B) CBD curves. (Upper) Abnormal curve. No CBD emptying seen after the peak. (Lower) CBD activity continuously increases in patient with severe SOD.

Patients with Normal Sphincter Pressure and No Clinical or Radiologic Evidence of SOD

Fourteen postcholecystectomy patients fell within this group (controls). All had normal basal sphincter pressure (range: 10–36 mmHg; mean: 23).

The CBD was normal in size in 11 patients (0.5–1.0 cm) and mildly dilated in 3 (1.3, 1.3 and 1.5 cm). All had normal contrast drainage from the CBD and, therefore, none met the ERCP criteria for SOD either.

Three males and 11 females comprised this group. Ages ranged from 26 to 66 yr (mean: 49) and time from cholecystectomy ranged from 1 to 24 yr. All were either asymptomatic or had a nonbiliary cause of the symptoms confirmed.

Scintigraphic Findings

The group of patients with SOD was scored from 6 to 11 by observer 1 (mean: 7.4 ± 3), and from 6 to 12 by observer 2 (mean: 8.1 ± 3) ($p = ns$). Common scintigraphic findings in these patients included: delayed hepatic peak, delayed biliary tree visualization, prominent bile ducts which remained prominent beyond 45 min, delayed bowel visualization (>15 min), poor CBD emptying retaining more than 50% of peak activity at 60 min (in many instances activity did not decrease after the peak and high CBD activity at 60 min which was equally intense or higher than liver parenchyma at 15 min (Table 2).

Patients in the control group were scored from 0 to 5 by observer 1 (mean: 1.6 ± 1.3), and from 0 to 4 by

TABLE 2
Scintigraphic Findings (Values in Controls and Abnormals)

Parameter	Controls			SOD group	
	Mean	Range	Units	Mean	Range
Liver peak	6.1	5–10	min	11.7	5–18
Biliary visualization	8.7	5–12	min	16.1	5–30
Biliary prominence*	0.4	0–3	score	2.1	1–3
Bowel visualization	11.2	5–20	min	33.3	10–60
CBD emptying	77.0	50–90	%	0.5	–100–50
CBD-to-liver ratio*	0.8	0–2	score	2.8	2–3
Scintigraphic score*	1.5	0–5	score	7.8	6–12

* Values refer to score assigned as per Table 1.

observer 2 (mean: 1.3 ± 1.3) ($p = ns$). Typical scintigraphic findings included: normal hepatic peak time, prompt biliary tree visualization, “thin” bile ducts in the 45-min image, bowel visualization before 15 min, good CBD emptying by 60 min (higher than 50%) and low CBD-to-liver ratio (Table 2).

There was no overlap of score values between the abnormal and control groups. Also, no classification errors were made by either observer. The true positive rate, true negative rate, and accuracy was 100% for both observers (Fig. 7).

Concurrence between the two observers was found in 24/26 (92%) of the cases.

Table 3 summarizes the scintigraphic findings. The range and mean values of each scintigraphic criteria are given for the control and abnormal groups. The values were calculated from the responses of both observers. For subjective criteria in which a measurement could not be made (i.e., prominence of biliary tree and CBD-to-liver ratio), the reported value is that of the score assigned as per Table 1.

Outcome

Nine patients diagnosed with SOD underwent endoscopic sphincterotomy. These included two with normal

TABLE 3
Sensitivity and Specificity of Individual Scintigraphic Criteria

Parameter	Sensitivity	Specificity
Liver peak	0.83	0.79
Biliary visualization	0.50	1.00
Biliary prominence	1.00	0.79
Bowel visualization	0.92	0.71
CBD emptying	1.00	0.93
CBD-to-Liver ratio	1.00	0.86
Final scintigraphic score	1.00	1.00

basal pressures described earlier, three with paradoxical CCK response and 4 with high basal pressures.

Symptoms disappeared or improved in seven patients who have required no further treatment. We performed post-therapy scintigrams in only 4 since the other three were followed at referring facilities. All four patients showed normalization of the scintigram (score <5).

Two patients had initial symptomatic improvement but experienced pain recurrence. For 4 and 10 mo after the initial sphincterotomy, scintigraphy showed unimproved tracer kinetics and repeat ERCP and manometry revealed re-stenosis of the sphincter. After initial success with a second sphincterotomy, their symptoms recurred and re-stenosis was reconfirmed. Surgical sphincteroplasty was then performed, resulting in complete symptomatic relief at the latest follow-up visit (9 and 12 mo, respectively). Scintigraphy after the surgical procedure was normal in both cases.

Three patients have had no endoscopic or surgical treatment. However, two have received calcium channel blockers, one with complete response (resolution of pain and weight gain) and the other with partial response. Two patients had procedure-associated pancreatitis which resolved with medical treatment. No one in the control group underwent sphincterotomy.

DISCUSSION

After a cholecystectomy, the normal biliary tree is transformed into a single-outlet system where intrahepatic ductal bile can flow only through the common duct into the duodenum. The alternate flow pathway into the gallbladder no longer exists. During contraction of the sphincter of Oddi in a normal patient, intraductal pressure remains normal because the biliary system can decompress by draining into the gallbladder. This organ acts as a pressure reservoir (14). On the other hand, sphincter contraction in a postcholecystectomy patient usually results in elevation of intraductal pressure because the reservoir effect of the gallbladder is no longer present (15). High intraductal pressure may cause pain (16), and together with a tight sphincter may lead to biliary stasis, ductal dilatation, and to delayed hepatobiliary radionuclide transit.

SOD is a disorder characterized by an abnormal sphinc-

Observer performance

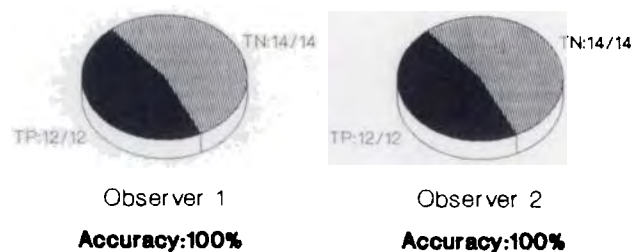


FIGURE 7. Observer performance.

ter pressure. This may be due to stenosis or dyskinesia and is often a cause of pain after a cholecystectomy (1).

Investigators have shown that functional outlet obstruction caused by the sphincter in this disease tends to delay hepatobiliary radionuclide transit (4–8). Hepatic tracer uptake, tracer transfer from liver to bile ducts, CBD emptying and transit to bowel are all delayed (4–11). Consequently, one may find tracer pooling within the ductal system (manifested by prominent or dilated ducts) and excess tracer retention in the CBD (11).

We have proposed a scintigraphic scoring system to diagnose SOD which takes into account all the above parameters. By incorporating all the abnormalities found in SOD, this score promised to be superior to previously used diagnostic criteria. The expectations were supported by the present study in which the score showed a perfect separation between patients with SOD and controls (sensitivity: 100%, specificity: 100%).

By combining quantitative and visual criteria, we were able to maintain the high sensitivity of visual analysis (11), while adding measurements such as %CBD emptying, T-max and scintigraphic score which provided discrete numerical values useful for comparing follow-up and post-therapy studies. Also, the interpretative confidence of the observers was reportedly improved by the quantitative data supplementing the visual assessment.

As an added benefit, visual analysis may help differentiate between diseases. Quantitative cholescintigraphy yields similar results in patients with liver dysfunction, cholestasis or SOD (1,4,5), making the differentiation dependent on clinical rather than on scintigraphic criteria (17). In our experience, the combination of prominent bile ducts and abnormal retention in the CBD (visual criteria 2 and 6) help make the differentiation because they are seen in SOD, but rarely in liver disease or cholestasis. However, this test cannot differentiate functional from structural obstruction.

One concern of all dynamic tracer studies is the potential of false-positive studies caused by low flow states. This is common in radionuclide kidney studies where delayed transit and tracer retention may be seen in dehydrated patients due to decreased urine flow. This could potentially occur also on hepatobiliary scans during states of decreased bile flow. In an attempt to prevent false-positive studies, we pretreated all patients with CCK, a substance believed to stimulate bile production (18,19). However, we did not test for CCK effect either on biliary kinetics or diagnostic accuracy of the test. Because of the short duration of CCK effect, one may consider administering the drug in a longer infusion. CCK may lower sphincter pressure and improve test specificity by enhancing biliary drainage in normal patients.

Our series is small, reflecting a low prevalence of SOD that probably occurs in only 0.8% of all postcholecystec-

tomy patients (2). However, our initial experience suggests that the proposed scoring system utilizing quantitative and visual criteria reliably identifies patients with SOD. The study is simple, safe and can be performed in virtually any nuclear medicine facility.

If the high accuracy persists as further investigation is made, this technique may provide the sensitivity and specificity necessary in a useful screening test for postcholecystectomy patients with suspected SOD.

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A Noninvasive Test of Sphincter of Oddi Dysfunction in Postcholecystectomy Patients: The Scintigraphic Score

Samuel Sostre, Anthony N. Kalloo, Ethan J. Spiegler, Edwaldo E. Camargo and Henry N. Wagner, Jr.

J Nucl Med. 1992;33:1216-1222.

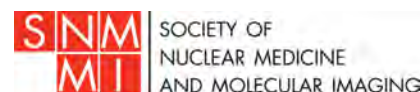
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LeVeen Shunt Imaging

Purpose:

Peritoneovenous shunts are useful for the treatment of intractable ascites. The shunt is a subcutaneously implanted polyethylene tube extending from the peritoneal cavity to the right atrium via the jugular vein. During inspiration when intraperitoneal pressure rises above the intrathoracic venous pressure, ascitic fluid flows into the venous system. A unidirectional pressure-sensitive valve prevents backflow of blood into the abdomen.

The most frequent cause of failure of these shunts is obstruction of the peritoneal end by fibrinoid material. Occlusion of the venous limb of the shunt is uncommon unless malfunction of the shunt valve persists backflow of blood into the tubing, or unless thrombosis occludes the vein. This imaging procedure evaluates the patency of LeVeen and Denver shunts.

Equipment, Reagents, and Supplies:

1. Scintillation camera/computer system with high resolution collimator.
2. PACS image review and archiving system.
3. Dose of 8-12 millicuries of Technetium-99m (Tc-99m) Macroaggregated Albumin (MAA). For children, calculate the dose from the weight/dose chart.
4. Sterile surgical gloves, Betadine solution, 4 x 4 cotton swabs, and a variety of L.P. needles (18-, 20-, and 22-gauge).
5. Imaging table.
6. Lidocaine (1%), 30 ml vial (10 mg/ml).
7. Consent for surgery or Procedure form.
8. One T.B. (1 ml) syringe.

Procedures:

1. Verify patient identity using two methods and verify inpatient orders.
2. Explain the procedure to the patient and answer appropriate questions and then obtain patient's signature on Consent form.
3. The physician intending to administer the Tc99m-MAA dose will first secure the patient's written consent.
4. Load the proper protocol from the camera/computer. Position the patient supine on the imaging table.
5. The physician will administer the dose of Tc-99m MAA by intraperitoneal injection. The injection is carried out much like peritoneocentesis. However, instead of obtaining fluid, the MAA is administered. Dispose of radioactive waste properly.
6. After sufficient pressure has been applied to the puncture site, ask the patient to move from side to side a few times in order to bring the MAA solution into equilibrium with any fluid which may be present in the peritoneum. This will ensure that the MAA will have an opportunity to reach the distal (collecting) end of the shunt.
7. Acquire scinti-photos over the lungs and peritoneum at 5, 15, 30, 45, and 60 minutes. The radiologist should then review the acquired images to determine if more are indicated.
8. A patent shunt will drain peritoneal fluid into the lungs. Therefore, a normal study will show that MAA is being delivered to the lungs.

LeVeen Shunt Imaging – Page 2 of 2

9. Produce screen captures of all images and transfer to PACS. Scan the test requisition and history sheet(s) into PACS. Compose a clinical note to describe the dose, personnel and any other pertinent information.
10. After the examination is completed, change the linen on the imaging table and prepare the room for another study.

Interpretation:

This is a physician-interpreted study.

References:

1. Operator's Manual of the radioisotope camera/computer.
2. Operator's Manual, image archiving computer system (PACS).
2. Product literature supplied with the MAA.
3. Nuclear Medicine Physics- Instrumentation and Agents, F. David Rollo, Editor, C. V. Mosby Company, 1977.
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Written by: Stephen A. Kuhn, August 1989

Updated by: S.Sheridan 12/2018

Reviewed by: S. Sheridan 4/2019

Liver Mapping with Intra-Hepatic Administration of Technetium-99m MAA

Principle:

Prior to Yttrium-90 hepatic radio-embolization, (Selective internal Radiation Therapy, SJRT). A technetium-99m (Tc-99m) macroaggregated albumin (MAA) scan is performed to map the liver area(s) targeted for treatment. This scintigraphic mapping is vital to assure tumor-targeted delivery of the Y-90 treatment. The interventional radiologist inserts and directs a catheter in the right or ten hepatic artery. Tc-99m MAA radioactive particles are then administered by injection via the catheter. After the patient leaves the interventional suite, he comes to nuclear medicine to obtain images of the lungs and abdomen. Imaging includes planar and detailed

SPECT views of the liver and abdomen observe any extra-hepatic distribution. Distribution and quantity of Tc99m MAA in the lung fields is of particular interest. Images are assessed for extra-hepatic uptake and quantification of the relative liver-to-lung activity is calculated.

Equipment, Reagents and Supplies:

1. Radioisotope camera/computer system with SPECT capabilities (preferably SPECT/CT) and high-resolution collimators.
2. Dose of 3-6 mCi of Technetium-99m macroaggregated albumin (Tc99m MAA) in a volume of 2-3 milliliters.
3. PACS image review and archiving system
4. Biohazard radioactive waste container and lead-shield.
5. Absorbent plastic-lined paper.
6. Cart to transport supplies to the Interventional Radiology (IR) suite.
7. Geiger-Mueller (G-M) survey instrument and items to perform contamination wipe testing.
8. Emergency spill kit.

Patient Preparation:

Patient preparation details are communicated to the patient by the IR radiologist and staff.

Notes:

The interventional radiologist will notify Nuclear Medicine personnel when the patient is ready for the Tc99m MAA dose.

Procedure:

1. The identity of the patient using two methods and verification of medical orders is performed by the radiologist and IR staff prior to sedation of the patient.
2. When the patient is ready for the Tc99m MAA, the radiologist or IR staff will call Nuclear Medicine. The NMT will assay the dose in a suitable dose calibrator and note the assay information on the prescription label. The Tc99m MAA syringe will be placed in a syringe shield and then in a carrier shield.

Liver Mapping Following Intra-Hepatic Administration of Technetium MAA – Page 2 of 3

The carrier will be put on board the transport cart. A new plastic biohazard container (with lid), absorbent plastic-lined paper, a G-M survey instrument, wipe testing supplies and an emergency spill kit will also be put on the cart.

3. The transport cart will be taken to Radiology Intervention Room (usually Room 7). Absorbent plastic-lined paper should be placed on the floor under the area where the Tc-99m MAA will be handled and administered. All radiation safe handling practices for radioactive materials must be observed.
4. Following the administration of the MAA dose, the intra-arterial catheter, tubing, stopcocks, syringes, and absorbent paper will be placed in the shielded biohazard container for transport back to Nuclear Medicine. All radioactive waste will be labeled and inventoried and placed in the Decay Store-room according to procedures approved by the Radiation Safety Officer (RSO).
5. The GM instrument will be used to monitor personnel, equipment, disposable materials and the room for contamination that may have occurred. Wipe testing of the floor will be done to detect removable contamination. In the event that contamination is detected, implement the spill cleanup procedure in accordance with methods approved by the (RSO).
6. Within an hour after the Tc99m MAA is administered, the patient will come to Nuclear Medicine for imaging. With an energy window of 20% centered on 140 keV, acquire 1 million-count planar images in anterior and posterior projections to include the lungs, liver and abdomen. Regions of interest (ROI) are placed around the liver and each lung in both projections. The counts in each ROI are determined. The geometric mean of the liver and lung ROIs is determined and used to calculate the liver-to-lung ratio. Transfer raw and processed images to PACS.
7. Acquire a SPECT/CT with the liver approximately centered in the field. Use 20-25 second stops. Process this data with the usual method to produce tomograms and fused images. Transfer raw and processed files to the PACS. Assign the PACS file to the Interventional Radiologist.
8. After imaging is completed, the patient will be returned to Radiology Recovery/Holding.
9. Prepare the imaging room for the next examination.

Processing:

Calculate the percent hepatic arterio-venous shunting:

1. Use identical ROIs for anterior and posterior images.
2. The effect of attenuation in the equation below does not exactly cancel because the values in the numerator and denominator are different.
Hepatic arterio-venous shunting = $A + B / A + B + C \times 100$.

Where: A = geometric mean of counts in the anterior and posterior right lung

B = geometric mean of counts in the anterior and posterior left lung

C = geometric mean of counts in the anterior and posterior liver

Geometric mean of two values (data points) is the square root of their product.

Example: Geometric mean of 9966 and 7917 = Square root of $9966 \times 7917 = 8882.6$

Include the A, B, C, and ratio values in the information sent to PACS. Numeric data maybe annotated on image files.

Results:

This is a physician-interpreted study.

References:

1. Operator's manual of the radioisotope camera/computer.
2. Operator's manual PACS, Picture Archiving Computer System.
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Written by: Stephen A. Kuhn, February 14, 2012.

Reviewed by: S.Sheridan 4/2019

Yttrium-90 (Y-90) microsphere Selective Internal Radiation Treatment (SIRT)

Principle:

Yttrium-90 (Y-90) microsphere Selective Internal Radiation Treatment (SIRT), via hepatic arterial administration, is a treatment modality for the management of patients with primary and metastatic liver cancer. Selectivity of the procedure is due to the unique pattern of hepatic arterial flow providing the overwhelming majority of the tumor blood supply.

Initial treatment indications were colorectal cancer metastases and hepatocellular carcinoma (HCC), mostly for palliation; however successful application of microspheres to a variety of solid tumors is expanding the accepted indications to include other unresectable metastatic liver tumors. More importantly, is down-sizing/down-staging of hepatic tumors as a bridge to subsequent surgical treatment appears promising.

The microspheres are biocompatible but not biodegradable, remaining permanently in the terminal arterioles of tumor vasculature and at the portal triad vessels in the normal liver following administration into the hepatic artery. Yttrium-90 (Y-90) has a half-life of 2.67 days and decays to stable Zirconium-90. It is a pure beta emitter with an average energy of 0.9337 MeV, and a mean tissue penetration of 2.5 mm (maximum range: 11 mm). Y-90 is permanently embedded within the resin structure. No significant amount of Y-90 leaches in the patient from the resin microspheres. A standard dose of resin microspheres is 2 GBq (54 mCi), containing approximately 50 million microspheres (range of 40 to 80 million).

Equipment, Reagents and Supplies:

1. Radioisotope camera/computer system with medium energy collimators.
2. Dose of Y-90 Microspheres; each vial contains 81 mCi on calibration day and time. The amount of radioactivity in each treatment dose will be determined by the Authorized User (AU) who will complete a Written Directive. Some treatments will require more than one dose. The amount specified on the Directive will be drawn from the vial by the NMT. The Y-90 calibration on the Capintec CRC 15R (SN158910) is #55. All calculations will be reviewed by the AU or physicist.
3. Other required supplies include V-vial and shielded holder, vent needle, syringe shield, two Nalgene (Mayo) jars, dose delivery set and box.
4. Absorbent plastic-lined paper.
5. Cart to transport dose and supplies to the Interventional Radiology suite.
6. Geiger-Mueller (G-M) survey instrument and dry wipe/stick to perform contamination wipe testing.
7. Emergency spill kit.
8. PACS image review and archiving system.
9. IR suite in Radiology, Level C

Patient Preparation:

Patient preparation details are communicated to the patient by the IR radiologist and staff.

Notes:

The interventional radiologist (IR) will notify Nuclear Medicine personnel when the patient is ready for the Y-90 treatment doses.

Procedure:

1. The long half-life of the Y-90 allows the dose to be prepared several hours ahead of the treatment time. The NMT will carefully follow the dose preparation steps supplied with the Y-90 microsphere kit. The kit includes a bulk vial of 81 mCi Y-90 spheres, V-vial and vial shield, syringe shield and vent needles.
2. Dose preparation requires a minimum of 20-30 minutes. Following dose preparation, survey the Hot Lab areas for contamination.
3. When the patient is ready for the Y-90, the interventional radiologist (IR) or IR radiology staff will call Nuclear Medicine. The NMT will use the designated cart to transport the shielded Y-90 dose(s), Mayo jars, dose-delivery box, delivery set, absorbent plastic-lined paper, a G-M survey instrument, wipe testing supplies and an emergency spill kit. The usual IR suite is Radiology Room 7.
4. The identity of the patient using two methods and verification of medical orders is performed by the radiologist and IR staff prior to sedation of the patient.
5. The NMT will provide and maintain security of the Y-90 radioactivity at all times. Minimize radiation exposure to other personnel in the interventional suite.
6. Prior to dose administration absorbent plastic-lined paper should be placed on the floor under the area where the AU will be handling the Y-90. All safe handling practices for radioactive materials must be observed.
7. Following the administration of the Y-90 microsphere dose, the intra-arterial catheter, tubing, stopcocks and syringes, will be placed in shielded Mayo jars.
8. The G-M instrument will be used to monitor personnel, equipment, and disposable materials. After departure of the patient, the room and equipment will be surveyed to detect any contamination that may have occurred. Wipe testing of the areas will be done to detect removable contamination. In the event that contamination is detected, implement the spill cleanup procedure in accordance with methods approved by the (RSO).
9. Transport residual radioactivity back to Nuclear Medicine where it will be labeled, inventoried and then placed in the John Stoddard Decay Storeroom according to the Radioactive Materials license (RAM) and procedures approved by the Radiation Safety Officer (RSO).
10. Complete all required forms for Quality Procedure Management (QMP) including final signatures of AU and IR. These forms must be scanned into a database in Radiation Oncology. Usually, the RSO will do this and return the forms to Nuclear Medicine for archiving in the QMP binder.
11. When the IR has determined the patient has recovered from the sedation, the patient will come to Nuclear Medicine for Y-90 imaging. Attach the medium energy collimators to a dual detector camera. Use the preset-Xenon-133 energy peak with a 20% window. Acquire 1-million-count planar images in anterior and posterior projections to include the liver and abdomen.
12. After imaging is completed, the patient should be returned to Radiology Recovery/Holding. Prepare the imaging room for the next examination.

13. Label all images and produce screen captures. Transfer all image files to the PACS. Scan all the QMP documents into PACS and add technologist notes. Assign the PACS file to the interventional radiologist for interpretation.

Results:

This is a physician interpreted study.

References:

1. Operator's manual of the radioisotope camera/computer.
2. Operator's manual PACS, Picture Archiving Computer System.
3. Product literature and instructions supplied with Y-90 Microspheres
4. Radiology Today, Vol. 11 No.9, P.20; April 2010
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Written by: Stephen Kuhn ; 6/2012, 12/2018

Updated by: S.Sheridan 4/2019

Liver and Spleen Imaging

Principle:

The radionuclide approach to imaging of the liver and spleen is based on phagocytosis of radiolabelled colloidal particles by the reticuloendothelial (Kupffer) cells, which line the sinusoids. Since 90% of the reticuloendothelial elements in the body are located in the liver, this constitutes a very effective mechanism for studying this organ. The colloidal agents employed remain in the Kupffer cells, and good anatomic images are obtainable during the first hour after injection.

Following I.V. administration of Technetium-99m Sulfur Colloid (Tc-99m S.C.), The agent is rapidly cleared from the blood with a nominal half time of about 2.5 minutes. Uptake is dependent upon both the relative blood flow rates and the functional capacity of the phagocytic cells. In the average normal patient, 80% to 90% of the dose will be phagocytized by the liver, 5% to 10% by the reticuloendothelial cells of the spleen, and the balance by the reticuloendothelial system of the bone marrow.

Images, which are obtained, visualize the pattern of phagocytosis and evaluate organ sizes, configuration and function. Focal space-occupying diseases such as metastases and abscesses can be detected.

Equipment, Reagents and Supplies:

1. Radioisotope camera/computer system with SPECT capabilities and high-resolution collimator.
2. Dose of 1-12mCi of Tc-99m S.C. for adults (adjust pediatric doses as per body weight chart).
3. PACS image review and archiving system.
4. Intravenous administration items.

Patient Preparation:

None.

Notes:

1. Ensure that barium radiologic examinations have not been done in the past 48 hours.
2. Ensure that the patient can move the arms away from abdomen to an overhead position.

Procedure:

1. Verify the identity of the patient using two methods and verify inpatient orders.
2. Explain the test procedure to the patient and answer appropriate questions.
3. Administer the dose of Tc-99m S.C. intravenously.
4. Wait 10 minutes before acquiring images. During this time, positioning of the patient and camera/computer preparation can be done.
5. Acquire planar liver/spleen views from posterior, anterior, right and left lateral projections and an anterior image with a sizing marker positioned on the abdomen at the level of the liver. If SPECT imaging is ordered, activate that acquisition protocol.

Liver and Spleen Imaging -Page 2

6. Produce and review a SPECT sinogram as a quality check.
7. Dismiss the patient, process data and send to PACS for interpretation.
8. Prepare the imaging room for the next examination.

Results:

This is a physician-interpreted study.

References:

1. Operator's manual of the radioisotope camera/computer.
2. Physicians' Desk Reference for Radiology and Nuclear Medicine, Leonard M. Freeman, M.D. and M. Donald Blafox, M.D., Ph.D., Editors, 1979/1980.
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Written by: Stephen A. Kuhn, December 1986

Updated by: Stephen A. Kuhn, September 1989, July 1995; 2/2012, S. Sheridan 4/2019

Red Blood Cell Liver Imaging

Principle:

Benign neoplasms in the liver are rare. These lesions usually are incidental findings at surgery or autopsy but may become massive and produce upper abdominal discomfort, nausea and vomiting, and a palpable smooth mass in the upper abdomen. Hemangioma is the most frequent benign tumor of the liver. It is indistinguishable from metastasis on Sulfur Colloid imaging and on ultrasonography. It can be diagnosed by its appearance on angiography. The incidence of hemangioma of the liver is variously reported at between 0.5% and 7%. These lesions are usually asymptomatic, although if extremely large they can produce compressive symptoms and may also be associated with pain if spontaneous thrombosis or hemorrhage occurs.

The cavernous hemangiomas of the liver have a variable appearance on radionuclide angiogram. Although they usually show decreased activity, normal or increased activity may be observed. A much more specific finding is increased activity at the site of the lesion seen on the static blood pool images obtained at five minutes to two hours following injection of the radionuclide. If the lesion is isodense (has a blood pool equivalent to the remainder of the liver), contrast-computed tomography studies may be indicated to further differentiate between hemangioma and other hepatic lesions. While the radionuclide red blood cell image is usually not useful for lesions smaller than approximately 2 cm in diameter, it is extremely good for evaluation of lesions in the 2-4 cm size range. It is important to consider the diagnosis of hemangioma before aspiration or biopsy is performed because biopsy of these lesions has occasionally produced fatal hemorrhage.

Note: The USP 797 guidelines apply to this procedure.

Equipment and Supplies:

1. Radioisotope camera/computer system capable of performing SPECT with high resolution collimator.
2. Ultratag RBC Technetium-99m labeling kit.
3. Dose of autologous Technetium-99m (Tc-99m), Ultratag-labeled red blood cells (RBCs); 20-30 millicuries. (Begin labeling with 20-30 millicuries of Tc99m pertechnetate.)
4. PACS image review and archiving system.
5. Intravenous administration items.

Procedure:

1. Verify the identity of the patient using two methods and verify inpatient orders.
2. Explain the test procedure and answer appropriate questions.

Red Blood Cell Liver Imaging – Page 2 of 3

3. Following the procedure for red blood cell labeling with Technetium-99m Pertechnetate obtain a venous blood specimen from the patient
4. All syringes, vials, and tubes which will contain the patient's blood during this labeling procedure will be identified with the patient's name, medical record number, and date. Successfully complete the labeling to provide the dose of autologous Tc-99m RBCs.
5. Prepare the camera/computer system for a dynamic acquisition. Position the patient so that an anterior radionuclide hepatic angiogram to be acquired during administration of the dose.
6. To eliminate the possibility of misadministration and the risk of patient exposure to bloodborne pathogens, the administration of biologic products (labeled cells) will be handled similarly to the administration of blood. This system requires that two persons will be present to cross-check the identification of labeled RBCs (dose) to be injected and patient identification.
7. The only exception to this system will be when only one patient and one Nuclear Medicine person are in the section at the time of administration.
8. Following the dynamic acquisition, select the proper SPECT acquisition protocol. Begin SPECT imaging about 5-10 minutes after the dynamic frames have been completed. After acquisition, review the SPECT data by producing a sinogram. If that appears satisfactory, reconstruct data according to the processing protocol. At approximately two hours after RBC administration, obtain another set of SPECT images. Review the sonogram and if satisfactory dismiss the patient.
9. Reconstruct the delayed SPECT data and transfer both sets of tomograms and the dynamic study to PACS. Scan the test requisition and patient history sheet(s) to PACS. Compose an informational clinical note to include patient dose and names of technologists who performed the exam.

Results:

This is a physician-interpreted study.

References:

1. Operator's manual of the radioisotope camera/computer.
2. Operator's Manual, PACS
3. Journal of Nuclear Medicine, 25:881-886, 1984.
4. Seminars in Nuclear Medicine, August 1984.
5. Diagnostic Nuclear Medicine, Vol. 2, 2nd Edition, Gottschalk, A., Hoffer, P. B., and Potchen, E. J., Editors, Baltimore, Williams and Wilkins, 1988, pp. 551-552.
6. MMWR, Vol. 41, No. 31, pp. 575-578.

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7. Central Iowa Health Bloodborne Pathogens Program as published on December 6, 1991 (based on requirements of the Occupational Safety and Health Administration, 29 CFR 1910.1030).
8. Society of Nuclear Medicine, "Specific Questions About USP 797", May 2009

Written by: Stephen A. Kuhn, September 1989

Updated by: S.Sheridan
4/2019

Liver Imaging with Xenon

Principle:

Xenon 133 is a radioactive gas commonly used for imaging of the lungs to study regional ventilation. It is chemically and physiologically related to elemental Xenon, a non-radioactive monoatomic gas that is physiologically inert except for anesthetic properties at high doses. Xenon 133 is a readily diffusible gas, which is neither utilized nor produced by the body. It passes through cell membranes; freely exchanges between blood and tissue; and tends to concentrate more in body fat than in blood, plasma, water, or protein solutions. In the concentrations recommended for diagnostic studies, it is physiologically inactive. Inhaled Xenon 133 will enter the alveolar wall and the pulmonary venous circulation via the capillaries. Most of the Xenon 133 that enters the circulation from a single breath is returned to the lungs and exhaled after a single pass through the peripheral circulation.

The ability to visualize the liver with radi xenon is closely related to the fat content of the liver. Hepatic uptake is most commonly seen in alcoholic fatty infiltration, diabetes mellitus, and obesity. The extent of Xenon 133 uptake in the liver in these conditions is closely correlated with the degree of steatosis seen histologically. Hepatomegaly due to fatty infiltration of the liver can be distinguished from other causes of hepatomegaly, such as viral hepatitis, with this examination.

Patient Preparation: None. Equipment, Reagents, and Supplies

1. Scintillation camera/computer with LEAP or low-energy, high-resolution collimator.
2. Xenon delivery device (Xenomatic 2000N) or disposable closed circuit breathing system for administration and rebreathing of the radiogas.
3. Appropriate mouthpiece or mask.
4. Dose of 6-40 millicuries of Xenon 133 gas; Xenon gas dispensing device.
5. PACS image review and archiving system.

Note:

Test explanation is very important to obtain patient

cooperation. Procedure:

1. Verify the identity of the patient using two methods and verify inpatient orders. Explain the procedure to the patient and answer appropriate questions.
2. Set up the camera/computer with the liver Xenon acquisition protocol. The protocol is designed to image the 81 keV photon of Xenon 133 at 20 % window.
3. Assay the vial of Xenon 133 and place it in the Xenon dispensing device for administration.
4. Position the detector for an anterior acquisition to eliminate attenuation effects of the table.

Liver Imaging With Xenon - 2

Set the Xenomatic to "Auto Fill" and when it is "Ready", position mouthpiece or mask and nose clamp on the patient. Start data acquisition on the camera and put the Xenomatic 2000N in the rebreath mode and administer Xenon 133 gas to the patient. As the Xenon is introduced into the air pathway, instruct the patient to inhale slowly and deeply and then exhale and inhale fully a second time. Rebreath images will be acquired in 60-second frames for a total of four minutes. The camera detector remains in the anterior projection for all of these acquisitions unless the radiologist has ordered other projections.

5. Set the Xenon device to the "washout" mode and complete a ten-minute washout phase.
This phase is usually acquired in 15-second frames. (Since a time/ activity curve may be generated, the washout frames are collected over a short period of time.) If the mouthpiece/delivery tube is removed during the washout time, caution the patient not to move because imaging may continue for several additional minutes. This is an extended washout time compared to routine lung ventilation studies so any Xenon concentration in the liver can be better differentiated from the bases of the lungs. Set the Xenomatic to the "End of Study" mode.
6. Produce screen captures of all image sets that were acquired and transfer to PACS. To obtain static-type images with a greater statistical level, computer addition of the frames may be required. The radiologist should review the study before dismissing the patient.
7. All bacterial filters, mouthpieces, and masks are disposable. When the Xenon device has returned to the "Ready" mode it may be turned off.

Calculations:

1. A time/Xenon activity curve on the liver area may be requested. Data analysis to determine these results may need to be done manually. This curve will allow the radiologist to determine the Xenon uptake amplitude, which is expressed as the ratio of maximum liver counts to soft tissue background counts.
2. The time/activity curve is also used to determine Xenon washout time expressed, as time required for liver counts to reach background activity.

Interpretation:

This is a physician-interpreted study.

References:

1. Operator's Manual, Xenon dispensing system.
2. Operator's Manual, Radioisotope camera/computer.
3. Operator's Manual, PACS system
4. Product literature supplied with Xenon 133 gas.
5. Gottschalk, A., M.D., P. B. Hoffer, M.D., and E. J. Potchen, M.D., Editors, Diagnostic Nuclear Medicine, Vol. 2, 1988.
6. Harbert, J., M.D., and A. F. G. DaRocha, M.D., Textbook of Nuclear Medicine, Vol. 2, 1984.

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7. Journal of Nuclear Medicine, Vol. 20, No.5, pp. 397-401, 1979.
8. Journal of Nuclear Medicine, Proceedings of the 27th Annual Meeting, Vol. 21, No.6, p. 76P.

Written by: Stephen A. Kuhn, December 1990

Updated by: S.Sheridan 4/2019

Lung Ventilation Imaging with
Xenon 133 Radio-gas and Disposable
Xenon 133 Rebreathing Circuit

(Alternative to Xenon 133 Gas Electronic Delivery Systems)

Purpose:

Ventilation imaging is clearly a sensitive means for detection of regional airway disease, such as emphysema and other forms of chronic obstructive lung disease. It is also a requirement for the diagnosis and management of pulmonary embolism. The ventilation study is also useful for preoperative as well as pre- and post-radiotherapy evaluation of regional function in bronchiogenic carcinoma for both involved and uninvolved lung. This procedure is helpful in the evaluation of pulmonary venous hypertension.

In the typical ventilation study with Xenon 133, the patient is positioned posteriorly in front of or over the scintillation camera and inhales Xenon 133 gas from an electronic delivery system. Images are acquired over a period of several minutes during rebreathing (equilibrium) and washout phases.

The disposable Xe 133 delivery and storage system allows for radio-gas ventilation imaging during times when electronic dispensers/delivery systems may be unusable.

Patient Preparation:

None

Equipment and Supplies:

1. Radioisotope imaging camera/computer with LEHR collimator.
2. PACS image review and archiving system
3. One disposable Xenon Rebreathing circuit (Biodex or equivalent brand).
Each package includes one disposable mouthpiece or mask, nose clamp, non-reusable conductive bacteria filter, soda lime granules with color indicator, collection bag and tubing.
4. Dose of 6-40 millicuries of Xenon 133 gas.
5. Oxygen source and tubing.
6. One disposable Xenon rebreathing system (Biodex or equivalent).
7. Imaging table or chair
8. Two hemostats, Kelly clamps or other suitable clamping devices.

Notes:

1. Test explanation is critical to obtain patient cooperation.
2. This procedure must be performed in a room with certified negative pressure. If a Xenon 133 gas spill occurs, vacate the area in observance of the "Spilled Gas Clearance Time" posted on or near the room door. An "Emergency Xenon Exhaust Factor" posting will be present on the door of each room that qualifies.

Lung Ventilation Imaging with Xenon 133 Radio-gas and Disposable
Xenon 133 Rebreathing Circuit -page 2 of 3

3. Patients receiving ventilation imaging must have a chest x-ray within 24-hours *this* study.
4. For best Xenon 133 image resolution reduce the patient-collimator distance.

Procedure:

1. Verify patient identity using two methods and verify physician orders.
2. Assure that a recent chest x-ray is available for comparison. Explain the procedure to the patient and answer appropriate questions.
3. Set up the scintillation camera with LEHR collimator and the pulmonary ventilation with Xenon acquisition protocol with 20% window. The camera will use a preset time of 30-60 seconds for each of the rebreathe and washout images. **If** the patient is able, obtain posterior, RPO and LPO rebreathe and posterior washout acquisitions.
4. Set up the disposable Xenon rebreathing system per instruction sheet.
 - a. Position an IV standard on a convenient side of the camera detector so it is out of the field of view. Suspend the Rebreathing System from the IV hanger using the Y-shaped collection bag manifold.
 - b. Position the patient supine or sitting on the camera detector to obtain the desired images. Assure the rebreathing unit with the collection bag is not in the view.
 - c. Clamp the tubing at position (1) with a Kelly clamp or hemostat. Be sure that the Room Vent Plug (G) is readily removable. To test, exert sufficient force to remove it and re-seal it in a manner which will maintain a gas seal, yet allow removal during the washout phase.
 - d. Remove the plug from the oxygen inlet port (F), attach O₂ to the Collection Bag (E). Experience will indicate the amount of O₂ needed but about half-full is usually sufficient. NOTE: Care must be taken not to overfill the Collection Bag, since the washout phase of the procedure requires that all the exhalations from the patient go into the Collection Bag. After the O₂ has been added to the bag, turn off the O₂ source and leave it connected to the bag in case more is needed.
 - e. If using a mouthpiece, place a nose clip (B) on the patient. Release the clamp from tubing position (1) and quickly assist the patient to insert the mouthpiece properly with no leaks around the mouth. Instruct the patient to exhale completely, start the camera acquisitions and administer the Xenon 133 gas into the Injection Site (C) as the patient begins the next inhalation.
 - f. **If** using a face mask, place the mask on the patient properly with no leaks between the cushion and the face. Instruct the patient to exhale completely, start the camera acquisitions and administer the Xenon 133 gas into the Injection Site (C) as the patient begins the next inhalation.
 - g. During these rebreathing (posterior, RPO and LPO) images, the patient is breathing through a closed-circuit system. When the patient is ready for Washout images simultaneously remove the plug from the Room Vent (G) and reapply the clamp on the tubing at position (1). The patient is now inhaling "outside air" and exhaling into the Collection Bag. Continue washout breathing until Xenon 133 has cleared from the lungs or the Collection Bag is full. Apply the second clamp to position (2) and quickly remove nose clamp and mouthpiece or mask from the patient.

Lung Ventilation Imaging with Xenon 133 Radio-gas and Disposable
Xenon 133 Rebreathing Circuit -page 3 of 3

- h. Place entire disposable unit in suitable hood to decay or discharge the Xenon 133 in the disposal vent in Room 1. **If** the Xenon 133 is to be decayed in storage, leave the clamps in place.
5. At all times during the procedure the operator must be prepared to accommodate the possibility of the patient rejecting the mouthpiece unexpectedly. Should this or any other Xenon 133 spill occur, exit the room and close the door. To minimize occupational exposure to personnel, allow a sufficient exhaust time (posted on door) before re-entry.
6. Produce screen capture files and transfer the images to PACS. Scan the test requisition and clinical information into PACS. Complete a PACS clinical note for the radiologist providing information about the test dose, indications, techniques and personnel involved in accomplishing the procedure. It is also helpful to give the location of the recent chest x-ray. **If** the referring physician requested a "hold patient and call report", include that comment and a phone number in the clinical note.
7. Verbally notify the radiologist when the PACS files are complete and ready for interpretation.

Normals:

This is a physician-interpreted study.

References:

1. Operator's manual, radioisotope camera/computer.
2. Operation manual, Disposable Xenon Rebreathing System
3. Operator's manual Picture Archiving Computer System.
4. Product and prescribing information sheet supplied with Xenon 133 radio-gas
5. Diagnostic Nuclear Medicine, Gottschalk, A., M.D., Hoffer, P., M.D. Potchen, E.J., M.D., Williams and Wilkins Publishing; 1988.
6. Nuclear Medicine and PET/CT, Christian, Paul E., Waterstram-Rich, Kristen M.; Sixth Ed 2007.
7. "Seminars in Nuclear Medicine", Vol38, No 6, November 2008.

Written by: Stephen a. Kuhn, Nuclear Medicine Supervisor, 08/2002

Updated by: S. Sheridan 4/2019

Lung Perfusion Imaging

Principle:

Lung perfusion imaging is used as an adjunct in the evaluation of pulmonary perfusion of adults and children. It is useful in the early detection of pulmonary emboli and in the evaluation of the status of pulmonary circulation in such conditions as pulmonary neoplasm, pulmonary tuberculosis and emphysema.

Imaging of the lungs is carried out with radioactive particles and the principle that blood flow can be determined when a tracer is completely removed from the bloodstream in a single passage through the organ. In these circumstances, if the tracer is evenly mixed with blood, its distribution within the lungs is proportional to blood flow. Following intravenous injection, the Technetium-99m labeled (Tc-99m) macro- aggregates of albumin are well mixed with blood in their passage through the heart. These particles are too large to pass through the pulmonary capillaries and become impacted in the terminal arterioles and other precapillary vessels. Their distribution is proportional to pulmonary arterial blood flow.

Patient Preparation:

All patients receiving lung perfusion imaging must have a chest radiograph within 24 hours of the study.

Equipment, Supplies and Reagents:

1. Radioisotope camera and computer with high resolution or general-purpose collimator.
2. Dose range of 3-6 millicuries of Technetium-99m Macroaggregated (human serum) Albumin.
3. Intravenous administration items; positioning block.
4. PACS image review and archiving system

Note:

A lung inhalation study is routinely performed before all lung perfusion examinations unless the indication is "differential function". Refer to the description of the ventilation lung test with xenon in this manual.

Procedure:

1. Verify the identity of the patient using two methods and verify inpatient orders.
2. Explain the procedure to the patient and answer questions.
3. Position the patient supine and administer the 5-millicurie dose of Macroaggregated Albumin (Tc-99m) intravenously. Care should be taken to avoid mixing blood in the syringe with the MAA. Imaging should begin within a few minutes and not more than one hour after injection. After administration of the dose in the supine position, the patient may sit for the imaging.
4. Select the protocol that will detect the 140 keV photons of Technetium with a 15% window. The general purpose or high-resolution collimator may be used.
5. Set up the imaging computer to acquire a series of static images in an intermediate size matrix.

Lung Perfusion Imaging – Page 2

6. Routinely, eight views are acquired: anterior, left and right anterior obliques, right and left laterals, posterior, left posterior oblique, and right posterior oblique in any sequence.
7. Transfer the lung ventilation and perfusion images to PACS and telephone the radiologist to alert that there is a study to interpret.
7. When the examination has been completed, dismiss the patient and prepare the room for another procedure.

Interpretation:

This is a physician-interpreted study.

References:

1. Operator's Manual, Radioisotope cameral computer.
2. Operator's Manual, PACS image system.
3. Product literature insert supplied with Macroaggregated Albumin.
4. Textbook of Nuclear Medicine, Vol. II, Clinical Applications, J. Harbert, M.D. and A. F. G. DaRocha, M.D., 2nd Edition, 1984.
5. Seminars in Nuclear Medicine, Lung Scan Update (Part 1), Vol. 32, No. 3, July 2002
6. Seminars in Nuclear Medicine, Lung Scan Update (Part II), Vol. 32, No. 4, October 2002

Written by: Stephen A. Kuhn, March 1988

Updated by: S. Sheridan 4/2019

Lung Ventilation Imaging with Technetium-99m

Purpose:

Ventilation imaging is clearly a sensitive means for detection of regional airway disease, such as emphysema and other forms of chronic obstructive lung disease. It is also a requirement for the diagnosis and management of pulmonary embolism. The ventilation study is also useful for preoperative as well as pre and post-radiotherapy evaluation of regional function in bronchiogenic carcinoma for both involved and uninvolved lung. This procedure is helpful in the evaluation of pulmonary venous hypertension.

A DTPA Technetium-99m (Tc-99m) aerosol ventilation study may be performed during times when Xenon 133 gas is unavailable and on patients who are not able to have ventilation imaging with radio-gas. This includes patients who are on respirators (ventilators).

DTPA is a small cation that is able to permeate the alveolar-capillary membrane and clear from the lung rapidly. The lung DTPA half-time is about 55 minutes. The combination of short half-time and the low amounts that are deposited in the lungs result in a radiation dose to patients. The radiation exposure for pre-perfusion DTPA aerosol is lower than Xenon 133.

The patient inhales Tc-99m DTPA aerosol (size of most particles less than 1 micron) for about 5 minutes from a lead-shielded radioaerosol delivery system. Images may begin immediately and are acquired in eight views: the posterior, left and right posterior obliques, right and left laterals and anterior and anterior obliques. This allows direct comparison with the eight perfusion images and increases the acumen of the examination.

Equipment and Supplies:

1. Scintillation camera/computer with high resolution collimator.
2. Lead shield for radio-aerosol unit and delivery system.
3. Aerosol kit; includes: disposable mouthpiece, adaptors and nose clamp, aerosol unit with DTPA reservoir and disposal bag.
4. Tc-99m DTPA dose introduced into the aerosol unit ideally should be about 15-40 millicuries in a 2 mL volume. If ventilation is done post-perfusion, use 30-40 millicuries of DTPA in 2 mL volume-20mCi/mL. However, the reservoir capacity is 6 mL and does allow for more than 2mL. If Tc-99m DTPA concentration is reduced, increase the patient's breathing time on the aerosol unit.
5. Oxygen and tubing capable of 8-12 flow rate; a patient on respirator will require the elbow accessory. The Respiratory Care technologist will make the final connection to the patient.
6. Portable Geiger-Mueller radiation instrument.
7. PACS image review and archiving system.
8. Sanitization wipes

NOTES:

1. Test explanation is important to obtain patient cooperation. The aerosol delivery systems have no valves and much shorter pathways. It allows virtually unrestricted breathing, which objectively, makes aerosol ventilation easier than Xenon for the patient.

3. All patients receiving ventilation (and perfusion) imaging must have a chest x-ray within 24 hours of the nuclear study.
4. Aerosol DTPA dosing may be done with the patient sitting or supine.
5. Sequence referred by the radiologists is aerosol ventilation prior to MAA perfusion. Perfusion imaging first can be performed first. When taking the option to perform aerosol ventilation post-perfusion, use a reduced Tc99m MAA dose of approximately 1 millicurie.

Procedure:

1. Verify patient identity using two methods.
2. Explain the procedure to the patient and answer appropriate questions.
3. Set up the scintillation camera with a Technetium-99m acquisition protocol to include 140 keV peaking and 20% window. The camera will be set to a preset for 300 k counts for each image.
4. For non-respirator patients, set up the Tc-99m DTPA radio-aerosol delivery system as follows:
 - a. **Place** aerosol unit into the lead shield. Connect and adjust the adaptor for sitting or supine patient.
 - b. Connect the oxygen source to the aerosol unit with tubing that has a female connector on each end. Inject the dose of Tc99m DTPA solution into the reservoir through the gray port on the unit.
 - c. Assist the patient to position the mouthpiece into his/her mouth to include the "flared" portion. Position the nose clamp on the patient's nose so only mouth inhalation can occur. (Note: Breathing masks are an option with aerosol administrations using Aero/Vent aerosol units.)
 - d. Open the valve on the oxygen regulator until 8-12 Umin. flows to the aerosol unit and the patient. Instruct the patient to inhale to a normal depth (tidal breathing) during the inhalation of the aerosol. If the patient can hold each breath for 4 seconds. dose deposition will be improved. Then exhale at normal rate. Note: Rapid deep breaths will tend to cause "hot spots". Patient ventilation with the oxygen/DTPA aerosol should continue for 2-3 minutes. There is sufficient aerosol intake for imaging when a Geiger-Mueller measures 1.5 mR/hr or higher at the surface of the patient's chest. This will produce a camera count rate of 500 cpm or higher. Images are not acquired until the aerosol ventilation is completed. During this time the disposal bag should be marked with the date and radionuclide (Tc-99m) that will be placed in it for decay storage.
5. At the end of the aerosol inhalation, remove the nose clamp and carefully remove the mouthpiece from the patient's mouth. Be careful to avoid contamination by the patient's saliva. Remove the plastic aerosol unit from the shield and place the entire unit in the disposal bag. Roll the bag shut and secure to assure containment. Place the bag it into a shielded radioactive waste receptacle for decay storage.
6. Begin acquisition of static ventilation images in eight views: the posterior, left and right posterior obliques, right and left laterals, anterior obliques and anterior. Proceed with the perfusion study.
7. Produce ventilation and perfusion screen capture images and transfer to PACS. Scan all appropriate paper forms into PACS and edit the study with additional information. Assure

- a recent (24-hours) chest x-ray has been completed. Contact the radiologist on duty or notify the Iowa Radiology coordinator that the exam is ready for interpretation.
8. Dismiss the patient and sanitize the exam room and equipment.

Procedure for Aerosol Dosing of Patients on a Ventilator:

1. To set up aerosol ventilation imaging for patients on respirators obtain the assistance of the Respiratory Care personnel and ask them to follow these steps:
 - a. Place a disposable aerosol device into the shield.
 - b. Attach an elbow connector to the exhaust port.
 - c. Attach the respirator tubing to the elbow connector.
 - d. Attach the respirator patient tubing to the breathing tube with a 22mm connector.
 - e. inject the dose of Tc-99m DTPA solution into the reservoir through the gray port on the aerosol unit.
 - f. A minimum of 8-12 Umin. of oxygen or air is required to form aerosol droplets. The respirator settings do not need to be altered to accomplish aerosol ventilation.
If
8-12 Umin of oxygen will saturate the patient, than use an air source on the delivery unit as a substitute for oxygen.
 - g. Respirator ventilation with the Tc-99m DTPA aerosol should be continued for 3-5 minutes. A G-M reading of 1.5 mR/hr or higher is an indication of adequate deposition.
2. Obtain as many of the usual eight aerosol images as possible. Perform the lung perfusion imaging as described above.
3. Produce ventilation and perfusion screen capture images and transfer to PACS. Scan all appropriate paper forms into PACS and edit the study with additional information. Assure that a chest x-ray has been performed within the last 24-hours. Contact the radiologist on duty or notify the Iowa Radiology coordinator that the exam is ready for interpretation.
4. Dismiss the patient and sanitize the exam room and equipment.

Normals:

This is a physician-interpreted study.

References:

1. Operator's manual, Radioisotope camera/computer system.
2. Operator's manual, PACS system.
3. Product literature supplied with Swirler or Aero/Vent disposable aerosol units.
4. Product literature supplied with Technetium 99m DTPA.
5. Diagnostic Nuclear Medicine, Vol. I, Gottschalk, A., Hoffer, P.B. and Potchen, J.E., 1988; pp. 530-531.
6. Principles and Practice of Nuclear Medicine, Early, P.J. and Sodee, D.B., Second Edition, pp. 461-462.
7. Seminars In Nuclear Medicine, Lung Imaging Update, Vol 32, No 3, July 2002

8. Seminars In Nuclear Medicine, Lung Imaging Update, Vol 32, No 4, October 2002
9. Aerosol Ventilation Imaging DVD and Booklet, Amici, Inc., January 2015.
10. Journal of Aerosol Medicine, Vol. 9, Supplement 1, 1996, "In Vivo Measurements of Aerosol Dose and Distribution: Clinical Relevance", Beth L. Laube, Ph.D., Johns Hopkins Univ., Baltimore, MD.
11. Seminars In Nuclear medicine, Acute Care, Vol43, No 2, March 2013.
12. The SNM Practice Guideline for Lung Scintigraphy, Draft v3.4

Written by: Stephen A. Kuhn, December 1996

Updated by: S.Sheridan 4/2019

PET/CT IMAGING CARDIAC VIABILITY IMAGING WITH GLUCOSE LOADING

PRINCIPLE:

PET/CT is a non-invasive diagnostic tool that provides tomographic images and quantitative parameters of perfusion, cell viability, proliferation and metabolic activity of tissues. These images demonstrate distribution of cardiac-glucose metabolism with the use of glucose labeled positron-emitting radionuclide. 18-Fluoro-deoxy-glucose (F18-FDG) is a glucose analog and is taken up by living cells via the first stages of the normal glucose pathways. The rationale behind its use for cardiac examination is that FDG is trapped in viable cells that may be stunned or hibernating. In these clinical situations, technetium-based cardiac perfusion agents are not helpful. A SPECT/CT with gated Tc99m-sestamibi (MIBI) scan is required prior (within 2 weeks) to the viability scan. The MIBI images provide a reference image for the F18-FDG comparison. Gated SPECT/CT imaging may be completed on the same day BEFORE the FDG Viability procedure begins.

EQUIPMENT AND SUPPLIES:

1. Dose range of 24-36mCi of Tc99m Sestamibi (Tc99m-MIBI) if gated SPECT/CT resting scan is done same day.
2. Dose of 10mCi of F18-FDG (+/- 20) administered IV.
3. Glucometer and associated supplies
4. Glucose beverage (Glucocrush or Glucola) 100g container.
5. Regular insulin, for IV administration.
6. SPECT/CT imaging system with physiologic synchronizer, if gated-SPECT/CT resting scan is done same day.
7. PET/CT scanner.
8. Digital computer system/software
9. PACS archiving and retrieval system.
10. Each cardiac viability procedure must be scheduled accordingly with the radiologist's schedule. Call the radiologist scheduler (cell 210-3969) at least one day prior to exam.
11. Each cardiac viability procedure must be added on the Radiology nurses' schedule at least one day prior to exam. To schedule, call the radiology nurse supervisor, or charge nurse.

SPECIAL INSTRUCTIONS:

Outpatients should not bring insulin. For in-patients with diabetes, consult with the patients nurse about whether the patient has sliding-scale insulin order. If gated-SPECT/CT or SPECT is done same day, the Tc99m-MIBI will be scheduled for 8am. F18-FDG viability testing will follow immediately. F18-FDG doses for insulin dependent patients should be calibrated for at least 1 hour later than anticipated administration time.

SPECIAL NOTES:

1. The glucose-loading process is conducted in the Radiology Adult Holding area.

2. The radiologist will interpret values, order the administration of insulin, and direct the Radiology RN in all decisions related to this portion of the exam.
3. An RN with insulin competency will administer all doses of IV insulin ordered by the directing radiologist.

PATIENT PREPARATION: (CHECK FOR INSULIN ALLERGY)

1. Caffeine consumption is restricted for 24-hours before this exam. (chocolate, soda, tea, coffee or Excedrin) Note: Decaffeinated products contain caffeine.
2. No nicotine for at least 4 hours prior to this exam.
3. Do not eat or drink for 6-12 hours before appointment. Water is an exception. TPN and other caloric solutions will be withheld for the required fasting period.
4. If applicable:
 - a. Metformin (Glucophage) Pioglitazone (Actos) and Rosiglitazone (Avandia) may be taken as scheduled.
 - b. Reduce Sulfonylurea (IE. Glimepiride, Glipizide, Glyburide) to a half dose on the morning of study.
 - c. Do not take Siagliptin (Januvia) or Saxagliptin (Onglyza) on the mornings of appointment.
 - d. Insulin-Dependent Diabetics should follow normal insulin-dietary schedule. Also, as applicable (patient should consult with their doctor regarding adjusting insulin use to these recommendations)
 - e. Reduce PM doses of insulin glargine (Lantus) and Levemir by half the evening before the study.
 - f. Reduce AM dose of intermediate or long-acting insulin (IE NPH, Levemir insulin combos, such as 70/30, 75/25, etc.) or Lantus by half the mornings of the study.
 - g. Take half basal dose of insulin pump on day of study.
 - h. Note: Patient should not take the following medication until right before they eat a normal meal: Nateglinide (starlix) Repaglinide (prandin), Pramlintide (Symlin) Exenated (Byetta) or Liraglutide (Victoza)
5. A resting gated SPECT/CT myocardial perfusion study is a pre-requisite and must be performed no more than two weeks prior to the FDG study. The gated SPECT/CT imaging may be obtained on the same day as the FDG exam.

PROCEDURE: NO IV CONTRAST IS GIVEN WITH VIABILITY IMAGING.

1. Verify the patient's identification using two methods.
2. Explain the exam to the patient and answer appropriate questions.
3. Establish an IV in the patient.
4. If not previously performed in last 2 weeks, obtain Tc99m MIBI 24-36mCi resting gated SPECT/CT then proceed to glucose loading phase for the PET examination. Following gated-SPECT/CT take a glucose beverage and copy of the glucose loading worksheet and escort the patient to radiology adult holding for glucose loading. The supervising radiologist and RN will administer the glucose beverage and insulin to bring the patient to the ideal blood glucose level for the FDG injection. This range is 120-150m/dl. Nuclear Medicine should be notified when the patient has reached this level and Nuclear Medicine will go to the Adult Holding and escort the patient to Nuclear Medicine level A.
5. Assure patient's blood glucose is within range using the glucometer.

6. Assay the dose of F18-FDG and administer the F18-FDG intravenously. To ensure that the patient's blood glucose is stable and still within the range of 120-150m/dl, use a glucometer to check the patient's glucose every 30 minutes following administration of the FDG. Report values below 120 to the radiologist.
7. Uptake phase for non-diabetic patients is 60-minutes post FDG injection. Uptake phase for diabetic patients is 90-minutes (or longer) post FDG injection.
8. Instruct patient to remove all metal (necklaces, EKG patches, zippers, and bras etc.)
9. Go to patient browser and select scheduler. Select and register the patient. Ensure last name, first name, DOB, gender, weight, height, and accession number are entered in the patient registration tab. Then press Exam. Under the PET icon, select the appropriate protocol. Under the routine tab of the PET portion of the exam, enter patient's dose, time of dose administration, glucose, and bed times.
10. Have the patient lie supine on the table with head towards the scanner. Secure patient using safety equipment (waist strap, head cushion, knee cushion and head pads).
11. Have patient raise their arms over their head in a comfortable position. Position laser light just below chin using inner laser light on scanner. Then iso-center your patient. Instruct the patient to lie still. Begin the acquisition.
 - a. Load topogram, once loaded, press the start button on the control panel.
 - b. Upon topogram completion, a purple box will appear. Move the scan field of view to place the heart in the center of the field of view. **There is only one 10 min bed.**
 - c. Once scan field of view is set, check to see if any metal artifacts are present on topogram. Use iMAR in the CT recon tab for reduction of any metal artifacts.
 - d. **No IV contrast is given**
 - e. Load CT and move table.
 - f. Once CT is complete, the bed will move automatically into the PET gantry to begin PET image acquisition.
12. Following completion of imaging, perform image quality review. Call directing Radiologist for image quality review. After Radiologist approval, dismiss the patient. Prepare the room and equipment for the next procedure.
13. Perform image reconstruction according to the parameters outlined by the physician.
14. Transfer files to McPACS and Vitrea-bridge for physician review and interpretation.
15. Scan the requisition, questionnaire and all other documents that will be needed for interpretation of the study into McPACS.

RESULTS: This is a physician-interpreted study.

REFERENCES:

1. Operator's Manual, PET/CT medical imaging system.
2. Operator's Manual, SPECT/CT medical imaging system.
3. Operator's instructions PACS image archiving and retrieval system.
4. Operator's Manual, glucometer
5. Siemens Biograph System 6.6 Up Grade
6. Seminars in Nuclear Medicine, Vol XXXII No. 1, January 2002.
7. Society of Nuclear Medicine and Molecular Imaging www.SNMMI.org
8. Tc99m Sestamibi Product insert
9. F18-FDG Product Insert.

Written by: Stephen Kuhn January 2017/Updated by: S. Sheridan 10/2020.

Myocardial Perfusion with Thallium 201 For Viability

Principle:

Thallous Chloride (TI-201) with no carrier added accumulates in viable myocardium in a manner analogous to potassium. The myocardial distribution of TI-201 correlates well with regional perfusion. Thallium images demonstrate areas of infarction and non-viable myocardium as "cold" or non-perfused regions.

After intravenous administration, TI-201 clears rapidly from the blood. Maximal concentration by normal myocardium occurs at about 10 minutes. About 3.7% is taken up by the heart. The biological $T_{1/2}$ in the heart is about 35.6 hours.

Equipment, Reagents, and Supplies:

1. Supply IV tray consisting of 0.9% NaCl, I.V. catheter, plug, syringes, aseptic pads, and tape.
2. Radioisotope imaging camera/computer system with low energy, high resolution collimators.
3. Dose range of Thallium-201 (Thallous Chloride), 2-4 millicuries and 1-2 millicurie dose calibrated 4 hour later.
4. Picture Archiving Computer system (PACs).

Preparations:

1. The patient should be fasting for at least four hours and preferably 8 hours, to minimize stomach uptake of TI-201 Cl. If the patient is diabetic the fasting time may be reduced to 4 hours.
2. Inpatients should have an intravenous access; peripheral vein using a 22-gauge or larger catheter or needle.
3. Patient must not have caffeine for at least 12 hours prior to test. This includes coffee, soft drinks, pain relievers containing caffeine, and stimulants such as vicrin.
4. Patient should discontinue nitroglycerin drip, patch and any other form.
5. No smoking, chewing tobacco, or nicotine substitutes at least four hours prior of the test.
6. No theophylline containing pharmaceuticals 48 hours prior to testing.
7. No persantine, or aminophylline 12 hours prior to testing.
8. No dipyridamole for at least 2 days prior to testing.

Procedure:

1. Use two patient identifiers to verify patient identity and verify test orders and indications.
2. Explain the procedure to the patient and answer appropriate questions.
3. Administer the Thallium-201 (TI-201 Cl) dose intravenously to the patient. Begin acquisition of SPECT images 5-10 minutes later. This is the immediate (resting) set of data.
4. Use the myocardial perfusion protocol for Thallium-201.
5. Image acquisition on females is performed with the bra removed.

Myocardial Perfusion with Thallium 201 (Tl-201), Viability Page- 2

6. Approximately four hours after the first administration of Tl-201 Cl, re-inject an additional 1.0 millicurie of Tl-201 Cl IV. After a 5-10 minute delay, re-acquire SPECT images under the description of "stress".
7. At about 24 hours after the initial dose of Tl-201 Cl, repeat SPECT acquisition under the description of "24 hour stress" or "day 2 stress".
8. Reconstruct tomogram images using the most appropriate filtering and reorientation.
- 9 Display the resting and 4-hour stress slices and make screen captures (SC).
10. Display the resting and 24-hour stress slices and make SCs.
11. Transfer the SCs to the PACS. Notify the referring physician when the images are ready for viewing on PACS.

Results:

This is a physician-interpreted study.

References:

1. Product insert supplied with Thallous Chloride (Tl-201).
2. Operator's Manual, Picker SX2000 radioisotope camera/computer.
4. Operator's Manual, PACS
5. Diagnostic Nuclear Medicine, Gottschalk, A. M.D., Hoffer, P. M.D., and Potchen, E. J., M.D., Williams and Wilkins, 2nd Edition, 1988.
6. Website: Atlas of Myocardial Perfusion SPECT,

Written by: Steven Kuhn, 9/1989

Updated by: S.Sheridan 4/2019

RENAL IMAGING WITH MAG3 AND CAPTOPRIL or ENALAPRILAT

Principle:

Captopril (Capoten) is an angiotensin-converting enzyme (ACE) inhibitor. It eliminates angiotensin II-induced glomerular arteriolar vasoconstriction, causes decreased GFR, urine flow, and salt retention in affected kidneys. This is the basis of captopril renography. In a kidney with renal artery stenosis, a decrease in renal function is seen after captopril administration. A non-captopril renal study with MAG3 must be obtained prior to this captopril interventional study.

Patient Preparation:

1. The patient must have a previous baseline pre-captopril renogram.
2. Discontinue captopril for 2 days prior to testing. Longer acting ACE inhibitors are discontinued for 7 days prior to test.
3. Fasting 4 hours prior to test; patient should drink water.
4. Patient must be well hydrated the morning of the test. As a guideline the patient should drink 10ml of water per kilogram of body weight. (24 oz of water for 150lb patient).

Equipment, Reagents, and Supplies:

1. Radioisotope camera/computer.
2. Two doses of a range of 5-12 millicuries of Tc-99m MAG3.
3. The patient must bring, one-25 mg oral captopril tablet.
4. Intravenous administration items for bolus injection and blood pressure cuff.
5. PACS image review and archiving system.

Procedure:

1. Verify the identity of the patient using two methods and verify inpatient orders.
2. Explain the procedure and answer appropriate questions.
3. A pre-captopril MAG3 (baseline) renal flow and function is obtained without diuretic (refer to "Renal Imaging with Technetium-99m MAG3" protocol).
4. A blood pressure determination is made and recorded.
5. The 25 mg Captopril medication is taken orally by the patient with water **or** intravenous injection of 40 micrograms/kg (max 2.5mg) of enalaprilat.
6. Allow a one-hour interval before the second Tc-99m MAG3 study is started or 10-20 mins if using enalaprilat IV. Blood pressure determinations must be made every 15-minutes and recorded during this interval.
7. Repeat the MAG3 flow and function using the same protocol used in the pre-captopril, baseline MAG3 study in step 3.
8. Once the exam is completed the patients blood pressure is measured and recorded prior to release.

Results:

This is a physician-interpreted study.

RENAL IMAGING WITH MAG3
AND CAPTOPRIL (CAPOTEN)- PAGE 2

Notes:

1. To minimize the radiation exposure dose to the bladder, the patient should be encouraged to increase fluid intake (unless contraindicated) and to void when the examination is completed and frequently thereafter for the next 4-6 hours.
2. The determination of labeling efficiency (quality control) of Tc-99m MAG 3 is a complicated and longer process than other Technetium agents. Allow Cardinal Health radiopharmacy extra time to prepare and quality control the dose.

References:

1. Operator's Manual, radioisotope camera/computer.
2. Operator's Manual, PACS.
3. Product literature (R6/90, A09610) supplied with Mertiatide (MAG 3) kit, Mallinckrodt Medical, Inc.
4. "Kit Preparation of Technetium-99m Mercaptoacetyltriglycine (MAG 3): Analysis, Biodistribution, and Comparison with Technetium-99m DTPA in Patients with Impaired Renal Function," Bannister, K. M., et al, The Journal of Nuclear Medicine, Vol. 31, No. 9, September 1990, pp. 1568-1573.

Written by: Stephen A. Kuhn, October 1992

Updated by: S. Sheridan 4/2019

Captopril MAG3 Renal
nmpro/sal:
11/01191
R:OS/92;07/93;01194;01196; 04/2007; 12/2018

Review by: Dr. Mervin Walker DO. 1/2019

Renal Imaging with Technetium-99m Dimercaptosuccinic Acid (DMSA)

Principle:

Renal Cortical scintigraphy with Tc-99m Dimercaptosuccinic Acid (Tc-99mDMSA) is useful in the detection of the cortical defects of acute pyelonephritis and scarring related to chronic pyelonephritis. Cortical scintigraphy can detect twice as many defects as ultrasound and four times as many defects as intravenous urography. The loss of function associated with acute pyelonephritis, when detected early and satisfactorily treated, can be reversed without scar formation. The sequelae of renal infection can be monitored by follow-up cortical scintigraphy. The common indications for DMSA imaging are acute pyelonephritis, renal scarring, relative functioning renal mass, solitary, or ectopic renal tissue (pelvic kidney), horseshoe and pseudo horseshoe kidney and allergy to iodinated contrast agents.

Tc99m DMSA is bound to proximal tubular cells with 40% to 65% of the injected dose present in the cortex 2 hours after the administration. The greater amount of activity in the cortex permits better resolution of cortical defects. DMSA is preferred in small infants and children.

Patient Preparation:

1. Patients less than 4 years of age and older children unable to cooperate in remaining motionless for a prolonged period will require sedation. The venous access is required for administration as well as the injection of IV sedation drugs.
2. Diuretic intervention may be needed in cases with capacious collecting system or obstruction system, which interfere with the interpretation of the percent differential renal function.
3. The patient should be at least normally hydrated unless sedation will be required.

Equipment and Supplies:

1. Radioisotope, camera with pinhole collimator.
2. A range dose of 2-6mCi Tc DMSA. Pediatric patient doses are based on the weight/dose chart. 2mCi Tc-DMSA is the minimum dose.
3. Intravenous administration items (IV, butterfly, stopcock, saline syringes, tape, etc)
4. Anatomical spot marker.
5. Sedation drugs, supplies, and pulse/oximeter if sedation is required.

Procedure:

1. Verify identity of the patient using two methods and verify inpatient orders. Explain the procedure to the patient and answer appropriate questions. Administer the Tc-99m DMSA intravenously in appropriate quantity 2 hours prior to imaging. Arrange for sedation if required. If sedation is required, perform imaging on the camera that allows all imaging with patient supine. (Use camera room 3 at IMMC)
2. Set up the camera to detect the 140 KeV photons of Technetium-99m with a 15% window. With the patient prone or supine, acquire pinhole images in posterior, RPO and LPO projections, one kidney at a time. Horseshoe and pelvic kidneys are better defined when imaged anteriorly to detect the connecting bridge of renal tissues anterior to the spine. Each image is for 7 minutes, into a 256 matrix. Adjust the distance so that the kidney fills about 75% of the field of view.

3. Acquire SPECT images IF SPECT is ordered from the ordering doctor only. Degree steps for 30 second per stop and into a 128 matrix.
4. Acquire a ten-minute, posterior projection, planar image of both kidneys with a high-resolution parallel collimator into a 256 matrix. Calculate percent differential function from this image data.

Processing:

1. To determine percent of renal differential (split) function, regions of interests (ROI) of each kidney and background areas are outlined on the computerized posterior image obtained with HR parallel collimator. Calculate percent of total counts (both kidneys) contained in each kidney.
2. To process SPECT (if ordered) use a SPECT processing icon in room 3. They are preset to butter-worth filter.
3. Transfer all image screen captures and analysis images and send to McPACs. Review the study with the radiologist.

Normal:

1. The split function normally varies from 50-50% to 44-56% (one kidney compared to the other).
2. A physician interprets all images and data.

Notes:

1. To minimize radiation exposure to the bladder, the patient should be encouraged to increase fluid intake and void frequently during the first 6-8hours following administration. If sedation is used, fluid intake should begin after imaging is completed.
2. Delayed imaging (up to 24 hours post administration) may be necessary for quantitation of split renal function when there is a severely obstructed collecting system.
3. Hepatic and biliary activity may be a problem when imaging patients with poor renal function.

References:

1. Operator's Manual, radioisotope camera/computer.
2. Operator's Manual, McPACs.
3. Society of Nuclear Medicine Procedure Guidelines Manual 2002-2002, pp. 157-159.

Glomerular filtration rate measured by 99mTc-DTPA renal dynamic imaging

GFR 99mTc-DTPA Renal Scan

Principle:

Gate's glomerular filtration rate (gGFR) measured by 99mTc-DTPA renal dynamic imaging and estimated GFR estimated by the chronic kidney disease epidemiology collaboration equation are two indexes used to evaluate renal function using Gates processing.

Patient Preparation:

Drink 8-16oz of water prior.

Equipment Supplies and Reagents:

Room 3 at IMMC. Syringe holder for counting of pre and post syringe. Tc99m DTPA 5mCi dose with a range of 2-10mCi.

Procedure:

Start IV, flush with NaCl to make sure the IV is working properly. Set up the acquisition pick the Icon GFR Renal scan.

1. Count the unshielded syringe of DTPA **before** injection to patient for 60 seconds 30 centimeters off gamma camera. (Set on top of the detector 30cm)
2. Set patient supine on imaging table. Position the patient to ensure kidneys will be in the field of view.
3. Load the dose of DTPA in the long tubing of the IV. Bolus inject of a flush of NaCl and starting the acquisition at the same time as bolus of NaCl.
4. Instruct the patient to hold still. Acquisition is 6mins.
5. **After** scan count the unshielded used DTPA syringe for 60 seconds 30 centimeters from gamma camera.
6. Click done with the acquisition. Display flow, filling and excretion and screenshot each.

Analysis and Calculations:

Acquisition set up pre/post syringe, Dynamic Renal Scan, and processing:

1. Matrix 256x256, zoom of 1.23, 60second using holder that is 30centimeters from the detector.
2. Matrix 64x64, zoom of 1.23, 15seconds/frame for 24 frames. Total dynamic time 6 minutes.
3. Under acquisition Icon pick all three sets of images to screenshot. (Flow phase 1, Filling phase 2, Excretion phase 3)
4. Select dynamic scan and pick GFR processing Icon. Please add patient height and weight. Draw ROI's on right and left kidneys along with background. Gates processing will generate a GFR results.
5. Screenshot the results pages. Send results page, Flow, Filling and Excretion phases screenshots and raw data to McPACs.
6. Radiologist will interpret scan.

Renal Imaging with Technetium-99m Gluceptate

Principle:

Technetium-99m Gluceptate has been shown by comparative renograms to concentrate in the kidneys by both glomerular filtration and tubular secretion. Kinetic studies have shown that while some of the activity is rapidly cleared through the urine, the remainder is retained in the renal cortex. Up to 15% of the injected dose is retained in the kidneys. The renal retention is greater in the cortex than in the medulla. The radiopharmaceutical may be bound to the proximal convoluted tubules which are located primarily in the renal cortex. In patients with renal disease, the blood clearance and urinary excretion of the agent are delayed. Labeled Gluceptate can, therefore, be used to evaluate renal perfusion, size, position, configuration, and function. It can be used to evaluate patients with sensitivity to radiologic contrast agents (Iodine). It is also indicated for confirmation of suspicious lesions found at pyelography and to evaluate and screen for renal vascular diseases.

Patient Preparation:

The patient must be at least normally hydrated.

Equipment and Supplies:

1. Radioisotope camera/computer with high-resolution collimators.
2. Radiolucent imaging table.
3. Dose of Technetium-99m Gluceptate (Tc-99m GH) in safety shield; 5-12 mCi for adults; pediatric patient doses are based on the weight/dose chart.
4. Intravenous administration items for bolus injection (blood pressure cuff, butterfly, stopcock, syringes, saline for flushing, and tape).
5. PACS image review and archiving system.

Procedure:

1. Set up the camera to detect the 140 keV photons of Technetium-99m with a 15-20% window, attach high-resolution collimator(s).
2. Verify identity of the patient using two methods and verify inpatient orders. Explain the procedure to the patient and answer appropriate questions.
3. Set up the camera/computer by selecting the proper acquisition protocol. Generally perfusion phase is 30-60 frames at 2 seconds each.
4. Using a butterfly-stopcock-flush technique and administer the Tc-99m Gluceptate as a bolus intravenously.
5. Start the camera/computer so that all aorta and renal perfusion data is acquired. The early perfusion phase is vital to gain accurate renal perfusion curve information.
6. When the perfusion phase is completed, the patient may be dismissed for approximately 2 hours.
7. At two hours post-injection, acquire one million-count static images with a small amount of magnification (1.33-1.4) in PA, LPO, and RPO projections. Obtain one PA view without the magnification mode. When imaging is finished, dismiss the patient and prepare the room for the next examination.
8. Analyze/process the data using to the current computer protocol/program. Produce capscreens of all curves/graphs and transfer to PACS along with the "raw" perfusion dynamic data.

Renal Imaging with Technetium-99m Gluceptate – 2 of 2

Normals:

This is a physician-interpreted study.

Notes:

To minimize radiation exposure to the bladder, the patient should be encouraged to increase fluid intake and void frequently during the next 4-6 hours.

References:

1. Operator's Manual, radioisotope camera and processing computer.
2. Operator's Manual, Picture Archiving Computer System (PACS).
3. Nuclear Medicine, William H. Blahd, M.D.
4. Seminars in Nuclear Medicine, Vol. 36, No. 1, January 2006.
5. NEN duPont product literature supplied with Glucoscan (Gluceptate).
6. Seminars in Nuclear Medicine, Vol41, No 1, January 2011.

Written by: Stephen A. Kuhn, November 1979

Updated by: S.Sherdian 4/2019

Renal GH/ss
10/06/87
R10/87;05/89;05/92;07/93;01194:1112008; 12/2018

Renal Imaging with Technetium-99m Mertiatide (MAG 3)

Principle:

Following intravenous injection of Technetium-99m Mertiatide (Tc-99m MAG 3), the perfusion, appearance, concentration, and excretion of the tracer in the kidney(s) can be monitored to assess renal blood flow and function. Although Technetium MAG 3 is highly plasma protein-bound following intravenous administration, the protein binding is reversible and the tracer is rapidly excreted by the kidneys via active tubular secretion and glomerular filtration. In normal volunteers, 89% of the agent was protein plasma-bound. In healthy subjects with normal renal function, MAG 3 was rapidly cleared from the blood. The plasma clearance was approximately 0.3 liters/minute, and the amount of MAG 3 excreted in the urine in three hours was nearly 90% of the dose. Patients with renal impairment have decreased blood clearance and a decrease in the amount excreted in the urine over three hours. In these patients, 78% of the tracer was plasma protein-bound after intravenous injection. The mean plasma clearance of MAG 3 was 0.03 liters/minute and 21.3% was excreted in three hours on the average. In both healthy subjects and patients with renal impairment, the plasma concentration time profile showed a bi-exponential decline.

Technetium MAG 3 can be used as a diagnostic agent in providing renal perfusion images and curves, renal function images and curves, and split function analysis. MAG 3 may be the preferred agent for transplant examinations. It can be used for renal studies of patients who cannot have IVP contrast agents.

Equipment, Supplies, and Reagents:

1. Radioisotope camera/computer system with high-resolution collimator; radiolucent imaging table for positioning patient supine.
2. Dose range of 5-12 millicuries Tc-99m MAG 3 with a syringe safety shield. This dose is adjusted lower for pediatric patients based on body weight. The minimum dose is 2 millicuries. MAG 3 should not be used more than six hours after preparation.
3. Four-way stopcock, butterfly infusion set, syringe with 10 ml of 0.9% sodium chloride, alcohol pads, tourniquet and other venipuncture supplies.
4. PACS image review and archiving system.

Patient Preparation:

Patient should be at least normally hydrated.

Procedure:

1. Verify the identity of the patient using two methods and verify inpatient orders.
2. Explain the study to the patient and answer appropriate questions.
3. Set up the radioisotope camera/computer to optimally detect the 140 keV photons of Tc-99m using a 15-20% window. Select the proper adult or pediatric protocol. If manual setup is needed, phase one (perfusion) is 30-60 frames at 1-2 seconds each and phase two (function) is 30-60 frames at 60 seconds each.
4. Position the patient on the table so that both renal areas are in the upper field of view of the camera detector and detector is posterior to the patient. This will usually allow a portion of the bladder to be included in the images.

5. Administer the Tc-99m MAG 3 dose intravenously in a "tight" bolus with stopcock-flush technique.
6. Start camera/computer acquisition to ensure recording of the entire perfusion phase so accurate curves can be made. The perfusion acquisition and the function acquisition (washout) will be combined in the same dataset for about 30 minutes of acquisition.
7. Format image data sets into screen capture files, produce renal perfusion, renal function and performance analysis files. Transfer these files and the raw data sets to the PACS. Compose a PACS clinical note to include name of technologists, describe the study, and the radioactive dose administered.
8. Dismiss the patient and prepare the room for the next examination.

Results:

This is a physician-interpreted study.

Notes:

1. To minimize the radiation exposure dose to the bladder, the patient should be encouraged to increase fluid intake (unless contraindicated) and to void when the examination is completed and frequently thereafter for the next 4-6 hours.
2. The determination of labeling efficiency (quality control) of Tc-99m MAG 3 is a complicated and longer process than other Technetium agents. Allow Cardinal Health radiopharmacy extra time to prepare and quality control the dose.

References:

1. Operator's Manual, radioisotope camera/computer.
2. Operator's Manual, PACS.
3. Product literature (R6/90, A09610) supplied with Mertiatide (MAG 3) kit, Mallinckrodt Medical, Inc.
4. "Kit Preparation of Technetium-99m Mercaptoacetyltriglycine (MAG 3): Analysis, Biodistribution, and Comparison with Technetium-99m DTPA in Patients with Impaired Renal Function," Bannister, K. M., et al, The Journal of Nuclear Medicine, Vol. 31, No.9, September 1990, pp. 1568-1573.
5. Seminars in Nuclear Medicine, Vol36, No 1, January 2006

Written by: Stephen A. Kuhn, November 1991

Updated by: 4/2019

Renal Imaging with Technetium-99m Mertiatide (MAG 3) and Diuretic Intervention

Principle:

Following intravenous injection of Technetium-99m Mertiatide (Tc-99m MAG 3), the perfusion, appearance, concentration, and excretion of the tracer in the kidney(s) can be monitored to assess renal blood flow and function. Although Technetium MAG 3 is highly plasma protein-bound following intravenous administration, the protein binding is reversible and the tracer is rapidly excreted by the kidneys via active tubular secretion and glomerular filtration. In normal volunteers, 89% of the agent was protein plasma bound. In healthy subjects with normal renal function, MAG 3 was rapidly cleared from the blood. The plasma clearance was approximately 0.3 liters/minute, and the amount of MAG 3 excreted in the urine in three hours was nearly 90% of the dose. Patients with renal impairment have decreased blood clearance and a decrease in the amount excreted in the urine over three hours. In these patients, 78% of the tracer was plasma protein-bound after intravenous injection. The mean plasma clearance of MAG 3 was 0.03 liters/minute and 21.3% was excreted in three hours on the average. In both healthy subjects and patients with renal impairment, the plasma concentration time profile showed a bi-exponential decline.

Technetium MAG 3 can be used as a diagnostic agent in providing renal perfusion images and curves, renal function images and curves, and split function analysis. MAG 3 may be the preferred agent for transplant examinations. It can be used for renal studies of patients who cannot have IVP contrast agents.

Equipment, Supplies, and Reagents:

1. Radioisotope camera/computer system with high-resolution collimator; radiolucent imaging table for positioning patient supine.
2. For adults, dose range of 5-12 millicuries Tc-99m MAG 3 with a syringe safety shield. This dose is adjusted lower for pediatric patients based on body weight. The minimum dose for any patient is 2 millicuries. MAG 3 should not be used more than six hours after preparation.
3. Four-way stopcock, butterfly infusion set, syringe with 10 ml of 0.9% sodium chloride, alcohol pads, tourniquet, and other venipuncture and IV administration supplies.
4. Furosemide diuretic, 20 to 100 mg vial to dose at 0.3-0.5 mg/kg with a maximum dose of 80 mg; requires nurse or physician for IV administration.
5. PACS image review and archiving system.

Patient Preparation:

1. Patient should be at least normally hydrated unless sedation will be needed.
2. Patient cooperation is required to maintain body position for about 35 minutes. Pediatric patients over the age of 4 months and under 6 years may need to be sedated.
3. Bladder catheterization is necessary in pediatric patients and those with suspected ureteral obstruction.
4. Non-catheterized patients must start the exam with an empty urinary bladder.

Procedure:

1. Verify the identity of the patient using two methods and verify inpatient orders.

2. Explain the study to the patient and answer appropriate questions.
3. Set up the radioisotope camera/computer with the proper adult or pediatric protocol. If manual setup is needed, phase one (perfusion) is 30-60 frames at 1-2 seconds each and phase two (function) is 30-60 frames at 60 seconds each.
4. Furosemide intravenous administration must be given by a nurse or physician. After the designated nurse or physician is present in the Nuclear Medicine department, position the patient supine on the table so that both renal areas are in the upper field of view of the camera detector and detector is posterior to the patient. This will usually allow a portion of the bladder to be included in the images.
5. Start camera/computer acquisition and immediately administer the Tc-99m MAG 3 dose intravenously in a "tight" bolus with stopcock-flush technique. The perfusion acquisition and the function acquisition (washout) will be combined in the same dataset for about 30 minutes of acquisition.
6. Furosemide (Lasix) administration dose is based on body weight in a concentration of 0.3 to 0.5 milligrams/kilogram. This drug is given over a period of about one minute. The administration should start when renal calyces are prominent. Visualization of urethral activity or urine in the bladder are also indications that the patient is ready for the furosemide. Usually these structures are visible within the first 10 minutes following administration of the Tc 99m MAG3.
7. Format image data sets into screen capture files, produce renal perfusion, renal function, and performance analysis files. These will include percent differential function and time/activity curves. Transfer the raw data set and all analysis files to the PACS. Window and level the raw data set so a cine of both phases can be viewed. Compose a PACS clinical note to include a description of the study, names of technologist(s) and nurse performing the various steps, and the amount of the radioactive dose and diuretic administered.
8. Dismiss the patient and prepare the room for the next examination.

Results:

This is a physician-interpreted study.

Notes:

1. To minimize the radiation exposure dose to the bladder and to maintain hydration, the patient should be encouraged to increase fluid intake (unless contraindicated) and to void when the examination is completed and frequently thereafter for the next 4-6 hours.
2. The determination of labeling efficiency (quality control) of Tc-99m MAG 3 is a complicated and longer process than other Technetium agents. Allow Cardinal Health Radiopharmacy extra time to prepare and quality control the dose. Pediatric doses of Tc99m MAG3 are usually not ordered from the radiopharmacy until the patient is totally prepared for the examination.

References:

1. Operator's Manual, radioisotope camera/computer.
2. Operator's Manual, PACS.
3. Product literature (R6/90, A09610) supplied with Mertiatide (MAG 3) kit.

4. "Kit Preparation of Technetium-99m Mercaptoacetyl triglycine (MAG 3): Analysis, Biodistribution, and Comparison with Technetium-99m DTPA in Patients with Impaired Renal Function," Bannister, K. M., et al, The Journal of Nuclear Medicine, Vol. 31, No. 9, September 1990, pp. 1568-1573.
5. Seminars in Nuclear Medicine, Vol 36, No 1, January 2006
6. **Nuclear Medicine Technology: Procedures and Quick Reference, Second Edition, Shackett, Pete, Lippincott 2009.**

Written by: Stephen A. Kuhn, November 1991

Update by: S.Sherdian 8/2021

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C. 20 Min to"-*YtRatio Cor1icol

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FIGURE 1. ROIs for the renogram phase (A), diuresis phase (B), 20 min to peak % ratio cortical renogram (C) and 20 min to peak % ratio determinations (D).

Renogram Phase Pattern

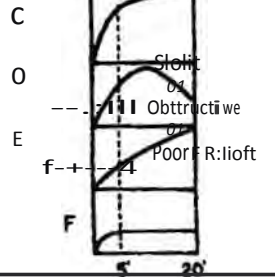
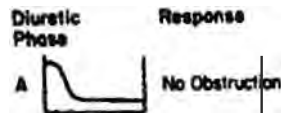


FIGURE 2. Stereotypical patterns of ^{99m}Tc-MAG3 renogram curves. Virtually all the typical patterns.



a bJ No Activity

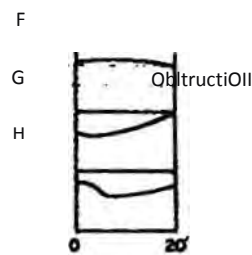
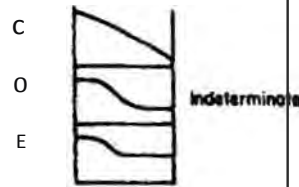


FIGURE 3. Stereotypical patterns of ^{99m}Tc-MAG3 diuresis phase time-activity renogram curves. Each of these patterns can accompany some but not all of the renogram curve patterns shown in Figure 1.

Diuretic Response Measurement

A. T\ 't - iDn
B. T\ 't - iDn
C. T\ 't - iDn

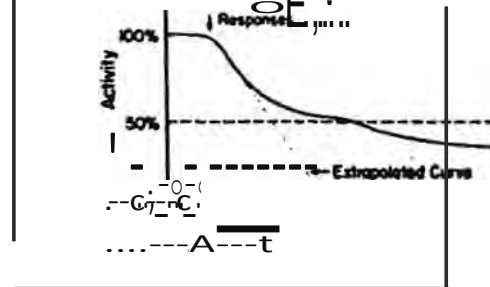


FIGURE 4. Stylized Furosemide response curve illustrates four methods of measuring the half-time clearance of the radio-nuclide from the collecting system of the kidney. (A) Half-time injection. The interval between the time of Furosemide injection and when there is 50% reduction of activity in the collecting system. (B) Half-time response. The interval between the time of the initial observed diuretic response (usually within 2 min after Furosemide injection) and when there is 50% reduction of activity in the collecting system. (C) Half-time injection, extrapolated. The interval between the time of injection and the time extrapolated curve from the initial observed diuretic response, which intersects with a 50% reduction of activity. (D) Half-time response, extrapolated. The interval between the time of the initial observed diuretic response and when the extrapolated curve intersects with a 50% reduction of activity. Note: other methods include a computer-derived exponential fit of the primary response and ratios of activity at differing time intervals.

Renal Transplant Imaging with Technetium-99m DTPA

Principle:

Below a certain threshold, chronic renal failure results from the loss of functional parenchyma of the kidneys. The progressive loss of nephrons, which may be caused by numerous diseases, leads to end stage renal disease (ESRD). Definitive treatments include dialysis and kidney transplantation. In the United States, an estimated 65,000 patients were treated by dialysis in 1983, and the number is expected to increase by 9,000 per year. Nearly 5,000 renal transplant operations are performed each year in the U.S. Chronic dialysis, though a life-saving treatment, is well tolerated by only a few individuals who can adapt to the strict regimen, enormous time commitment, and dietary limitations. For these reasons, transplantation retains a prominent place in the management of renal failure.

As the number of successfully transplanted kidneys has increased, the understanding of all of the problems and potential complications has greatly improved. Problems after transplantation pertinent to Nuclear Medicine are ischemic damage to the cadaveric kidney; hyperacute, acute, accelerated, and chronic immunologic processes (rejection); and surgical complications which include urine leaks, hematoma, wound infection, and obstructions of various etiologies.

Dynamic imaging with Technetium-99m Pentetate (Tc-99m DTPA) permits evaluation of both the perfusion and the excretory function of the transplanted kidney. Curves are derived from regions of interest placed over the aorta, transplanted kidney, and background. Various flow patterns and the curve data are helpful in the differentiation of ATN (acute tubulointerstitial nephropathy) and acute rejection. The dynamic sequence following the perfusion helps to evaluate the anatomy in regard to the presence of obstruction, urine leaks, lymphocele, hematoma, or infarction.

Following intravenous administration, Tc-99m DTPA rapidly distributes throughout the extracellular fluid space from which it is normally promptly cleared from the body by renal glomerular filtration. There should be little or no binding of the chelate by the renal parenchyma.

Since Tc-99m DTPA is excreted by glomerular filtration, the images of the kidney obtained in the first few minutes after injection represent the vascular pool within the kidney. Subsequent images of the kidney represent radioactivity which is in the urine, both in the collecting system and the renal pelvis.

Patient Preparation:

1. The patient should be normally hydrated.
2. Most studies are ordered to be performed with 18-24 hours of the transplant surgery.

Equipment, Reagents, and Supplies:

1. Radioisotope camera/imaging computer with general purpose or high resolution collimator.
2. Dose range of 15-20 mCi of Tc-99m DTPA.
3. Intravenous administration items for bolus injection butterfly, stopcock, syringes, saline for flushing etc.
4. PACS image review and archiving system.

Renal Transplant Imaging with Technetium 99m DTPA - 2

5. Radiation syringe shields.

Procedure:

1. Verify the identity of the patient using two methods and verify inpatient orders.
2. Explain the procedure and answer appropriate questions.
3. Set up the camera to accept 140 keV photons of Tc-99m at a 15% window.
Transplanted kidneys are surgically-placed anteriorly in the abdomen. Position the area of the transplanted kidney under the detector (anterior and judged by the surgical dressing) near the center of the field of view. Ensure that the aorta, graft, transplanted kidney, and bladder are included.
4. Usually the function phase is acquired for 25-30 minutes.
5. Usually these patients have a central or PIC line which should be used for the DTPA administration. Use the stopcock-saline-flush technique to deliver a tight bolus of Tc-99m DTPA.
6. Start the camera/computer to ensure that all aorta and renal perfusion data is acquired. The early perfusion phase is vital to gain accurate renal perfusion curve information.
7. When the two dynamic phases (25 minutes) of imaging are complete, process the dynamic perfusion and function frames with the renal analysis software. This will generate time/activity curves on both the perfusion and the function phases. It will analyze time-to-peak counts for the aorta and kidney on the perfusion phase. Screen capture this information. Annotate the images with the source of the transplanted kidney; cadaveric or living-related donor.
8. Produce screen capture image files of all raw frames. Transfer all screen capture and raw images to PACS. Transfer the raw image file to LE02.

Results:

This is a physician-interpreted study.

Notes:

1. Tc-99m DTPA used for this procedure should be formulated (reconstituted) within one (1) hour prior to clinical use.
2. To minimize radiation dose to the bladder, the patient should be encouraged, if not contraindicated, to increase fluid intake and empty bladder frequently during the next 4-6 hours.

References:

1. Operator's Manuals, camera/computer.
2. Operator's Manual, PACS system.
3. Product literature supplied with DTPA kit (Pentetate).
4. "Radionuclide Renal Imaging," Part 1, J. M. Jacobs, M.D., and A. Taylor, Jr., M.D., Applied Radiology, January/February 1985, pp. 23-37.
5. Nuclear Medicine in Clinical Urology and Nephrology, "Renal Transplantation," Dubovsky, Eva V., Ch. 13.

Renal Transplant Imaging with
Technetium 99m DTPA - 3

Written by: Stephen A. Kuhn, June
1992

Updated by: S. Sheridan 4/2019

Renal Transplant DTPN00072
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R:07/93;01/94;06/95;0412007; 12/201

Lung Ventilation Imaging with Xe-133 Gas

Purpose:

Lung ventilation imaging is clearly a sensitive mean for detection of regional airway disease, such as emphysema and other forms of chronic obstructive lung disease. It is also a requirement for the diagnosis and management of pulmonary embolism. The ventilation study is also useful for preoperative as well as pre-and post-radiotherapy evaluation of regional function in bronchogenic carcinoma for both involved and uninvolved lung. This procedure is helpful in the evaluation of pulmonary venous hypertension.

In the typical Xe-133 radio-gas pulmonary ventilation study, the patient is positioned in front of or over the scintillation camera and inhales from a lead-shielded delivery system. Images are acquired over a period of several minutes during rebreathing (equilibrium) and washout phases. During the rebreathing phase, posterior images are required.

Equipment and Supplies:

1. Camera/computer with LEAP or high-resolution collimator.
2. Xe-133 delivery system.
3. Disposable facemask, bacteria filter, or mouthpiece and nose clamp.
4. Dose range of 6-40mCi of Xe-133 gas vial.
5. Oxygen supply and tubing.
6. Xe-133 gas dispenser.
7. Imaging table or chair.
8. Soda-lime granules and Desiccant (silica gel) granules.
9. PACs image review and archiving system.

Notes:

1. Test explanation is critical to obtain patient cooperation.
2. This procedure may only be conducted in rooms 1 and 2. These rooms have certified negative air pressure.
3. If a Xe-133 gas spill occurs in these rooms vacate the area in observance of "Spilled gas clearance time" posted on the door.
4. If this study is conducted with the patient supine on an imaging table, assure that the camera table distance is minimized.
5. All patients receiving ventilation imaging must have a CXR within 24 hours. Prior to the study.

Procedure:

1. Verify patient identity using two methods and verify inpatient orders.
2. Explain the procedure to the patient and answer any questions.
3. Set up the scintillation camera with the Xe-133 acquisition protocol. This camera will be set to a preset time of Single breath/rebreathe 45 seconds, 30 seconds for each of the washout images.
4. Attach the proper collimator to the detector.
5. Set up the Xe-133 delivery system per the operator's manual. Change out soda lime and drierite. Have 8-10 liters of O₂ next to delivery system.

6. Use the posterior supine position to start the ventilation images.
7. Plug in the Xe-133 machine and set the timer to 10mins, push the button, put the 8-10liters of O₂ to the machine and fill the bag/balloon.
8. Prepare the patient with a mask or mouthpiece and nose-clamp. The patient will then be breathing ambient room air.
9. From the "room air", move the lever to "add Xeon single breath equilibrium". Start the camera acquisition.
10. As the dose of 6-40mCi of Xe-133 is introduced into the mask or mouthpiece, instruct the patient to slowly breathe deeply for about 2 respirations, while acquiring the single breath image.
11. Instruct the patient to resume breathing normally. Continue with the acquisitions, acquiring posterior rebreathing.
12. After 1 ½ minutes of single breath move the lever to wash out and acquire washout images.
13. When sufficient washout is obtained, remove the mask or mouthpiece and nose-clamp from the patient.
14. Use the display protocol, and label images.
15. Unplug, move the lever back to start.
16. Proceed to perfusion study.

Patient preparation: None.

Equipment and Quality Control Notes:

1. Change out Soda-lime granules and Drie-rite granules.
2. Monthly perform the trap monitor check and document.

This is a physician interpreted study.

Written by: S. Sheridan 8/2023

Approved by: Dr. Jabour

Nuclear Medicine Quantification of Lung Perfusion

Indication:

Used as a prediction of postoperative lung function. This can be important in preoperative evaluation of patients with lung cancer. Perfusion scintigraphy is the current method to assess the fractional contribution of lung function of the remaining lung.

Equipment:

1. Radioisotope camera and computer with HR collimator.
2. Other materials and equipment as required for perfusion without quantification. (See "Lung Perfusion Imaging", in this manual.)

Procedure:

1. Identify the patient using two methods and verify the physician order. Explain the procedure and answer appropriate questions.
2. Administer the proper amount of Tc99m macroaggregates (MAA) intravenously. Acquire lung images in the anterior, posterior, right and left lateral projections.
3. Apply perfusion quantization software or manually set three regions (top, middle and lower) over each lung, obtain/calculate count information and percentage of total in each region.
4. Produce screen captures of this information and the planar images. Transfer the screen captures to the Picture Archiving Computer System (PACS). Scan all documents into PACS and enter additional detail information (dose of agents).
5. Dismiss the patient and prepare the imaging room for another patient.

Patient

Preparation:

None.

Normals:

This is a physician-interpreted

study. References:

1. Operator's Manual, radioisotope camera/computer.
2. Product literature supplied with Technetium 99m macroaggregates (MAA).
3. Operator's Manual, PACS.
4. American Journal of Roentgenology, (AJR 2002; 178:667-672)

Written by: Stephen A. Kuhn

Updated by: S. Sheridan 4/2019

Lymphoscintigraphy with Sentinel Node Imaging (Extremity or Melanoma)

Principle:

The lymphatic system is a partially closed circulatory system that conducts water, electrolytes, proteins, enzymes, and migrating cells from the interstitial space back into the vascular system. Identification of lymph drainage is a challenge that may be very difficult when based only on clinical anatomical localization. There has been growing interest in the use of radioagents for imaging studies to trace the lymph drainage patterns. Technetium 99m (Tc-99m) Lymphoseek (tilmanocept) is the preferred agent. Lymphoscintigraphy visualizes the dynamics of lymph transit through regional lymphatics and the sentinel node. Early metastatic spread from melanoma commonly occurs via the lymphatics. Lymphoscintigraphy has been found useful to demonstrate the lymph shed and sentinel node from truncal melanomas. This imaging technique is helpful to evaluate the sometimes uncertain lymph shed from melanomas of the head, neck, and shoulders.

Equipment, Supplies and Reagents:

1. Radioisotope camera with high resolution collimator, imaging computer and PACS system.
2. Four (4) doses of 125 microcuries each of Technetium 99m Lymphoseek. Unit doses will be drawn into 1cc-syringes (TB). All radioactive patient doses are delivered directly to the Hot Lab in Nuclear Medicine.
3. Items such as aseptic drape (Brachial Angiography), plastic-lined absorbent pads, gloves, and needles. Radiologists should wear long-sleeved shirt, jacket or barrier gown. Some radiologists prefer to also wear safety goggles.
4. Surgical site ink marker, injection-site lead shielding and Co-57 spot markers.

Patient Preparation:

If the patient has hair in the injection field, some radiologists will desire that it be removed. This is personnel preference and shaving is not routinely performed. Ask the injecting radiologist, on a case-by-case basis, if hair should be removed prior to administration of the radio-tracer.

Physician Qualifications:

Radiologists who administer Technetium 99m Lymphoseek for this procedure must Authorized Users (be listed) on the RAM License.

Lymphoscintigraphy and Sentinel Node-Page 2 of 3

Procedure:

1. When the patient arrives in Nuclear Medicine use AIDET protocol, verify the identity of the patient by two methods.
2. Direct the patient to an examination/imaging room and bring the assayed doses of radiopharmaceutical to the room in proper shielding. Explain the procedure to the patient and answer questions.
3. Take a "time out", ask the patient why he/she is here and verify the location of the melanoma site. Position an incisional drape around the area to be injected. The radiologist will administer the doses of Tc-99m Lymphoseek intradermally on the edge or in approximately equal spacing around the periphery of the melanoma site. The radiologist may massage the injected area for a few minutes.
4. Using a gamma camera/computer with high resolution or collimator and 140 keV MCA with a 15-20% window, acquire static frames with about 100k counts or 5 minutes. Annotate them with the time-of-day initiated.
6. Be certain the appropriate lymph node-bearing areas are in the field of view of the camera. It may be necessary to place a lead shield(s) over the injection sites after the initial image has been taken. This will reduce the count rate originating from the injection sites and permit better visualization of lymphatics. The remainder of the images may be done with the shield in place or the injection site outside the field of view. Acquire a series of images at 5 to 10-minute intervals until the sentinel node is visualized. When the melanoma site is near the body mid-line, the physician may request images of lymph node-containing regions in the contra-lateral area. The physician should be called to review images and place ink markers on the skin of the patient corresponding to the position of the node. The radiologist will determine when the study is terminated. It is possible that the study could require 2 hours to be completed.
8. Label all images with orientation and time taken so the radiologist knows the elapsed time post injections. Produce screen captures and transfer to PACS, scan all documents into PACS and edit the PACS file to include dose information. Assign the interpretation to the radiologist who worked with the case.
9. The ink marker(s) on the patient's skin will be used in surgery during the SLN node excision. This imaging study is usually performed on the same day as surgery. The patient usually travels to Outpatient Surgery from Nuclear Medicine. Sentinel node tissue that is excised in surgery will undergo analysis in the Laboratory pathology/tissues department adjacent to surgery.
10. Document the radioactive administrations into the SynTRAC system. Check for radioactive contamination in the room; sanitize the room and prepare for the next patient.

Interpretation:

This is a physician-interpreted study.

References:

1. Seminars in Nuclear Medicine, L. M. Freeman, M.D. and M. D. Blafox, M.D., Ph.D., Editors, Vol. XIII, No.1, January 1983.
2. Textbook of Nuclear Medicine, Volume II, Clinical Applications, J. Harbert, M.D. and A. F. G. DaRocha, M.D., 2nd Edition, 1984.
3. Product literature supplied with Lymphoseek.
4. Operator's Manual radioisotope camera.
5. Operator's Manual Picture Archiving Computer System.
6. \VWw.Society of Nuclear Medicine.org
7. Wallace AM, Hoh CK, Ellner SJ, Darrah DD, Schulteis G, Vera DR. Lymphoseek: a molecular imaging agent for melanoma sentinel lymph node mapping. Ann Surg Oncol. 2007;14:913-921.

Written by: Stephen A. Kuhn 6/2015

Updated by: S.Sheridan 4/2019

Meckel's Diverticulum Imaging

Principle:

Meckel's diverticulum, a remnant of the omphalomesenteric duct, occurs in the terminal ileum. It is present in 1-3% of the general population. In approximately one-fourth of these cases, symptoms arise, usually rectal bleeding (hematochezia), with or without other abdominal symptoms. Ectopic gastric mucosa is found in 57% of symptomatic patients with Meckel's diverticulum. Usually, it is manifested in children and is difficult to diagnose preoperatively because roentgen-graphic contrast studies including selective angiography fail to visualize the diverticulum.

Bleeding results from mucosal ulceration caused by hydrochloric acid and pepsin secreted by the ectopic gastric mucosa which lines the diverticulum. The presence of mucus-secreting cells, which concentrate Technetium (Tc-99m) pertechnetate in the same manner as normal gastric mucosa, provides the rationale for imaging the abdomen with this radiotracer.

Equipment and Supplies:

1. Scintillation camera/computer with high-resolution collimator.
2. PACs image review and archiving system.
3. Dose of Tc99m pertechnetate, 20-25mCi for adults. At pediatric dose is computed from the weight/dose chart or age.
4. Intravenous administration items: Syringe, butterfly, and skin preparation pads.

Patient Preparation:

Patient must be NPO for a minimum of 4 hours. Patient must be clear of barium for 3 days prior to Meckel's scan. The concern is that barium attenuates in the diverticulum and causes a false negative. Less commonly barium increases irritation of the bowel caused by "barium loading" that could produce excessive blood flow blush and result in a false positive.

Procedure:

1. Verify the patient's identity using two methods and verify inpatient orders. Explain the test to the patient and/or parents accompanying that patient and answer appropriate questions.
2. Set up a scintillation camera to detect the 140 KeV photons of the Tc99m with a 15% window. Follow the camera/computer chart or protocol to set other parameters.
3. Administer the dose of Tc99m pertechnetate intravenously with the patient supine.
4. Position the bladder at the very bottom of the field of view. This will center the area of interest on most patients.
5. Acquire dynamic images for one hour in the anterior projection. To reduce the "dumping" of Tc99m tracer from stomach into intestine do not move the patient.
6. Additional static views may requested by the radiologist in the right and/or left lateral projections or with longer stop conditions.
7. Use "right" side indicator.

8. Produce screen capture files of all images and transfer them and the original dynamic series to PACs.
9. Review all images with the radiologist before dismissing the patient.
10. Prepare and clean room for next patient.

Results:

This is a physician-interpreted study.

References:

1. Operator's Manual, Radioisotope camera.
2. Operator's Manual, PACs image system.
3. Nuclear Medicine in Clinical Pediatrics, H. Handmaker and J. M. Lowenstien 1975.
4. Journal of Nuclear Medicine, Vol. 17, No. 6, P. 530 June 1976.
5. Journal of Nuclear Medicine, Vol 16, No. 6, p. 515 June 1975.
6. Review of Meckel's and Nuclear Medicine Imaging, Helen Anne D'Alessandro, M.D. virtual Hospital website.
7. SNMMI web page Jan 2020

Written by: Stephen A. Kuhn, Feb 1984

Updated by: S. Sheridan 2/2020

Approved by: Dr. Paul Jabour and Dr. David Lacey

Regarding Family Members in the Nuclear Cardiac Stress Room During Testing:

Cardiovascular Services Department guidelines allows a family member to be in the cardiac stress room during the test if that presence gains the cooperation of the patient. The decision to allow the person to stay in the room is made by the doctor, physician assistant or nurse conducting the stress test.

When a cardiac stress test is performed in conjunction with administration of radionuclides there are radiation safety rules and regulations to be considered. The main precautions are to avoid exposure and contamination of the family member in the event of a radioactive spill. The family member should remain away from the end of the treadmill and in a place where spills or contamination are least likely.

The necessity to allow extra people in the nuclear cardiac stress room should be rare. Questions about implementing these guidelines should be given to the nuclear medicine supervisor or the supervisor of cardiovascular services.

Nuclear Medicine Supervisor: Sharon Sheridan CNMT

Myocardial Perfusion Imaging With Adenosine Pharmacological Stress

Principle:

Adenosine pharmacological coronary vasodilatation in conjunction with myocardial scintigraphy is an alternate to dynamic exercise testing for the diagnosis of coronary artery disease and assessment of the extent of the myocardium at risk, especially in patients who are unable to perform adequate exercise. Adenosine (Adenoscan), which is commercially synthesized, is an antiarrhythmic agent that is chemically unrelated to the other classes of antiarrhythmics. Adenosine is a naturally occurring purine nucleoside found in all cells of the body. Adenosine is removed from circulation very quickly.

The half-life is estimated to be less than ten seconds. Hepatic and renal function is not required for metabolism, so hepatic or renal failure should have no effect on its activity. Adenosine does have side effects, but due to its very short half-life, they are generally self-limiting and reversible with infusion of aminophylline. Side effects include facial flushing, headache, shortness of breath/dyspnea, chest pressure, lightheadedness, nausea, and others.

Technetium 99m Sestamibi (MIBI) accumulates in viable myocardium in a manner analogous to potassium and either may be used to image the perfusion with adenosine stress. The myocardial distribution of the MIBI radioagent correlates well with regional perfusion. Imaging shows areas of infarction as "cold" or nonperfusing regions which are confirmed by recirculation (resting) imaging, electrocardiogram (EKG), and enzyme changes. Regions of transient myocardial ischemia corresponding to areas perfused by coronary arteries with partial stenosis are visualized as cold spots when radiotracers are administered in conjunction with the Adenosine. These regions demonstrate partial or near complete resolution on recirculation imaging.

Equipment, Reagents, and Supplies:

1. For one-day protocol obtain two doses of Technetium 99m MIBI from Cardinal Health Radiopharmacy; dose ranges are 8-16 millicuries (mCi) and 24-36 mCi and the initial dose given is always the smaller one (rest). Allow 60 minutes for preparation and delivery of doses. For patients in the 285-325 pound range, ask the cardiologist or radiologist to approve weight-based doses (1 additional millicurie/15 pounds). For two-day protocol, obtain one 30 millicurie MIBI dose for each day. A two-day protocol should be used for outpatients who are over 325 pounds. Some referring doctors who conduct the treadmill stress will specify a two-day (stress/rest) study regardless of the patient's weight.
2. Adenosine is for intravenous use at a dose of 140 micrograms/kg of body weight per minute of infusion for a total of four minutes. Example: 70-kg patient x 0.14 x 4 minutes equals 39.2 mg of Adenosine). Adenosine doses are obtained from the Omnicell station.

Myocardial Perfusion Imaging with Adenosine Pharmacological Stress – Page 2 of 4

4. Radioisotope camera/computer with high-resolution collimator(s) capable of SPECT acquisition and processing; interfaced with physiologic synchronizer (R-R trigger).
5. EKG monitoring equipment capable of 12-lead assessment or equivalent.
6. Blood pressure monitoring device and emergency heart cart with
7. Defibrillator instrument on standby near the area of Adenosine administration.
8. PACS image review and archiving system
9. Vial of aminophylline, 500 mg and a 10-ml syringe.
10. Graseby Syringe Pump for adenosine administration.
11. Disposable microbore tubing and 6 inch T-connector extension set and needles for adenosine syringe.
12. Patient consent form.

Patient Preparation:

1. Twelve hours prior to the test, the patient must have no agents that contain aminophylline, persantine, coffee, tea, or other caffeine-containing products.
2. Patient must **not** smoke or use other nicotine-containing substances for 4 hours prior to this test.
3. No theophylline containing pharmaceuticals 48 hours prior to testing.
4. Patient should discontinue sublingual nitroglycerin for 2 hours.
5. No dipyridamole for at least 2 days prior to testing.
6. The patient should be fasting for at least four hours and preferably eight. Water and a light snack may be taken after the stress portion is finished.
7. Patients should void before the start of each imaging session.
8. Stress and resting images on female patients are performed with bras removed.
9. Obtain the weight of the patient to determine compatibility with the imaging table and detectors of the camera system.

Procedure:

1. When utilizing the two-day protocol, the stress portion is usually conducted first.
2. Inpatient exams are one-day with the resting part done first. Verify patient identity using two methods and verify inpatient orders. The protocols are as follows:
 - a. rest injection of 8-16 mCi Tc99m MIBI, (assure that the residual in the syringe is minimal), acquire resting images 45-60 minutes post injection;
 - b. 1-4 hour after injection of rest dose, conduct the pharmacological (adenosine) stress test.

The person conducting the stress will instruct the nuclear medicine technologist to inject a stress dose of 24-36 mCi Tc99m MIBI; acquire images at 45-minutes to

Myocardial Perfusion Imaging with Adenosine Pharmacological Stress – Page 3 of 4

- 4 hours post injection; the earlier time is preferable.
3. Appointment time for stress myocardial perfusion imaging should correspond with adenosine stress testing to be done by EKG Cardiac Services personnel in conjunction with imaging. The referring doctor or other qualified personnel will conduct/supervise the stress and monitor the patient.
 4. Start a saline lock as follows:
 - a. Locate a suitable vein on the arm opposite from where the blood pressure will be monitored. The antecubital area is preferred.
 - b. Cannulate vein with an angioset or catheter needle.
 - c. When a small amount of blood comes back into the needle, attach the plug and introduce 1-3ml of 0.9% sterile saline to check for good infusion.
 - d. Secure the angioset or catheter needle in place with tape so that during exercise, it will stay in the vein. The use of an arm board may be necessary to prevent bending of the elbow and preserve the I.V. site during the stress test.
 5. Obtain the weight of the patient to be used to calculate the dose of adenosine.
 6. The doctor, physician's assistant, or nurse will setup the Graseby syringe pump or supervise the nuclear medicine technologist doing so, to deliver the adenosine at a rate of 140 micrograms/kg/minute for a total of four minutes. A 70-kg patient requires 39.2 mg to be administered over a four-minute interval. Withdraw the calculated amount of adenosine and connect microbore tubing and T-connector extension to the syringe. Attach a needle to the end of the T-connector and prime the line to expel the 0.5-ml of air. The syringe of adenosine is overfilled by an amount, which will compensate for the volume of liquid that the tubing holds (60 inches of microbore is 0.6 mL.) The adenosine solution should be advanced manually into the IV line up to the point of the needle so when the pump is started, the drug will begin to infuse with little delay. Keep the heart cart and defibrillator near the room and ready for immediate needs. Aminophylline is an antagonist to adenosine and is sometimes used to reverse the effects. Keep a 500- mg vial of Aminophylline and a 10-ml syringe on hand. Target time for administration of stress MIBI dose is at 2-minutes into adenosine infusion.

NOTE: Prior to the administration of the stress dose of Technetium 99m MIBI, visually confirm that the adenosine is infusing.
 7. The patient will be observed for a post-stress period of about 5-10 minutes to ensure stability. At the appropriate post-injection time (45-60 minutes), acquire SPECT images.
 8. Set up the camera/computer system with the SPECT acquisition protocol to detect the appropriate photon energy level of the imaging agent. Imaging is performed with LEHR collimators at 45-60 minutes post administration of stress MIBI.
 9. Process all cardiac images to generate rest/stress tomograms, QGS and QPS analyses.
 10. Transfer processed study to PACS for physician interpretation. Exams that will be interpreted by a cardiologist will be processed and transferred to the Xerlora and assigned to the ordering cardiology group.

Myocardial Perfusion Imaging with Adenosine Pharmacological Stress – Page 4 of 4

Results:

This is a physician-interpreted study.

References:

1. Operator's Manual radioisotope camera/computer.
2. Operator's Manual, PACS
3. Operator's Manual, Physiologic synchronizer /monitor
4. Operator's Manual, Graseby Syringe Pump, Model3400.
5. Product insert supplied with Technetium-99m Sestimibi (MIBI).
6. Maximal Vasodilatation, a brochure from Fujisawa USA, Inc., 1995. "Pharmacy Focus," IMMC, Vol. 4, No. 12, December 1990.
7. Seminars in Nuclear Medicine, Vol. XXXIX, No.3, May 2009

Written by: Stephen A. Kuhn, January 1991

Updated by: S. Sheridan 4/2019

Myocardial Perfusion Stress with Dobutamine and Sestamibi

This protocol will be used in Nuclear Medicine by Iowa Heart Center cardiologists for administration of Dobutamine stress testing and imaging with Technetium 99m Sestamibi (Tc99m Cardiolite). This is a Rest/Stress sequence.

1. Following the completion of the resting myocardial image acquisition, EKG/Treadmill personnel will attach EKG leads and obtain a baseline EKG.
2. The patient must have an I.V. line and pump with D5W infusing TKO. The Iowa Heart Center personnel will **provide the Dobutamine** which will be piggybacked into this line. (Dobutamine, 50 mg in 4 ml is mixed with 50 ml D5W.)
3. When all is ready for Dobutamine administration, the infusion is started at 5 mg/kg/min.
4. After 3 minutes the infusion rate is increased to 10 mg/kg/min. The same routine is continued for 20 mg/kg/min, then 30 mg/kg/min and finally 40 mg/kg/min. The infusion may be discontinued prior to 40 mg/kg/min for the following reasons:
 - a. 85% peak heart rate is obtained.
 - b. Patient's vital signs, EKG etc. dictate stopping the drug.
 - c. Patient's symptoms warrant the discontinuance of the infusion.
5. At peak heart rate or 40 mg/kg/min, the Tc 99m Cardiolite (24-36 mCi) is administered intravenously. Dobutamine infusion is continued for an additional 2 minutes after the Cardiolite injection. Then the Dobutamine is turned off and the D5W is continued TKO.
6. Myocardial perfusion imaging is performed in the usual fashion at 45-60 minutes post Cardiolite injection.
7. Transfer all SPECT rest/stress images, QGS and QPS analyses files to PACS. Notify the cardiologist when the study is ready for interpretation.

References:

1. Iowa Heart Center Rest - Stress Dobutamine Protocol.
2. Operator's Manual, Radioisotope Camera/Computer.
3. Literature supplied with Cardiolite.
4. Operator's Manual, PACS image archiving system

Written by: Stephen A. Kuhn, January 1997

Reviewed: S. Sheridan 4/2019

Myocardial Perfusion Imaging Lexiscan and Treadmill testing

Objective:

Lexiscan is a coronary artery vasodilator used to increase myocardial blood flow when treadmill stress testing is contra-indicated for Myocardial Perfusion Imaging. Lexiscan results in modest increase in heart rate and a modest decrease in both systolic and diastolic blood pressures.

Indications:

1. Patient is physically incapable of treadmill stress testing secondary to pulmonary issues, peripheral vascular disease, musculoskeletal conditions, neurological disorders, etc.
2. Left Bundle Branch Block
3. Medical treatment which cannot be discontinued for accurate treadmill testing (beta blockers, calcium channel blockers)
4. Abdominal Aortic Aneurysm
5. Pacemaker that does not allow MPHR to be achieved via treadmill stress testing
6. Inability to achieve 85% MPHR during treadmill stress testing

Contraindications:

1. Patients with active wheezing due to asthma, COPD, emphysema, lung disease, etc.
2. Known sensitivity to adenosine
3. Greater than 1st degree heart block (without pacemaker)
4. Sick sinus syndrome
5. Recent MI
6. Systolic BP of less than 90
7. Resting Heart Rate 40 BPM or less unless cleared with a physician
8. Use of Methylxanthines products (caffeinated beverages- 'decaf' included, caffeine-containing medications, aminophylline or theophylline derivatives) in the last 12 hours
9. Use of Dipyridamole (Aggrenox) in the last 48 hours
10. Recent, active seizure disorders

Lexiscan Dose:

Lexiscan is administered via a single bolus dose prefilled syringe. Every patient receives 0.4 mg/5mL (0.08 mg/ml) of Lexiscan over approximately a 10-20 second infusion time. Lexiscan dosage is NOT based on patient weight or other factors.

Patient Preparation:

1. No caffeine for 12 hours prior to test: coffee, decaf coffee, teas, sodas, chocolate or energy drinks
2. Do not eat a full meal within 4 hours of your test. Water, juice, milk, toast and crackers are allowed.
3. Patient must not smoke or use other nicotine-containing substances for 4 hours prior to this test.
4. Hold only the medications instructed to hold, see below:
 - a. Dipyridamole (Aggrenox) - 48 hours
 - b. Methylxanthines (caffeine-containing drugs, aminophylline, theophylline) - 12 hours
 - c. Erectile dysfunction meds - 24 hours

- d. Patient should discontinue sublingual nitroglycerin for 2 hours. Nitro paste/patch remove and wait 30mins prior to injection of Tc99m-MIBI.
5. If using an inhaler, bring it to the appointment.

Side Effects:

1. Shortness of breath – encourage patient to keep breathing
2. Headache – encourage patient to use pain medication if needed (Tylenol, etc.)
3. Flushing
4. Chest discomfort/pain
5. Dizziness
6. Nausea
7. Abdominal discomfort
8. Musculoskeletal discomfort

Indications for Reversal of Lexiscan:

1. Severe hypotension (systolic BP less than 80)
2. New onset of symptomatic 2nd degree or complete heart block
3. Severe chest pain with 2 mm or more ST depression
4. Signs of poor perfusion (pallor, cyanosis)
5. Difficulty breathing

Treatment of Adverse Reactions:

1. Aminophylline may be administered by slow (50-100 mg over 30-60 seconds) intravenous injection, in doses from 50-250 mg to help with severe, persistent side effects.

Treadmill Stress Test:

A treadmill stress test is done for those patients who are able to walk on a treadmill and achieve at least 85% MPHR for their age. Nuclear imaging is done prior to, and post treadmill stress testing. Treadmill testing is always encouraged; however, if a patient is unable to walk on the treadmill due to pulmonary disease, physical limitations, or other contraindications as listed below, pharmacological stress testing would be indicated.

One day or two-day Lexiscan/treadmill Stress test:

1. Patients undergoing 2 Day Studies
 - a. Patients with BMI > 40 will be scheduled to do their test on 2 days.
 - b. The dose for both days' rest, and stress, will be 30mCi, Range 24-36mCi Tc99m MIBI.
 - c. Follow basic procedures as above, doing half of test on day One, and the second half on day Two.
 - d. Prefer to do stress test half on day One, but not a rule.
 - e. Patients required to complete entire test, both days 1 & 2, within 1 week of each other.
 - f. All acquisition and processing protocols apply the same.
2. Inpatient exams are one-day with the resting part done first unless patient is over >40BMI. Verify patient identity using two methods and verify inpatient orders. The protocols are as follows:

- a. Rest injection of 8-16mCi Tc99m MIBI, stress injection of 24-36mCi Tc MIBI. (assure that the residual in the syringe is minimal) acquire resting images 30-45 minutes post injection.
- b. 1-4hour after injection of rest dose, conduct the pharmacological (Lexiscan) stress test and or treadmill.

Procedure:

1. Establish or confirm patency of I.V. access with saline flush prior to use.
2. Patient will be evaluated for any underlying lung disease (asthma, COPD) that may require use of an inhaler prior to stress testing.
3. Cardiology department conducting the stress test will instruct the nuclear medicine technologist to inject a stress dose of 24-36mCi Tc99m MIBI; and acquire images 30mins-4hrs post injection; the earliest time is preferable.
4. **Lexiscan** shall be injected over a 10-20 second time frame and flushed with 5 ml of 0.9% NaCl. The nuclear isotope will then be injected and followed by an additional 5 ml of 0.9% NaCl.
5. **Treadmill:** Inject the isotope at a minimum of 85% target heart rate. Once patient has reached 85%, patient should exercise until he/she becomes symptom limited & cannot physically walk more than one more minute.
6. The patient will be observed for the post-stress period of about 5-10minutes to ensure stability. At the appropriate post-injection time (30min-4hrs), acquire SPECT images.
7. Symbia S and Symbia T have icon protocols set up to use for both resting and stress images. Imaging is performed with LEHR collimators at 30min-4 hrs post administration of resting and stress isotope.
8. Process all cardiac image to generate rest/stress tomograms. Send slices to McPACs. Please see Xelera blue book for set by step processing in Xelera.
9. Transfer processed study to Xelera Cardiac PACs for cardiologist interpretation and assign to the ordering cardiology group.

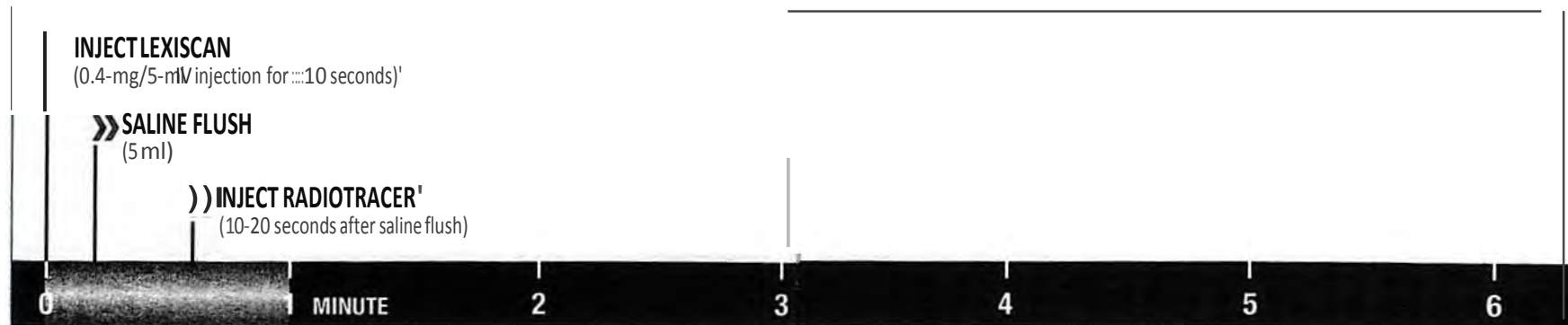
Results:

This is a physician-interpreted study.

DOSING & ADMINISTRATION

INJECTION PROTOCOL FOR LEXISCAN

Lexiscan is administered as a 0.4-mg/5-ml rapid IV injection (≈10 seconds) from a prefilled syringe. No dose adjustment is needed for body weight.



• Flush after radionuclide administration per your lab protocol.

- » Administer Lexiscan as a rapid (approximately 10 seconds) injection into a peripheral vein using a 22-gauge or larger catheter or needle¹
- » Administer a 5-ml saline flush immediately after the injection of Lexiscan¹
- » Administer the radionuclide myocardial perfusion imaging agent 10-20 seconds after the saline flush. The radionuclide may be injected directly into the same catheter as Lexiscan¹

Lexiscan supplied as:

- » Single-use prefilled syringe containing regadenoson 0.4 mg/5 ml (0.08 mg/ml)¹
- » Single-use vial containing regadenoson 0.4 mg/5 ml (0.08 mg/ml)¹

SAFETY CONSIDERATIONS

Side effects may occur during or after the procedure. Patients should be told to inform their physician if side effects occur.

Before initiating stress MPI with Lexiscan, use caution and be sure that appropriate resuscitation equipment and trained staff are available.

Lexiscan overdose may result in serious reactions. Aminophylline may be administered in doses ranging from 50 mg to 250 mg by slow IV injection (50 mg to 100 mg over 30-60 seconds) to attenuate severe and/or persistent adverse reactions to Lexiscan.

PLEASE SEE IMPORTANT SAFETY INFORMATION ON PAGES 12 AND 13. PLEASE SEE FULL PRESCRIBING INFORMATION ON THE BACK COVER.

MYOCARDIAL PERFUSION IMAGING WITH THALLIUM (TL201) REGADENOSON PHARMACOLOGICAL STRESS

Principle:

Regadenoson (Lexiscan) pharmacological coronary vasodilatation in conjunction with myocardial scintigraphy is an alternate to dynamic exercise testing for the diagnosis of coronary artery disease and assessment of the extent of the myocardium at risk, especially in patients who are unable to perform adequate exercise. Regadenoson is a modified form of the adenosine molecule with an additional side chain. Activation of the A_{2A} adenosine receptor by regadenoson produces coronary vasodilation and increases coronary blood flow. The effect of regadenoson on coronary blood flow is sustained for approximately 2.3 minutes, and decreases to less than twice the baseline level within 10 minutes.

The recommended intravenous (IV) dose of regadenoson is 5 mL (0.4 mg). No dose adjustment is needed to account for body weight. Lexiscan is supplied in a prefilled syringe and is administered as a rapid injection (approximately 10 seconds) into a peripheral vein using a 22-gauge or larger catheter or needle.

Regadenoson does have side effects, most are mild and transient, with onset soon after dosing that resolve within 15 minutes of dosing; headache, if present, resolves within 30 minutes of dosing. In trials aminophylline was used to treat adverse reactions in 3% of regadenoson patients and 2% of adenosine patients.

Thallous Chloride (Tl-201 Cl) accumulates in viable myocardium in a manner analogous to potassium and may be used to image myocardial perfusion with regadenoson stress. The myocardial distribution of the Tl-201Cl radioagent correlates well with regional perfusion. Imaging shows areas of infarction as "cold" or non-perfusing regions which are confirmed by redistribution imaging, electrocardiogram (EKG), and enzyme changes. Regions of transient myocardial ischemia corresponding to areas perfused by coronary arteries with partial stenosis are visualized as cold (ischemic) areas on the regadenoson stress images. These regions demonstrate partial or near complete resolution on delayed redistribution imaging.

Equipment, Reagents, and Supplies:

1. Dose of Thallous-201 Chloride will be in the range of 2-4 millicuries for the pharmacological stress.
2. Regadenoson is for intravenous use, recommended dose is 5 mL (0.4mg). No dose adjustment is needed to account for body weight. Regadenoson doses are obtained from the Pharmacy.
3. Intravenous catheter(s), plugs, syringes, aseptic pads, tape, and gauze.
4. Radioisotope camera/computer with high-resolution collimator(s) capable of SPECT acquisition and processing.
5. EKG monitoring equipment capable of 12-lead assessment or equivalent.
6. Blood pressure monitoring device and emergency heart cart with defibrillator instrument on standby in the room or near the area of regadenoson administration.
7. Picture Archiving Computer system (PACS).
8. Vial of aminophylline, 500 mg and a 10-ml syringe.
9. Patient consent form.

MYOCARDIAL PERFUSION IMAGING WITH THALLIUM-201 AND REGADENOSON PHARMACOLOGICAL STRESS – PAGE 2 OF 3

Preparations:

1. The patient should be fasting for at least four hours and preferably 8 hours.
2. Inpatients should have an intravenous access; peripheral vein using a 22-gauge or larger catheter or needle.
3. Patient must not have caffeine for at least 12 hours prior to test. This includes coffee, soft drinks, pain relievers containing caffeine, and stimulants such as vivarin.
4. Patient should discontinue nitroglycerin drip, patch and any other form.
5. No smoking, chewing tobacco, or nicotine substitutes at least four hours prior of the test.
6. No theophylline containing pharmaceuticals 48 hours prior to testing.
7. No persantine, or aminophylline 12 hours prior to testing.
8. No dipyridamole for at least 2 days prior to testing.
9. Co-ordinate the time of testing with the EKG department (nurse and EKG tech).

Procedure:

1. Verify the identity of the patient using two methods. For inpatients, verify the test order in the medical chart.
2. Send the completed request and a copy of the physician's testing order to the Pharmacy department so a dose of regadenoson can be dispensed.
3. The technologist will ascertain the medications and insure that the patient has been NPO and did not smoke in the last four hours. If there are any questions concerning any medication such as inhalers interfering with the procedure the nurse or supervising physician will clarify.
4. If absent, a saline lock is started by the nuclear medicine technologist.
5. The patient is then taken to the Cardiac Stress room at which time the EKG technician will attach leads to the patient and obtain baseline EKG tracings for the nurse.
6. Once an acceptable baseline EKG has been finished, the nurse will administer the regadenoson, as a rapid IV injection (approximately 10 seconds) followed with a 5-10 mL saline flush; 10-20 seconds after this flush, the nuclear medicine technologist will administer the stress dose of 2-4 millicuries of Thallous-201 Chloride followed by a 5-10 mL saline flush.
7. Once the pharmacological stress and post-stress monitoring are complete, a three lead EKG is established and the patient is positioned on the imaging table in a supine position with both arms above the head. Stress imaging is accomplished with the appropriate Gated SPECT stress acquisition protocol. Note that the time interval of Thallium-201 administration to start of imaging should be within 10-15 minutes to avoid effects of redistribution.
8. After the stress imaging the patient will spent 3-4 physically-quiet hours during which recirculation of Thallium-201 will occur. At the completion of this interval, another series of Thallium-201 SPECT images will be obtained. (No additional administration of Thallium-201 is given prior to this redistribution imaging.) The redistribution images will be the resting series to be compared with the stress tomograms. Usually cardiac gating is not included in the redistribution acquisition.

MYOCARDIAL PERFUSION IMAGING WITH THALLIUM-201 AND REGADENOSON PHARMACOLOGICAL STRESS-PAGE 2 OF 3

9. The patient is then released and the appropriate processing protocol is followed. Transfer tomographic images, analyses and data files to the PACS. Scan the test request, stress test record sheet (s) and EKG tracings into PACS; indicate who will interpret the exam; include additional information in PACS as needed.

Results:

This is a physician-interpreted study.

References:

1. Operator's Manual radioisotope camera/computer.
2. Operator's Manual, PACS
3. Operator's Manual, Physiologic synchronizer /monitor
- 3 Product insert supplied with Thallium 201 Chloride.
6. Lexiscan (regadenoson) Dosing & Administration, a brochure from Astellas Pharma US, Inc., 2008.
7. Seminars in Nuclear Medicine, Vol. XXXIX, No.3, May 2009

Updated by: S. Sheridan 4/2019

99mTechnetium-HDP Imaging for Transthyretin Cardiac Amyloidosis

Overview:

Patient Selection:

Individuals with heart failure and unexplained increase in left ventricular wall thickness.
Individual over the age of 60yrs with unexplained heart failure with preserved EF.
Evaluation of cardiac involvement in individuals with known or suspected familial amyloidosis.

Test Preparation:

No specific test preparation is required.

Imaging Procedure:

1. Verify the patient using two methods.
2. When PYP is not available, Tc99m HDP may be used as an alternate imaging agent with a dose range of 22.5mCi – 27.5mCi.
3. Wait 2.5-hour planar imaging and 3 hours SPECT imaging.
4. Supine position.

PLANAR IMAGING (Symbia T) 2.5 hour post injection.

- a. Under Cardiac PYP Amyloidosis-Statics
- b. Anterior, Lateral and Left Anterior Oblique of chest.
- c. 750K with Magnification 1.46.
- d. 140Kev 15-20% window.
- e. Collimators: Low energy, high resolution.
- f. Matrix 64x64.
- g. Draw ROI's please see table 2.

SPECT IMAGING 3 hour post injection. (No SPECT/CT)

- a. Under Cardiac PYP Amyloidosis-SPECT
- b. Angular range: 360 degrees
- c. Detector configuration: 180 degrees
- d. Number of views/detector: 40
- e. Time per stop: 20seconds magnification=1.0

PROCESSING PLANAR imaging:

Quantifying myocardial 99mTc-HDP Uptake:

1. Quantitative: Myocardial to contralateral lung ratio of uptake at 2.5 hours.
 - a. Circular target regions of interest (ROI) are drawn over the heart and the planar image and are mirrored over the contralateral chest to account of background and ribs. See figure 1.

- b. Total and absolute mean counts are measured in each ROI. A heart contralateral (H/CL) ratio is calculated as the fraction of heart ROI mean counts to contralateral chest ROI mean counts.
- c. H/CL ratios of ≥ 1.5 at one hour classified as ATTR positive and ratios < 1.5 as ATTR negative (4).

3-hour SPECT (NO SPECT/CT)

1. Semi-quantitative: visual comparison to bone (rib) uptake at 3 hours.
2. Using Cardiac PYP Amyloidosis-SPECT/Processing on Symbia T.
3. After 3 hour SPECT patient is finished.

PLEASE SEE ATTACHED TABLES FOR REFERENCE.

SCREEN SAVES:

1. White on black planar images.
2. Anterior ROI's with counts.
3. Slices SPECT.
4. Send raw data.

RESULTS: This is a physician-interpreted study.

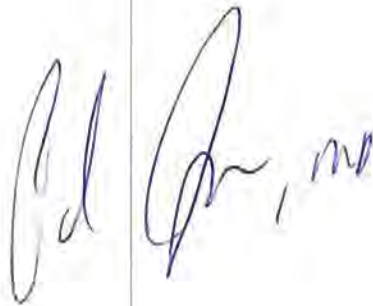


Table 2. Semi-quantitative Visual Grading of Myocardial ^{99m}Tc -PYP Uptake by Comparison to Bone(rib) Uptake

Grade	Myocardial ^{99m}Tc -PYP Uptake
Grade 0	no uptake and normal bone uptake
Grade 1	uptake less than rib uptake
Grade 2	uptake equal to rib uptake
Grade 3	uptake greater than rib uptake with mild/absent rib uptake

Figure 1. Quantitation of Cardiac ^{99m}Tc -PYP Uptake Using Heart to Contralateral Lung (H/CL) Ratio

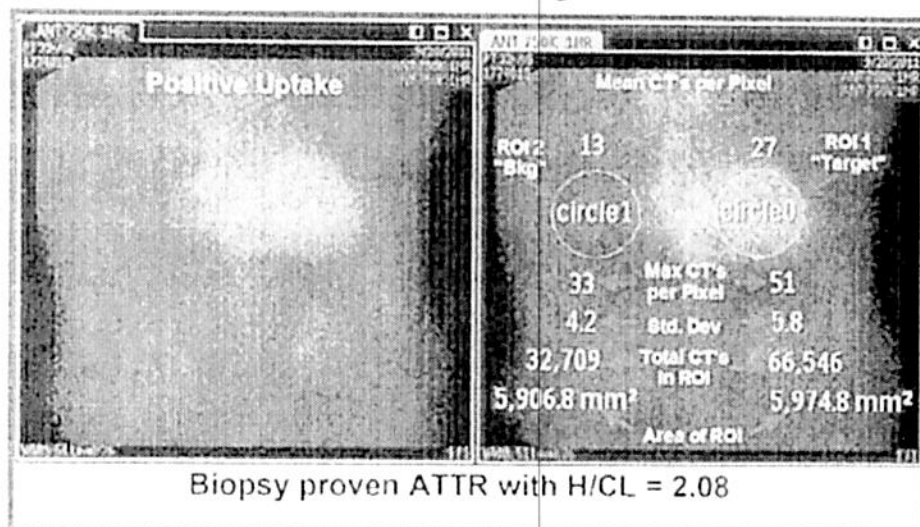
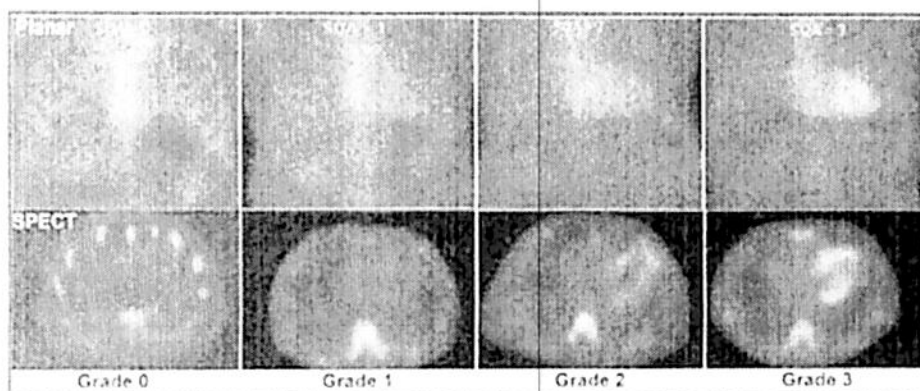


Figure 2. Grading ^{99m}Tc -PYP Uptake on Planar and SPECT Images



BILLING

ASNC would recommend:

- For planar with SPECT report CPT 78803 Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s), tomographic (SPECT).
- When reporting CPT 78803, planar imaging of a limited area or multiple areas should be included with the SPECT.
- For the HCPCS level II code report A9538 ^{99m}Tc-pyrophosphate, diagnostic, per study dose, up to 25 millicuries.
- For a single planar imaging session alone (without a SPECT study), report CPT 78800 Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s), limited area

REFERENCES:

- (1) Ruberg FL, Berk JL. Transthyretin (TTR) cardiac amyloidosis. *Circulation* 2012;126:1286-300.
- (2) Perugini E, Guidalotti PL, Salvi F, Cooke RM, Pettinato C, Riva L et al. Noninvasive etiologic diagnosis of cardiac amyloidosis using ^{99m}Tc-3,3-diphosphono-1,2-propanodicarboxylic acid scintigraphy. *Journal of the American College of Cardiology* 2005;46:1076-84.
- (3) Gertz MA, Brown ML, Hauser MF, Kyle RA. Utility of technetium Tc ^{99m} pyrophosphate bone scanning in cardiac amyloidosis. *Archives of internal medicine* 1987;147:1039-44.
- (4) Bokhari S, Castano A, Poznanski T, Desisle S, Latif F, Maurer MS. (^{99m}Tc-pyrophosphate scintigraphy for differentiating light-chain cardiac amyloidosis from the transthyretin-related familial and senile cardiac amyloidosis. *Circulation Cardiovascular imaging* 2013;6:195-201.
- (5) Falk RH, Quarta CC, Dorbala S. How to image cardiac amyloidosis. *Circulation Cardiovascular imaging* 2014;7:552-62.
- (6) Hutt DF, Quigley AM, Page J, Hall ML, Burniston M, Gopaul D et al. Utility and limitations of 3,3-diphosphono-1,2-propanodicarboxylic acid scintigraphy in systemic amyloidosis. *European heart journal cardiovascular Imaging* 2014;15:1289-98.

Written by: S.Sheridan 1/2019

Approval by: Dr. Brent Wolford 11/2019

Updated by: Dr. Jabour 4/2025

Cardiac PYP/1-2020

Skeletal (Bone) Imaging

Principle:

Nuclear Medicine bone imaging is a highly sensitive, noninvasive method of examining the bones. Total skeletal (bone) imaging has a broad range of applications. It is useful for the early detection of metastatic bone lesions prior to x-ray changes; to determine the extent of known primary and metastatic lesions; to assist in the planning of radiotherapy portals; to evaluate the age of compression fractures of the vertebral column; to screen preoperative patients with malignancies known to metastasize early to bone such as breast, lung, and prostate; to diagnose osteomyelitis in its early stages; and to localize lesions prior to bone biopsies.

Single photon emission computed tomography (SPECT) bone imaging enhances the bone scan by providing cross-sectional anatomical detail and image contrast that previously was unavailable. Multiphase (three-phase) bone imaging is performed in some nuclear examinations of the bones to provide valuable information with regard to the vascularity of a lesion. This involves a dynamic flow study of the area of interest, with rapid sequential images taken every 2-5 seconds followed by a blood pool image at five minutes post-injection of the imaging agent.

Equipment and Supplies:

1. Radioisotope camera/computer with high resolution collimator.
2. Whole body imaging table (SPECT/CT table for SPECT/CT study).
3. Adult dose of 10-30 millicuries of Technetium-99m Medronate (Tc-99m MDP). For children, follow the weight/dose chart.
4. Intravenous administration items.
5. PACS image review and archiving system.

Procedure:

1. Verify patient identity using two methods and verify inpatient orders.
2. Explain the procedure to the patient and answer appropriate questions.
3. Three-phase examinations are performed for indications that include extremity pain, trauma, and post surgical status. The area of interest is positioned in the camera's field of view as the radiopharmaceutical dose is administered. Follow the camera/computer protocol to optimize the system to detect the 140 keV photons of Technetium, 15% window width, frame time, and number of frames. Administer the 99mTc. MDP dose intravenously. Acquire a set of dynamic frames. At approximately five minutes following injection, acquire a high resolution planar blood pool image.
4. If not restricted, instruct the patient to drink more fluids than usual to improve clearance of the dose from the blood by the kidneys and reduce exposure. Instruct the patient regarding the return time for the final images 2-3 hours from injection. Encourage the patient to empty the urinary bladder frequently during this time.
5. Bone imaging for indications such as cancer staging or restaging do not require three-phase technique. Administer the Tc-99m MDP intravenously. It may be added to any IV access and most I.V. fluids. If not restricted, instruct the patient to drink more fluids than usual to improve clearance of the dose from the blood and reduce exposure. Wait 2-3 hours before imaging. Encourage the patient to empty the urinary bladder frequently during this time.

Skeletal Imaging – Page 2 of 2

6. Prepare for the final images (whole body or planar views) by setting the current camera/computer protocol which will optimize the detection of Tc-99m at 15-20% window.
7. Allow the patient to empty the urinary bladder just prior to beginning the images. Acquire whole body images in posterior and anterior views.
8. The radiologist may want to review the images before the patient is dismissed so the need for additional views and/or SPECT/CT imaging can be determined.
9. If SPECT/CT acquisition is necessary, set up the camera/computer from the current protocol which will define the number of angles, frame time, and type of orbit.
10. If SPECT/CT data was acquired, check the quality by reviewing a sinogram of the data. If there is no quality problem, dismiss the patient. Process the data according to the protocol for three projection tomographic reconstruction. Generate fused axial and fused coronal tomograms files. Transfer screen captures of these images to PACS. In addition, transfer the CT B-30s, fused axial, fused coronal and Corrected Recon NM files to PACS and LE02
11. Prepare the room for the next patient study.

Results:

This is a physician-interpreted study.

References:

1. Operator's Manual, radioisotope camera/computer system.
2. Operator's Manual, PACS archiving system.
3. Nuclear Medicine, William H. Blahd, M.D., 2nd Edition.
4. Diagnostic Nuclear Medicine, A. Gottschald, M.D. and E. J. Patchen, M.D., 1976.
5. Literature supplied with the Medronate compound.
6. An Atlas of Planar and SPECT Bone Scans, Ignac Fogelman, M.D. and B. David Collier, M.D., 1989.
7. Diagnostic Nuclear Medicine, Vol. 2, 2nd Edition, A. Gottschalk, M.D., P. B. Hoffer, M.D., and E. J. Patchen, M.D., 1988.
8. Nonosseous Abnormalities on Bone Scans, Journal of Nuclear Medicine Technology Volume 31, Number 3, 2003, 149-153
9. Seminars in Nuclear Medicine, Skeletal Scintigraphy Update, Vol 40, No 1, Jan 2010.

Written by: Stephen A. Kuhn, May 1989

Updated by: S. Sheridan 4/2019

Spleen Imaging with Technetium-99m Heat-Denatured Red Blood Cells

Principle:

Radionuclide imaging of the spleen supplies useful information in many clinical situations. Enlarged or atrophied spleens, accessory or ectopic spleens, space-occupying lesions and infarcts are among the abnormalities identified by this procedure. The heat-damaged, or heat-denatured, RBC study is used to assess for the presence and location of splenic tissue in a variety of clinical scenarios. One of the functions of the spleen is removal of damaged and obsolescent blood cells. Normal RBCs are deformable and pass readily through the spleen. However, through the process of heating, RBCs undergo fragmentation and spherocytosis, leading to increased stiffness and, consequently, entrapment by the spleen. This makes the heat-damaged RBC study a sensitive and specific method of identifying splenic tissue.

Because of the rapid splenic sequestration of the damaged RBCs, imaging can begin 30 min after injection. Planar and SPECT scans should be performed. When the study is a search for accessory splenic tissue, the entire abdomen must be imaged. The study may be done in the setting of prior trauma with splenic rupture to assess for implants of splenic tissue; if the diaphragm may have been violated during the trauma, then the thorax must be imaged as well to assess for implants there.

Equipment and Supplies:

1. Radioisotope camera/computer system with high resolution collimator.
2. Dose of Technetium 99m labeled heat-denatured RBCs; 3-5 millicuries;
pediatric dose is a minimum of 1 millicurie.
3. Vial of heparin, 2 milliliters with concentration of 1000 U/ml.
4. Syringe and supplies for intravenous puncture; syringe shield for re-injection.
5. One arm-band, Typenex identification system.
6. Proper DOT shipping container for blood products.
7. Radioisotope imaging camera/computer.
8. PACS image review and archiving system.

- Notes:**
1. USP 797 Guidelines apply during this procedure.
 2. This protocol was revised (March 2011) to show the Tc99m RBC labeling and the heat-denaturing process are now performed by the Radiopharmacy. The nuclear medicine clinic/department no longer uses Ultratag on the blood before sending it to the Radiopharmacy.
 3. The Radiopharmacy requires about 90-120 minutes to pick-up, radio-label, heat-denature and deliver the dose of Tc99m RBCs. Consider this when scheduling imaging time on the camera.

Procedure:

1. Verify the identity of the patient using two methods and verify indications and test order.
2. Explain the test to the patient and answer appropriate questions.
3. In a heparinized syringe, obtain 1-3 milliliters of patient's blood. (Note: only 10-15 units of heparin should be used/milliliter of blood.)

4. Write the patient's name, date of birth, and medical record and "Nuclear Medicine" on the label portion of a Typenex arm-band. Affix the top copy (pressure-sensitive label) to the syringe containing the blood specimen and place the bracelet portion of the Typenex on the patient's wrist. Cut off the excess length of arm-band which contains small, green alphanumeric ID labels. Affix one small label to the radiopharmacy test requisition and one on the "NM Test Requisition form"; send the remainder to Cardinal Radiopharmacy for use during the labeling and heat-denaturing processes. Complete the "Tc99m RBC Study Customer Worksheet" and send it to Cardinal Radiopharmacy with the blood specimen.
5. Place proper DOT package labels on the outside of the blood shipping container. Request that Cardinal Radiopharmacy send a driver to pick up the blood specimen. At the radiopharmacy, the blood specimen will be labeled with Technetium 99m using the Ultratag system. The Tc99m labeled RBCs will then be denatured with a controlled-heating process.
6. The heat-denatured Tc-99m RBCs will be assayed and returned in a syringe as a unit dose of radio-labeled cells.
7. Adult imaging dose is 3-5 mCi of Tc-99m heat-denatured RBCs. Reduce this amount for pediatric patients based on weight or age, with a minimum of 1 mCi. Use a double identification of the patient and labeled RBC dose by two employees. Identify the specimen and the patient by the unique Typenex ID and one other method. Administer the dose of Technetium-99m denatured RBC intravenously.
8. Starting about 20-30 minutes after IV administration, planar and SPECT scans should be performed. When the indication is search for accessory splenic tissue, the entire abdomen must be imaged. The planar images include acquisition of anterior, posterior and lateral planar images. Follow the camera/computer protocol which usually would be set for 1000K/acquisition. SPECT or SPECT/CT rotational imaging should be acquired at 25-30 seconds per stop.
9. Process the SPECT frames with filtered back-projection or iterative reconstruction. Produce screen cap image files of planar and SPECT data. Transfer images to PACS, compose a clinical note to include indications, other clinical information, doses of agents and names of personnel involved in the procedure.
10. Request a radiologist to review the PACS images prior to dismissing the patient.
11. When the study is complete, prepare the room for another patient/procedure.

Results:

This is a physician-interpreted study.

References:

1. Operator's Manual, radioisotope camera/computer
2. Operator's Manual, PACS image review and archiving system.
3. "The Spleen," in Clinical Scintillation Scanning, Freeman, L. M. and Johnson, P.M., Editors, New York, Harper and Row, 1969, pp. 414-445.
4. Eckelman, W., et al, "Visualization of the Human Spleen with Tc-99m-Labeled Red Blood Cells," in Journal of Nuclear Medicine, Vol. 12, No. 6, pp. 310-311.

5. Whole Blood Collection instruction/information, Cardinal Radiopharmacy Services.
6. [Spleen, Pathology Outlines.com](#), April 2006
7. Atkins HL, Goldman AG, Fairchild RG, et al. Splenic sequestration of ^{99m}Tc labeled heat treated red blood cells. *Radiology*. 1980;136:501–503

Updated by: S.Sheridan 4/2019

THYROID IMAGING WITH TECHNETIUM-99M PERTECHNETATE (Tc^{99m}M04)

PRINCIPLE:

Technetium-99m in the chemical form of pertechnetate can be satisfactorily used for thyroid imaging. The pertechnetate is trapped by the thyroid but is not incorporated into thyroid hormone. Evaluation of nodular thyroid disease, a major application of thyroid imaging, is helpful in the assessment of function in existing thyroid nodules, distinction of a solitary nodule from generalized thyroid disease, and possible detection of occult thyroid malignancy. Imaging is ordered usually if the patient has palpable findings or and ultrasound detects evidence of nodules. Nodules that show an increase in uptake of radiotracer are not considered a risk for cancer. However, nodules showing decreased uptake may be at an increased risk for cancer. Hyperfunctioning nodules, particularly those that are 3 cm or more, may be associated with hyperthyroidism.

PATIENT PREPARATION:

1. No iodinated x-ray contrast within the last 4 weeks if the contrast type is unknown. If known, consult "Common Drugs and Chemical Substances that Influence Thyroid Uptake of Iodine" published by Syncor (CardinalHealth).
2. No thyroid medications for 6 weeks if the medication is unknown. If known, consult "Common Drugs and Chemical Substances that Influence Thyroid Uptake of Iodine" published by Syncor (CardinalHealth).

EQUIPMENT AND SUPPLIES:

1. Gamma camera/computer system with a pinhole collimator.
2. Tc-99m Pertechnetate, range of 2-10 millicuries
3. Intravenous administration supplies
4. Cobalt-57 spot marker
5. PACS review and archiving system

PROCEDURE:

1. Attach pinhole collimator to the gamma camera.
2. Verify the identity of the patient with two methods and verify inpatient orders. Explain the procedure and obtain the patient's history and list the medications the patient is currently taking. Ask the patient if they have had radiographic contrast within the last four to eight weeks.
3. Set up camera by entering the appropriate data and use the current Tc99m imaging protocol.
4. Intravenously administer the dose of Tc99m Pertechnetate.
5. Wait about 10-15 minutes before starting imaging.
6. Position the patient supine under the pinhole collimator at a distance of 2.5 inches from the anterior neck.
7. Begin anterior projection picture marking the right side of the thyroid with a Cobalt57 spot marker.
8. Using the same technique, acquire LAO and RAO projections.
9. Transfer the image files to PACS and have them reviewed by the radiologist before dismissing the patient.

Written by: **Mark Flickinger**

Updated by: **S. Sheridan 4/2019**

Iodine-123 Thyroid Uptake and Imaging

Principle:

Sodium Iodide-123 (NaI-123) is readily absorbed from the upper gastrointestinal tract. Following absorption, the iodide is distributed primarily within the extracellular fluid of the body. It is trapped and organically bound by functioning thyroid tissue.

The fraction of the administered dose which is accumulated in the gland may be a measurement of thyroid function in the absence of drugs or other diagnostic procedure which influence iodine accumulation by thyroid tissue.

Imaging of the distribution pattern of I-123 within the neck and chest can evaluate thyroid morphology, localize thyroid lesion, evaluate suspected substernal masses, and delineate ectopic thyroid tissue in anomalous gland development. Radioiodine uptake (RAIU) values may be obtained at 4-6 hours and 24 hours after oral administration of the I-123.

Patient Preparation:

1. Patient should be fasting 6-8hrs.
2. The patient should have had no radiographic contrast in the past 4 weeks. If this preparation is not in place the test should be rescheduled for the appropriate time.
3. The patient must be free of influence from thyroid medication (anti-thyroid and supplemental thyroid hormonal medication). If the patient is not properly prepared in the category, consult the booklet, "Common Drugs and Chemical Substances That Influence Thyroid Uptake of Iodine", compiled by Syncor Pharmacy Services. The test should be rescheduled for the appropriate time.

Equipment, Reagents and Supplies:

1. Scintillation thyroid probe system, with Cs-137 sealed disk source and calibration fixture.
2. Radioisotope camera/computer with pinhole collimator.
3. PACs image review and archiving system.
4. Dose of I-123; the recommended oral dose for adults is 200-400uCi of I-123 sodium iodide in capsule form. Pediatric (18 years old and under) doses are weight-based.

Iodine -123 (NaI-123)

1. Physical half-life is 13.2hours.
2. Decays by electron capture emitting 159 keV gamma rays (83%) and 28 keV (average) Tc x-rays (87%).
3. Specific gamma ray constant is 1.5 R/mCi hr at 1 cm.

Notes:

1. Assure daily quality assurance (QA) has been successfully completed on the thyroid probe system prior to patient use. This requires a 1-minute daily background and a 1-minute daily calibration with Cs-137 standard disk. **Assure the correct 'Staff Name' is on the QA file.**
2. Note the QA is considered acceptable when the FWHM value is less than 10% and when the energy peak is between 430-480.

Procedure:

1. Verify the identity of the patient using two methods. Explain test procedure and answer appropriate questions. Obtain medication and radiographic contrast history form the patient. If a contraindication (recent iodinated contrast, PTU, Synthroid etc.) are present, follow guidelines established by the supervising radiologist.
2. From the Atom-Lab 960 home page, select "testing thyroid uptake, add patient (enter the patient's name, DOB, physician, MRN, technologist name). Select-Study-I-123 uptake. Use the red LED and distance bar set to 25 cm to position the neck phantom containing the I-123 capsules. Retract the red LED to turn off and move the distance bar out of the field before counting. Counting the reference standard (I-123 dose) Acquire a 3-minute patient (laboratory) background count.
3. Administer the I-123 capsule(s) to the patient orally with water. Doses with 2 or 3 capsule may ingested on at a time. Note: since capsules could have I-123 on the outside surfaces, gloves should be worn when handing them; ungloved fingers/hands should not touch the capsules. The patient should continue to fast for one additional hour after ingesting the I-123 capsules. Instruct the patient to return at an appropriate time later that same day for thyroid uptake determination and imaging at 4-6 hours. The second uptake is obtained at about 24hrs post I-123 dose.
4. In patients with suspected or known substernal masses, the radiologist may want to start the imaging with a parallel hole collimator detector to visualize a larger area. Anterior, RAO, LAO, and thyroid marker images are obtained after the patient is positioned supine under the pinhole-collimated detector. Note: The thyroid marker/ruler image is located in the processing/viewing area of the images. All projections are acquired at the distance required to produce an "actual size" thyroid image, usually 3 inches from the thyroid. Follow the camera chart or protocol for other parameters. Set the camera to detect the 159keV photons of I-123 at a 20% window. Each image should use an acquisition time of 10minutes or 100K counts. Send the series of images to PACs.
5. To complete the thyroid uptake, from the home page select Testing, Thyroid Uptake, select correct patient, Select study, I-123 uptake. Position the patient's thyroid as in step 2 above. When the thyroid count has completed, position the probe over the thigh. Assure the bladder area is not in the field of view of the probe. Acquire a thigh-background count. Assure the "staff" name is correct on the report. Note: The sequence of these counts may be reversed.
6. Following completion of the 24-hour uptake, print as Uptake Report page from the Atom-Lab 960. Scan the report, the test requisition, and patient questionnaire into PACS. Transfer the camera images to the PACs and complete the technologist notes.
7. The Front panel of the Atom-Lab 960 should be locked or system shutdown at the end of each workday.

Calculation Example:

$$RAIU = \frac{\text{Neck Counts (cpm)} - \text{Thigh Counts (cpm)}}{\text{Admin. Counts (cpm)} - \text{Background Counts (cpm)}} \times 100\%$$

Results:

1. Thyroid uptake (RAIU) at 4-6 hours normal=2-14% and 24 hours=7-29%

2. Images and uptake are interpreted by a radiologist.

Notes:

The patient should be questioned carefully regarding recent and current medication and /or procedures involving radiographic media to avoid unnecessary radiation exposure. The booklet, Common Drugs and Chemical Substances That influence Thyroid Uptake of Iodine. (1993) prepared by Cardinal Health/Syncor International Corporation, is a valuable source of the information. A copy is included in the procedure manual.

References:

1. Operator's Manual, radioisotope camera/computer.
2. Product literature supplied with I-123.
3. Operator's Manual, Biodex Atom Lab 960 Uptake system.
4. Common Drugs and Chemical Substances That Influence Thyroid Uptake of Iodine, 1993 prepared by Cardinal radio-pharmacy.

Approved: Dr. Paul Jabour

Written: Stephen Kuhn/Sharon Sheridan

Iodine-123 Thyroid Whole-body Imaging

Principle:

Sodium Iodide-123 (NaI-123) is readily absorbed from the upper gastrointestinal tract. Following absorption, the Iodide is distributed primarily within the extracellular fluid of the body. It is trapped and organically bound by functioning thyroid tissue.

The fraction of the administered dose which is accumulated in the gland may be a measurement of thyroid function in the absence of drugs or other diagnostic procedure which influence Iodine accumulation by thyroid tissue.

Imaging of the distribution pattern of I-123 within the neck, chest and whole-body can evaluate thyroid morphology, localize thyroid lesion, evaluate suspected substernal masses, and delineate ectopic thyroid tissue in anomalous gland development.

Patient Preparation:

1. Patient should be fasting 6-8hrs.
2. The patient should have had no radiographic contrast in the past 4 weeks. If this preparation is not in place the test should be rescheduled for the appropriate time.
3. The patient must be free of influence from thyroid medication (anti-thyroid and supplemental thyroid hormonal medication). If the patient is not properly prepared in the category, consult the booklet, "Common Drugs and Chemical Substances That Influence Thyroid Uptake of Iodine", compiled by Syncor Pharmacy Services. The test should be rescheduled for the appropriate time.

Equipment, Reagents and Supplies:

1. Radioisotope camera/computer for whole-body scan and images.
2. PACs image review and archiving system.
3. Dose of I-123; the recommended oral dose for adults is 3 mCi of I-123 sodium Iodide in capsule form. Range dose is 2-4mCi. Pediatric (18 years old and under) doses are weight-based.

Iodine -123 (NaI-123)

1. Physical half-life is 13.2hours.
2. Decays by electron capture emitting 159 keV gamma rays (83%) and 28 keV (average) Tc x-rays (87%).
3. Specific gamma ray constant is 1.5 R/mCi hr at 1 cm.

Procedure:

1. Verify the patient using two methods. Administer the I-123 capsule(s) to the patient orally with water. Doses with 2 or 3 capsule may ingested on at a time. Note: since capsules could have I-123 on the outside surfaces, gloves should be worn when handling them; ungloved fingers/hands should not touch the capsules. The patient should continue to fast for one additional hour after ingesting the I-123 capsules. Instruct the patient to return at an appropriate time later that same day for thyroid whole-body imaging at 6 hours.
2. Have the patient empty their bladder just prior to imaging.

3. Acquire whole-body images in anterior and posterior views, and static head and neck images.
4. The whole-body images should have 350Kcts/min. Static images should go for 10mins each.

Results:

1. Images are interpreted by a radiologist.
2. Patients with abnormal I-123 scan will be treated with therapeutic doses of I-131 followed by whole-body scan 7-10 days later.

Notes:

The patient should be questioned carefully regarding recent and current medication and /or procedures involving radiographic media to avoid unnecessary radiation exposure. The booklet, Common Drugs and Chemical Substances That influence Thyroid Uptake of Iodine. (1993) prepared by Cardinal Health/Syncor International Corporation, is a valuable source of the information. A copy is included in the procedure manual.

References:

1. Operator's Manual, radioisotope camera/computer.
2. Product literature supplied with I-123.
3. The Usefulness of I-123 Whole-body scans in Evaluating Thyroid Carcinoma and Metastases.
4. Common Drugs and Chemical Substances That Influence Thyroid Uptake of Iodine, 1993 prepared by Cardinal radio-pharmacy.

Approved: Dr. Paul Jabour
Written: Sharon Sheridan

Treatment of Hyperthyroidism With Iodine-131

Principle:

Hyperthyroidism is a clinical symptom complex caused by elevated thyroid hormone levels. Of the disorders in which it appears, the most common is Grave's disease; toxic nodular goiter (Plummer's disease) is considerably less frequent. Of the three major modalities used in the treatment of hyperthyroidism, Iodine-131 appears to be generally preferred for the majority of adult patients. Its efficacy is unquestioned and sufficient data have accumulated in the 40 years of its use to provide convincing evidence of its safety.

Patient Preparation:

1. Fasting 8-12 hours prior to the administration of the Iodine-131 or at the discretion of the treating physician.
2. UnityPoint Health Des Moines radiation safety guidelines for administration of Iodine-131 to females of child-bearing age (12-50 inclusive) require the patient be tested for pregnancy within 72 hours or less before the I-131 dose is given. Pregnancy testing must be quantitative HCG performed on blood specimen. An HCG level of less than 5mIU/ml is considered negative for pregnancy. When the patient's clinical information/history documents that a hysterectomy has been performed, the authorized user may omit the pregnancy test.
3. The Iodine 131 treatment dose is calculated from diagnostic radioiodine thyroid uptake values. The RAIU determination should be obtained within four weeks of the treatment.

Equipment, Reagents and Supplies:

1. Dose of Iodine-131 as Sodium Iodide, as directed by the physician performing the treatment. (These doses are usually ordered from Cardinal Pharmacy in capsule form. To order, a signed doctor's written directive must be faxed to the radiopharmacy the day prior to the scheduled treatment.)
2. Dose calibrator capable of assaying the Iodine-131 prior to administration.
3. One copy of IMMC General Consent form (Adm 158 1/94), Written Directive form and Iodine Quality Management Audit form.
4. PACS archiving system.

Procedure:

1. Obtain the result of screening (blood specimen) beta HCG test performed within 72 hours prior to the treatment. This value must indicate that the patient is not pregnant. Do **not** proceed with this treatment until a negative pregnancy test is documented. Print a copy of the negative pregnancy result for the radiologist to review prior to the patient pre-treatment consultation.
2. The radiologist will explain the treatment to the patient and obtain a completed IMMC General Consent form and a signed "Staff Questionnaire and Release Determination" form (includes patient instructions). A written directive from the radiologist treating the patient is required.
3. An Iodine Quality Management Audit form must be completed. Patient identity must be verified using two methods; the dose must be within 20% of the amount on the written directive.

4. Following the pre-treatment consultation with the radiologist, the dose of Iodine-131 is administered orally to the patient with water. Caution: Iodine-131 capsules should never be touched by the patient. Instruct the patient to "deliver" the capsule to their mouth using the plastic vial the capsule was shipped in.
5. The patient is required to remain in the Nuclear Medicine Department for 30 minutes after the administration. This will assure that the patient will have assistance should the dose cause nausea. To reduce exposure to employees, visitors and other patients in the area, position the patient in a room or area which will provide the most distance from other people. After this time, the patient should be instructed to notify the Nuclear Medicine department if vomiting should occur within the next 24-hours. Before dismissing also instruct him/her to follow-up with their physician.
6. Record the dose administered in the SynTRAC patient logging system.
7. Scan the treatment request and dosage information into the PACS for archiving and dictation.

Notice to Physicians and Technologists Regarding Bioassay:

The CIHS RAM license was amended in March 2007 to show no requirement for bioassays when the Iodine-131 doses are in capsule form. Bioassay within 24-96 hours is still required:

1. if liquid Iodine 131 must be used
2. if the capsule is broken or shows any sign of damage
3. if the patient vomits following the administration of the dose
4. if there is any abnormal occurrence involving the administration of Iodine 131.

References:

1. Product literature supplied with Iodine-131 dose.
2. Diagnostic Nuclear Medicine, Vol. 2, A. Gottschalk, P.B. Hoffer, and E. J. Potchen, Second Edition, 1988.
3. "Radiation Machines and Radioactive Materials Rules", Iowa Department of Public Health, Des Moines, Iowa; 07/01/05.
4. CIHS Radioactive Materials License
5. Operator's Manual, PACS

Written by: Stephen A. Kuhn, September 1995

Updated by: S. Sheridan 4/2019

Quality Management Program

PURPOSE

The purpose of the Quality Management Program is to provide high confidence that any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131 is in accordance with the written directive of the authorized user.

TRAINING

Any personnel performing procedures using greater than 30 microcuries of either I-125 or I-131 will be trained to follow the procedures outlined below.

PROCEDURE:

1. Each patient receiving a dose of either I-125 or I-131 exceeding 30ucCi will have an authorized user, or a physician under his supervision, sign and date a written directive prior to administration of the dose. This written directive must specify the patient's name, radiopharmaceutical, dose, date to be administered, and route of administration. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive. All written directives will be kept for three (3) years following the date of administration.
2. A written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing directive will be acceptable, provided the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.
3. Prior to each administration, the patient's identity is to be verified by more than one method as the individual named

in the written directive. First, identify the patient by asking and confirming his or her name. (If the patient is unable to respond, two of the alternate forms of patient ID listed below will be utilized.) Second, identify the patient by comparison with corresponding information in the patient's record: date of birth, address, social security number, signature, name on the patient's ID bracelet, hospital ID card, or the name on the patient's medical insurance card.

4. The individual administering the radiopharmaceutical will confirm, prior to administration, that the radiopharmaceutical dosage and route of administration are in agreement with the written directive. This will include assaying the radiopharmaceutical in the dose calibrator within thirty (30) minutes of administration and comparing the results with the prescribed dose recorded in the written directive.
5. If the Nuclear Medicine technologist does not understand how to carry out the written directive or cannot clearly read the written directive, he or she must contact the authorized user who prepared the written directive before continuing the procedure.
6. A written record of the amount and name of the radiopharmaceutical administered, along with the date and signature (or initials) of the person administering the dose, will be kept for each patient. These records will be kept for at least three (3) years.
7. A review of each administration will be performed to ensure that all requirements have been met. This review will be documented on the attached patient audit form. A second review will be made by an authorized user or other supervised individual to confirm that all requirements of the QMP have been met. Both reviewers will sign the patient audit form.
8. Reviews will be conducted at intervals not to exceed 12 months. The review will include all administrations from the previous 12 months up to the date of the review. This review will include the following: radiopharmaceutical administered, route of administration, recordable events, misadministrations, and any deviations from the written directive. An attempt will be made to determine the cause of any deviations and actions needed to prevent their recurrence. A record of these reviews, including the evaluations and findings of the review, will be kept on the attached audit form for three (3) years.
9. The licensee shall evaluate and respond, within 30 days after discovery, to each recordable event by assembling the relevant facts including the cause, and identifying what, if any, corrective action is required to prevent recurrence.

record, in auditable form, shall be retained for three (3) years.

10. The licensee shall notify the appropriate parties within 24 hour a of any therapy misadministration. The notification procedure will follow the regulations outlined in IDPH 641-41.2(14)"a" to 41.2(14)"b". Misadministrations involving diagnostic procedures will be handled according the regulations outlined in IDPH 641-41.2(14) ^{11C11}. A record of each misadministration will be kept for ten years. The record shall contain the names of all individuals involved in the event, including the physician, allied health personnel, the patient, and the patient's referring physician, the patient's social security number or identification number if one has been assigned, a brief description of the event, the effect on the patient, and the action taken, if any, to prevent recurrence.

At each quarterly Radiation Safety Committee meeting, these findings will be reviewed to ensure that the Quality Management Program is effective. At each annual meeting of the Radiation Safety committee the QMP's policies and procedures will be reevaluated to determine whether the program needs to be revised in order to be more effective. If any revisions to the QMP are needed, they will be implemented and submitted to the IDPH within 30 days of the review date. Records of each review, including evaluations and findings of the review, will be kept for three (3) years.

Updated by: S. Sheridan; 12/2018

Policy for Administration of Iodine-131 Quantities Greater Than 30 Microcuries Quality Management Program

1. Cardinal Radiopharmacy requires a signed copy of the "Physician's Written Directive" form to complete the ordering of Iodine 131 doses. The form may be faxed. It must be signed by an Authorized User licensed for Iodine 131 and include date of order, patient's name, Iodine 131 form (capsule or liquid), procedure to be performed (therapy or diagnostic), date of procedure, activity requested, time of procedure, indication, printed name of Authorized User, and signature of person responsible for placing the order. Please note that radio-pharmacy policy considers any quantity of Iodine 131 over 100 microcuries as a therapy dose.
2. This completed, physician written directive is also required by Iowa Health Des Moines RAM license prior to any administration of Iodine-131 dose that is greater than 30 (thirty) microcuries.
3. The physician written directive should be signed by an Authorized User who is listed (approved) on the radioactive materials (RAM) license for Iodine 131, category 641-41.2(37), hyperthyroidism treatment. The completed directive will be scanned into PACS along with the images files as a part of the patient's medical record.
4. Administration of dosages of Iodine-131 greater than 30 microcuries require prior verification of patient identity by more than one method by two licensed- employees. Patient identity should be confirmed by name and at least one of the following: by comparison with corresponding information in the patient's record such as birth date, address, social security number, signature, name on the patient's ID bracelet or name on the patient's medical insurance card.
5. UnityPoint Health Des Moines radiation safety guidelines for administration of Iodine-131 to females of child-bearing age (12-50 inclusive) require the patient be tested for pregnancy within 72 hours or less before the I-131 dose is given. Pregnancy testing must be quantitative HCG performed on blood specimen. An HCG level of less than 5mIU/ml is considered negative for pregnancy. When the patient's clinical information/history documents that a hysterectomy has been performed, the authorized user may omit the pregnancy test.
6. To eliminate the incidence of misadministration and the risk of patient exposure to unnecessary radiation, prior to the administration of Iodine-131 in quantities greater than 30 microcuries the dosage and route of administration will be confirmed by the person administering the Iodine-131 and one other licensed-employee to verify agreement with the physician's written directive. The Iodine dose measured in the dose calibrator will be compared with the amount on the physician's written directive.
7. Questions about the written directive must be clarified by the Authorized User that signed the written directive.

Policy for Administration of Iodine 131, QMP-Page 2 of 2

8. To document compliance with this policy completion of a Quality Management Program (QMP), Patient Treatment Audit form is required. This will include the names and signatures of both licensed-employees that conducted the administration of the Iodine-131.
9. As with all doses of radiopharmaceuticals, the administration will be documented to include a written record of time and date, dosage given, route of administration, and signature or initials of personnel.
10. **If the Iodine 131 administered is in liquid form or more than 175 millicuries**, thyroid bioassay is required. The bioassay must be determined during the period of time which starts the **first day after administration and ends the fourth day after administration**, measure the thyroid burden of each individual who helped prepare or administer radioiodine with a suitable instrument. Document the thyroid bioassay evaluation and retain the record indefinitely.
11. Compliance with this policy is reviewed quarterly as part of the radio-pharmaceutical Quality Management Program and Radiation Safety programs.

References:

1. Iowa Health Des Moines ALARA Program, Radiation Safety Manual, Section 9.0; April 2010.
2. "Medical Use of Radioactive Material For Diagnostic and Therapeutic Procedures Regulatory Guide", Iowa Department of Public Health; revision 09/07/2010.
3. International Journal of Pediatric Endocrinology, Vol., 2010 (2010), Page 4.

Written by: Stephen A. Kuhn, October 1993

Updated by: S. Sheridan; 12/2018

Whole Body Imaging with I-131 and Thyrogen Stimulation

Principle:

Post-surgical clinical management of patients found to have thyroid carcinoma includes whole body imaging with I-131 (Nal-131). This is useful in the detection and localization of thyroid metastasis. Thyrogen (thyrotropin alfa, recombinant TSH) is administered intramuscularly (IM) one and two days prior to the I-131 imaging dose. Thyrogen provides adequate stimulation in the presence of synthetic thyroid hormone replacement. Thyroglobulin blood test should also be used as a patient management tool. The thyroglobulin test is primarily used as a tumor marker to evaluate the effectiveness of treatment for thyroid cancer and as a sensitive monitor for recurrence. The blood specimen is drawn about 72 hours after the second Thyrogen injection. Most metastases of thyroid cancer are found in the lymph nodes; the next most common sites are lung and bone.

Notes:

1. Thyrogen is only purchased by the IMMC pharmacy department and is in the Omni-cell in radiology. A RN will administer the Thyrogen and the "MAR" in EPIC will drop a charge for the Thyrogen.
2. The written directive must be signed by an Authorized User who is approved for I-131 administration on the Radioactive Material License category 641-41.2(37), hyperthyroidism treatment. This completed "directive" will be scanned into PACs along with the images files as a part of the patient's chart.
3. Order a 5mCi I-131 capsule from Cardinal Health's pharmacy and fax the signed Authorized User's written directive to the radio-pharmacist. This is a requirement; the "directive" is equivalent to a medication prescription and the dose cannot be prepared or shipped without it.

Patient Preparation:

1. UnityPoint Health Des Moines radiation safety guidelines for administration of I-131 to females of childbearing age (12-50 inclusive) require the patient be tested for pregnancy within 72 hours of less before the I-131 dose is given. Pregnancy testing must be quantitative HCG performed on blood specimen. An HCG level of less than 5mIU/ml is considered negative for pregnancy. When the patient's clinical information/history document that a hysterectomy has been performed, the authorized user may omit the pregnancy test.
2. Native thyroid tissue must be ablated; surgical ablation is preferred.
3. Two doses of Thyrogen/recombinant TSH are administered by a physician or RN as intramuscular injection according to package instruction on two consecutive days.
4. The oral I-131 capsule is administered the day after the second injection and image follow about 48 hours later.
5. Fasting for about 6-8 hours prior to I-131 capsule and 1 hour following administration.

Equipment, Reagents and Supplies:

1. Radioisotope camera/computer with high energy collimators.
2. PACs image review and archiving system.
3. Dose of I-131 5mCi for adults. (18 years and older)

4. Completed, signed "authorized user written directive" for administration of I-131.
5. Copy of "Patient Audit form I-131 Quality Assurance" (QMP)
6. Two licensed-team members to certify correct patient, correct procedure, and correct radioiodine dose.
7. Co-57 anatomical marker.

Procedure:

1. Patient identify must be confirmed by name and at least one of the following: by comparison with corresponding information in the patient's record such as birth date, address SS#, signature, name of the patient's ID bracelet or name of the patient medical insurance card. Verify imaging orders. Explain the test procedure and answer appropriate questions. To eliminate any potential for misadministration of radioactive material, the patient identification, I-131 dosage and route of administration will be confirmed by the NMT administering the I-131 and one other licensed team member. They will also verify agreement with the authorize user's written directive. The I-131 dose measured in the dose calibrator will be compared with the amount on the written directive.
2. When administering the dose to the patient, use techniques that will minimize the radiation exposure to persons in the area. Imaging should be performed about 48hours following administration of an imaging dose. Review the date and time for the images with the patient.
3. Attach the high energy collimators to the radioisotope camera and set it up to optimize the detection of the 364 keV photons of I-131 with 20% window. Follow the camera chart or protocol to set other parameters. Set up the imaging computer to acquire whole body images.
4. Following that position the patient supine and acquire a series of head and neck imaged in the anterior, and RAO/LAO projections. Use a Co-57 anatomical marking source on each of these projections to outline the position of suprasternal notch, chin and on the obliques the angle of the jaw and nose.
5. When all images have been acquired, produce screen captures and transfer them to PACs. Review the images with the radiologist. More images may be indicated. Pinhole images are occasionally required.
6. Assure that the thyroglobulin blood test is drawn. Some of the patients for this test will have a follow-up appointment with their physician in radiation oncology. Check these details before dismissal the patient.
7. Prepare the imaging system and the room for the next examination.

Notice to Physician and Technologists:

In March 2007 the CIHS RAM license with amended to remove the requirement for bioassay when I-131 is in capsule form. Bioassay is still a requirement for any liquid doses of I-131, capsule doses in quantities exceeding 175mCi and in the event of ruptured capsule.

This is a physician-interpreted study.

References:

1. Operator's Manual radioisotope/ camera computer/ PACs archiving system.
2. Nuclear Imaging in Oncology Edmund Kim M.D. and Thomas P. Haynie M.D.
3. Product literature supplied with I-131.

4. Iowa Department of Public Health, Chapter 41, "Safety Requirements for the Use of Radiation Machines and Certain Uses of Radioactive Materials"
5. A Clinician's Guide to Nuclear Medicine, Andrew Taylor MD Emory University School of Medicine, David M. Schuster MD. Asheville VA Medical Center and Naomi Alzarake, MD Emory University School of Medicine 2nd edition.

Written by: Stephen A. Kuhn Jan 1998

Updated by: Sharon Sheridan 2/2023

Approved by: Dr. Paul Jabour

IOWA METHODIST MEDICAL CENTER
Nuclear Medicine Department
Patient Treatment Audit Form
Quality Management Program (QMP)

Iodine 125, Iodine 131, Phosphorus 32,
Samarium 153, Strontium 89

PATIENT NAME: _____ Age: _____

MEDICAL RECORD NUMBER: _____

PROCEDURE ORDERED: _____ DATE: _____

1. BETA (Blood) HCG obtained: _____ Yes _____ Result _____ NA
2. Authorized User's Written Directive Present: Yes No
3. Patient Identification by Name: Yes No
4. Comparison Identification: Required Second Method of Identification (check **all** that were used)
Date of Birth Address _____ Social Security Number
____ Signature _____ ID Bracelet _____ Hospital ID Card
Insurance Card Other Method
5. Administered Activity Within 20% of Authorized User's Written Directive? Yes No
If No, Explain:- _____
6. Administered Activity Within 10% of Authorized User's Written Directive? Yes No
If No Explain: _____
7. Radionuclide Administered (check one): I-131 I-125 P-32 Sm-153 Sr-89
8. Dose Administered: (**Enter ONLY IMMC assayed amount**) _____ millicurie _____ microcurie
9. Route of Administration: (check one) Oral Intravenous Other
10. Administered by: _____ Print Name
11. Is there any Deviation From Written Directive? No Yes
If Yes, explain :- _____

Form Completed By: _____ Print Name: _____ Date: _____

Second Review By: _____ Print Name: _____ Date: _____
(NMT, physicist or physician)

DESCRIPTION

Thyroge(thyrotropin alfa for injection) contains a highly purified recombinant form of human thyroid stimulating hormone (TSH), a glycoprotein which is produced by recombinant DNA technology. Thyrotropin alfa is synthesized in a genetically modified Chinese hamster ovary cell line.

Thyrotropin alfa is a heterodimeric glycoprotein comprised of two non-covalently linked subunits: an alpha subunit of 92 amino acid residues containing two N-linked glycosylation sites and a beta subunit of 118 residues containing one N-linked glycosylation site. The amino acid sequence of thyrotropin alfa is identical to that of human pituitary thyroid stimulating hormone.

Thyrogen®

thyrotropin alfa for injection

Both thyrotropin alfa and naturally occurring human pituitary thyroid stimulating hormone are synthesized as a mixture of glycosylation variants. Unlike pituitary TSH, which is secreted as a mixture of sialylated and sulfated forms, thyrotropin alfa is sialylated but not sulfated. The biological activity of thyrotropin alfa is determined by a cell-based bioassay. In this assay, cells expressing a functional TSH receptor and a cAMP-responsive element coupled to a heterologous reporter gene, luciferase, enable the measurement of rhTSH activity by measuring the luciferase response. The specific activity of thyrotropin alfa is determined relative to an internal Genzyme reference standard that was calibrated against the World Health Organization (WHO) human TSH reference standard.

Thyrogen is supplied as a sterile, non-pyrogenic, white to off-white lyophilized product, intended for intramuscular (IM) administration after reconstitution with Sterile Water for Injection, USP. Each vial of Thyrogen contains 1.1 mg thyrotropin alfa, 36 mg Mannitol, 5.1 mg Sodium Phosphate, and 2.4 mg Sodium Chloride.

After reconstitution with 1.2 mL Sterile Water for Injection, USP, the thyrotropin alfa concentration is 0.9 mg/mL. The pH of the reconstituted solution is approximately 7.0.

Clinical Pharmacology

Pharmacodynamics

Thyrotropin alfa (recombinant human thyroid stimulating hormone) is a heterodimeric glycoprotein produced by recombinant DNA technology. It has comparable biochemical properties to the human pituitary TSH. Binding of thyrotropin alfa to TSH receptors on normal thyroid epithelial cells or on well-differentiated thyroid cancer tissue stimulates iodine uptake and organification, and synthesis and secretion of thyroglobulin (Tg), triiodothyronine (T₃), and thyroxine (T₄).

In patients with thyroid cancer, a near-total or total thyroidectomy is usually performed. Thyroidectomy is usually followed by radioiodine treatment to remove any remnant of normal thyroid tissue and microscopic residues of malignant tissue. Prior to radioiodine remnant ablation, serum TSH elevation is necessary to promote uptake of radioiodine by thyroid cells or thyroid cancer cells. Elevation of TSH may be achieved by withholding of synthetic thyroid hormone medication after thyroidectomy, with subsequent rise of endogenous pituitary thyroid stimulating hormone; or by administration of thyrotropin in the setting of synthetic thyroid hormone administration. After remnant ablation, patients are placed on synthetic thyroid hormone supplements to replace endogenous hormone and to suppress serum levels of TSH in order to avoid TSH-stimulated tumor growth. Thereafter, patients are followed for the presence of remnants, or of residual or recurrent cancer, by thyroglobulin (Tg) testing, usually with radioiodine imaging. This follow-up testing is most effective when conducted under TSH stimulation, achieved either by thyroid hormone withdrawal or administration of thyrotropin. Thyroid hormone withdrawal results in hypothyroidism with subsequent elevation of endogenous pituitary TSH; when thyrotropin is used, patients remain on thyroid hormone suppressive therapy and are euthyroid.

Pharmacokinetics

The pharmacokinetics of Thyrogen were studied in 16 patients with well-differentiated thyroid cancer given a single 0.9 mg IM dose. Mean peak concentrations of 116 ± 138 mIU/L were reached between 3 and 24 hours after injection (median of 10 hours). The mean apparent elimination half-life was 25 ± 10 hours. The organ(s) of TSH clearance in man have not been identified, but studies of pituitary-derived TSH suggest the involvement of the liver and kidneys.

Clinical Trials

Clinical Trials of Thyrogen as an Adjunctive Diagnostic Tool:

Three clinical trials were conducted in 358 evaluable patients with well-differentiated thyroid cancer to compare 48-hour radioiodine (I¹³¹) whole body scans obtained after Thyrogen to whole body scans after thyroid hormone withdrawal. One of these trials also compared Tg levels obtained after Thyrogen to those on thyroid hormone suppressive therapy, and to those after thyroid hormone withdrawal. All Tg testing was performed in a central laboratory using a radioimmunoassay (RIA) with a functional sensitivity of 2.5 ng/mL.

Only successfully ablated patients (defined as patients who have undergone total or near-total thyroidectomy with or without radioiodine ablation, and with < 1% uptake in the thyroid bed on a scan after thyroid hormone withdrawal without detectable anti-thyroglobulin antibodies) were included in the Tg data analysis. The maximum Thyrogen Tg value was obtained 72 hours after the final Thyrogen injection, and this value was used in the analysis (see DOSAGE AND ADMINISTRATION).

Diagnostic Radioiodine Whole Body Scan Results

Table 1 summarizes the scan data in patients with positive scans after withdrawal of thyroid hormone from the diagnostic phase 3 studies:

Table 1: Scan Data in Patients with Positive Scans			
	#scan pairs by disease category	#(%)scan pairs in which Thyrogen™ scan	#(%)scan pairs in which Thyrogen scan failed to detect metastatic disease
First scan (1.1 mg IM Qd x 3)			
positive for remnant or cancer in thyroid bed	48	39 (81)	9 (19)
metastatic disease	15	11 (73)	4 (27)
total positive withdrawal scans *	63	50 (79)	13 (21)
Second scan (0.9 mg IM qd x 3)			
positive for remnant or cancer in thyroid bed	35	30 (86)	5 (14)
metastatic disease	9	6 (67)	3 (33)
total positive withdrawal scans *	44	36 (82)	8 (18)
Third scan (0.9 mg IM qd x 3)			
positive for remnant or cancer in thyroid bed	41	35 (85)	6 (15)
metastatic disease	14	12 (86)	2 (14)
total positive withdrawal scans *	55	47 (85)	8 (15)

* Across all studies, uptake was detected on the Thyrogen scan but not observed on the scan after thyroid hormone withdrawal in 5 patients with remnant or cancer in the thyroid bed.

Across the two clinical studies, the Thyrogen scan failed to detect remnant and/or cancer localized to the thyroid bed in 16% (20/124) of patients in whom it was detected by a scan after thyroid hormone withdrawal. In addition, the Thyrogen scan failed to detect metastatic disease in 24% (9/38) of patients in whom it was detected by a scan after thyroid hormone withdrawal.

Thyroglobulin (Tg) Results:

Thyrogen Tg Testing Alone and in Combination with Diagnostic Whole Body Scanning: Comparison with Results after Thyroid Hormone Withdrawal

In Tg antibody negative patients with a thyroid remnant or cancer as defined by a withdrawal Tg ≥ 2.5 ng/mL or a positive scan (after thyroid hormone withdrawal or after radioiodine therapy), the Thyrogen Tg was 2.5 ng/mL in 69% (40/58) of patients after 2 doses of Thyrogen, and in 80% (53/66) of patients after 3 doses of Thyrogen. Across both dosage groups, 45% had a Tg ≥ 2.5 ng/mL on thyroid hormone suppressive therapy.

In these same patients, adding the whole body scan increased the detection rate of thyroid remnant or cancer to 84% (49/58) of patients after 2 doses of Thyrogen and 94% (62/66) of patients after 3 doses of Thyrogen.

Thyrogen Tg Testing Alone and in Combination with Diagnostic Whole Body Scanning in Patients with Confirmed Metastatic Disease:

Metastatic disease was confirmed by a post-treatment scan or by lymph node biopsy in 35 patients. Thyrogen Tg was ≥ 2.5 ng/mL in all 35 patients while Tg on thyroid hormone suppressive therapy was < 2.5 ng/mL in 79% of these patients.

In this same cohort of 35 patients with confirmed metastatic disease, the Thyrogen Tg levels were below 10 ng/mL in 27% (31/111) of patients after 2 doses of Thyrogen and in 13% (31/24) of patients after 3 doses of Thyrogen. The corresponding thyroid hormone withdrawal Tg levels in these 6 patients were 15.6 – 137 nIU/mL. The Thyrogen scan detected metastatic disease in 1 of these 6 patients (see INDICATIONS AND USAGE, Considerations in the Use of Thyrogen).

As with thyroid hormone withdrawal, the intra-patient reproducibility of Thyrogen testing with regard to both Tg stimulation and radioiodine imaging has not been studied.

Clinical Trials of Thyrogen as an Adjunct to Radioiodine Therapy to Achieve Thyroid Remnant Ablation:

A randomized prospective clinical trial comparing the rates of thyroid remnant ablation achieved after preparation of patients either with hypothyroidism or Thyrogen has been performed. Patients (n = 63) with low-risk well-differentiated thyroid cancer underwent near-total thyroidectomy, then were equally randomized to the Hypothyroid group (serum TSH > 25 pIU/mL) or thyroxine replacement (Euthyroid group; serum TSH < 5 pIU/mL). Patients in the Euthyroid group then received Thyrogen 0.9 mg IM daily on two consecutive days, and then radioiodine 24 hours after the second dose of Thyrogen. All patients received 100 mCi I¹³¹ ± 10% with the intent to ablate any thyroid remnant tissue. The primary endpoint of the study, which was the success of ablation, was assessed 8 months later by a Thyrogen-stimulated radioiodine scan. Patients were considered successfully ablated if

near-thyroid remnant study, using the SF-36 Health Survey, a standardized, patient-administered instrument assessing QOL across eight domains measuring both physical and mental functioning. In the diagnostic study and in the remnant ablation study, following Thyrogen administration, little change from baseline was observed in any of the eight OOL domains of the SF-36. Following thyroid hormone withdrawal in the diagnostic study, statistically significant negative changes were noted in all eight OOL domains of the SF-36. The difference between treatment groups was statistically significant ($p < 0.001$) for all eight OOL domains, favoring Thyrogen over thyroid hormone withdrawal (Figure 1). In the remnant ablation study, following thyroid hormone withdrawal, statistically significant negative changes were noted in five of the eight OOL domains (physical functioning, role physical, vitality, social functioning, and mental health). The difference between treatment groups was statistically significant ($p < 0.05$), favoring Thyrogen over thyroid hormone withdrawal.

Table 2: Results from the Remnant Ablation Clinical Trial

Group	Mean Age (Yr)	Gender (F:M)	Cancer Type (Pap: Fol)	Ablation Criterion (Measure at 8 Months)	
				Thyroid Bed Activity $< 0.1\%$	No Visible Thyroid Bed Activity
THW (N=28)	43	24:6	29:1	28/28 (100)	24/28 (86)
rTSH (N=32)	44	26:7	30:3	32/32 (100)	24/32 (75)

• 60 per protocol patients with interpretable scan data.
95% CI for difference in ablation rates, rTSH minus THW, = -6.9% to 27.1%.

• Interpretation by 2 of 3 reviewers.
95% CI for difference in ablation rates, rTSH minus THW, = -30.5% to 9.1%.

Abbreviations: lot = follicular, pap = papillary, THW = thyroid hormone withdrawal

The mean radiation dose to blood was 0.266 ± 0.061 mGy/MBq in the Euthyroid group and 0.395 ± 0.135 mGy/MBq in the Hypothyroid group ($p < 0.0001$). Radioiodine residence time in remnant tissue was $0.9:1.3$ hours in the Euthyroid group and $1.4:1.5$ hours in the Hypothyroid group. It is not known whether this difference in radiation dose would convey a clinical benefit.

A follow-up study was conducted on patients who previously completed the initial study. The main objective of the follow-up study was to confirm the status of thyroid remnant ablation by using Thyrogen-stimulated radioiodine static neck imaging after a median follow-up of 3.7 years (range 3.4 to 4.4 years) following radioiodine ablation. Thyroglobulin testing was also performed.

Sixty-one male and female thyroidectomized patients who participated in the original study (Table 2) were planned for inclusion in this follow-up study. Fifty-one patients were enrolled in this study; 48 received Thyrogen for remnant neck/whole body imaging and/or Tg testing (three patients underwent the collection of medical history portion of the study but did not undergo stimulated neck/WB scanning or testing). Patients were still considered to be successfully ablated if there was no visible thyroid bed uptake on the scan, or if visible, uptake was less than 0.1% (Table 3).

Table 3: Summary of Thyroid Remnant Ablation During the 3.7-Year Follow-Up of Patients Treated in the Initial Study

Uptake in Thyroid Bed	Follicular Group (n=18) N (%)	Follicular rTSH Group (n=25) N (%)
No Visible Uptake in Thyroid Bed or Uptake $< 0.1\%$	18 (100)	25 (100)

• THW = Thyroid Hormone Withdrawal

Of note, 9 patients (distributed similarly in both treatment groups: 5 former Hypothyroid and 4 former Euthyroid patients) received approximately 100 mCi (3.7 GBq) or more during the period between the end of the initial study and the initiation of this follow-up study. When considering only the patients who did not receive radioiodine during the period between studies, 100% of patients in both treatment subgroups (15 former Hypothyroid and 22 former Euthyroid patients) were successfully ablated according to the predefined study criteria.

Successful ablation also can be inferred when the Thyrogen-stimulated serum Tg level is < 2 ng/mL, although a lower Tg level might also be used as a criterion by some experts. The presence of antithyroglobulin antibodies can render results of thyroglobulin assays uninterpretable. A total of 17 patients in the former Hypothyroid group and 20 patients in the former Euthyroid group had antithyroglobulin antibody levels < 5 units/mL. Of these patients, 16/17 (94%) of patients in the former Hypothyroid group and 19/20 (95%) of patients in the former Euthyroid group had stimulated serum thyroglobulin levels of < 2 ng/mL.

No patient had a definitive cancer recurrence during the 3.7 years of follow-up. Overall, 48/51 patients (94%) had no evidence of cancer recurrence, 1 patient had possible cancer recurrence (although it was not clear whether this patient had a true recurrence or persistent tumor from the regional disease noted at the start of the initial study), and 2 patients could not be assessed.

In summary, in this study and its follow-up study, Thyrogen was noninferior to thyroid hormone withholding for elevation of TSH levels as adjunctive therapy to radioiodine for post-surgical ablation of remnant thyroid tissue.

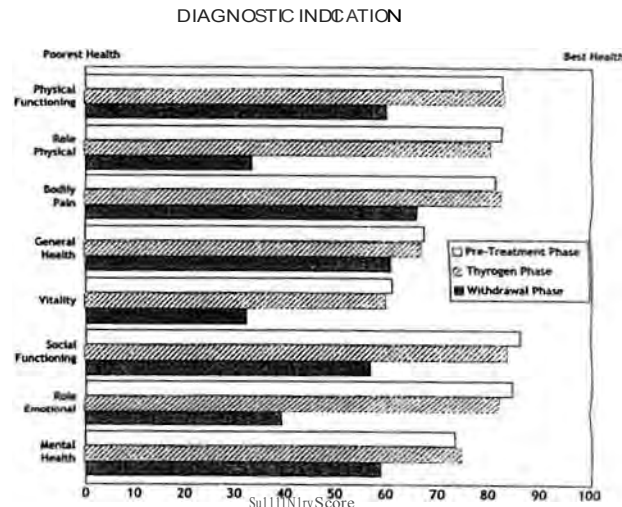
Several publications describe studies or series of patients in which Thyrogen was used as an adjunct to radioiodine for the ablation of thyroid remnant tissue. Some publications found comparable rates of remnant ablation whether patients were prepared using hypothyroidism or Thyrogen, whereas another publication found that hypothyroidism had a better rate of success than Thyrogen, although in that study the radioiodine was administered 48 hours rather than 24 hours after the second dose of Thyrogen. Follow-up for 2.5 years of patients undergoing ablation at Memorial Sloan-Kettering has shown that use of Thyrogen results in a low rate of tumor recurrence that is comparable to the rate seen after use of withdrawal from thyroxine.⁶

Quality of Life

Quality of Life (QOL) was measured during both the diagnostic and ablation study of thyroid remnant study, using the SF-36 Health Survey, a standardized, patient-administered instrument assessing QOL across eight domains measuring both physical and mental functioning. In the diagnostic study and in the remnant ablation study, following Thyrogen administration, little change from baseline was observed in any of the eight OOL domains of the SF-36. Following thyroid hormone withdrawal in the diagnostic study, statistically

significant negative changes were noted in all eight OOL domains of the SF-36. The difference between treatment groups was statistically significant ($p < 0.001$) for all eight OOL domains, favoring Thyrogen over thyroid hormone withdrawal (Figure 1). In the remnant ablation study, following thyroid hormone withdrawal, statistically significant negative changes were noted in five of the eight OOL domains (physical functioning, role physical, vitality, social functioning, and mental health). The difference between treatment groups was statistically significant ($p < 0.05$), favoring Thyrogen over thyroid hormone withdrawal.

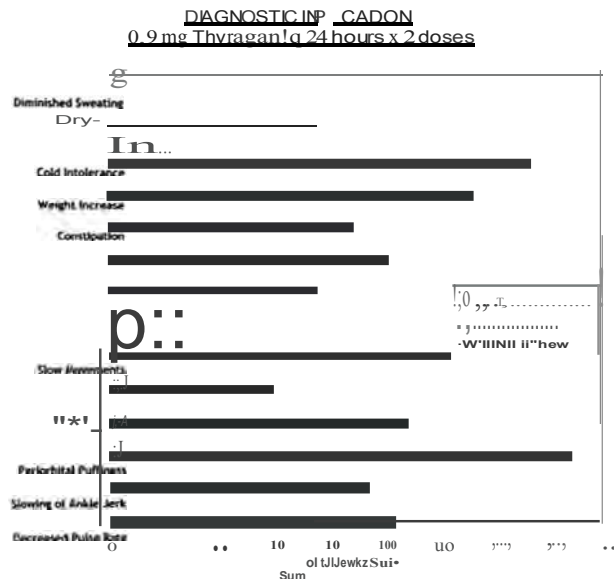
FIGURE 1 - SF-36 HEALTH SURVEY RESULTS: QUALITY OF LIFE DOMAINS



Hypothyroid Signs and Symptoms - Diagnostic Indication:

Thyrogen administration was not associated with the signs and symptoms of hypothyroidism that accompanied thyroid hormone withdrawal as measured by the Billiwicz scale. Statistically significant worsening in all signs and symptoms were observed during the hypothyroid phase ($p < 0.01$) (Figure 2).

FIGURE 2 - HYPOTHYROID SYMPTOM ASSESSMENT BILLIWICZ SCALE



INDICATIONS AND USAGE

Thyrogen (thyrotropin ella for injection) is indicated for use as an adjunctive diagnostic tool for serum thyroglobulin (Tg) testing with or without radioiodine imaging in the follow-up of patients with well-differentiated thyroid cancer.

Thyrogen (thyrotropin ella for injection) is indicated for use as an adjunctive treatment for radioiodine ablation of thyroid tissue remnants in patients who have undergone a near-total thyroidectomy for well-differentiated thyroid cancer and who do not have evidence of metastatic thyroid cancer.

Potential Clinical Uses:

- Thyrogen Tg testing may be used in patients with an undetectable Tg on thyroid hormone suppressive therapy to exclude the diagnosis of residual or recurrent thyroid cancer (see CLINICAL PHARMACOLOGY, Clinical Trials, Thyroglobulin (Tg) Results).
- Thyrogen treatment may be used in combination with radioiodine (I-131) to ablate thyroid remnants following near-total thyroidectomy in patients without evidence of metastatic disease.

3. Thyrogen testing may be used in patients requiring serum Tg testing and radioiodine imaging who are unwilling to undergo thyroid hormone withdrawal testing and whose treating physician believes that use of a less sensitive testis justified.
4. Thyrogen treatment and testing may be used in patients who are either unable to mount an adequate endogenous TSH response to thyroid hormone withdrawal or in whom withdrawal is medically contraindicated.
- Considerations in the Use of Thyrogen:

- When Thyrogen-stimulated Tg testing is performed in combination with diagnostic imaging, there remains a meaningful risk of missing a diagnosis of thyroid cancer or of underestimating the extent of disease. Therefore, thyroid hormone withdrawal Tg testing with radioiodine imaging remains the standard diagnostic modality to assess the presence, location and extent of thyroid cancer.
- Although Thyrogen appeared noninferior to thyroid hormone withholding in a study of postsurgical thyroid remnant ablation, long-term clinical outcome data are limited. Due to the relatively small clinical experience with Thyrogen in remnant ablation, it is not possible to conclude whether long-term thyroid cancer outcomes would be equivalent after use of Thyrogen or use of thyroid hormone withholding for TSH elevation prior to remnant ablation.
- Clinicians employ a wide range of Tg activities to achieve remnant ablation in patients who have been prepared by withholding of thyroid hormone. The primary study of Thyrogen for remnant ablation employed 100 mCi Tg in all patients. Data are inadequate to determine if a lower dose of radioiodine would be effective when Thyrogen is used as an adjunct to radioiodine in postsurgical thyroid remnant ablation.
- Thyrogen Tg levels are generally lower than, and do not correlate with Tg levels after thyroid hormone withdrawal (see CLINICAL PHARMACOLOGY, Thyroglobulin (Tg) Results).
- A newly detectable Tg level or a Tg level rising over time after Thyrogen, or a high index of suspicion of metastatic disease, even in the setting of a negative or low-stage Thyrogen radioradme scan, should prompt further evaluation such as thyroid hormone withdrawal to definitively establish the location and extent of thyroid cancer. On the other hand, none of the 31 patients studied with undetectable Thyrogen Tg levels (< 2.5 ng/mL) had metastatic disease. Therefore, an undetectable Thyrogen Tg level suggests the absence of clinically significant disease (see CLINICAL PHARMACOLOGY, Clinical Trials).
- The decisions whether to perform a Thyrogen radioiodine scan in conjunction with a Thyrogen serum Tg test and whether and when to withdraw a patient from thyroid hormone are complex. Pertinent factors in these decisions include the sensitivity of the Tg assay used, the Thyrogen Tg level obtained, and the index of suspicion of recurrent or persistent local or metastatic disease. In the clinical trials, combination Tg and scan testing did enhance the diagnostic accuracy of Thyrogen in some cases (see CLINICAL PHARMACOLOGY, Clinical Trials).
- The signs and symptoms of hypothyroidism which accompany thyroid hormone withdrawal are avoided with Thyrogen (see CLINICAL PHARMACOLOGY, Clinical Trials, of Life, Hypothyroid Signs and Symptoms).

PRECAUTIONS

(see INDICATIONS AND USAGE, Considerations in the Use of Thyrogen)

General

The use of Thyrogen (thyrotropin alfa for injection) should be directed by physicians knowledgeable in the management of patients with thyroid cancer.

There have been reports of deaths in which events leading to death occurred within 24 hours after administration of Thyrogen. A 77-year-old non-thyroidectomized patient with a history of heart disease and spinal metastases who received 4 Thyrogen injections over 6 days in a special treatment protocol experienced a fatal MI 24 hours after he received the last Thyrogen injection. The event was likely related to Thyrogen-induced hyperthyroidism. In post-marketing experience, there have been rare reports of events leading to death that occurred within 24 hours or administration of Thyrogen in patients with multiple serious medical problems. For patients for whom Thyrogen-induced hyperthyroidism could have serious consequences, hospitalization for administration of Thyrogen and post-administration observation should be considered. Such patients might include those with known heart disease, extensive metastatic disease, or other known serious underlying illness.

Thyroglobulin (Tg) antibodies may confound the Tg assay and render Tg levels uninterpretable. Therefore, in such cases, even with a negative or low-stage Thyrogen radioiodine scan, consideration should be given to evaluating patients further with, for example, a confirmatory thyroid hormone withdrawal scan to determine the location and extent of thyroid cancer.

Thyrogen should be administered intramuscularly only. It should not be administered intravenously.

TSH antibodies have not been reported in patients treated with Thyrogen in the clinical trials, although only 27 patients received Thyrogen on more than one occasion.

Caution should be exercised when Thyrogen is administered to patients who have been previously treated with bovine TSH and, in particular, to those patients who have experienced hypersensitivity reactions to bovine TSH.

Thyrogen is known to cause a transient but significant rise in serum thyroid hormone concentration when given to patients who have substantial thyroid tissue still *in situ*. Therefore, caution should be exercised in patients with a known history of heart disease and those with occult residual thyroid tissue (see ADVERSE REACTIONS).

Patients who have been pretreated with glucocorticoids should be considered for patients in whom tumor expansion may compromise vital anatomic structures (such as trachea, central nervous system, or extensive macroscopic lung metastases) (see ADVERSE REACTIONS).

Careful evaluation of benefit-risk relationships should be assessed for high-risk elderly patients with functioning thyroid tumors undergoing Thyrogen administration. This may result in palpitations or cardiac rhythm disorder (see ADVERSE REACTIONS).

Elimination of Thyrogen is significantly slower in dialysis-dependent end-stage renal disease (ESRD) patients, resulting in prolonged elevation of TSH levels (see ADVERSE REACTIONS).

Drug-Drug Interactions

Formal interaction studies between Thyrogen and other medicinal products have not been performed. In clinical trials, no interactions were observed between Thyrogen and the thyroid hormones triiodothyronine (T3) and thyroxine (T4) when administered concurrently.

The use of Thyrogen allows for radioiodine imaging while patients are euthyroid on triiodothyronine (T3) and/or thyroxine (T4). Data on radioiodine kinetics indicate that the clearance of radioiodine is approximately 50% greater in euthyroid patients than in hypothyroid patients, who have decreased renal function. Thus, radioiodine retention is less in euthyroid patients at the time of imaging and this factor should be considered when selecting the activity of radioiodine for use in radioiodine imaging.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term toxicity studies in animals have not been performed with Thyrogen to evaluate the carcinogenic potential of the drug. Thyrogen was not mutagenic in the bacterial reverse mutation assay. Studies have not been performed with Thyrogen to evaluate the effects on fertility.

Pregnancy Category C

Animal reproduction studies have not been conducted with Thyrogen.

It is also not known whether Thyrogen can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Thyrogen should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether the drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Thyrogen is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients below the age of 16 years have not been established.

Geriatric Use

Results from controlled trials indicate no difference in the safety and efficacy of Thyrogen between adult patients less than 65 years and those greater than 65 years of age.

ADVERSE REACTIONS

Adverse reaction data were derived from post-marketing surveillance and clinical trials. The percentages in Table 4 below represent adverse reactions experienced by 481 thyroid cancer patients who participated in the clinical trials for Thyrogen. Most patients received 2 intramuscular injections, 0.9 mg of thyrotropin alfa per injection, 24 hours apart.

The safety profile of patients who received Thyrogen as an adjunctive treatment for radioiodine ablation of thyroid tissue remnants who have undergone a thyroidectomy for well-differentiated thyroid cancer did not differ from that of patients who received Thyrogen for diagnostic purposes.

The most common adverse events (>5%) reported in clinical trials were nausea (11.9%) and headache (7.3%). Events reported in 2-1% of patients in the combined trials are summarized in Table 4. In some studies, an individual patient may have participated in both the Euthyroid phase (Thyrogen) and Hypothyroid phase (withdrawal).

Table 4: Summary of Adverse Events by Euthyroid Phase and Hypothyroid Phase in All Clinical Trials (1%)

Preferred Term	Euthyroid Phase 481 Patients n (%)	Hypothyroid Phase 418 Patients n (%)
Nausea	57 (11.9)	13 (3.1)
Headache	35 (7.3)	5 (1.2)
Fatigue	16 (3.3)	4 (1.0)
Hypercholesterolemia	0 (0.0)	13 (3.1)
Vomiting	14 (2.9)	3 (0.7)
Dizziness	12 (2.5)	0 (0.0)
Paraesthesia	8 (1.7)	0 (0.0)
Asthenia	7 (1.5)	0 (0.0)
Insomnia	7 (1.5)	0 (0.0)
Blood Cholesterol Abnormal	0 (0.0)	6 (1.4)
Diarrhea	6 (1.2)	0 (0.0)
Nasopharyngitis	5 (1.0)	0 (0.0)
Thyroglobulin Present	5 (1.0)	0 (0.0)

Post-marketing experience indicates that Thyrogen administration may cause transient (<48 hours) influenza-like symptoms [also called flu-like symptoms (FLS)], which may include fever (>100°F/38°C), chills/shivering, myalgia/arthritis, fatigue/asthenia/malaise, headache (non-focal), and chills.

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Very rare manifestations of hypersensitivity to Thyrogen have been reported in clinical trials, post-marketing settings and in a special treatment program involving patients with advanced disease; these are urticaria, rash, pruritus, flushing and respiratory signs and symptoms.

In clinical trials no patients have developed antibodies to thyrotropin alia, either after single or repeated (27 patients) use of the product.

Four patients out of 55 (7.3%) with CNS metastases who were followed in a special treatment protocol experienced acute hemiplegia, hemiparesis or pain one to three days after Thyrogen administration. The symptoms were attributed to local edema and/or focal hemorrhage at the site of the cerebral or spinal cord metastases. In addition, one case each of acute visual loss and of laryngeal edema with respiratory distress, requiring tracheotomy, with onset of symptoms within 24 hours after Thyrogen administration, have been reported in patients with metastases to the optic nerve and paratracheal areas, respectively. In addition, sudden, rapid and painful enlargement of locally recurring papillary carcinoma has been reported within 12-48 hours of Thyrogen administration. The enlargement was accompanied by dyspnea, stridor or dysphonia. Rapid clinical improvement occurred following glucocorticoid therapy. It is recommended that pretreatment with glucocorticoid be considered for patients in whom local tumor expansion may compromise vital anatomic structures.

There have been reports of deaths in which events leading to death occurred within 24 hours after administration of Thyrogen. A year-old non-thyroidectomized patient with a history of heart disease and spinal metastases who received 4 Thyrogen injections over 6 days in a special treatment protocol experienced a fatal MI 24 hours after he received the last Thyrogen injection. The event was likely related to Thyrogen-induced hyperthyroidism. In post-marketing experience, there have been rare reports of events leading to death that occurred within 24 hours of administration of Thyrogen in patients with multiple serious medical problems. For patients for whom Thyrogen-induced hyperthyroidism could have serious consequences, hospitalization for administration of Thyrogen and post-administration observation should be considered. Such patients might include those with known heart disease, extensive metastatic disease, or other known serious underlying illness.

Information from post-marketing surveillance, as well as from the literature, suggests that elimination of Thyrogen is significantly slower in dialysis-dependent end stage renal disease (ESRD) patients, resulting in prolonged elevation of TSH levels. ESRD patients who receive Thyrogen may have markedly elevated TSH levels for several days after treatment, which may lead to increased risk of headache and nausea.

Post-marketing data include cases of atrial arrhythmias in elderly patients with pre-existing cardiac disease who received Thyrogen, and suggest that use of Thyrogen in this group should be considered carefully.

OVERDOSAGE

There has been no reported experience of overdose in humans. However, in clinical trials, three patients experienced symptoms after receiving Thyrogen doses higher than those recommended. Two patients had nausea after a 2.7 mg IM dose, and in one of these patients, the event was accompanied by weakness, dizziness and headache. Another patient experienced nausea, vomiting and hot flashes after a 3.6 mg IM dose.

In addition, one patient experienced symptoms after receiving Thyrogen intravenously. This patient received 0.3 mg Thyrogen as a single intravenous bolus and, 15 minutes later experienced severe nausea, vomiting, diaphoresis, hypotension (BP decreased from 115/66 mm Hg to 81/44 mm Hg) and tachycardia (pulse increased from 75 to 117 bpm).

DOSAGE AND ADMINISTRATION

A two-injection regimen is recommended for Thyrogen administration.

The two-injection regimen is Thyrogen 0.9 mg intramuscularly (IM), followed by a second 0.9 mg IM injection 24 hours later.

After reconstitution with 1.2 mL Sterile Water for Injection, a 1.0 mL solution (0.9 mg thyrotropin alia) is administered by intramuscular injection to the buttock.

For radioiodine imaging or remnant ablation, radioiodine administration should be given 24 hours following the final Thyrogen injection. Diagnostic scanning should be performed 48 hours after radioiodine administration, whereas post-therapy scanning may be delayed additional days to allow background activity to decline.

The following parameters utilized in the second Phase 3 study are recommended for diagnostic radioiodine scanning with Thyrogen:

- A diagnostic activity of 4 mCi (148 MBq) ^{131}I should be used.
- Whole body images should be acquired for a minimum of 30 minutes and/or should contain a minimum of 140,000 counts.
- Scanning times for single (spot) images of body regions should be 10-15 minutes or less if the minimum number of counts is reached sooner (i.e. 60,000 for a large field of view camera, 35,000 counts for a small field of view).

For radioiodine ablation of thyroid tissue remnants, the activity of ^{131}I is carefully selected at the discretion of the nuclear medicine physician. Studies with Thyrogen were conducted using 100 mCi \pm 10% of ^{131}I . Data are inadequate to determine if a known activity of radioiodine would be effective when Thyrogen is used as an adjunct to radioiodine in postsurgical thyroid remnant ablation.

For serum Tg testing, the serum sample should be obtained 72 hours after the final injection of Thyrogen.

INSTRUCTIONS FOR USE

Thyrogen (thyrotropin alia for injection) is for intramuscular injection to the buttock. The powder should be reconstituted immediately prior to use with 1.2 mL of Sterile Water for

Injection, USP. Each vial of Thyrogen and each vial of diluent, if provided, is intended for single use. Discard unused portion of the diluent.

Thyrogen should be stored at 2-8°C (36-46°F). Each vial, after reconstitution with 1.2 mL of the accompanying Sterile Water for Injection, USP, should be inspected visually for particulate matter or discoloration before use. Any vials exhibiting particulate matter or discoloration should not be used.

If necessary, the reconstituted solution can be stored for up to 24 hours at a temperature between 2°C and 8°C, while avoiding microbial contamination.

DO NOT USE Thyrogen after the expiration date on the vial. Protect from light.

HOW SUPPLIED

Thyrogen (thyrotropin alia for injection) is supplied as a sterile, non-pyrogenic, lyophilized product. It is available either in a two-vial or a four-vial kit. The two-vial kit contains two 1.1 mg vials of Thyrogen (thyrotropin alia for injection). The four-vial kit contains two 1.1 mg vials of Thyrogen, as well as two 10 mL vials of Sterile Water for Injection, USP.

NDC 58468-1849-4 (4-vial kit)

NDC 58468-0030-2 (2-vial kit)

Store at 2-8°C.

Rx ONLY

Thyrogen (thyrotropin alia for injection)

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- Brokhin M, Robbins R, Omry G, Martorella A, Fleisher M, Tuttle RM. Recombinant human TSH (rhTSH)-assisted radioactive iodine remnant ablation (ARA) achieves very low short term clinical recurrence rates which are not significantly different than traditional thyroid hormone withdrawal (THW). Abstract # 232, American Thyroid Assn., 2006.

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Thyrogen is a registered trademark of Genzyme Corporation.

genzyme

GENERAL

therapeutics



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Whole Body Imaging with Iodine-131 (Without Thyrogen Stimulation)

Principle:

Whole-body imaging with sodium Iodine-131 (NaI-131) is useful in the detection and localization of thyroid metastasis. Postoperative restaging and management of thyroid carcinoma requires elevated TSH blood level so that remaining thyroid tissue is stimulated to take-up the radioiodine. Whole-body imaging can be performed at 4-6 weeks after surgery. Subsequent imaging is usually done at one, three and five years and every five years after that, assuming that no new disease is detected. Follow-up exam exams require discontinuation of all thyroid replacement medication for a period of six weeks, which will usually raise the TSH and produce symptoms of hypothyroidism. Most metastases of thyroid cancer are found in the lymph nodes; the next most common sites are lung and bone.

Patient Preparation:

1. UPH radiation safety guidelines for administration of Iodine-131 to females of child-bearing age (12-50 inclusive) require the patient be tested for pregnancy within 72 hours of less before the I-131 dose is given. When the patient's clinical information/history indicates that a hysterectomy has been performed, the authorized user may omit the pregnancy test. Pregnancy testing must be performed on patient's blood specimen and determine the HCG level. An HCG level of less than 5mIU/ml is considered negative for pregnancy.
2. Native thyroid tissue must be ablated; surgical ablation is preferred.
3. On Pediatric patients please discontinue all thyroid replacement medication for a period of 14 days so the TSH levels rise above 30mIU/L.
4. For patients 18 years or older discontinue all thyroid replacement medication for a period of six weeks so the TSH level rises above 30mIU/L.
5. Fasting for 8 hours prior to I-131 capsule and 1 hour following.
6. Imaging begins about 72 hours after the oral I-131 is given.

Equipment, Reagents and Supplies:

1. Radioisotopes camera/computer with medium or high energy collimator.
2. Mc-PACs image review and archiving system.
3. Dose of I-131 sodium iodine; 5mCi for adults.
4. Completed QMP Authorized Users written directive form.

Notes:

1. The radiopharmaceutical dosage of Iodine-131 for the examination is greater than 30uCi. Follow the established policy which requires a written directive must be signed by an authorized User who is approved for I-131 administration on the Radioactive Material License 641-41.2(37), hyperthyroidism treatment. This completed directive will be scanned into McPACS along with the image files as a part of the patient medical record.
2. Order a 5mCi Iodine-131 oral capsule from the radio-pharmacy and fax the signed Authorized Users written directive to the radio-pharmacist. This is a requirement; the directive is equivalent to a medication prescription and the dose cannot be prepared or

shipped without it. Schedule the imaging appointment for approximately 72 hours after the I-131 is ingested.

Procedure:

1. Patient identity must be confirmed by name and at least one of the following: by comparison with corresponding information in the patient record such as birth date, address, signature, name on the patient ID bracelet or name on the patient's medical insurance card. Verify imaging orders. Explain the test procedure and answer appropriate questions. To eliminate any potential for misadministration of radioactive material, the patient identification, Iodine-131 dosage and route of administration will be confirmed by the NMT administering the Iodine-131 and one other licensed-team member. They will also verify agreement with the authorize user's written directive. The iodine dose measured in the dose calibrator will be compared with the amount on the written directive.
2. When administering the dose to the patient, use techniques that will minimize the radiation exposure to persons in the area. Imaging should be performed about 72 hrs following the administration of an imaging dose. Review the date and time for the images with the patient. Assure that a thyroglobulin blood test is scheduled to be drawn at the sometime before the completion of the I-131 scan.
3. Attach the high energy collimators to the radioisotope camera and set it up to optimize the detection of the 364 KeV photon of the I-131 with a 20% window. Follow the camera chart or protocol to set other parameters. Set up the imaging computer to acquire whole-body images.
4. Following that, position the patient supine and acquire a series of head and neck images in the anterior, RAO and LAO lateral projections at 30 degrees. Use a Co-57 anatomical marking source on each of these projections to outline the position of the super-sternal notch, chin and (on the RAO/LAO) the angle of the jaw and nose.
5. When all images have been acquired, produce screen captures and transfer them to McPACS. Review the image and the radiologist. More images maybe indicated. Pinhole image are occasionally required.
6. Some patients will have a follow-up appointment with a physician in Radiation Oncology. Check this possibility before dismissal the patient.
7. Prepare the imaging system and the room for the next examination.

Notice to Physician and Technologist:

Bioassay is only required if a liquid form of I-131 is administrated.
This is a physician-interpreted study.

References:

1. Operator's manual radioisotope camera/computer.
2. Nuclear Imaging in Oncology
3. Product literature supplied with I-131
4. American Thyroid Association Guidelines for peds WB and treatments.

Written: Steve Kuhn/Sharon Sheridan

Approved: Dr. Paul Jabour

Tumor imaging with Iobenguane Sulfate (I-123 MIBG)

Principle:

Radioiodine labeled Iobenguane Sulfate, also known as meta-iodobenzylguanidine sulfate, (MIBG) localizes in pheochromocytoma and neuroblastoma tumors. Neuroblastoma is the most common malignant extra cranial tumor found among pediatric patients. Neuroblastoma metastasizes quickly with a predilection for bone and bone marrow. Early and precise detection of primary neuroblastoma and metastasis will improve prognosis. Iodine-123 MIBG (AdreView-I-123) is helpful in characterizing undiagnosed tumors as neuroblastomas, as well as in distinguishing the disease from lymphoblastic leukemias and other small round-cell tumors that do not take up this imaging tracer. AdreView images reflect the functional behavior of the tumor cells, thus allowing clearer characterization of even small tumors in comparison with similar appearing but non-malignant tissues. AdreView provides adjunctive information to complement anatomic imaging procedures such as CT and MRI.

Biochemical laboratory testing is effective to diagnose pheochromocytoma but there may be difficulty in locating all the tumor sites, which may be multiple. The majority of pheochromocytomas is sporadic and is localized within the adrenal gland. In up to 10% of cases there can be multifocal and/or metastatic disease present at virtually any site within the body. Location and surgical removal of all tumors is critical to control of symptoms and cure of the disease. I-123 MIBG scintigraphy can detect extra-adrenal and metastatic tumors, as well as recurrent and/or residual malignancy in areas disturbed by surgery.

Nuclear Medicine imaging is indicated as an adjunctive diagnostic study for the localization of primary or metastatic pheochromocytomas and neuroblastomas. The MIBG radiopharmaceutical resembles norepinephrine in the molecular structure. MIBG uptake into the cytoplasm of sympathoadrenal tissue occurs by an active sodium and energy-dependent mechanism. Once within the cytoplasm, a significant fraction of MIBG then enters the intercellular hormone vesicles by means of an active uptake mechanism. Since these vesicles are highly concentrated in tumors, such a mechanism might explain the success of I-123 MIBG in revealing the tumor's actual size and extent.

Normal biodistribution and excretion of Iobenguane Sulfate leads to localization in adrenergic storage granules of the adrenal gland. It is also localized in the salivary glands, liver, spleen and urinary bladder. Variable amounts of Iodine-123 activity are seen in the myocardium and lungs. The normal adrenal medulla is infrequently visualized and is never seen with more than faint activity. Clearance from the blood is rapid, with approximately 67% of the dose excreted into the urine in the first 24 hours after administration.

Iobenguane I-123 (AdreView) is produced by the General Electric and distributed by Cardinal Health Radiopharmacy in unit doses.

Equipment and Supplies:

- I. Scintillation camera/computer system capable of performing SPECT/CT with low-energy, high-resolution collimators.

2. Dose of AdreView, Iodine-123 MIBG, for adults is 3-12 millicuries. Pediatric doses are calculated by body weight or age with a minimum dose of 2.0 millicuries.
3. Intravenous administration materials; syringe(s), winged infusion set(s) or saline lock, skin preparation pads, tourniquet, and gauze.
4. PACS.
5. Syringe radiation shield and protective shielding for reaction vial.
6. Dose calibrator.

Precautions:

1. Iobenguane Sulfate 1-123 is cleared by glomerular filtration and is not dialyzable. Caution should be exercised when administering the drug to patients with renal failure. MIBG is not recommended in anephric patients. The radiation dose to the anephric patient would be substantially increased due to the delayed biological elimination of the drug. Also, because of the lack of clearance, the target-to-background ratios would severely compromise the outcome of the study. MIBG use in patients with impaired renal function should be carefully considered. As with all radioiodinated compounds, the patient should be well hydrated before and during examination.
2. Although iodinated contrast imaging agents have been confirmed to cause anaphylactic reactions in patients with hypersensitivity to iodine, the incidence of hypersensitivity reactions to MIBG is rare. Since hypersensitivity or immune reactions are not concentration dependent, emergency treatment measures should be available.

Adverse Reactions:

1. Transient episodes of marked hypertension have been reported in patients after injection of Iobenguane Sulfate 1-123. Some of these patients were on antihypertensives and others were not.
2. Nausea, vomiting and sleepiness have been reported after injection of higher than the recommended doses of Iobenguane. The "no effect level" for these reactions has not been identified. An episode of fever, chills and hypotension has been reported. In clinical trials, no deaths have been attributed to the agent.

Drug Interactions:

1. There are literature reports about patients and about in-vitro systems which suggest that the following drugs have the potential to decrease uptake of Iobenguane Sulfate 1-123 in neuroendocrine tumors and may lead to false negative results if administered concomitantly: antihypertensive drugs (labetalol, reserpine, calcium channel blockers), amitriptyline and derivatives, imipramine and derivatives, doxepin, amoxapin, and loxapin, sympathetic-amines (phenylephrine, phenylpropylamine, pseudoephedrine, ephedrine) and cocaine.
2. The clinical studies were not designed to show which drugs could cause false negative results. It is unknown if other drugs in the same classes have the same potential to inhibit the uptake of Iobenguane. Increasing the dose of Iobenguane will not overcome any potential uptake-limiting effect of these drugs.

Patient Preparation:

1. Prior to administration of MIBG 1-123 the patient's thyroid gland should be blocked with Potassium Iodide Oral Solution (SSKI) at 120 mg KI/day (0.12 ml/day) or Lugol's Solution at 40 mg I/day (0.3 ml/day). The blocking iodine should be administered one day before and daily for 5 to 7 days after the dose of MIBG.
2. The patient must have an I.V. access (lock or fluid line) for administration of the I-123 Iobenguane dose.
3. Before administration of the dose, the patient should be well hydrated. After administration, the patient must be encouraged to drink fluids liberally. Elimination of extra fluid intake will help reduce the radiation dose.
4. During and following the injection, patients with known or suspected pheochromocytoma should be carefully monitored for hypertensive crises.
5. The half-life of Iodine-123 is about 12 hours and imaging should be performed the following day.

Dose Availability:

1. I-123 MIBG is not available for delivery on Mondays or Fridays. Doses should be ordered as soon as a testing appointment is confirmed. Appointments for administration of the I-123 MIBG (Day 1) should be in the early afternoon (1:30pm). Doses must be ordered by 2:30pm Monday, Tuesday or Wednesday, to receive it for administration the next afternoon. Three hours should be allowed for each imaging appointment (Day 2).
2. Prior to administration measure the dose with a suitable radioactivity dose calibration system. Use the potentiometer on the dose calibrator for Iodine 123. Identify the dose of I-123 MIBG with the usual information (date, time of assay, and activity).

Procedure:

1. Verify the patient's identity using two methods and verify inpatient orders for this examination. Verify that the patient has received a thyroid blocking agent. Obtain a detailed patient history.
2. Explain the test procedure to the patient and answer appropriate questions. I-123 MIBG doses are not replaceable on the same day and are very expensive. To reduce incidents of infiltration check the functionality of existing I.V. lines or locks with saline prior to attempting MIBG infusion. If IV access is questionable, establish a fresh access. Iobenguane Sulfate I-123 should be slowly administered intravenously over 15-30 seconds (longer if necessary).
3. Since the possibility of rebound hypertension exists, if indicated, the patient's vital signs should be carefully monitored during and after the injection. Discard needles, syringes and other disposable materials in accordance with regulations governing the disposal of radioactive and biohazard waste.

4. Imaging is accomplished the day following the administration of the MIBG. Acquire images of the entire body anterior and posterior using a gamma camera/computer with low-energy, high-resolution collimators. Set up the camera to detect the 159 keV gamma emissions of Iodine-123 using a 20% symmetric window. Position the camera detector as close to the body as possible. Since neuroblastomas can involve extremities, when the indication for the study is neuroblastoma include images of the arms and legs.
5. Acquire SPECT/CT imaging from the top of the head through the mid-thigh area on all pediatric patients. This is routine for all pediatric studies so the skeletal structures can be carefully evaluated for disease. This will usually require at least a 2-bed scan. Process all SPECT/CT data to produce I-123 MIBG tomograms, fused axial and fused coronal files.
6. Following the processing, transfer SPECT tomograms (as screen-captures), the CT B-30s, fused axial, fused coronal and Corrected Recon NM files to LE02 and PACS.
7. Check the images with a radiologist, this is particularly important in the sedated patient.
8. At the conclusion of the imaging session, prepare the room for the next patient.

Interpretation:

This is a physician-interpreted study.

References:

1. Diagnostic Nuclear Medicine, Second Edition, Editors: Alexander Gottschalk, M.D., Paul B. Hoffer, M.D., E. James Potchen, M.D.; Williams and Wilkins, 1988.
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4. Operator's Manual, radioisotope camera/computer.
5. Operator's Manual, dose calibrator.
6. Operator's Manual, PACS.
7. "Improved lesion detection from spatially adaptive, minimally complex, Pixon reconstruction of planar scintigraphic images", Carl A. Wesolowski, Amos Yahilc, Richard C. Puetterd, Paul S. Babyna, David L. Gildaya, Mustafa Z. Khana; Elsevier Medical Publishing, August 2004.
8. Internet site: http://www.eanm.org/scientific_info/guidelines/gl_onco_mibg.pdf

Written by: Stephen A. Kuhn, May 2006

Updated by: S. Sheridan 4/2019

Tumor Imaging with Indium-111 Pemetreotide (Octreotide)

Principle:

The radiolabelled somatostatin analog, Octreotide (OctreoScan) DTPA, localizes in primary and metastatic somatostatin receptor-rich tumors. When labeled with Indium-111 (In-111), it functions as an agent for determining location and extent of neuroendocrine disease.

Somatostatin is a peptide hormone consisting of 14 amino acids. It is present in the hypothalamus, the cerebral cortex, the brain stem, the gastrointestinal tract and the pancreas.

After intravenous administration of the radiolabelled Octreotide dose, normal tissue accumulation occurs in the pituitary, thyroid gland, the spleen, liver, the kidneys, and the urinary bladder. The presence of radioactivity in the intestines can be minimized by the use of laxatives for 24-hour imaging. The gallbladder is occasionally seen on the planar images and often on the 24-hour

SPECT images. Nontumor tissue accumulation of the Octreotide agent also may occur after surgery, external beam radiotherapy to the lung, bleomycin treatment (lung), or following upper respiratory infections in the nasopharynx and pulmonary hilum. OctreoScan is supplied as a preparation kit by Mallinckrodt Medical Inc. Which includes a unit dose of Indium-111 Chloride? The prepared, unit dose agent is obtained from Cardinal Radiopharmacy.

Equipment and Supplies:

1. Radioisotope camera/computer system capable of SPECT (preferably SPECT/CT) with medium energy collimators. A very large field-of-view, dual-detector system is the most efficient.
2. Dose of In-111 Octreotide: 4-6 millicuries, prepared within the last six hours. This imaging agent is only available on Mondays and Tuesdays.
3. Intravenous administration materials: syringes, winged infusion or other IV access devices and other items required for venipuncture.
4. PACS image review and archiving system.
5. Syringe radiation shield and other attenuating devices for dose transportation.
6. Laxative such as bisacodyl or equivalent, (optional per radiologist).
7. Dose calibrator with Indium-111 channel

Adverse Reactions:

The following adverse effects were observed in clinical trials at a frequency of less than 1% of 538 patients: dizziness, fever, flush, headache, hypotension, changes in liver enzymes, joint pain, nausea, sweating, and weakness. These adverse effects were transient. Also in clinical trials, there was one reported case of bradycardia and one case of decreased hematocrit and hemoglobin. Pentetreotide is derived from octreotide which is used as a therapeutic agent to control symptoms

from certain tumors. The usual dose of Indium-111 pentetreotide is approximately 5-20 times less than for octreotide and is subtherapeutic. The following adverse reactions have been associated with octreotide in 3-10% of patients: nausea, injection site pain, diarrhea, abdominal pain/discomfort, loose stools, and vomiting. Hypertension and hyper- and hypoglycemia have also been reported with the use of octreotide.

Patient Preparation:

1. The patient must have an IV access for administration of Indium-III Octreotide. (Do not use "straight stick" method)
2. Prior to administration of this imaging agent the patient should be well-hydrated. After administration the patient should be encouraged to drink fluids liberally. Elimination of extra fluid intake will help reduce the radiation dose by flushing unbound, Indium-III labeled octreotide by glomerular filtration.
3. A mild laxative, such as magnesium citrate, is routinely taken by the patient the evening prior to the 48-hour SPECT imaging. This step may be omitted in cases where the patient has chronic diarrhea or multiple bowel movements.
4. If octreotide therapy is being given to the patient, discontinue 24-48 hours prior to administration of Indium-III OctreoScan and monitor patient for signs of withdrawal.

Procedure:

1. Verify the patient's identity using two methods and verify inpatient test orders and proper indications.
2. Explain the test procedure to the patient and answer appropriate questions.
3. To eliminate incidents of dose infiltration never use "straight stick" method of IV access. If IV access exists when patient arrives, push physiologic saline to assure proper function. Administer dose of Indium-111 OctreoScan and flush to assure complete delivery into the blood. Use proper methods to discard radioactive syringes and other IV devices.
4. Obtain the first whole body (WB) images at 4-6 hours after administration of agent. Protocol and workflows for this reside on the camera imaging system and will set 20% Indium-III window, matrix size etc.
5. At approximately 24-hours after administration of the Indium-III OctreoScan, repeat the WB images. Format both WB images into dual-intensity screen captures (SC), send to PACS and review images with a radiologist to assess the need for other techniques at this time. Delayed imaging following laxative may be required.
6. SPECT/CT acquisitions will be routinely obtained at approximately 48 hours. Perform the SPECT areas from base of skull to thigh, process these data sets with iterative reconstruction, produce screen capture files of 3-plane tomograms, fused coronal and axial tomograms. Transfer the 3-plane SPECT tomograms, CT B30's, corrected recon SPECT, fused coronals, and fused axial files to PACS and to LE02 for review by the radiologist prior to dismissing the patient.
7. When finished prepare the imaging system and room for the next study.

Interpretation:

This is a physician-interpreted study.

References:

1. Product literature supplied with the Indium-III OctreoScan agent.
2. Operator's Manual, radioisotope camera/computer.

3. Operator's Manual, dose calibrator.
4. Operator's Manual, PACS system.
5. Website, Carcinoid Tumors and Carcinoid Syndrome Diagnosis
6. Seminars in Nuclear Medicine, Vol36, No 3, July 2006

Written by: Stephen A. Kuhn, January 18, 1998

Updated by: S. Sheridan 4/2019

PET/CT IMAGING SKULL-THIGH PROTOCOL

Principle:

PET/CT is a non-invasive diagnostic tool that provides tomographic images and quantitative parameters of perfusion, cell viability, proliferation and metabolic activity of tissues. These images result from the use of different substances of biological interest (sugars, amino acids, metabolic precursors and hormones) labeled with positron-emitting radionuclides.

FDG is a glucose analog and is taken up by living cells via the first stages of the normal glucose pathways. The rationale behind its use of cancer diagnosis is based on the increase glycolytic activity in neoplastic cells. FDG is trapped in the cancer cells due to their high glycolytic activity and is excreted from the body through the urinary track system. A 60 minute interval between FDG administration and image scan is satisfactory to obtain good tumor/background ratio of the tracer.

The cell alterations related to neoplastic transformation are associated with functional impairments that are discernible before structural alterations occur. Therefore, using F18-FDG reveals the presence of a tumor while conventional morphological diagnostic modalities do not yet detect evidence of lesions.

The amount of F18-FDG uptake in tumors correlates with tumor growth and viability, so the PET scan and the possible metabolic quantifications may provide useful information about tumor characterization, patient prognosis and monitoring the response to anticancer therapies. Utilizing PET/CT with F18-FDG is becoming more widespread for the diagnostic assessment of patients with suspected malignancies, tumor staging, and therapy monitoring.

EQUIPMENT AND SUPPLIES:

1. F-18 FDG dose is adjusted by the patient's weight. Adult doses are calculated using 0.14 mCi/kg. (Minimum 5 mCi +/- 20% & Maximum 15 mCi +/- 20%.) Pediatric doses are calculated using 0.10 mCi/kg. (Minimum 1 mCi +/- 20% & Maximum 10 mCi +/- 20%).
2. Glucometer and associated supplies.
3. PET/CT Scanner
4. Digital computer system/software
5. McPACS archiving and retrieval system
6. IV contrast as per ordering doctor/ per protocol.
7. Contrast injector, syringe and tubing.
8. Access to previous PET exams for comparison.

PATIENT PREPARATION:

1. Please see PET/CT Patient Prep Form.
2. Patient fasting is required for 6 hours. This may be reduced to 4 hours in a diabetic patient. Water may be given during the fasting time.
3. TPN and other caloric solutions should be withheld for 5 hours so "fasting" blood glucose can be achieved.
4. Prior to IV contrast administration, review the patient's medical history. Assure that there are no contraindications. Please review the radiology GFR flow chart.

PROCEDURE:

1. Verify the patient's identification using two methods.
2. Using the Accu-chek Monitor, check the patient's glucose. Levels must be below 200mg/dl. If the patient's glucose level is above 200 mg/dl or below 40 mg/dl, a physician must be notified immediately.
3. Establish an IV in the patient. If IV contrast is to be given, outpatient must have a normal GFR level within last 30 days, and inpatient within 2 days. If this timeframe has surpassed, please order and draw a STAT CRT level. Please check GFR chart. If contrast is to be used for the exam, prepare the prescribed volume in the injector.
4. Assay F18-FDG dose and administer dose into the IV tubing and flush with at least 10ccNaCl.
5. After uptake phase of 60 minutes, then direct the patient to use the restroom and empty their bladder.
6. Instruct patient to remove all metal (earrings, watches, belts, zippers, dentures, and bras etc.)
7. Go to patient browser and select scheduler. Select and register the patient. Ensure last name, first name, DOB, gender, weight, height, and accession number are entered in the patient registration tab. Then press Exam. Under the PET icon, select the appropriate protocol. Under the routine tab of the PET portion of the exam, enter patient's dose, time of dose administration, glucose, and bed times.
8. Have the patient lie supine on the table with head towards the scanner. Secure patient using safety equipment (waist strap, head cushion, knee cushion and head pads). Attach the IV contrast tubing to the patient's intravenous access site if contrast is to be given.
9. Have patient raise their arms over their head in a comfortable position. Position laser light two finger's width above top of head using inner laser light on scanner. Then iso-center your patient. Instruct the patient to lie still. Begin the acquisition.
 - a. Load topogram, once loaded, press the start button on the control panel.
 - b. Upon topogram completion, a purple box will appear. Move the scan field of view to the top of the head. Drag the bottom arrows to mid-thigh to set your scan field of view. It may be necessary to increase or decrease number of beds according to patient's height. Bed times are adjusted according to the patient's BMI:
 - i. BMI <30 1.5 min/bed
 - ii. BMI >30 2.0 min/bed
 - iii. BMI >40 2.5 min/bed
 - c. Once scan field of view is set, check to see if any metal artifacts are present on topogram. Use iMAR in the CT recon tab for reduction of any metal artifacts.
 - d. Load CT and move table.
 - e. If IV contrast is indicated, administer contrast, and hit start on scanner for CT to begin simultaneously to ensure adequate contrast enhancement.
 - f. Once CT is complete, the bed will move automatically into the PET gantry to begin PET image acquisition.
10. Following completion of imaging, perform image quality review. If no motion artifacts are present, dismiss the patient. Prepare the room and equipment for the next procedure.
11. Perform image reconstruction according to the parameters outlined by the physician.
12. Transfer files to McPACS and Vitrea-bridge for physician review and interpretation.

13. Scan the requisition, questionnaire and all other documents that will be needed for interpretation of the study into McPACs.

SPECIAL NOTE FOR PET/CT IMAGING WITH THE INDICATION OF HEAD AND NECK CANCER

1. One additional min/bed should be added to two beds in the area of interest for all PET/CT studies (staging and restaging) of head-and-neck cancers. This will provide the physician a close up of the head and neck region with more statistical detail.
2. Head and neck imaging will be acquired during the skull-thigh acquisition.
3. Have patient place arms at their sides for imaging of head-and-neck cancers.
4. Perform fused image reconstruction of head and neck using the All-Pass filter.

RESULTS

This is a physician-interpreted study.

References:

1. Operator's Manual, PET/CT medical imaging system.
2. Operator's instructions, PACs image archiving and retrieval system.
3. Seminars in Nuclear Medicine, Vol 38, No 2 March 2008
4. Journal of Nuclear Medicine Technology, Vol 35, No 3 Sept 2007.
5. Operator's Manual contrast injector
6. GFR flow chart

Written by: Steve Kuhn

Updated by: Sharon Sheridan

Approved by: Dr. Lacey and Dr. Jabour 10/2020

BRAIN IMAGING METABOLIC EVALUATION PROTOCOL

PRINCIPLE:

PET/CT is a non-invasive diagnostic tool that provides tomographic images and quantitative parameters of perfusion, cell viability, proliferation and metabolic activity of tissues. These images result from the use of different substances of biological interest (sugars, amino acids, metabolic precursors and hormones) labeled with positron-emitting radionuclides. FDG is a glucose analog and is taken up by living cells via the first stages of the nominal glucose pathways.

PET with CT image fusion of the brain is useful in studying Alzheimer's disease, Parkinson's disease, seizures, and dementias. FDG is excreted from the body through the urinary track system. A 90 minute interval between FDG administration and brain scan should be observed to optimize brain/background ratio of the tracer.

EQUIPMENT AND SUPPLIES:

1. Dose of 8 mCi of F-18 FDG. (+/- 20% or range 6.4-9.6mCi)
2. Glucometer and associated supplies.
3. PET/CT scanner.
4. Digital computer system/software.
5. McPACs archiving and retrieval system.
6. Access to previous imaging for comparison.

PATIENT PREPARATION:

1. Please see PET/CT Patient Prep Form.
2. Patient fasting is required for 6 hours. This may be reduced to 4 hours in a diabetic patient. Water may be given during the fasting time.
3. TPN and other caloric solutions should be withheld for 5 hours so "fasting" blood glucose can be achieved.
4. **No IV contrast** is given with brain FDG imaging.

PROCEDURE:

1. Verify the patient's identification using two methods.
2. Using the Accu-chek Monitor, check the patient's glucose. Levels must be below 200mg/dl. If the patient's glucose level is above 200 mg/dl or below 40 mg/dl, a physician must be notified immediately.
3. Establish an IV.
4. Assay F18-FDG dose and administer dose into the IV tubing and flush with at least 10ccNaCl.
5. After uptake phase of 90 minutes, then direct the patient to use the restroom and empty their bladder.
6. Instruct patient to remove all metal (earrings, removable dentures, hearing aids, glasses, hair pins, etc.)
7. Go to patient browser and select scheduler. Select and register the patient. Ensure last name, first name, DOB, gender, weight, height, and accession number are entered in the patient

registration tab. Then press Exam. Under the PET icon, select the appropriate protocol. Under the routine tab of the PET portion of the exam, enter patient's dose, time of dose administration, glucose, and bed time.

8. Have the patient lie supine on the table with head towards the scanner with head positioned in the head holder. Secure patient using safety equipment (waist strap, head cushion, knee cushion and head pads).
9. Have patient rest their arms along the sides of their body in a comfortable position. Position laser light two finger's width above top of head using inner laser light on scanner. Then iso-center your patient. Instruct the patient to lie still. Begin the acquisition.
 - a. Load topogram, once loaded, press the start button on the control panel.
 - b. Upon topogram completion, a purple box will appear. Drag bulls eye in center up or down to center the brain. **There is only one 10 minute bed.**
 - c. Once scan field of view is set, check to see if any metal artifacts are present on topogram. Use iMAR in the CT recon tab for reduction of any metal artifacts.
 - d. **No IV contrast given.**
 - e. Load CT and move table. Press start button on control panel to begin CT.
 - f. Once CT is complete, the bed will move automatically into the PET gantry to begin PET image acquisition.
10. Following completion of imaging, perform image quality review. If no motion artifacts are present, dismiss the patient. Prepare the room and equipment for the next procedure.
11. Perform image reconstruction using All-Pass filter.
12. Transfer files to McPACS and Vitrea-bridge for physician review and interpretation.
13. Scan the requisition, questionnaire and all other documents that will be needed for interpretation of the study into McPACS.

RESULTS:

This is a physician-interpreted study.

REFERENCES:

1. Operator's instructions, McPACS image archiving and retrieval system.
2. Operator's Manual, glucometer.
3. Nuclear Medicine and PET/CT, sixth Addition, Mosby, 2007
4. Seminars in Nuclear Medicine, Vol 41, No. 4, July 2011
5. Siemens Biograph Systems 6.6 Upgrade.

Written by: Stephen Kuhn May 2012

Updated by: Sharon Sheridan 10/2020 approved by: Dr. Jabour & Dr. Lacey

AMYVID Florbetapir F-18 PET Brain Scan

Principle:

Amyvid is a radioactive diagnostic agent for PET imaging of the brain to estimate B-amyloid neurotic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease and other causes of cognitive decline.

Equipment and supplies:

1. Dose of 10 mCi of F-18 Florbetapir/AMYVID. (+/- 20% or range 8-12mCi)
2. PET/CT scanner.
3. Digital computer system/software.
4. McPACs archiving and retrieval system.
5. Access to previous imaging for comparison.

Patient Preparation:

1. Well hydrated patient, no preparation.
2. **No IV contrast** is given with AMYVID PET brain imaging.

Procedure:

1. Verify the patient's identification using two methods.
2. Establish an IV.
3. Assay Florbetapir F18 dose and administer a bonus dose into the IV tubing and flush with at least 10ccNaCl. (Amyvid Florbetapir F-18 dose will have a large volume of up to 10ml)
4. After uptake phase of 30-50 minutes, then direct the patient to use the restroom and empty their bladder.
5. Instruct patient to remove all metal (earrings, removable dentures, hearing aids, glasses, hair pins, etc.)
6. Go to patient browser and select scheduler. Select and register the patient. Ensure last name, first name, DOB, gender, weight, height, and accession number are entered in the patient registration tab. Then press Exam. Under the PET icon, select the appropriate protocol. Under the routine tab of the PET portion of the exam, enter patient's dose, time of dose administration, and bedtime.
7. Have the patient lie supine on the table with head towards the scanner with head positioned in the head holder. Secure patient using safety equipment (waist strap, head cushion, knee cushion and head pads).
8. Have patient rest their arms along the sides of their body in a comfortable position. Position laser light two finger's width above top of head using inner laser light on scanner. Then iso-center your patient. Instruct the patient to lie still. Begin the acquisition.
 - a. Load topogram, once loaded, press the start button on the control panel.
 - b. Upon topogram completion, a purple box will appear. Drag bulls' eye in center up or down to center the brain. **There is only one 10-minute bed.**
 - c. Once scan field of view is set, check to see if any metal artifacts are present on topogram. Use iMAR in the CT recon tab for reduction of any metal artifacts.
 - d. **No IV contrast given.**

- e. Load CT and move table. Press start button on control panel to begin CT.
 - f. Once CT is complete, the bed will move automatically into the PET gantry to begin PET image acquisition.
9. Following completion of imaging, perform image quality review. If no motion artifacts are present, dismiss the patient. Prepare the room and equipment for the next procedure.
10. Perform image reconstruction using All-Pass filter.
11. Transfer files to McPACS and Vitrea-bridge for physician review and interpretation.
12. Scan the requisition, questionnaire and all other documents that will be needed for interpretation of the study into McPACS.
13. Physicians interpret on Syngo brain software.

Results:

This is a physician-interpreted study.

References:

1. Highlights of Prescribing information AMYVID product insert. 2012.

PET/CT WHOLEBODY PROTOCOL

Principle:

PET/CT is a non-invasive diagnostic tool that provides tomographic images and quantitative parameters of perfusion, cell viability, proliferation and metabolic activity of tissues. These images result from the use of different substances of biological interest (sugars, amino acids, metabolic precursors and hormones) labeled with positron-emitting radionuclides.

FDG is a glucose analog and is taken up by living cells via the first stages of the normal glucose pathways. The rationale behind its use of cancer diagnosis is based on the increase glycolytic activity in neoplastic cells. FDG is trapped in the cancer cells due to their high glycolytic activity and is excreted from the body through the urinary track system. A 60 minute interval between FDG administration and image scan is satisfactory to obtain good tumor/background ratio of the tracer.

The cell alterations related to neoplastic transformation are associated with functional impairments that are discernible before structural alterations occur. Therefore, using F18-FDG reveals the presence of a tumor while conventional morphological diagnostic modalities do not yet detect evidence of lesions.

The amount of F18-FDG uptake in tumors correlates with tumor growth and viability, so the PET scan and the possible metabolic quantifications may provide useful information about tumor characterization, patient prognosis and monitoring the response to anticancer therapies. Utilizing PET/CT with F18-FDG is becoming more widespread for the diagnostic assessment of patients with suspected malignancies, tumor staging, and therapy monitoring.

EQUIPMENT AND SUPPLIES:

1. F-18 FDG dose is adjusted by the patient's weight. Adult doses are calculated using 0.14 mCi/kg. (Minimum 5 mCi +/- 20% & Maximum 15 mCi +/- 20%.) Pediatric doses are calculated using 0.10 mCi/kg. (Minimum 1 mCi +/- 20% & Maximum 10 mCi +/- 20%).
2. Glucometer and associated supplies.
3. PET/CT Scanner
4. Digital computer system/software
5. McPACS archiving and retrieval system
6. IV contrast as per ordering doctor/ per protocol.
7. Contrast injector, syringe and tubing.
8. Access to previous PET exams for comparison.

PATIENT PREPARATION:

1. Please see PET/CT Patient Prep Form.
2. Patient fasting is required for 6 hours. This may be reduced to 4 hours in a diabetic patient. Water may be given during the fasting time.
3. TPN and other caloric solutions should be withheld for 5 hours so "fasting" blood glucose can be achieved.
4. Prior to IV contrast administration, review the patient's medical history. Assure that there are no contraindications. Please review the radiology GFR flow chart.

PROCEDURE:

1. Verify the patient's identification using two methods.
2. Using the Accu-chek Monitor, check the patient's glucose. Levels must be below 200mg/dl. If the patient's glucose level is above 200 mg/dl or below 40 mg/dl, a physician must be notified immediately.
3. Establish an IV in the patient. If IV contrast is to be given, outpatient must have a normal GFR level within last 30 days, and inpatient within 2 days. If this timeframe has surpassed, please order and draw a STAT CRT level. Please check GFR chart. If contrast is to be used for the exam, prepare the prescribed volume in the injector.
4. Assay F18-FDG dose and administer dose into the IV tubing and flush with at least 10ccNaCl.
5. After uptake phase of 60 minutes, then direct the patient to use the restroom and empty their bladder.
6. Instruct patient to remove all metal (earrings, watches, belts, zippers, dentures, and bras etc.)
7. Go to patient browser and select scheduler. Select and register the patient. Ensure last name, first name, DOB, gender, weight, height, and accession number are entered in the patient registration tab. Then press Exam. Under the PET icon, select the appropriate protocol. Under the routine tab of the PET portion of the exam, enter patient's dose, time of dose administration, glucose, and bed times.
8. Have the patient lie supine on the table with feet towards the scanner. Secure patient using safety equipment (waist strap, head cushion, knee cushion and head pads). Attach the IV contrast tubing to the patient's intravenous access site if contrast is to be given.
9. Have patient rest their arms along the sides of their body in a comfortable position. Position laser light two finger's width above top of head using inner laser light on scanner. Then iso-center your patient. Instruct the patient to lie still. Begin the acquisition.
 - a. Load topogram, once loaded, press the start button on the control panel.
 - b. Upon topogram completion, a purple box will appear. Move the scan field of view to the top of the head. Drag the bottom arrows to toes to set your scan field of view. It may be necessary to increase or decrease number of beds according to patient's height. Bed times are adjusted according to the patient's BMI:
 - i. BMI <30 1.5 min/bed
 - ii. BMI >30 2.0 min/bed
 - iii. BMI >40 2.5 min/bed
 - c. Once scan field of view is set, check to see if any metal artifacts are present on topogram. Use iMAR in the CT recon tab for reduction of any metal artifacts.
 - d. Load CT and move table.
 - e. If IV contrast is indicated, administer contrast, and hit start on scanner for CT to begin simultaneously to ensure adequate contrast enhancement.
 - f. Once CT is complete, the bed will move automatically into the PET gantry to begin PET image acquisition.
10. Following completion of imaging, perform image quality review. If no motion artifacts are present, dismiss the patient. Prepare the room and equipment for the next procedure.
11. Perform image reconstruction according to the parameters outlined by the physician.
12. Transfer files to McPACS and Vitrea-bridge for physician review and interpretation.
13. Scan the requisition, questionnaire and all other documents that will be needed for interpretation of the study into McPACS.

SPECIAL NOTE FOR PET/CT IMAGING FOR LEGS

1. Bed time for legs is 1 min/bed from mid-thigh through toes.
2. Leg images will be acquired during the WB acquisition.

RESULTS:

This is a physician-interpreted study.

REFERENCES:

1. Operator's Manual, PET/CT medical imaging system.
2. Operator's instructions, PACs image archiving and retrieval system.
3. Seminars in Nuclear Medicine, Vol 38, No 2; March 2008.
4. Journal of Nuclear Medicine Technology, Vol 35, No 3, September 2007.
5. Operator's Manual, contrast injector

Written by: Stephen Kuhn 5-2008

Updated by: Sharon Sheridan 10/2020, approved Dr. Jabour & Dr. Lacey

PET/CT IMAGING: AXUMIN

PRINCIPLE:

PETNET Solutions is the USA distributor of F-18 (Fluciclovine). This imaging agent is trademarked as Axumin, by Blue Earth Diagnostics, Inc. Axumin PET/CT imaging is a non-invasive diagnostic tool that provides tomographic imaging and quantitative parameters in the detection and localization of recurrent prostate cancer. The low physiologic background of this agent results in good lesion-to-background ratios from the localization of Axumin within body tissues and prostate cancer.

EQUIPMENT AND SUPPLIES:

1. Dose of 10 mCi (+/-20%) F-18 Fluciclovine Axumin
2. PET/CT scanner.
3. Digital computer system/software.
4. McPACs archiving and retrieval system.
5. Access to previous imaging for comparison.

PATIENT DOSE

1. Dose of 10 mCi (+/-20%) F-18 Fluciclovine Axumin administered IV.
2. Axumin order must be submitted at a minimum of 48-hours prior to the patient's appointment time.
3. Axumin is available on Monday, Tuesday or Friday with the information as follows:
 - a. Patient should check in at 1:30pm, appointment time 2:00pm and dose calibration time is 2:30pm.
 - b. Use: <https://apps.mipetsource.com/home/#/login> to order doses.
 - c. The dose reservation time must be reserved. Verify that the date and calibration time are correct. Enter the patient's name and submit the order. Print the order and keep until patient's appointment. PET NET's phone number for references: 1-877-473-8638.

PATIENT PREPARATION:

1. Advise the patient not to eat or drink for at least 4 hours prior to exam (TPN and other caloric solutions should be withheld for the 4 hour period). If the patient has not fasted, the bio-distribution may be altered and this should be taken into account during image interpretation.
2. Advise the patient to avoid any significant exercise for at least one day prior to PET imaging. If the patient has not avoided exercise, the bio-distribution may be altered and this should be taken into account during image interpretation.

3. The administration of intravenous CT contrast media is not required for Axumin studies. Use of contrast introduces delay in acquiring the PET images and degrades the quality.

PROCEDURE: (NO IV CONTRAST GIVEN)

1. Verify the patient's identification using two methods. Explain the exam to the patient and answer appropriate questions. Offer the patient an opportunity to use the restroom. Instruct patient to remove all metal (earrings, watches, belts, zippers, and dentures, etc.)
2. Establish an IV in the patient's right arm.
3. Go to patient browser and select scheduler. Select and register the patient. Ensure last name, first name, DOB, gender, weight, height, and accession number are entered in the patient registration tab. Then press Exam. Under the PET icon, select the appropriate protocol
4. Assay and inspect the dose visually for particulate matter and discoloration before administration. Do not use the drug if the solution contains particulate matter or is discolored.
5. Have the patient lie supine on the table with head towards the scanner. Secure patient using safety equipment (waist strap, head cushion, knee cushion and head pads).
6. Have patient raise their arms over their head in a comfortable position. Position laser light two finger's width above top of head using inner laser light on scanner. Then iso-center your patient. Instruct the patient to lie still. Begin the acquisition.
 - a. Load topogram, once loaded, press the start button on the control panel.
 - b. Upon topogram completion, a purple box will appear. Move the scan field of view to the bottom of scrotum then drag the upper arrows to top of head to set your scan field of view. It may be necessary to increase or decrease number of beds according to patient's height. **Bed times are 5 minutes/bed through pelvis.** The remaining bed times are adjusted according to the patient's BMI:
 - i. BMI <30 1.5 min/bed
 - ii. BMI >30 2.0 min/bed
 - iii. BMI >40 2.5 min/bed
 - c. Once scan field of view is set, check to see if any metal artifacts are present on topogram. Use iMAR in the CT recon tab for reduction of any metal artifacts.
 - d. Load CT and move table.
7. Administer the dose, after the scan field of view is set and CT is loaded, as an intravenous bolus injection and flush with at least 10ccNaCl. Injection into the right arm vein is suggested when possible. Stasis in the left axillary vein may be misinterpreted as a metastatic lymph node (Virchow node). If the right arm cannot be used, be aware of the possibility of image interpretation error.
 - a. Begin the CT acquisition with the yellow radiation button on the gantry.

- b. Dose the patient in Syntrac.
 - c. Under the routine tab of the PET portion of the exam, enter patient's dose, time of dose administration, and confirm bed times.
 - d. Begin PET image acquisition within 3-5 minutes after administration of the Axumin. Following IV Axumin administration, the tumor-to-normal tissue ratio is highest between 4-10 minutes after infusion, with a 60% reduction in mean tumor uptake at 90 minutes after injection. Typical scan time is 30-40 minutes.
8. Following completion of imaging, perform image quality review. If no motion artifacts are present, dismiss the patient. Prepare the room and equipment for the next procedure.
 9. Perform image reconstruction according to the parameters outlined by the physician.
 10. Transfer files to McPACS and Vitrea-bridge for physician review and interpretation.
 11. Scan the requisition, questionnaire and all other documents that will be needed for interpretation of the study into McPACS.

RESULTS:

This is a physician-interpreted study.

REFERENCES:

1. Operator's Manual, PET/CT medical imaging system.
2. Operator's instruction, PACs image archiving and retrieval system.
3. F-18 Axumin imaging and interpretation manual, version 1.1 December 2016.
4. NCCN clinical Practice Guidelines on Oncology: Prostate Cancer 2016, v3. 2016.
5. Society of Nuclear Medicine and Molecular Imaging, Axumin Reader's course.
6. PETNET F-18 ordering portal.
7. Blue Earth Diagnostics, Inc., Axumin (F-18 Fluciclovine) Injection product overview; image acquisition training, 2016.

Written by: Stephen A. Kuhn

Updated by: S. Sheridan 10/2020

PET/CT IMAGING: THYROID WITH THYROGEN STIMULATION

PRINCIPLE:

Thyrogen is a form of TSH that is produced in bacteria by Genzyme Corp. (Braintree's, MA) and purified for human use. The Food and Drug Administration (FDA) has approved thyrogen for both diagnostic testing and therapy. Thyrogen is used for evaluating the recurrence of thyroid cancer. The use of thyrogen allows the patient to continue their replacement thyroxine.

PET/CT is a non-invasive diagnostic tool that provides tomographic images and quantitative parameters of perfusion, cell viability, proliferation and metabolic activity of tissues. These images result from the use of different substances of biological interest (sugars, amino acids, metabolic precursors and hormones) labeled with positron-emitting radionuclides.

FDG is a glucose analog and is taken up by living cells via the first stages of the normal glucose pathways. The rationale behind its use of cancer diagnosis is based on the increase glycolytic activity in neoplastic cells. FDG is trapped in the cancer cells due to their high glycolytic activity and is excreted from the body through the urinary track system. A 60 minute interval between FDG administration and image scan is satisfactory to obtain good tumor/background ratio of the tracer.

The cell alterations related to neoplastic transformation are associated with functional impairments that are discernible before structural alterations occur. Therefore, using F18-FDG reveals the presence of a tumor while conventional morphological diagnostic modalities do not yet detect evidence of lesions.

The amount of F18-FDG uptake in tumors correlates with tumor growth and viability, so the PET scan and the possible metabolic quantifications may provide useful information about tumor characterization, patient prognosis and monitoring the response to anticancer therapies. Utilizing PET/CT with F18-FDG is becoming more widespread for the diagnostic assessment of patients with suspected malignancies, tumor staging, and therapy monitoring.

EQUIPMENT AND SUPPLIES:

1. Two vial of Thyrogen, 0.9 mg each.
2. F-18 FDG dose is adjusted by the patient's weight. Adult doses are calculated using 0.14 mCi/kg. (Minimum 5 mCi +/- 20% & Maximum 15 mCi +/- 20%.) Pediatric doses are calculated using 0.10 mCi/kg. (Minimum 1 mCi +/- 20% & Maximum 10 mCi +/- 20%).
3. Glucometer and associated supplies.
4. PET/CT Scanner
5. Digital computer system/software
6. McPACS archiving and retrieval system
7. Access to previous PET exams for comparison.

PATIENT PREPATION: (NO CONTRAST IS GIVEN)

This is a four or five day procedure with steps as follows:

1. Day 1 IM (buttocks) administration of 0.9mg reconstituted Thyrogen (dose one).
2. Day 2 IM (buttocks) administration of 0.9mg reconstituted Thyrogen (dose two).
3. Day 4 The patient will undergo a PET/CT imaging with F18 FDG, without iodine contrast material. (Contraindicated because of possible need to treat the patient with radioiodine.)
 - a. Day 4 blood drawn for thyroglobulin blood tumor marker assay after stimulation by the Thyrogen (Some physicians will order thyroglobulin levels pre and post thyrogen stimulation.
 - b. Please see PET/CT Patient Prep Form.
 - c. Patient fasting is required for 6 hours. This may be reduced to 4 hours in a diabetic patient. Water may be given during the fasting time.
 - d. TPN and other caloric solutions should be withheld for 5 hours so “fasting” blood glucose can be achieved.

PROCEDURE:

1. Verify the patient's identification using two methods.
2. Using the Accu-chek Monitor, check the patient's glucose. Levels must be below 200mg/dl. If the patient's glucose level is above 200 mg/dl or below 40 mg/dl, a physician must be notified immediately.
3. Establish an IV in the patient.
4. Assay F18-FDG dose and administer dose into the IV tubing and flush with at least 10ccNaCl.
5. After uptake phase of 60 minutes, then direct the patient to use the restroom and empty their bladder.
6. Instruct patient to remove all metal (earrings, watches, belts, zippers, dentures, and bras etc.)
7. Go to patient browser and select scheduler. Select and register the patient. Ensure last name, first name, DOB, gender, weight, height, and accession number are entered in the patient registration tab. Then press Exam. Under the PET icon, select the appropriate protocol. Under the routine tab of the PET portion of the exam, enter patient's dose, time of dose administration, glucose, and bed times.
8. Have the patient lie supine on the table with feet towards the scanner. Secure patient using safety equipment (waist strap, head cushion, knee cushion and head pads). Attach the IV contrast tubing to the patient's intravenous access site if contrast is to be given.
9. Have patient rest their arms along the sides of their body in a comfortable position. Position laser light two finger's width above top of head using inner laser light on scanner. Then iso-center your patient. Instruct the patient to lie still. Begin the acquisition.
 - a. Load topogram, once loaded, press the start button on the control panel.
 - b. Upon topogram completion, a purple box will appear. Move the scan field of view to the top of the head. Drag the bottom arrows to toes to set your scan field of view. It may be necessary to increase or decrease number of beds according to patient's height. Bed times are adjusted according to the patient's BMI:
 - i. BMI <30 1.5 min/bed
 - ii. BMI >30 2.0 min/bed
 - iii. BMI >40 2.5 min/bed

- c. Once scan field of view is set, check to see if any metal artifacts are present on topogram. Use iMAR in the CT recon tab for reduction of any metal artifacts.
 - d. **NO IV contrast given.**
 - e. Load CT and move table. Press start button on control panel to begin CT.
 - f. Once CT is complete, the bed will move automatically into the PET gantry to begin PET image acquisition.
10. Following completion of imaging, perform image quality review. If no motion artifacts are present, dismiss the patient. Prepare the room and equipment for the next procedure.
 11. Perform image reconstruction according to the parameters outlined by the physician.
 12. Transfer files to McPACS and Vitrea-bridge for physician review and interpretation.
 13. Scan the requisition, questionnaire and all other documents that will be needed for interpretation of the study into McPACS.

SPECIAL NOTE FOR PET/CT IMAGING FOR LEGS

1. Bed time for legs is 1 min/bed from mid-thigh through toes.
2. Leg images will be acquired during the WB acquisition.

RESULTS:

This is a physician-interpreted study.

REFERENCES:

1. Operator's Manual, PET/CT medical imaging system.
2. Operator's instructions, PACs image archiving and retrieval system.
3. Seminars in Nuclear Medicine, Vol 38, No 2 March 2008
4. Journal of Nuclear Medicine Technology, Vol 3, No 3 Sept 2007.
5. <http://www.petnetsolutions.com/portal/petnet>
6. Thyrogen Stimulated Testing, PET/CT Cedars-Sinai Health Systems.

Written by: Stephen Kuhn

Updated by: Sharon Sheridan 10/2020 approved by: Dr. Jabour & Dr. Lacey

PET/CT Myocardial Sarcoidosis

PRINCIPLE:

Sarcoidosis is a multi-system disease characterized by the formation of noncaseating granulomas. Lung and intrathoracic lymph nodes are classic sites of involvement; however, sarcoidosis can affect any site in the body. The clinical course is extremely variable, and the imaging features are diverse and dependent on the affected site, degree of inflammation, and treatment the patient receives. Atypical manifestations and imaging findings can make diagnosis and/or management challenging. In addition, assessment of treatment response can be difficult in the setting of chronic disease. Fluorine 18 fluorodeoxyglucose (FDG) PET/CT is sensitive for assessment of the inflammatory activity of sarcoidosis in any organ. Although FDG PET/CT is not included in the standard workup for sarcoidosis, there has been growing evidence that supports the value of this examination in guiding diagnosis and management. FDG PET/CT may be especially useful for assessing reversible granuloma, treatment response, disease extent, occult disease, and cardiac or osseous sarcoidosis, and determining the most suitable biopsy site. Capability to image the entire body during a single examination is advantageous in cases of systemic disease such as sarcoidosis. 18F-FDG PET has many advantages in assessing disease activity and monitoring treatment response in patients with cardiac sarcoidosis.

EQUIPMENT AND SUPPLIES:

1. Dose range of 24-36mCi of Tc99m Sestamibi (Tc99m-MIBI) if gated SPECT/CT resting scan is done same day.
2. F-18 FDG dose is adjusted by the patient's weight. Adult doses are calculated using 0.14 mCi/kg. (Minimum 5 mCi +/- 20% & Maximum 15 mCi +/- 20%.) Pediatric doses are calculated using 0.10 mCi/kg. (Minimum 1 mCi +/- 20% & Maximum 10 mCi +/- 20%).
3. Glucometer and associated supplies
4. SPECT/CT imaging system with physiologic synchronizer, if gated-SPECT/CT resting scan is done same day.
5. PET/CT scanner.
6. Digital computer system/software
7. PACS archiving and retrieval system
8. IV contrast as per ordering doctor/ per protocol.
9. Contrast injector, syringe and tubing
10. Access to previous imaging for comparison.

PATIENT PREPARATION:

Patient to have a high fat, high protein, low-carbohydrate diet for 24 hours prior to scan. This has been shown to reduce glucose uptake by normal myocardium. Patient should fast 12 hours prior to scan with the exception of water.

Food examples: Plain meat without breading, such as beef, pork, chicken, or fish, plain eggs and nuts. Water, black coffee, or tea without sweetener, milk or creamer. Do NOT eat processed foods. NO sauces, dressings, of breading. Salt, pepper, and butter are okay.

1. Caffeine consumption is restricted for 24-hours before this exam. (chocolate, soda, tea, coffee or Excedrin) Note: Decaffeinated products contain caffeine.
2. No nicotine for at least 4 hours prior to this exam.
3. Do not eat or drink for 12 hours before appointment. Water is an exception. TPN and other caloric solutions will be withheld for the required fasting period.
4. A resting gated SPECT/CT myocardial perfusion study is a pre-requisite and must be performed no more than two weeks prior to the FDG study. The gated SPECT/CT imaging may be obtained on the same day as the FDG exam.
5. Hold Metformin 48 hours prior to exam.
6. Please see PET/CT Patient Prep Form for any additional instructions.

PROCEDURE:

1. Verify the patient's identification using two methods.
2. Explain the exam to the patient and answer appropriate questions.
3. Establish an IV in the patient.
4. If not previously performed in last 2 weeks, obtain Tc99m MIBI 24-36mCi resting gated SPECT/CT.
5. Using the Accu-chek Monitor, check the patient's glucose. Levels must be below 200mg/dl. If the patient's glucose level is above 200 mg/dl or below 40 mg/dl, a physician must be notified immediately.
6. Assay the dose of F18-FDG and administer the F18-FDG intravenously.
7. After uptake phase of 60 minutes, then direct the patient to use the restroom and empty their bladder.
8. Instruct patient to remove all metal (earrings, necklaces, EKG patches, watches, belts, zippers, dentures, and bras etc.)
9. Go to patient browser and select scheduler. Select and register the patient. Ensure last name, first name, DOB, gender, weight, height, and accession number are entered in the patient registration tab. Then press Exam. Under the PET icon, select the appropriate protocol. Under the routine tab of the PET portion of the exam, enter patient's dose, time of dose administration, glucose, and bed times for both the PET cardiac and PET skull to thigh acquisitions.
10. Have the patient lie supine on the table with head towards the scanner. Secure patient using safety equipment (waist strap, head cushion, knee cushion and head pads). Attach the IV contrast tubing to the patient's intravenous access site if contrast is to be given.
11. Have patient raise their arms over their head in a comfortable position. Position laser light two finger's width above top of head using inner laser light on scanner. Then iso-center your patient. Instruct the patient to lie still. Begin the acquisition.
 - a. Load topogram, once loaded, press the start button on the control panel.
 - b. Upon topogram completion, a purple box will appear for each PET acquisition.
 - i. For the cardiac acquisition, move the scan field of view to place the heart in the center of the field of view. **The PET cardiac acquisition is one 10 min bed.**

- ii. For the skull to thigh acquisition, move the scan field of view to the top of the head. Drag the bottom arrows to mid-thigh to set your scan field of view. It may be necessary to increase or decrease number of beds according to patient's height. Bed times are adjusted according to the patient's BMI:
 - 1. BMI <30 1.5 min/bed
 - 2. BMI >30 2.0 min/bed
 - 3. BMI >40 2.5 min/bed
 - c. Once scan field of view is set, check to see if any metal artifacts are present on topogram. Use iMAR in the **ALL** CT recon tabs (Including both cardiac and skull to thigh) for reduction of any metal artifacts.
 - d. No IV contrast is given for cardiac acquisition.**
 - e. Load CT and move table for cardiac acquisition.
 - f. Once cardiac CT is complete, the bed will move automatically into the PET gantry to begin cardiac PET image acquisition.
 - g. Then begin CT acquisition of skull to thigh.
 - h. If IV contrast is indicated, administer contrast, and hit start on scanner for CT to begin simultaneously to ensure adequate contrast enhancement.
 - i. Once CT is complete, the bed will move automatically into the PET gantry to begin PET image acquisition of skull to thigh.
- 12. Following completion of imaging, perform image quality review. Call directing Radiologist for image quality review. After Radiologist approval, dismiss the patient. Prepare the room and equipment for the next procedure.
 - 13. Perform image reconstruction according to the parameters outlined by the physician.
 - 14. Transfer files to McPACS and Vitrea-bridge for physician review and interpretation.
 - 15. Scan the requisition, questionnaire and all other documents that will be needed for interpretation of the study into McPACS.

RSNA : "PET/CT in the Diagnosis and Workup of Sarcoidosis: Focus on Atypical Manifestations"
Gensuke Akaike □, Malak Itani, Hardik Shah, Jitesh Ahuja, Burcak Yilmaz Gunes, Richard Assaker, Fatemeh Behnia

PET/CT (NETSPOT) GA-68 DOTATATE

PRINCIPLE:

PET DOTATATE is a non-invasive diagnostic tool that provides localization of somatostatin receptor positive neuroendocrine tumors (NETs) in adult and pediatric patients.

EQUIPMENT AND SUPPLIES:

1. Dose of 5.4 of Ga-68 dotatate (+/- 20%).
2. PET/CT scanner.
3. Digital computer system/software.
4. McPACs archiving and retrieval system.
5. IV contrast as per ordering doctor/ per protocol.
6. Contrast injector, syringe and tubing.
7. Access to previous imaging for comparison.

PATIENT DOSE:

1. 5.4mCi Ga-68 dotatate (+/-20%) Ga -68 emits 511Kev and has a half-life of 66mins.
2. Pediatric patients weight based 0.54mCi/kg up to 5.4mCi +/- 20%
3. The doses can be ordered for 8am, 12:00pm, and 4:00pm. Cardinal Health can only work on 1 dose per time/place. Have the patient come in 45 minutes **BEFORE** calibration time, to ensure IV is placed and patient is ready for the injection of the dose at calibration time.
4. Order the dose online with Cardinal Health NuTrac 24hrs prior to patient appointment.

PATIENT PREPARATION:

1. Instruct patient to drink a sufficient amount of water to ensure adequate hydration prior to administration of Ga68 dotatate. Patients should drink and void frequently during the first hours following administration to reduce radiation exposure.
2. Patients should be off short-acting somatostatin medications for 24hours. Patients should be off long-acting somatostatin medication for 28 days.
3. Patient fasting is required for 6 hours. TPN and other caloric solutions should be withheld. This may be reduced to 4 hours in a diabetic patient. Water may be given during the fasting time.
4. No bowel preparation needed.
5. Prior to IV contrast administration, review the patient's medical history. Assure that there are no contraindications. Please review the radiology GFR flow chart.

PROCEDURE:

1. Verify the patient's identification using two methods.
2. Establish an IV in the patient.
3. Assay Ga-68 dose and administer dose into the IV tubing and flush with at least 10ccNaCl.
4. After uptake phase of 60 minutes (Only 40 min if the patient's weight is over 200 pounds), then direct the patient to use the restroom and empty their bladder.

5. Instruct patient to remove all metal (earrings, watches, belts, zippers, dentures, and bras etc.)
6. Go to patient browser and select scheduler. Select and register the patient. Ensure last name, first name, DOB, gender, weight, height, and accession number are entered in the patient registration tab. Then press Exam. Under the PET icon, select the appropriate protocol. Under the routine tab of the PET portion of the exam, enter patient's dose and time of dose administration.
7. Have the patient lie supine on the table with head towards the scanner. Secure patient using safety equipment (waist strap, head cushion, knee cushion and head pads).
8. Have patient raise their arms over their head in a comfortable position. Position laser light two finger's width above top of head using inner laser light on scanner. Then iso-center your patient. Instruct the patient to lie still. Begin the acquisition.
 - a. Load topogram, once loaded, press the start button on the control panel.
 - b. Upon topogram completion, a purple box will appear. Move the scan field of view to the top of the head. Drag the bottom arrows to mid-thigh to set your scan field of view. It may be necessary to increase or decrease number of beds according to patient's height. Bedtimes are **4 min/bed**.
 - c. Once scan field of view is set, check to see if any metal artifacts are present on topogram. Use iMAR in the CT recon tab for reduction of any metal artifacts.
 - d. Load CT and move table.
 - e. If IV contrast is indicated, administer contrast, and hit start on scanner for CT to begin simultaneously to ensure adequate contrast enhancement.
 - f. Once CT is complete, the bed will move automatically into the PET gantry to begin PET image acquisition.
 - g. Following completion of imaging, perform image quality review. If no motion artifacts are present, dismiss the patient. Prepare the room and equipment for the next procedure.
9. Perform image reconstruction according to the parameters outlined by the physician.
10. Transfer files to McPACS and Vitrea-bridge for physician review and interpretation.
11. Scan the requisition, questionnaire and all other documents that will be needed for interpretation of the study into McPACS.

RESULTS: This is a Physician-interpreted study.

Written by: Sharon Sheridan

Approved by: Dr. Jabour

List of somatostatins:

lanreotide *Long-acting (doses last ~ 4 weeks)*

neuroendocrine tumors, gastroenteropancreatic tumors, acromegaly

lanreotide acetate (Somatuline) *Long-acting (doses last ~ 4 weeks)*

neuroendocrine tumors, gastroenteropancreatic tumors, acromegaly, carcinoid syndrome

octreotide *Short-acting (doses last ~ 8 hours)*

neuroendocrine tumors, acromegaly, carcinoid syndrome, vasoactive intestinal peptide-secreting tumor, associated diarrhea, bleeding esophageal varices, Zollinger-Ellison syndrome

octreotide acetate (Sandostatin) *Short-acting (doses last ~ 8 hours)*

bleeding esophageal varices, acromegaly, carcinoid syndrome, diarrhea, vasoactive intestinal peptide-secreting tumor

octreotide acetate (Sandostatin LAR Depot) (Bynfezia Pen) *Long-acting (doses last ~ 4 weeks)*

acromegaly, carcinoid syndrome, neuroendocrine tumor, vasoactive intestinal peptide-secreting tumor

pasireotide (Signifor LAR) *Long-acting (doses last ~ 4 weeks)*

neuroendocrine tumors, acromegaly, carcinoid syndrome, Cushing's syndrome

pasireotide diaspertate (Signifor) *Short-acting (doses last ~ 12 hours)*

pituitary dependent hypercortisolism, pancreatic fistula

PET/CT IMAGING: PLYARIFY F-18-PSMA

PRINCIPLE:

PLYARIFY (piflufolastat) is indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer.

- With suspected metastasis who are candidates for initial definitive therapy.
- With suspected recurrence based on elevated serum prostate-specific antigen (PSA) level.

PLYARIFY (piflufolastat) F-18 binds to cells that express PSMA, including malignant prostate cancer cells, which overexpress PSMA. F-18 is a beta emitting radionuclide that enables positron emission tomography.

EQUIPMENT AND SUPPLIES:

1. Dose of 9mCi or a dose range of (7.2mCi-10.8mCi) of F-18 Piflufolastat.
2. PET/CT scanner.
3. Digital computer system/software.
4. McPACs archiving and retrieval system.
5. Access to previous imaging for comparison.

PATIENT DOSE:

1. Patient dose 9.0mCi with a dose range of 8-10mCi of F-18 Piflufolastat. F-18 emits 511Kev and a half-life of 109.8 minutes.
2. Ordering doses Monday-Friday and Calibration times: 1-5pm.

PATIENT PREPARATION:

1. Instruct patients to drink water to ensure adequate hydration prior to administration of F-18-PSMA and to continue drinking and voiding frequently for the first few hours following administration to reduce radiation exposure.
2. The administration of intravenous CT contrast media is not required for PLYARIFY F-18-PSMA.
3. Patients do not need to be NPO.

PROCEDURE: **NO IV CONTRAST GIVEN.**

1. Verify the patient's identification using two methods.
2. Establish an IV in the patient.
3. Assay F-18 dose and administer dose into the IV tubing and flush with at least 10ccNaCl as a bolus intravenous injection.
4. After uptake phase of 60 minutes then direct the patient to use the restroom and empty their bladder. Starting image acquisition more than 90minutes may adversely impact imaging performance.
5. Instruct patient to remove all metal (earrings, watches, belts, zippers, dentures, etc.)
6. Go to patient browser and select scheduler. Select and register the patient. Ensure last name, first name, DOB, gender, weight, height, and accession number are entered in the patient registration tab. Then press Exam. Under the PET icon, select the appropriate protocol. Under

the routine tab of the PET portion of the exam, enter patient's dose, time of dose administration, and bedtimes.

7. Position the patient supine on the table with head towards the scanner. Secure patient using safety equipment (waist strap, head cushion, knee cushion and head pads).
8. Have patient raise their arms over their head in a comfortable position. Image acquisition should start from mid-thigh and proceed to the skull. Instruct the patient to lie still. Begin the acquisition.
 - a. Load topogram, once loaded, press the start button on the control panel.
 - b. Upon topogram completion, a purple box will appear. Move the scan field of view to the top of the head. Drag the bottom arrows to mid-thigh to set your scan field of view. It may be necessary to increase or decrease number of beds according to patient's height. Bedtimes are **4mins/ pelvis and abdomen, 2mins/ chest, and head.**
 - c. Once scan field of view is set, check to see if any metal artifacts are present on topogram. Use iMAR in the CT recon tab for reduction of any metal artifacts.
 - d. **NO IV contrast given.**
 - e. Load CT and move table. Press start button on control panel to begin CT.
 - f. Once CT is complete, the bed will move automatically into the PET gantry to begin PET image acquisition.
 - g. Following completion of imaging, perform image quality review. If no motion artifacts are present, dismiss the patient. Prepare the room and equipment for the next procedure.
9. Perform image reconstruction according to the parameters outlined by the physician.
10. Transfer files to McPACS and Vitrea-bridge for physician review and interpretation.
11. Scan the requisition, questionnaire and all other documents that will be needed for interpretation of the study into McPACS.

RESULTS:

This is a Physician-interpreted study.

Written by Sharon Sheridan CNMT

Approved by: Dr. Jabour

PET GA-68 PSMA-11 scan

PRINCIPLE:

Ga 68 PSMA-11 Injection is indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer:

- with suspected metastasis who are candidates for initial definitive therapy.
- with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level.

EQUIPMENT AND SUPPLIES:

1. Recommended Dosage In adults, the recommended amount of radioactivity to be administered for PET is 111 MBq to 259 MBq (3 mCi - 7.7 mCi) administered as an intravenous bolus injection.
2. PET/CT scanner.
3. Digital computer system/software.
4. McPACs archiving and retrieval system.
5. Access to previous imaging for comparison.

PATIENT DOSE:

1. 6.0 mCi Ga-68-PSMA-11 Ga -68 emits 511Kev and has a half-life of 68mins.

PATIENT PREPARATION:

1. Instruct patient to drink enough water to ensure adequate hydration prior to administration of Ga68-PSMA-11. Patients should drink and void frequently during the first hours following administration to reduce radiation exposure.
2. Patients do not need to be NPO. No bowel preparation needed.

PROCEDURE: ***NO IV CONTRAST GIVEN.***

1. Verify the patient's identification using two methods.
2. Establish an IV in the patient.
3. Assay Ga-68-PSMA dose and administer dose into the IV tubing and flush with at least 10ccNaCl.
4. After uptake phase of 60 minutes, then direct the patient to use the restroom and empty their bladder.
5. Instruct patient to remove all metal (earrings, watches, belts, zippers, dentures, and bras etc.)
6. Go to patient browser and select scheduler. Select and register the patient. Ensure last name, first name, DOB, gender, weight, height, and accession number are entered in the patient registration tab. Then press Exam. Under the PET icon, select the appropriate protocol. Under the routine tab of the PET portion of the exam, enter patient's dose, time of dose administration, glucose, and bedtimes.
7. Have the patient lie supine on the table with head towards the scanner. Secure patient using safety equipment (waist strap, head cushion, knee cushion and head pads).

8. Have patient raise their arms over their head in a comfortable position. Position laser light two finger's width above top of head using inner laser light on scanner. Then iso-center your patient. Instruct the patient to lie still. Begin the acquisition.
 - a. Load topogram, once loaded, press the start button on the control panel.
 - b. Upon topogram completion, a purple box will appear. Move the scan field of view to the top of the head. Drag the bottom arrows to mid-thigh to set your scan field of view. It may be necessary to increase or decrease number of beds according to patient's height. Bedtimes are **4 min/bed**.
 - c. Once scan field of view is set, check to see if any metal artifacts are present on topogram. Use iMAR in the CT recon tab for reduction of any metal artifacts.
 - d. **NO IV contrast given.**
 - e. Load CT and move table. Press start button on control panel to begin CT.
 - f. Once CT is complete, the bed will move automatically into the PET gantry to begin PET image acquisition.
 - g. Following completion of imaging, perform image quality review. If no motion artifacts are present, dismiss the patient. Prepare the room and equipment for the next procedure.
9. Perform image reconstruction according to the parameters outlined by the physician.
10. Transfer files to McPACS and Vitrea-bridge for physician review and interpretation.
11. Scan the requisition, questionnaire and all other documents that will be needed for interpretation of the study into McPACS.

RESULTS:

This is a Physician-interpreted study.

Written by: Sharon Sheridan

Approved by: Dr. Jabour

General Considerations for Pediatric PET/CT Imaging

UnityPoint Health Des Moines John Stoddard Cancer Center

Sedation or Anesthesia

The criteria for which children may need sedation or anesthesia for a PET/CT scan are similar to those of other lengthy medical procedures: patients who are mentally impaired, young children who cannot cooperate or tolerate, and those who are claustrophobic. In short, any patient with characteristics that may interrupt or disrupt the Quiet Time and/or PET/CT scan should be scheduled for sedation or anesthesia. The expiration time of the imaging agent is approximately 45 minutes after the patient's imaging appointment. This narrow window of usability means that sedation must be planned prior to the appointment time.

Patient Pre-Test Preparations

Patients should not eat or drink caloric-laden beverages for at 4-6 hr before injection of the imaging agent. The purpose of fasting is to reduce the circulating insulin levels, which rise after a meal and drive glucose and the imaging agent, F18 Flurodioxyglucose (FDG), into muscles, and to reduce circulating blood glucose levels. Hyperglycemia can result in poor uptake of FDG into tissues as the elevated blood glucose competes with FDG for transport into cells. In patients undergoing anesthesia, the fasting requirements for anesthesia are often more stringent than those required for PET alone and thus take precedence. A blood glucose level is usually obtained prior to administration of the FDG.

Patient should not have barium 3-5 days prior to PET/CT exams. Foley bladder catheterization is necessary. If patient has unilateral kidney a creatinine level may be required.

Imaging Protocol

For many patients, sedation will be required prior to the administration of the FDG to assure a true quiet period is achieved. This is needed to reduce muscle uptake while the metabolic uptake of FDG occurs. The patient will stay in a special Quiet room during this time. Following this, the patient will be moved to the adjacent PET/CT imaging room, placed on the imaging pallet and the scan will be performed. Most providers order pediatric PET/CT as whole body acquisitions. This will require about 30 minutes. The minimum pediatric F18 FDG dose is 5 mCi.

(S.Sheridan, Nuclear Medicine and PET/CT-515-241-6458)

Updated by: S. Sheridan 4/2019

Pluvicto (Lu-177 vipivotide tetraxetan) Treatment Protocol

Indication: Pluvicto is a radioligand therapeutic agent indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy.

Dosage/Administration:

Select patient for treatment using Locametz or F-18-PSMA imaging agent based on PSMA expression in tumors. 200mCi Lu-177 vipivotide tetraxetan, beta-emitting, 6.7 day half-life.

1. Recommended dose: 7.4 GBq (200mCi) every 6 weeks for up to 6 doses.
2. Dose interruption, reduction or permanent discontinuation may be required due to adverse reactions. Please see Table 1 below.
3. No contraindications.
4. Adverse reactions: fatigue, dry mouth, nausea, anemia, decreased appetite, and constipation. Lab abnormalities are decreased lymphocytes, decreased hemoglobin, decreased leukocytes, decreased platelets, decreased calcium, and decreased sodium.

Table 1: Recommended Dosage Modifications of PLUVICTO for Adverse Reactions		
Adverse Reaction	Severity	Dosage Modification
Myelosuppression (Anemia, thrombocytopenia, leukopenia, or neutropenia) [see Warnings and Precautions (5.2)]	Grade 2	Withhold PLUVICTO until improvement to Grade 1 or baseline.
	Grade ≥ 3	Withhold PLUVICTO until improvement to Grade 1 or baseline. Reduce PLUVICTO dose by 20% to 5.9 GBq (160 mCi).
	Recurrent Grade ≥ 3 myelosuppression after one dose reduction	Permanently discontinue PLUVICTO.
Renal toxicity [see Warnings and Precautions (5.3)]	Defined as: <ul style="list-style-type: none"> Confirmed serum creatinine increase (Grade ≥ 2) Confirmed CLcr < 30 mL/min; calculate using Cockcroft-Gault with actual body weight 	Withhold PLUVICTO until improvement.
	Defined as: <ul style="list-style-type: none"> Confirmed $\geq 40\%$ increase from baseline serum creatinine <u>and</u> Confirmed $> 40\%$ decrease from baseline CLcr; calculate using Cockcroft-Gault with actual body weight 	Withhold PLUVICTO until improvement or return to baseline. Reduce PLUVICTO dose by 20% to 5.9 GBq (160 mCi).
	Grade ≥ 3 renal toxicity	Permanently discontinue PLUVICTO.
	Recurrent renal toxicity after one dose reduction	Permanently discontinue PLUVICTO.

Dry mouth [see Adverse Reactions (6.1)]	Grade 2	Withhold PLUVICTO until improvement or return to baseline. Consider reducing PLUVICTO dose by 20% to 5.9 GBq (160 mCi).
	Grade 3	Withhold PLUVICTO until improvement or return to baseline. Reduce PLUVICTO dose by 20% to 5.9 GBq (160 mCi).
	Recurrent Grade 3 dry mouth after one dose reduction	Permanently discontinue PLUVICTO.
Gastrointestinal toxicity [see Adverse Reactions (6.1)]	Grade ≥ 3 (not amenable to medical intervention)	Withhold PLUVICTO until improvement to Grade 2 or baseline. Reduce PLUVICTO dose by 20% to 5.9 GBq (160 mCi).
	Recurrent Grade ≥ 3 gastrointestinal toxicity after one dose reduction	Permanently discontinue PLUVICTO.
Fatigue [see Adverse Reactions (6.1)]	Grade ≥ 3	Withhold PLUVICTO until improvement to Grade 2 or baseline.
Electrolyte or metabolic abnormalities [see Adverse Reactions (6.1)]	Grade ≥ 2	Withhold PLUVICTO until improvement to Grade 1 or baseline.
AST or ALT elevation [see Adverse Reactions (6.1)]	AST or ALT > 5 times ULN in the absence of liver metastases	Permanently discontinue PLUVICTO.
Other non-hematologic toxicity [see Adverse Reactions (6.1)]	Any unacceptable toxicity	Permanently discontinue PLUVICTO.
	Any serious adverse reaction that requires treatment delay of > 4 weeks	Permanently discontinue PLUVICTO.
	Any recurrent Grade 3 or 4 or persistent and intolerable Grade 2 adverse reaction after one dose reduction	Permanently discontinue PLUVICTO.

Preparation Instructions:

1. Use aseptic technique and radiation shielding when handling or administering Pluvicto, using tongs as needed to minimize radiation exposure.
2. Inspect the vial visually under a shielded screen for particulate matter and discoloration prior to administration. Discard the vial if particulates or discoloration are present.
3. Do not inject the Pluvicto solution directly into any other intravenous solution.
4. Confirm the amount of radioactivity delivered to the patient with an appropriate calibration dose calibrator prior to and after Pluvicto administration.
5. Dispose of any unused medicinal product or waste material in accordance with local and federal laws.

Administration using Gravity method: (Similar to Lu-177 Dotatate Treatment, Infusion done within an hour following USP 825 guidelines.)

1. Verify patient's identity and set up for Pluvicto administration.
2. Insert a 2.5 cm, 20-gauge needle (short needle) into the Pluvicto vial and connect via catheter to 0.9% sterile sodium chloride solution. This is used to transport the Pluvicto solution during the infusion. Ensure that the short needle **does not** touch the Pluvicto solution in the vial and **do not** connect the short needle directly to the patient. **Do not** allow the sodium chloride solution to flow into the Pluvicto vial prior to the initiation of the Pluvicto infusion and **do not** inject the Pluvicto solution directly into the sodium chloride solution.
3. Insert a second needle that is 9 cm, 18-gauge (long needle, or spinal needle) into the Pluvicto vial, ensuring that the long needle touches and is secured to the bottom of the Pluvicto vial during the entire infusion. Connect the long needle to the patient by an intravenous catheter that is pre-filled with 0.9% sterile sodium chloride solution and that is used exclusively for the Pluvicto infusion into the patient.
4. Pluvicto must be administered as an IV infusion **within 30 minutes**. **Do not** administer as an IV bolus.
5. Prevention of infiltration is critical. Check the IV line patency prior to administration.
6. During infusion place GM meter over the IV tubing, checking for isotope infusion flow. After the first 15 minutes, the GM meter should start to move to background.
100mL/hour for 5minutes
300mL/hour for following 15 minutes.
During infusion, ensure that the fluid level in the Pluvicto vial does not go above the black sharpie line mark. If it does, stop the pump and inject air (around 5 mL) into the line, or change out the long needle.
Once the reading is stable for at least 5 minutes, stop the flow from the saline bag and close the saline line.
7. Follow the infusion with an IV flush of 20 mL of 0.9% sterile sodium chloride.

Administration using Syringe Method:

1. If Gravity method fails, (ie the vial fills up and removing air does not work.) Please perform the syringe method.
2. Stop the pump and clamp both the Pluvicto line and saline line.
3. Remove the Pluvicto line from the long needle but leave the long needle in the Pluvicto vial.
4. Detach the Pluvicto line from the patient and place in the hot Lu-177 Pluvicto mayo jar.

5. In the Lu-177 supply box, there is a 20cc syringe and Beta Syringe shield. Please place the Beta shield on the 20cc syringe.
6. Hook up the Beta syringe to the long needle in the vial of Pluvicto. Draw up the dose with the vial sitting upright, like a Y90 draw. (Do not turn the vial over to try to draw with the vial upside down.) Draw all the Pluvicto out of the vial.
7. Hook the Pluvicto syringe up to the patient, unclamp the IV and administer the Pluvicto dose to the patient over 2-5 minutes. Please do not bolus the dose.
8. Once complete please see below on disassembly and disposal.

DISASSEMBLY AND DISPOSAL

1. Clamp patient line.
2. Disconnect tubing from the patient catheter, cap the line and the patient catheter to prevent radioactive contamination.
3. Disconnect saline tubing from the short needle.
4. Use GM survey meter to check for contamination.
5. Place in plastic container and transport back to Nuclear Medicine. Assay the vial and syringe if syringe method is used for residual activity in the dose calibrator. Use tongs when handing the vial to minimize radiation exposure.
6. Carefully remove the long needle with tubing attached and place in a sharp's container for radioactive waste. Remove short needle and place it in sharps/radioactive waste container.
7. Store vial in Decay closet until disposal. Some vials may have a long half-life impurity in which case they would need to be disposed of by a vendor.
8. Take Vital Signs post treatment and survey patient at 1 meter and record reading.
9. Perform and record surveys and wipe tests after patient has vacated the treatment room.

Warnings and Precautions:

1. Pluvicto contributes to a patient overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk for cancer.
2. Minimize radiation exposure to patient, medical personnel, and household contacts during and after treatment with Pluvicto in accordance with IDPH patient release guidance and instructions to the patient for follow-up radiation protection at home.
3. Ensure patients increase oral fluid intake and advise patients to void as often as possible to reduce bladder radiation.
4. Precautions: Myelosuppression, Renal Toxicity, Embryo-fetal toxicity, and infertility.

RADIATION ONCOLOGY PROCEDURES:

At Consult

1. Patient to sign consent form and Radiation Safety guidelines form.
2. Radiation Oncologist signs written directive form.
3. Start preauthorization process.
4. Order Pluvicto dose and other supplies for procedure, notify Nuclear Medicine and reserve treatment room.
5. Patient to have labs drawn for complete blood counts and eGFR to assess kidney function.

2 -3 Days Before Treatment

1. Physician to assess the patient.
2. Patient to get Labs for standard blood tests. Go over treatment procedures and radiation safety guidelines with patient.
3. Verify presence of all supplies and signed consent form.

Day of Treatment

1. Have patient change into hospital gown and take vitals.
2. Ensure patient has copies of Radiation Safety guidelines, discharge instructions, and future appointment schedule for labs and subsequent treatments as needed.
3. Nuclear Medicine Tech will start IV (18, 20, or 22-gauge if unable to get 20 IV set).
4. Open 500 mL, 0.9% sterile sodium chloride, prime IV pump infusion set and program to 100 mL/hour.
5. Administer antiemetics (e.g. Ondansetron) only if needed per Radiation Oncologist. If so, Pluvicto is administered 30 minutes post Ondansetron.
6. If a family member is present, have them leave the room during Pluvicto infusion.
7. Just prior to Pluvicto administration, have the patient use the bathroom to empty bladder.
8. Inform Radiation Oncologist (AU for the procedure). The Radiation Oncologist is available for the Pluvicto infusion.
9. Pluvicto is administered at a rate of 100 mL/hour for 5 minutes and then 300 mL/hour for the next 15 minutes. The infusion is started at a slower rate to assess the patient.
10. Nuclear Medicine technologist will take vitals post Pluvicto administration, remove IV, discharge patient and give the forms back to Nursing.

Radiation Safety Guidelines for Patients treated with Pluvicto

Please follow the guidelines below to minimize radiation exposure to others.

For the first 3 days after each treatment:

- Sleep in a separate bedroom and avoid intimate contact.
- Maintain a distance of 6 feet from others. Use a general guideline of being no closer than 3 feet for not more than 1 hour per day.
- Minimize public transportation and use of public facilities. Avoid extended time in public places.
- Drink plenty of fluids and urinate frequently. Sit down while urinating to avoid splashing. If you have a Nephrostomy tube, empty the bag as often as possible and keep the bag away from yourself while sleeping.
- Close the lid and double flush the toilet after each use. Wash hands with soap every time. Use separate towels and washcloths.
- If a caregiver provides assistance, have them wear disposable gloves.
- Return to work after 3 days if desired and only if able to meet guidelines regarding distance to others.

For the first 7 days after each treatment:

- Maintain a distance of 6 feet and sleep in a separate bedroom from infants, children, and pregnant women.
- Refrain from sexual activity.

For the first 15 days after each treatment:

- Sleep in a separate bedroom from infants, children, and pregnant women.

Birth Control:

Use effective contraception during treatment and for 4 months after the final dose.

If you have any questions regarding these guidelines, please feel free to contact your Radiation Oncologist at 515-241-4330.

I have read (or had them read to me) and understand these guidelines:

Signature

Date

Pluvicto Written Directive

Patient Name: _____ DOB: _____ MR# _____

Radiopharmaceutical: Pluvicto (lutetium Lu 177 vipivotide tetraxetan) Dose Sequence: # _____

Prescribed Dose: _____ mCi; Route: IV infusion Date of administration: _____

AU Name: _____ AU Signature _____ Date: _____

Therapy Administration Record

Radiopharmaceutical Verified ___ Yes ___ No; Expected Dose _____ mCi; Batch # _____

Assayed Dose in Vial (A): _____ mCi on Date: _____ at Time: _____

Pt. Verification: Name and DOB: ___ Yes ___ No; Patient has Radiation Safety Guidelines: ___ Yes ___ No

Pretreatment Vital Signs: Temp: _____ ° F BP: _____ / _____ Pulse: _____ /min

IV Start Location: _____ Gauge: _____ at Time: _____ by: _____

Flow Rate of Pluvicto with 0.9% Sterile Sodium Chloride solution: _____ mL/hour

Start Time: _____ End Time: _____

Residual Dose in Vial (B): _____ mCi; Dose Delivered to Patient (A – B): _____ mCi

Post treatment Vital Signs: Temp: _____ ° F BP: _____ / _____ Pulse: _____ /min

IV Removal: Intact: ___ Yes ___ No at Time: _____ by: _____

Dose rate at 1 m from patient after infusion: _____ mR/hr (should be < 8.6 mR/hr)

Survey and Wipe Results

Survey Meter: _____ Model: _____ S/N: _____ Last Cal: _____ Bkg: _____ mR/hr

Well Counter: _____ Model: _____ S/N: _____ Last Cal: _____ Bkg: _____ cpm

Efficiency: _____; Wipe Results in dpm = (Wipe in cpm – Bkg in cpm)/ Efficiency factor

Area	Room Floor	Infusion Chair	Bathroom Floor	Sink	Toilet at 30 cm from seat
Survey (mR/hr)					
Wipe (cpm)					
Wipe (dpm)					

Room outline
Modification of Written Directive:

___ No Exceptions. AU signature not required.

___ Yes, Reason: _____ AU signature: _____ Date: _____

NM Technologist: _____ Signature: _____ Date: _____

Medical Physicist: _____ Signature: _____ Date: _____

Post Lu-177 Pluvicto and Lutathera Imaging

Principal: Pluvicto is a radioligand therapeutic agent indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy. The recommended Pluvicto dose is 200 mCi every 6 weeks for up to 6 doses. Lutathera is indicated for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults. The recommended Lutathera dose is 200 mCi every 8 weeks for a total of 4 doses. Post therapy imaging is recommended for the evaluation of treatment response.

Test Preparation: No specific test preparation is required.

Camera Equipment:

- Radioisotope camera/computer system.
- Medium Energy Collimators.
- PACS image review and archiving system.

Procedure:

- Verify the identity of the patient using 2 methods.
- Explain the scan to the patient and answer any questions.
- Have the patient remove any metal objects.
- Position the patient supine, with arms down, on the imaging table with a pillow positioned lengthwise underneath their head and the knee cushion under their legs. Use the arm strap for supporting their arms.
- Bring the table to cart height and position the patient in the scanner so that top of shoulders are in the field of view.
- Set up the radioisotope camera/computer with the proper protocol by selecting the SPECT_CT category and selecting LU177 MULTI BED.
- In the acquisition, under stop conditions tab, change the time per view to 22 sec/frame. Change the number of scans to 2. Change the orbit to Noncircular. Prepare the acquisition.
- For each pop up request, please select and use the Co-57 flood source.
- Press play to begin the acquisition.
- The MULTI BED acquisition will SPECT the chest first, followed by the abdomen/pelvis.
- When the SPECT acquisition is complete, select the CT Acquisition Tab and select Prepare.
- Load the Topogram for the CT. A load warning will populate. Press Load. Finish moving the patient in with the move button. Then select the START button when populated.
- DO NOT adjust the topogram field of view. The topogram will auto match the SPECT field of view when the topogram is completed.

- After the topogram, adjust the mAs in the scan tab if needed and load the scan.
- Move patient into the scanner using the move button until the Start button populates.
- Start the CT.
- Press the recon button to recon the images. When the recons are finished, close the patient.
- Next, select the Quality Control tab, within the acquisition. Pause the activity. Delete the activity under the Activities tab across the top of the acquisition's work bar.
- Next, select the Tomo Reconstruction tab, within the acquisition. Delete the activity under the Activities tab across the top of the acquisition's work bar.
- Next, select the Image Registration tab, within the acquisition. Delete the activity under the Activities tab across the top of the acquisition's work bar.
- Then select the Flexible Display tab, within the acquisition. Select play to view the images.
- Select Complete to complete and end the acquisition. An error message will populate; press ok.
- Under SPECT CT PROCESSING on the workstation, load the patient's raw data into the icon labeled LU177 CAP PROC.
- Select complete when all tabs, within the processing workstation, are checkmarked.
- Load the CT B30's and the [WB RECON-AC] into the 3D Tab and process the fused axials, coronals, and sagitals.

Image Transfer:

- Send the following images to PACS & IMAGE_ROUTER_DMM: Topo, CT B30's, Patient Protocol, [WB Recon - AC], Fused Axials, Fused Coronals, and Fused Sagitals.
- Send the following images to Radmetrics: Topo, CT B30's, and Patient Protocol.

Results:

- This is a physician-interpretted study.

Written by: B. Vande Kamp, 7/2025

Approved by: Dr. Paul Jabour, 7/2025



Cerebral Perfusion Study (Cerebral Death Determination)

Principle:

Dynamic cerebral perfusion (radionuclide brain blood flow imaging) has developed as a reliable confirmatory test for a clinical diagnosis of cerebral brain death. Cerebral death occurs when there is irreversible necrosis of the supratentorial structures of the brain. It results in a liquefaction of brain substance with increased intracranial pressure that causes intracranial arterial perfusion to cease.

In 1977, the National Institute of Neurological and Communicative Disorders and Stroke (NINDS) proposed that a confirmatory test related to cerebral flow be carried out in all cases in which an early decision of cerebral death is required. This may occur in situations where there are medico-legal or transplant considerations. Unequivocal absence of intracranial arterial blood flow is sufficient confirmatory evidence of clinical brain death, even though there may be delayed or faint filling of intracranial venous sinuses. The carotid arteries should appear clearly and sharply in the neck to ensure that a good bolus injection was achieved.

Equipment and Supplies:

1. Scintillation camera/computer system with LEHR collimator. A single detector camera imaging system is preferred.
2. Technetium 99m labeled Ceretec blue, (HMPAO) or DTPA may be used in doses of 15-30 millicuries for adults. Pediatric doses are decreased, based on the patient's body weight, down to a minimum of 10 mCi. Questions regarding pediatric doses or techniques should be referred to the radiologist. Note: Ceretec blue that is to be positioned between dose syringe and needle or patient's IV access
3. Syringe radiation shield and other shielding.
4. Blood pressure cuff, intravenous puncture items required to perform an IV bolus injection with saline flush, aseptic pads, and scalp tourniquet.
5. PACS image review and archiving system.

Procedure:

1. Verify the patient's identity using two methods. Verify inpatient orders for this examination. Explain the test procedure to the nurse and other persons who bring and support the patient during the procedure.
2. Position an occlusive scalp tourniquet around the patient's head just above the cerebral orbits to minimize scalp perfusion and interference from branches of the external carotid artery. The tourniquet remains in place during all imaging.
3. Prepare the computer with the appropriate protocol, which will acquire the 140 keV photons of Technetium 99m in serial dynamic imaging at 1-2 seconds per frame for a total of 60-120 seconds. Position the camera detector

Perfusion Study (Cerebral Death Determination) - 2

- anteriorly to the patient's head for the cerebral blood flow (CBF) imaging.
4. Technetium-99m (Tc-99m), Ceretec blue (HMPAO) or DTPA, are used as imaging agents in a dose of 15-30 millicuries. See comments in the "Equipment and Supplies" section for smaller doses for pediatric patients. If Ceretec blue is used, the dose is filtered as it is administered intravenously using a bolus technique with a blood pressure cuff, butterfly set, and saline flush. (If the patient has a good IV or a central line, they may be used.) Just prior to the release of the pressure cuff, start the camera/computer to ensure that all data is recorded. A good bolus injection is important to the accurate interpretation of this study. The carotid arteries should appear clearly and sharply in the neck to ensure that a good bolus injection was achieved. If there is any question as to the technical validity of the study, it must be repeated.
 5. After completion of the dynamic perfusion images, set up the camera computer to acquire high-count (1,000,000) planar static views of the head. Acquire views in anterior and both laterals projections. Start acquisition approximately five minutes post-injection.
 6. Transfer all images to the PACS system and allow the radiologist to review the data for completeness.

Interpretation:

This is a physician-interpreted study.

References:

1. Diagnostic Nuclear Medicine, Vol. II, 2nd Edition, Alexander Gottschalk, M.D., Paul B. Hoffer, M.D., E. James Potchen, M.D., Editors; Williams and Wilkins, 1988.
2. Product literature supplied with Ceretec blue, (HMPAO).
3. Operator's Manual, radioisotope camera computer.
4. Operator's Manual, PACS image review and archiving system.

Written by: Stephen A. Kuhn

Updated by: S. Sheridan 4/2019

Cisternography With Indium-III DTPA

Principle:

Following injection into the lumbar intrathecal space, Indium In-111 DTPA is partially absorbed into the blood from the spinal subarachnoid space and rapidly excreted in the urine. The remainder flows to the basal cisterns and the subarachnoid space around the convexity of the brain, is absorbed into the blood, and then rapidly excreted in the urine.

At two hours after injection in normal patients, the radiopharmaceutical has migrated into the infratentorial cisterns and entered the Sylvian fissures. The tentorial limit of the posterior fossa is well illustrated in the posterior view. By six hours, the activity has flowed through the Sylvian fissures and is seen over and between the cerebral hemispheres. Activity is still present in the cisterns beneath the tentorium but is decreased in concentration compared with the two-hour study. Twenty-four hours after injection, the radiopharmaceutical is located predominantly over the cerebral hemispheres and is concentrated in the parasagittal region. There is little activity remaining in the posterior fossa.

Indium In-111 DTPA is indicated for use in the diagnostic scintigraphic evaluation of the cerebrospinal fluid pathways. This includes diagnoses related to cerebral atrophy, hydrocephalus, subarachnoid obstructions, shunt patency and extracranial drainage of cerebrospinal fluid.

Equipment, Reagents, and Supplies:

1. Radioisotope camera with medium energy (300 keV) collimators.
2. Dose of In-111 DTPA 1-1.5 mCi for adults; pediatric patients receive doses based on body weight. This radio-agent must be ordered 24-hours in advance. Note In-111 DTPA arrives in a bulk vial. The dose must be prepared just prior to administration. Complete
3. The Lumbar puncture (LP) is performed in the Radiology Department under fluoroguidance.
4. Cobalt-57 anatomical marker(s).
5. PACS image review and archiving system.

Patient Preparation:

1. The patient preparation and instructions are the same as lumbar punctures performed for other indications. Radiology fluoroscopy personnel will communicate necessary preparations; usually no dietary restrictions are required.
2. For indications of extra-cranial CSF, nasal pledgets may be placed and later analyzed for presence of In-111.

Procedure:

1. Verify patient identity using two methods. The nuclear medicine technologist will be assisting the radiologist by taking the dose to the room where the lumbar puncture is done.
2. An opportunity is usually available to explain the imaging aspects of the examination to the patient after the lumbar puncture has been completed.

Cisternography with Indium-111 DTPA – Page 2 of 2

3. Comply with the regulation to perform contamination wipes in areas where radioactive materials were used or administered.
4. Arrange an approximate time in the morning for the LP to be done. Ask Radiology to call Nuclear Medicine when the LP is about to begin. The dose will then be taken to the room in appropriate shielding. After collecting a spinal fluid specimen, the syringe containing the dose of In-111 DTPA is connected to the spinal needle.
5. Since the dose volume is small, the physician should flush (irrigate) the LP needle and any tubing that was used to maximize the delivery of the dose into the spinal fluid space.
Take the LP needle and any tubing used in the administration to the Nuclear Medicine department for proper disposal.
6. Provide the patient and/or nurse the approximate imaging times.
7. Set up the radioisotope camera to accept the 171 and 245 keV photons of In-111. Medium energy collimators are required.
8. Anterior, posterior, and both laterals image acquisitions of the brain may be acquired at approximately 1-2 hours, 4-6 hours, 24, and 48-hours post-tracer administration. Use a marker to indicate the right side. Obtain additional images as directed by the radiologist.
9. Produce screen capture files and transfer them to the PACS system for review and interpretation by the radiologist.
10. Following dismissal of the patient sanitize the imaging

room. Note:

Many patients referred for this test are unsteady on their feet. If they are transported to Nuclear Medicine in a wheelchair, be prepared to give extra assistance when they move to an imaging chair or table.

Interpretation:

This is a physician-interpreted

study. References:

1. Operator's Manual, radioisotope camera/computer.
2. Textbook of Nuclear Medicine, Vol. II, Clinical Applications, John Harbert, M.D. and Antonio F. G. DaRocha, M.D., 2nd Edition, 1984.
3. Product information literature supplied with Amersham Indium DTPA.

Written by: Stephen A. Kuhn

Updated by: S. Sheridan 4/2019

Cardiac Gated Blood Pool Study

Purpose:

Radionuclide gated imaging of the heart, multi-gated acquisition (MUGA), is a noninvasive procedure used to quantitate cardiac ventricular ejection fractions. This procedure also provides information about myocardial wall motion. It is useful to evaluate patients with symptoms of cardiac abnormalities in regional myocardial wall motion. The study allows the evaluation of chamber sizes, demonstrates the extent of myocardial dysfunction. And evaluates phase and amplitude data and diastolic parameters. The study is indicated to establish a baseline of cardiac performance before some chemotherapy agents are administered.

Equipment and Supplies:

1. Radioisotope camera/computer system with general purpose (LEAP) or high-resolution collimator.
2. Physiologic synchronizer/ECG monitor device.
3. ECG electrodes, disposable razor, and wire leads.
4. Dose of Technetium 99m Pertechnetate to provide labeled autologous red blood cells (RBCs), 20-30 mCi.
5. Ultratag RBC labeling kit (Mallinckrodt).
6. Intravenous administration items such as syringes, butterflys, alcohol pads, etc.
7. PACS image review and archiving system.

Procedure:

1. Verify the identity of the patient using two methods and verify inpatient orders. Explain the study to the patient and answer appropriate questions. Obtain a small amount of the patient's whole blood for Tc99m-RBC labeling (reference the Ultratag labeling procedure to produce autologous Tc99m-RBCs).
2. Set up the camera/computer system with the acquisition protocol for Tc99m detection with a 15% window.
3. Attach ECG electrodes in the standard RA, LA, and LL configuration. The RA and LA can be placed on the upper chest. With G.E. equipment, the best R-wave detection in some patients is obtained when LL is actually on the left leg.
4. To avoid misadministration and the risk of patient exposure to bloodborne pathogens, the administration of biologic products (labelled cells) will be handled similarly to the administration of transfused blood or blood products. This system requires that two persons be present to crosscheck the identification of labeled RBCs (dose) to be re-injected and the patient's identification.
5. The only exception to this system will be when only one patient and only one nuclear medicine technologist are present at the time of the labeling.
6. Intravenously inject the dose of Tc99m-RBCs. With the patient supine, position the camera detector about 45 degrees LAO and 5-10 degrees caudad tilt. Bring the detector as close to the patient's chest as possible and use the P-scope or the computer CRT to position the beam in the field. Adjust the LAO angle to achieve the maximum LV-RV separation.
7. Follow the computer procedure and acquire the image data set. Then position the camera detector in a 5-8 degree RAO projection and repeat an image acquisition. Acquire a third left acquisition in the left lateral (80-90 degrees) projection.

Cardiac Gated Blood Pool Study (MUGA) - Page2

8. Review the images in the cine mode display on the computer CRT and check the quality of the data. Disconnect the ECG leads from the patient, remove the electrodes, and dismiss the patient. Prepare the room for another patient.

Processing:

1. Spatial and temporal smoothing are performed on each view and may be part of an automated or semiautomated processing protocol. Refer to the computer operator's manual for step-by-step descriptions.
2. Determine the left ventricular ejection fraction (LVEF) on the LAO view and a right ventricular ejection fraction (RVEF) if requested. Analysis data will include wall motion histogram, amplitude and diastolic/systolic parameter information.
3. Transfer the raw and processed image files to PACS.

Normals:

This is a physician-interpreted study. Ejection fraction normal is greater than 50%.

References:

1. Operator's Manual. radioisotope camera/computer.
2. Operator's Manual, physiologic synchronizer/ECG monitor.
3. Bland, William H., M.D.. Nuclear Medicine, 2nd Edition, 1971.
4. Literature supplied with the Ultratag RBC labeling kit.
5. Morbidity and Mortality Weekly Report. Vol. 41, No. 31, pp.S75-S78.
6. Iowa Methodist Medical Center Bloodborne Pathogens Program as published on December 6, 1991 (based on requirements of the Occupational Safety and Health Administration, 29 CFR 1910.1030).
7. Society of Nuclear Medicine Procedure Guidelines Manual, 2001-2002.
8. Operator's Manual, PACS system

Written by: Stephen Kuhn

Updated by: S. Sheridan 4/2019

Parathyroid Imaging *with* Technetium-99m-Sestamibi

Principle:

The normal parathyroid glands lie along the posterior medial surfaces of the thyroid lobes anterior to the longus colli muscle and medial to the common carotid arteries. Each normal gland is usually no larger than 5 mm in size. Larger glands represent parathyroid tumors or hyperplasia. Primary hyperparathyroidism is characterized by hypercalcemia due to uncontrolled secretion of parathormone (PTH) by one or more hyper-functioning parathyroid glands. If it goes untreated. This condition may lead to serious skeletal, gastrointestinal, urinary tract, and neuralgic sequelae. Surgical excision is the treatment of choice. Directed surgery following diagnostic imaging minimizes operative and anesthesia time, lessens morbidity, and improves the success rate.

Parathyroid imaging is a useful technique in the evaluation of patients with parathyroid adenomas and hyperplasia. Technetium-99m MIBI (Sestamibi) has superior radiopharmaceutical properties, which offer several technical and interpretive advantages over other agents that have been used in the past. A listing of these characteristics includes; optimal gamma emission (140 keV), relatively high injected dose for abundant photons. favorable dosimetry. high parathyroid- to-thyroid ratio, unaffected by medications, simple protocol, shorter acquisition times, and compatible with SPECT acquisition.

Equipment, Reagents and Supplies:

1. Dose range for adults 20-30 mCi MIBI. Dose is adjusted by body weight for pediatric patients.
2. Butterfly infusion set and other I.V. administration items.
3. Radioisotope camera/computer imaging system.

Patient Preparation:

Caution the patient that remaining motionless will be very important to the quality of the procedure.

Procedure:

1. Verify the identity of the patient using two methods and verify inpatient orders.
2. Explain the test and answer appropriate questions.
3. For adult patients, administer an intravenous dose of about 20-30 millicuries of Technetium-99m MIBI. Use a winged infusion (butterfly) set so the quality of the venipuncture can be verified.
4. Images should be performed with low energy, high-resolution collimator. Enter the name of the parathyroid protocol in the computer. The protocol sets up a window of 15% around the 140 keV energy peak of the Technetium-99m. The protocol sets up 7-minute acquisitions for each view.
5. After a 15 minute delay, following injection of the dose, position the patient on the imaging table. Patient position is critical if the surgeon is to use this information to guide the operation. The patient should be positioned anterior to the camera just as he would be on the operating table...with a roll under the shoulders and the neck extended. The

Parathyroid Imaging – 2 of 2

neck is kept midline for all studies. LAO and RAO are obtained by moving the camera 31 degrees. Do not turn the patient's head. Rotating the camera any further than this means that the patient's shoulder gets in the way. Resolution increases as the collimator approaches the area to image. Good parathyroid images are obtained with a distance of 8 cm or less. These points are extremely important so that all scans on each patient are obtained with the camera the same distance from the patient's neck; therefore, there is uniformity of each view. Additionally, this will provide uniformity from patient to patient making these scans easier to interpret. Extend the neck as far as possible (to mimic the position on the operating room table) while still comfortable, so as to decrease chances of movement.

6. Acquire two anterior images; one to include the heart and mediastinum and an anatomical marker on the sternal notch and one anterior static of the neck to include parathyroid gland. Proceed to acquire neck images in the RAO and LAO projections.
7. After a 2 hour delay post injection, acquire another set of images in the same projections. Again, include the sternal notch marker on the mediastinum view.
8. Acquire SPECT/CT images. Process the data following the Siemens Symbia T iterative reconstruction and image fusion protocol. Transfer the processed files to PACS.

Interpretation:

This is a physician-interpreted examination.

References;

1. Operator's Manual, radioisotope camera/computer system.
2. Operator's Manual, PACS system
3. "Improved Parathyroid Scintigraphy with Tc-99m MIBI. a Superior Radiotracer". Applied Radiology, March 1994, pp. 37-40.
4. Technical product literature supplied with Sestamibi, E.I. du Pont December 1990.
5. "Detection and Localization of Parathyroid Adenomas in Patients With Hyperparathyroidism Using a Single Radionuclide Imaging Procedure With Technetium-99m-Sestamibi (Double Phase Study)", The Journal of Nuclear Medicine, Vol. 33, No. 10, October 1992, pp. 1801-1806.
6. Parathyroid.com Internet Site.

Written by: Stephen A. Kuhn. May 1994

Updated by: S. Sheridan 4/2019

.Y p '

Parathyroid imaging MIBI

nmpro/1k

R:O\$11219<1:10/11194:06/95;04/2004; 04/2007; 12/2018

99mTechnetium-Pyrophosphate Imaging for Transthyretin Cardiac Amyloidosis

Overview:

Patient Selection:

Individuals with heart failure and unexplained increase in left ventricular wall thickness.
Individual over the age of 60yrs with unexplained heart failure with preserved EF.
Evaluation of cardiac involvement in individuals with known or suspected familial amyloidosis.

Test Preparation:

No specific test preparation is required.

Imaging Procedure:

1. Verify the patient using two methods.
2. Dose patient 10-20mCi 99m Tc-PYP intravenously.
3. Wait 1-hour planar imaging and 3 hours SPECT imaging.
4. Supine position.

PLANAR IMAGING (Symbia T) 1 hour post injection.

- a. Under Cardiac PYP Amyloidosis-Statics
- b. Anterior, Lateral and Left Anterior Oblique of chest.
- c. 750K with Magnification 1.46.
- d. 140Kev 15-20% window.
- e. Collimators: Low energy, high resolution.
- f. Matrix 64x64.
- g. Draw ROI's please see table 2.

SPECT IMAGING 3 hour post injection. (Symbia T No SPECT/CT)

- a. Under Cardiac PYP Amyloidosis-SPECT
- b. Angular range: 360 degrees
- c. Detector configuration: 180 degrees
- d. Number of views/detector: 40
- e. Time per stop: 20seconds magnification=1.0

PROCESSING PLANAR imaging:

Quantifying myocardial 99mTc-PYP Uptake there are two approaches to quantification:

1. Quantitative: Myocardial to contralateral lung ratio of uptake at 1 hour.
 - a. Circular target regions of interest (ROI) are drawn over the heart and the planar image and are mirrored over the contralateral chest to account of background and ribs. See figure 1.
 - b. Total and absolute mean counts are measured in each ROI. A heart contralateral (H/CL) ratio is calculated as the fraction of heart ROI mean counts to contralateral chest ROI mean counts.

- c. H/CL ratios of ≥ 1.5 at one hours classified as ATTR positive and ratios < 1.5 as ATTR negative (4).

3-hour SPECT (NO SPECT/CT)

1. Semi-quantitative: visual comparison to bone (rib) uptake at 3 hours.
2. Using Cardiac PYP Amyloidosis-SPECT/Processing on Symbia T.
3. After 3 hour SPECT, patient is finished.

IMAGE INTERPRETATION:

1. The anterior and lateral planar image as well as the rotating projection images and reconstructed SPECT images are reviewed in standard cardiac imaging planes using commercial software.
2. Myocardial 99mTc-PYP uptake patterns are categorized as absent, focal, diffuse or focal on diffuse.
3. Scans with focal 99mTc-PYP uptake could represent rib fracture or previous myocardial infarction. Following a myocardial infarction, myocardial 99mTc-PYP uptake may be positive for up to 7 days and rarely may remain persistently positive.

PLEASE ATTACHED TABLES FOR REFERENCE.

SCREEN SAVES:

1. White on black planar images.
2. Anterior ROI's with counts.
3. Slices SPECT.
4. Send raw data.

RESULTS: This is a physician-interpreted study.

Table 2. Semi-quantitative Visual Grading of Myocardial ^{99m}Tc -PYP Uptake by Comparison to Bone(rib) Uptake

Grade	Myocardial ^{99m}Tc -PYP Uptake
Grade 0	no uptake and normal bone uptake
Grade 1	uptake less than rib uptake
Grade 2	uptake equal to rib uptake
Grade 3	uptake greater than rib uptake with mild/absent rib uptake

Figure 1. Quantitation of Cardiac ^{99m}Tc -PYP Uptake Using Heart to Contralateral Lung (H/CL) Ratio

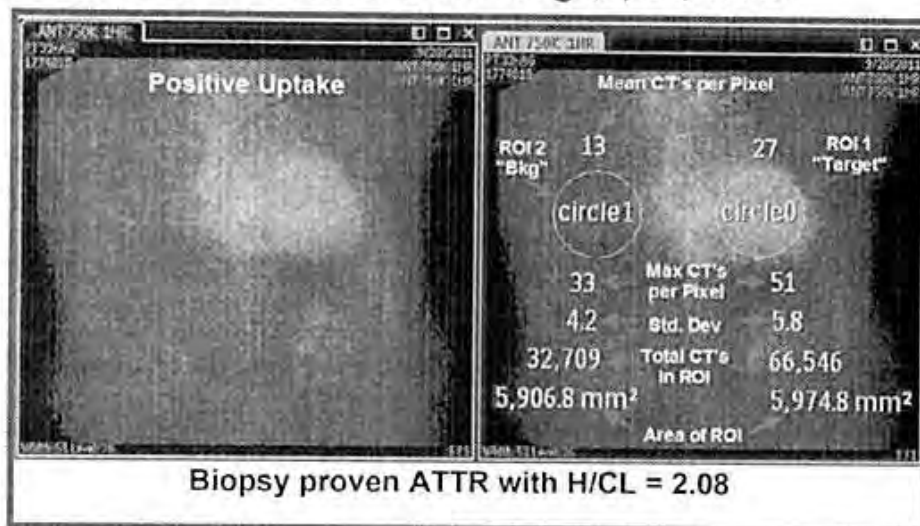
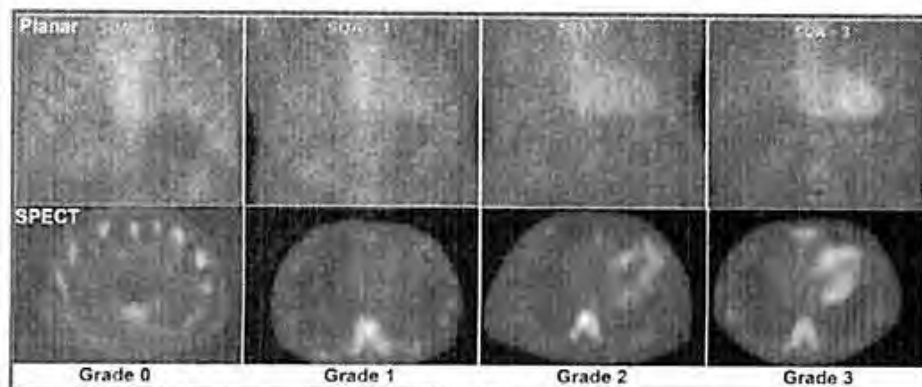


Figure 2. Grading ^{99m}Tc -PYP Uptake on Planar and SPECT Images



BILLING

ASNC would recommend:

- For planar with SPECT report CPT 78803
Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); tomographic (SPECT).
- When reporting CPT 78803, planar imaging of a limited area or multiple areas should be included with the SPECT.
- For the HCPCS level II code report A9538 ^{99m}Tc-pyrophosphate, diagnostic, per study dose, up to 25 millicuries.
- For a single planar imaging session alone (without a SPECT study), report CPT 78800 Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); limited area.

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