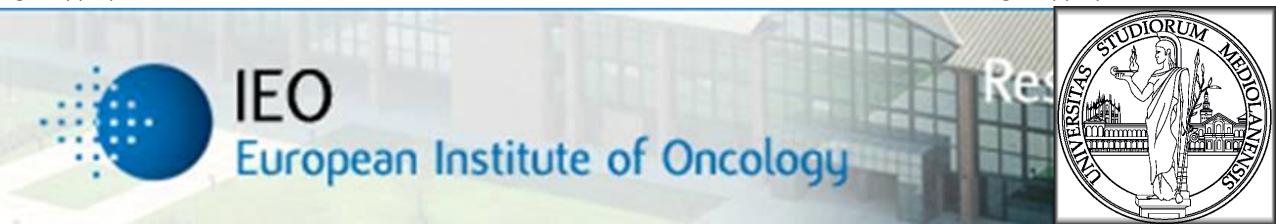
ONCO-RADS in 10 cases

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Oncologically Relevant Findings Reporting and Data System (ONCO-RADS): Guidelines for the Acquisition, Interpretation, and Reporting of Whole-Body MRI for Cancer Screening

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Conflicts of interest are listed at the end of this article.

1. NO RADIATION

Histotype N° of				Rule out			Rule in		
	pts		SE	NPV	-LR	SP	PPV	+LR	
Bone M+ (Prostate) ¹	402	MRI	95%	/	/	96%	/	/	
	1012	PET	87%	/	/	97%	/	/	
Bone & soft tissue M+ (any	1070	MRI	86%	/	0.15	97%	/	32.3	
cancer) ²	1070	PET	85%	/	0.16	96%	/	22.7	
All cancers (primary &	1067	MRI	90%	96%	0.12	95%	89%	11.8	
mets) ³		PET	89%	/	0.07	97%	/	26.8	

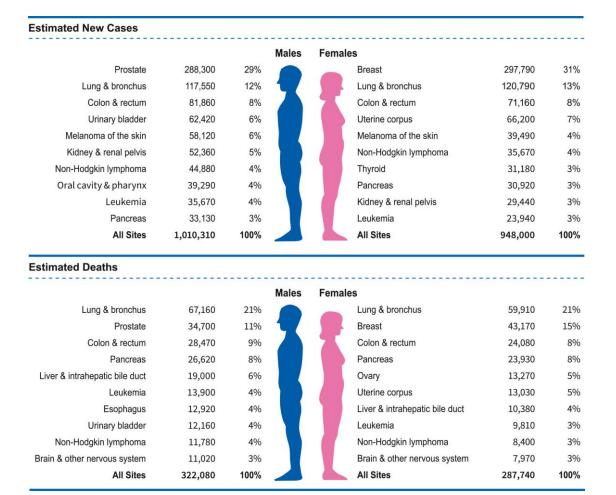
WB-MRI → False positive rate → 4.6%
WB-MRI → False negative rate → 10.2%

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2. WB-MRI can detect the most common cancers *Top-ten 2023*

- The «Big Three» (Screened already)
 - 1. Prostate / Breast
 - 2. Lung
 - Colon & Rectum

- Other common ca. (Not screened)
 - Urinary bladder
 - Kidney, NHL
 - Pancreas, etc.



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3. WB-MRI is recommended for cancer screening in the following cancer predisposition syndromes

*Same or separate sitting

Syndromes	Age	Most common cancers	Anatomical coverage
Li-Fraumeni syndrome (LFS) ¹⁻⁸	Any (Annual)	Sarcomas & osteosarcomas, premenopausal breast cancer, adrenocortical carcinomas, central nervous system tumours (Astrocytomas, glioblastomas, medulloblastomas, choroid plexus carcinomas)	Vertex to the heels (Contrast-enhanced brain sequences*, Breast MRI*)
Hereditary Paraganglioma- Pheocromocytoma syndromes (HPP) ⁹⁻¹⁰	From 6-8yy (every 2 years)	Paraganglioma, pheochromocytoma (>Renal cancers, GIST, pituitary adenomas, etc.)	Skull base to mid-thighs
Constitutional mismatch repair deficiency syndrome (CMMRD) ¹¹⁻¹⁴			Vertex to heels (Contrast-enhanced brain sequences*)
Hereditary retinoblastoma ¹⁵	From 8yy (Annual)	Retinoblastoma (>Sarcomas & osteosarcomas, melanoma, lung cancer, SCC, brain tumours, urogenital & GI tumours)	Vertex to mid-thighs (Contrast-enhanced brain sequences*)
 TORONTO protocol ESMO guidelines ESO-ESMO guidelines NCCN guidelines 8 	UKCGG Consensus (Group guidelines 10. Garcia-Carbonero et al 11. AACR	13. C4CMMRD14. IRRD consortium15. Greer MC, et al.

Survival benefit for individuals with LFS undergoing surveillance¹

	Individuals	Cancers	Detection rate*
Ballinger ML et al. (2017)	578	39	6.74 %
Mai PL et al. (2017)	116	5	4.3 %
Villani A et al. (2016)	59	19	32 %
Paixão et al. (2018)	59	2	3,4%
Bojadzieva J et al. (2018)	53	8	15.1 %
Saya S et al. (2017)	44	6	13.6 %
Tewattanarat N. et al. (2022)	31	7	22,6%

1. Villani A et al., Lancet Oncol. 2016 Sep;17(9):1295-305.

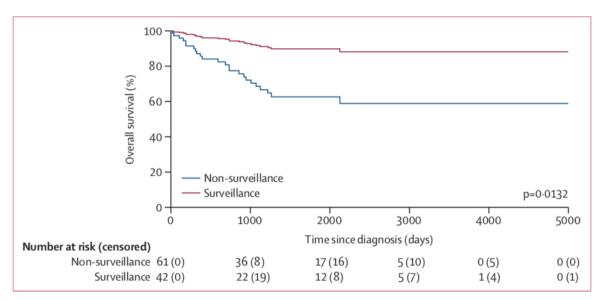


Figure 1: Overall survival in the surveillance and non-surveillance groups

Number at risk refers to the number of tumours, not individuals.

*Surveillance protocol included physical examination and frequent biochemical and imaging studies (WB-MRI, brain MRI, breast MRI, mammography, abdominal and pelvic ultrasound, and colonoscopy)

*On initial screening

3. WB-MRI is recommended for cancer screening in the following cancer predisposition syndromes

*Same or separate sitting

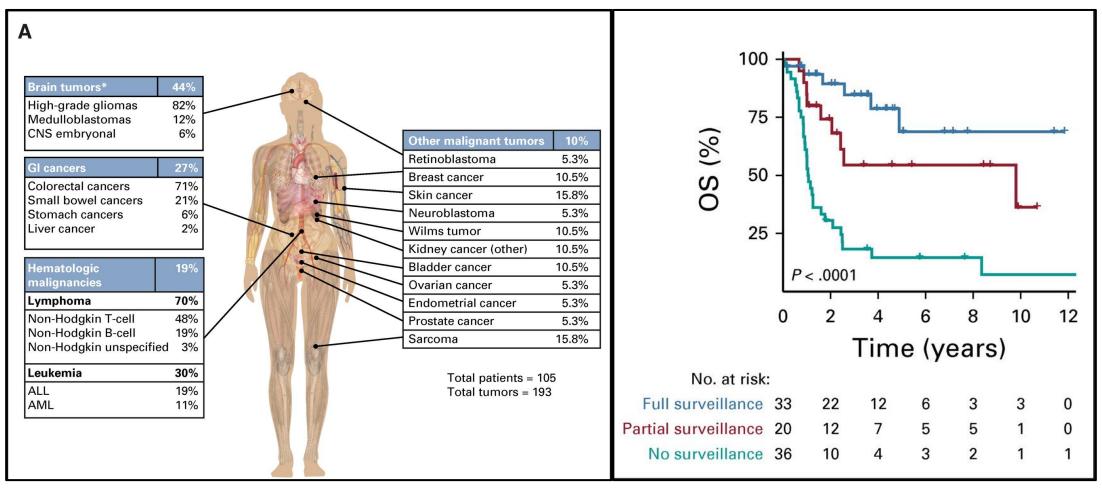
Syndromes	Age	Most common cancers	Anatomical coverage
Li-Fraumeni syndrome (LFS) ¹⁻⁸	Any (Annual)	Sarcomas & osteosarcomas, premenopausal breast cancer, adrenocortical carcinomas, central nervous system tumours (Astrocytomas, glioblastomas, medulloblastomas, choroid plexus carcinomas)	Vertex to the heels (Contrast-enhanced brain sequences*, Breast MRI*)
Hereditary Paraganglioma- Pheocromocytoma syndromes (HPP)9-10	From 6-8yy (every 2 years)	Paraganglioma, pheochromocytoma (>Renal cancers, GIST, pituitary adenomas, etc.)	Skull base to mid-thighs
Constitutional mismatch repair deficiency syndrome (CMMRD) ¹¹⁻¹⁴	From 6-8yy (Annual)	Haematological tumours, brain/central nervous system tumours, colorectal and other intestinal tract cancers	Vertex to heels (Contrast-enhanced brain sequences*)
Hereditary retinoblastoma ¹⁵	From 8yy (Annual)	Retinoblastoma (>Sarcomas & osteosarcomas, melanoma, lung cancer, SCC, brain tumours, urogenital & GI tumours)	Vertex to mid-thighs (Contrast-enhanced brain sequences*)
 TORONTO protocol ESMO guidelines ESO-ESMO guidelines NCCN guidelines 8 	UKCGG Consensus	Group guidelines 10. Garcia-Carbonero et al 11. AACR	13. C4CMMRD14. IRRD consortium15. Greer MC, et al.

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Hereditary Paraganglioma- Pheocromocytoma syndromes (HPP)9-10	From 6-8yy (every 2 years)	Paraganglioma, pheochromocytoma (>Renal cancers, GIST, pituitary adenomas, etc.)	Skull base to mid-thighs
Constitutional mismatch repair deficiency syndrome (CMMRD) ¹¹⁻¹⁴	From 6-8yy (Annual)	Haematological tumours, brain/central nervous system tumours, colorectal and other intestinal tract cancers	Vertex to heels (Contrast-enhanced brain sequences*)
Hereditary retinoblastoma ¹⁵	From 8yy (Annual)	Retinoblastoma (>Sarcomas & osteosarcomas, melanoma, lung cancer, SCC, brain tumours, urogenital & GI tumours)	Vertex to mid-thighs (Contrast-enhanced brain sequences*)
 TORONTO protocol ESMO guidelines ESO-ESMO guidelines NCCN guidelines 	UKCGG Consensus (Kumamoto et al.	Group guidelines 10. Garcia-Carbonero et al 11. AACR	13. C4CMMRD14. IRRD consortium15. Greer MC, et al.

Survival benefit for individuals with CMMRD undergoing surveillance¹



1. Durno C et al. J Clin Oncol. 2021 Sep 1;39(25):2779-2790

3. WB-MRI is recommended for cancer screening in the following cancer predisposition syndromes

*Same or separate sitting

Syndromes	Age	Mos	st co	mmon cancers	I	Anatomical coverage
Li-Fraumeni syndrome (LFS) ¹⁻⁸	Any (Annual)	Sarcomas & osteosarcomas, premenopausal breast cancer, adrenocortical carcinomas, central nervous system tumours (Astrocytomas, glioblastomas, medulloblastomas, choroid plexus carcinomas)		cancer, adrenocortical carcinomas, central nervous system tumours (Astrocytomas, glioblastomas,		ex to the heels rast-enhanced brain sequences*, t MRI*)
Hereditary Paraganglioma- Pheocromocytoma syndromes (HPP) ⁹⁻¹⁰	From 6-8yy (every 2 years)	Paraganglioma, (>Renal cancers, G	•	chromocytoma uitary adenomas, etc.)	Skull	base to mid-thighs
Constitutional mismatch repair deficiency syndrome (CMMRD) ¹¹⁻¹⁴	From 6-8yy (Annual)	Haematological tumours, brain/central nervous system tumours, colorectal and other intestinal tract cancers			ex to heels rast-enhanced brain sequences*)	
Hereditary retinoblastoma ¹⁵	From 8yy (Annual)	Retinoblastoma (>Sarcomas & osteosarcomas, melanoma, lung cancer, SCC, brain tumours, urogenital & GI tumours)			ex to mid-thighs rast-enhanced brain sequences*)	
1. TORONTO protocol 5	GENTURIS guideline	25	9.	Rednam SP et al	13.	C4CMMRD
2. ESMO guidelines 6		Group guidelines	10.	Garcia-Carbonero et al	14.	IRRD consortium
3. ESO-ESMO guidelines 7			11.	AACR	15.	Greer MC, et al.
4. NCCN guidelines 8	Australian Reccomn	nendations	12.	US task force		

4. WB-MRI is increasingly used for Cancer Screening Individuals of the general population

- Advantages¹⁻²²
 - Offered in «health checks»
 - High sensitivity
 - Reasonable examination times
 - No side effects

NO RADIATION - NO INJECTION

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- 3. Lo GG, et al. Hong Kong Med J, 2008; 14: 90–96
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- 8. Cieszanowski A, et al. PLoS One. 2014 Sep 26;9(9)
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- 10. Tarnoki DL, et al. Radiol Oncol, 2015; 49(1): 10–16
- 11. Ulus S, et al. Pol J Radiol. 2016 Aug 30;81:407-14
- 12. Saya S, et al. Fam Cancer. Springer; 2017;16(3):433-440.
- 13. Perkins BA, et al. Proc Natl Acad Sci USA 2018 Apr 3;115(14):3686-3691.
- 14. Lee SY, et al. PLoS One. 2018;13(11):e0206681.
- 15. Petralia G, et al. Magn Reson Imaging Clin N Am. 2018 Nov;26(4):495-507.
- 16. Petralia G, et al. Radiol Med. 2018 Nov 14.
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- 19. Hou YCC, et al. Proc Natl Acad Sci U S A 2020;117(6):3053-3062.
- Petralia G, et al. Radiol Med. 2021 Nov;126(11):1434-1450.
- 21. Basar Y. Et al. Eur J Radiol. 2021 Apr;137:109584.
- 22. Ji Na Kim et al. Eur J Radiol. 2022; 110239

Evidence for the use of WB-MRI in the general population

Challenges

- Cancer → About 2%
 - How to *maximise potential*?
 - Oncological expertise in multi-organ evaluations
- Incidental findings → Up to 99%
 - How to *minimise harm*?
 - Trust a negative WB-MRI and do not over-investigate
 - » High NPV & low prevalence of cancer

	Subjects	Cancer	Incidental findings
Bamberg F et al. (2015)	30,000	Ongoing	Ongoing
Hegenscheid K et al. (2013)	2,500	5,9%*	/
Baumgart D et al. (2007)	1007	0.44 %	/
Cieszanowski A et al. (2014)	666	1.05 %	99%
Basar Y et al. (2021)	576	2.6 %	/
Goede SC et al. (2005)	298	0.33 %	/
Lee SY et al. (2018)	229	0.8%	93%
Lo GG et al. (2008)	132	1.5 %	94%
Ulus S et al. (2016)	118	1.7 %	72%
Tarnoki DL et al. (2014)	22	4.5 %	91%

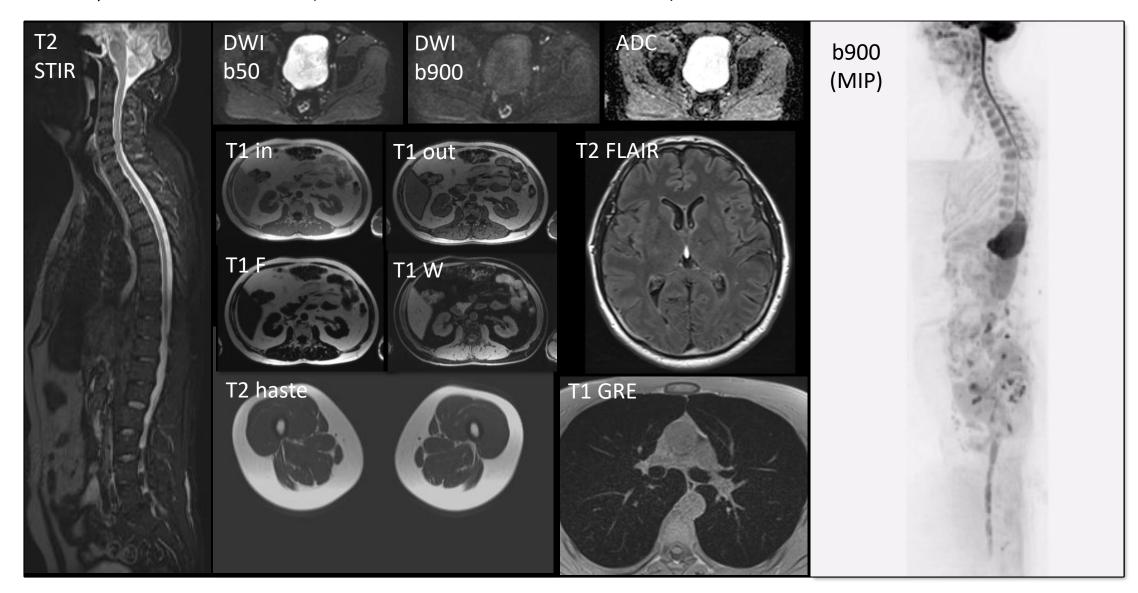
^{*} No histological confirmation

Three aims of ONCO-RADS

Standardise

1. Acquisition

WB-MRI protocol @1.5 & 3T (standard 50 mins / short 35 mins)



Abnormal findings assigned to one of the 7 body regions (bone, head, neck, chest, abdomen, pelvis, limbs)

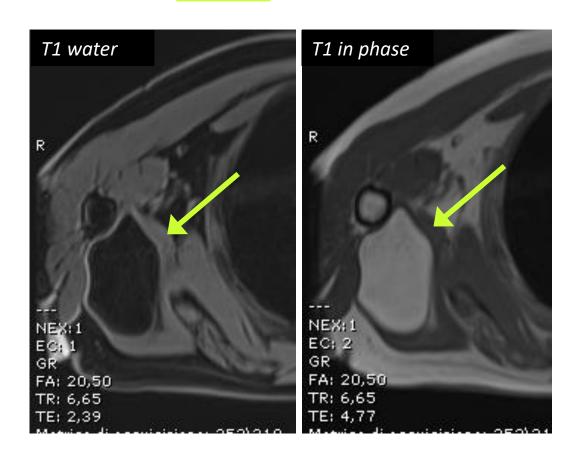
ONCO-RADS category (1 to 5)

- ONCO-RADS 1: normal
- ONCO-RADS 2: benign finding highly likely
- ONCO-RADS 3: benign finding likely
- ONCO-RADS 4: malignant finding likely
- ONCO-RADS 5: malignant finding highly likely

Abnormal findings assigned to one of the 7 body regions (bone, head, nec<mark>k</mark>, chest, <mark>a</mark>bdomen, pelvis, limbs)

ONCO-RADS category (1 to 5)

- ONCO-RADS 1: normal
- ONCO-RADS 2: benign finding highly likely
- ONCO-RADS 3: benign finding likely
- ONCO-RADS 4: malignant finding likely
- ONCO-RADS 5: malignant finding highly likely
- 57yo, M (General population)
 - Asymptomatic
 - No history of cancer
 - PSA and FOBT are normal
 - Heavy smoker (>20 cigarettes per day x 20 years)

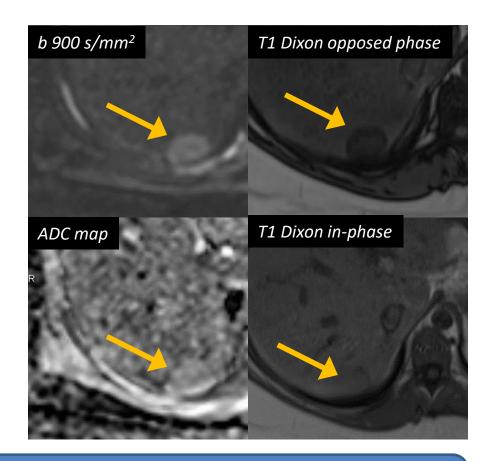


ONCO-RADS 2 → No follow-up

Abnormal findings assigned to one of the 7 body regions (bone, head, neck, chest abdomen, pelvis, limbs)

ONCO-RADS category (1 to 5)

- ONCO-RADS 1: normal
- ONCO-RADS 2: benign finding highly likely
- ONCO-RADS 3: benign finding likely
- ONCO-RADS 4: malignant finding likely
- ONCO-RADS 5: malignant finding highly likely
- 29yo, F (LFS)
 - 2013 → Breast cancer
 - 2017 → Right inguinal dermatofibrosarcoma protuberans
 - 2018 → Recurrence (Surgery + RT)
 - 2020 → WB-MRI for cancer screening

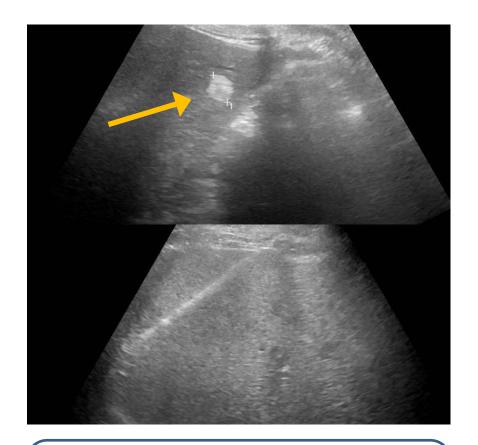


ONCO-RADS 3 → Biopsy (feasible)

Abnormal findings assigned to one of the 7 body regions (bone, head, neck, chest<mark>,</mark> abdomen, pelvis, limbs)

ONCO-RADS category (1 to 5)

- ONCO-RADS 1: normal
- ONCO-RADS 2: benign finding highly likely
- ONCO-RADS 3: benign finding likely
- ONCO-RADS 4: malignant finding likely
- ONCO-RADS 5: malignant finding highly likely
- 29yo, F (LFS)
 - 2013 → Breast cancer
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 - 2020 → WB-MRI for cancer screening

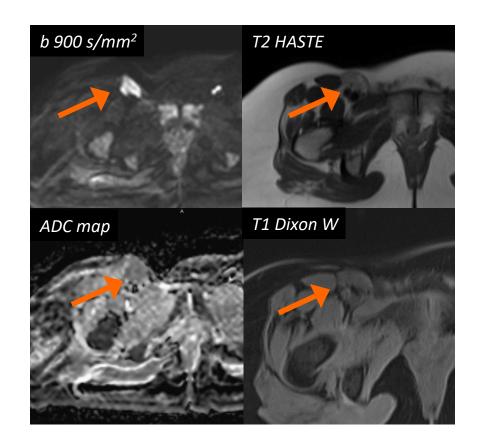


Macrovescicular steatosis (intracellular) Signs of chronic inflammation & ductal hyperplasia/metaplasia STABLE AFTER 3 YEARS

Abnormal findings assigned to one of the 7 body regions (bone, head, neck, chest, abdomen, pelvis, imbs)

ONCO-RADS category (1 to 5)

- ONCO-RADS 1: normal
- ONCO-RADS 2: benign finding highly likely
- ONCO-RADS 3: benign finding likely
- ONCO-RADS 4: malignant finding likely
- ONCO-RADS 5: malignant finding highly likely
- 29yo, F (LFS)
 - 2013 → Breast cancer
 - 2017 → Right inguinal dermatofibrosarcoma protuberans
 - 2018 → Recurrence (Surgery + RT)
 - 2020 → WB-MRI for cancer screening



ONCO-RADS 4 → Biopsy / Surgery

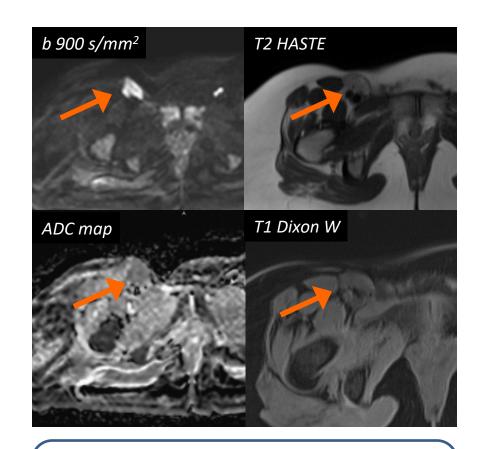
Abnormal findings assigned to one of the 7 body regions (bone, head, neck, chest, abdomen, pelvis, imbs)

ONCO-RADS category (1 to 5)

- ONCO-RADS 1: normal
- ONCO-RADS 2: benign finding highly likely
- ONCO-RADS 3: benign finding likely
- ONCO-RADS 4: malignant finding likely
- ONCO-RADS 5: malignant finding highly likely

• 29yo, F (LFS)

- 2013 → Breast cancer
- 2017 → Right inguinal dermatofibrosarcoma protuberans
- 2018 → Recurrence (Surgery + RT)
- 2020 → WB-MRI for cancer screening

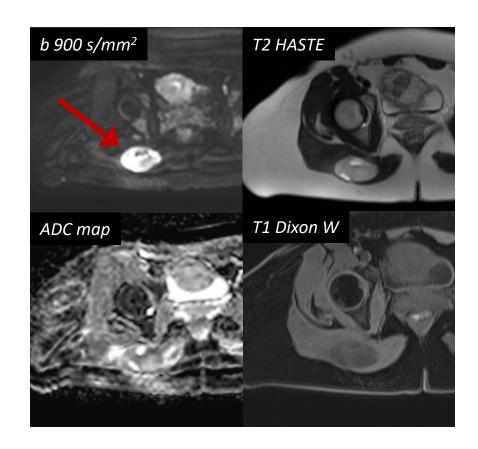


US-guided biopsy → Likely
dermatofibrosarcoma protuberans
After resection → Dermatofibrosarcoma
protuberans

Abnormal findings assigned to one of the 7 body regions (bone, head, neck, chest, abdomen, pelvis, limbs)

ONCO-RADS category (1 to 5)

- ONCO-RADS 1: normal
- ONCO-RADS 2: benign finding highly likely
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- ONCO-RADS 4: malignant finding likely
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 - 2013 → Breast cancer
 - 2017 → Right inguinal dermatofibrosarcoma protuberans
 - 2018 → Recurrence (Surgery + RT)
 - 2020 → WB-MRI for cancer screening

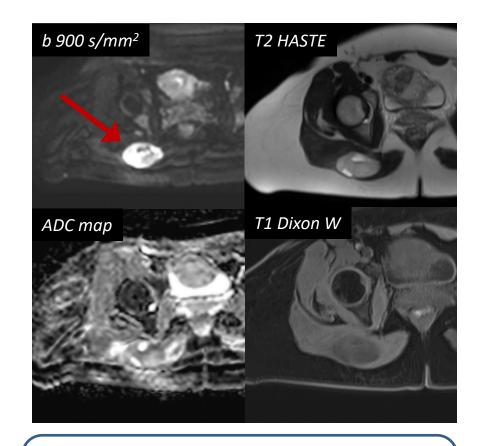


ONCO-RADS 5 → Surgery / Biopsy

Abnormal findings assigned to one of the 7 body regions (bone, head, neck, chest, abdomen, pelvis, limbs)

ONCO-RADS category (1 to 5)

- ONCO-RADS 1: normal
- ONCO-RADS 2: benign finding highly likely
- ONCO-RADS 3: benign finding likely
- ONCO-RADS 4: malignant finding likely
- ONCO-RADS 5: malignant finding highly likely
- 29yo, F (LFS)
 - 2013 → Breast cancer
 - 2017 → Right inguinal dermatofibrosarcoma protuberans
 - 2018 → Recurrence (Surgery + RT)
 - 2020 → WB-MRI for cancer screening



US-guided Biopsy → Likely dermatofibrosarcoma protuberans

After resection \rightarrow High grade sarcoma

Table 4: Examples of the Most Frequently Observed Abnormal Findings in the Head, Neck, and Chest

ONCO-RADS			
Category	Head	Neck	Chest
Category 1, normal finding	Normal	Normal	Normal
Category 2, benign finding highly likely	Diffuse white matter alterations, diffuse mucosal thickening of paranasal sinuses, pharynx and/ or larynx, arachnoid cysts	Nonsuspicious thyroid nodule <1 cm (in individuals <35 y),* nonsuspicious thyroid nodule <1.5 cm (in individuals ≥35 y),* lipoma	Lung nodules <6 mm,† thymic hyperplasia, pericardial cysts, lipoma
Category 3, benign finding likely	Isolated white matter alterations, focal mucosal thickening of paranasal sinuses, pharynx and/ or larynx	Nonsuspicious thyroid nodule ≥1 cm (in individuals <35 y),* nonsuspicious thyroid nodule ≥1.5 cm (in individuals ≥35 y)*	Lung nodules 6–8 mm,† pneumonia, pleural effusion
Category 4, malignant finding likely	Brain lesion(s) suspicious for cancer (primary or metastatic)	Thyroid nodule(s) (solid), salivary gland solid lesion	Lung nodules >8 mm, mediastinal mass
Category 5, malignant finding highly likely	Brain lesion(s) with aggressive features, very suspicious for cancer (primary or metastatic)	Thyroid nodule(s) with aggressive features, very suspicious for cancer	Lesions with aggressive features, very suspicious for cancer, to lung, mediastinum
Other findings, including anatomic variations	Hydrocephalus, hemorrhage, cavum septum pellucidum, cavum vergae, mega cisterna magna, Chiari malformations	Thyroglossal duct cyst	Pneumothorax, thoracic aortic aneurysm, azygos lobe, thoracic aorta variants (eg, right-sided aortic arch, double aortic arch)

Table 5: Examples of the Mo	ost Frequently Observed Abnormal Findings in the	e Abdomen and Pelvis
ONCO-RADS Category	Abdomen	Pelvis
Category 1, normal finding	Normal	Normal
Category 2, benign finding highly likely	Hemangioma (liver and spleen), cyst and hemorrhagic cyst <30 mm (kidney),* angiomyolipoma (kidney), adenoma (adrenal gland), steatosis (liver), lithiasis (gallbladder), lipoma	Benign prostatic hyperplasia (prostate), simple adnexal cyst ≤3 cm (postmenopausal), [†] simple adnexal cyst ≤5 cm (premenopausal), hemorrhagic adnexal cyst ≤5 cm (premenopausal), [†] ovarian fibroid, [†] uterine leiomyoma, para-ovarian cyst, luteal body
Category 3, benign finding likely	Solitary liver nodule ≥10 mm, solid likely focal nodular hyperplasia or adenoma, complex cyst (kidney), hemorrhagic cyst >30 mm (kidney),* pancreatic cyst ≤2.5 cm [‡]	Thickening of colorectal wall, simple adnexal cyst >3 cm (postmenopausal), simple adnexal cyst >5 cm (premenopausal), hemorrhagic adnexal cyst (postmenopausal), hemorrhagic adnexal cyst >5 cm (premenopausal)
Category 4, malignant finding likely	Lesion(s) suspicious for cancer in liver (solid nodules), kidney (solid lesion or cystic lesion with solid component),* pancreatic cyst with worrisome features (≥3 cm, thick wall, mural nodule, main pancreatic duct >7 mm) [‡]	Lesion(s) suspicious for cancer to uterus (eg, focal endometrial thickening), prostate (impeded diffusion and hypointensity on T2-weighted image in the peripheral zone), colon and rectum, simple adnexal cyst ≥10 cm, adnexal cyst with solid tissue, thick irregular septa, papillary projections, locules with different signal intensity [†]
Category 5, malignant finding highly likely	Lesion(s) with aggressive features in liver, kidney, pancreas, pancreatic cyst with high-risk features (solid component within the cyst, main pancreatic duct >10 mm, common bile duct dilatation) [‡]	Lesion(s) with aggressive features, very suspicious for cancer, to uterus, ovary, prostate, colon and rectum
Other findings, including anatomic variations	Abdominal aortic aneurysm, pancreas divisum, annular pancreas accessory spleen, inferior vena cava variants (persistent right posterior cardinal vein, persistent left supracardinal vein, retro-aortic left renal vein)	Fluid collection, uterine duplication anomalies (eg, uterus didelphys, bicornuate uterus septate uterus)

Table 6: Examples of Most Frequently Observed Abnormal Findings in the Bones and Limbs

ONCO-RADS Category	Bones	Limbs
Category 1, normal finding	Normal	Normal
Category 2, benign finding highly likely	Hemangioma, cyst, fat-poor bone marrow, bone island, enchondroma, healed fractures	Intramuscular hemangioma, lipoma
Category 3, benign finding likely	Bone lesion(s) with nonspecific features	Soft-tissue lesion(s) with unspecific features
Category 4, malignant finding likely	Bone lesion(s) suspicious for cancer (primary or metastatic)	Soft-tissue lesion(s) suspicious for cancer (primary or metastatic)
Category 5, malignant finding highly likely	Bone lesion(s) with aggressive features, very suspicious for cancer (primary or metastatic)	Lesion with aggressive features, very suspicious for cancer
Other findings, including anatomic variations	Fracture, transitional vertebrae (eg, lumbarization of S1, sacralization of L5)	Intramuscular hematoma

Note.—The threshold for assigning ONCO-RADS categories should be adapted to the individual's risk category (general population or higher risk including cancer predisposition syndromes). ONCO-RADS = Oncologically Relevant Findings Reporting and Data System.

3. Reporting

- Standardised reporting templates are available
 - Published in Supplemental Material (Appendix E3)
 - Download for free

Appendix E3: Blank standardized report

INDICATION:

Cancer screening.

High-risk individual (syndrome, etc)/asymptomatic individual of the general population

TECHNIQUE:

Whole-body MRI (vertex to feet/mid thighs, including proximal upper limbs only).

Sequences: Whole-spine sagittal T1 W / T2 W STIR, axial TSE T2 W, axial GRE T1 Dixon, axial DW (b-values = $50 \& 900 \text{ s/mm}^2$).

Reconstructions: in-line (Water-only and Fat-only images, ADC maps), off-line (relative fat fraction, MIP, MPR).

FINDINGS:

MRI bone:

No suspicious bone lesions.

Spinal canal dimensions within normal limits.

Sacral root cysts (ONCO-RADS category 2).

Vertebral body hemangioma/hemangiomas of Cx, Ty, Lz (ONCO-RADS category 2).

MRI head:

No suspicious brain lesions.

Ventricular system within normal limits.

Midline structures are not displaced.

Diffuse white matter alterations (ONCO-RADS category 2).

Mucosal thickening of the paranasal sinuses (ONCO-RADS category 2).

MRI neck:

Pharyngeal and laryngeal findings within limits.

No cervical enlarged lymph nodes.

Non-suspicious thyroid nodule < 1 cm/1.5 cm in the right/left lobe/s (ONCO-RADS category 2).

MRI chest:

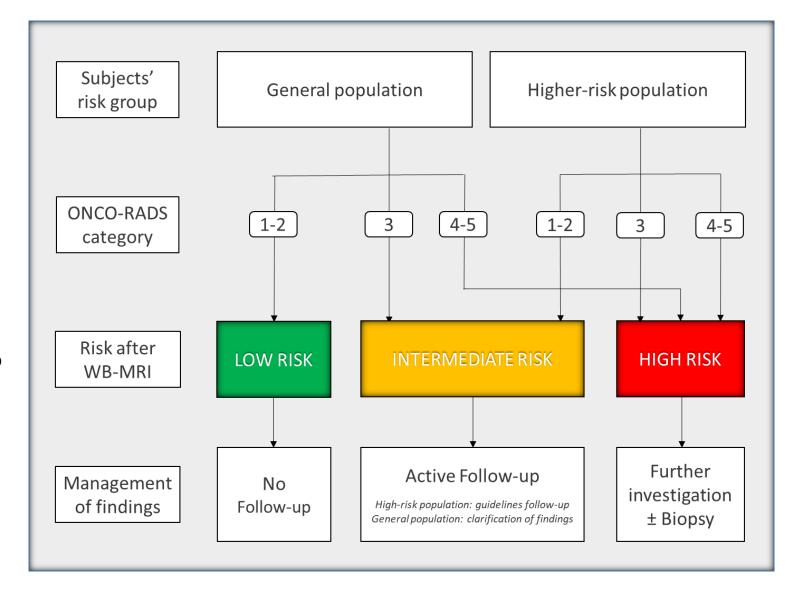
No suspicious lesions in either lung.

No enlarged mediastinal lymph nodes visible.

No enlarged supra-/subclavicular lymph nodes visible.

In addition, management of findings «tailored» to the risk group

- High-risk populations
 - ONCO-RADS category 1-2 →
 Guidelines follow-up
 - ONCO-RADS category 3-4-5 →
 Further investigation ± Biopsy
- General population
 - ONCO-RADS category 1-2 →
 No follow-up
 - ONCO-RADS category 3 →
 Clarification of findings according to
 established guidelines for the
 management of incidental findings
 - ONCO-RADS category 4-5 →
 Further investigation ± Biopsy



Last, but not least → "Clinical" radiologist

- Before WB-MRI examination
 - WB-MRI → <u>Addition</u> to standard screening tests (and never in substitution)
 - Mammography, PAP smears, FOBT/colonoscopy
 - Avoid false reassurances
- After WB-MRI examination
 - Communication of the result
 - To ensure an appropriate comprehension
 - To lower anxiety related to the outcomes



Giacomo Agostini, 15 motorcycle world championships