Advancing the Management of Gallstone and Common Bile Duct Stone Disease

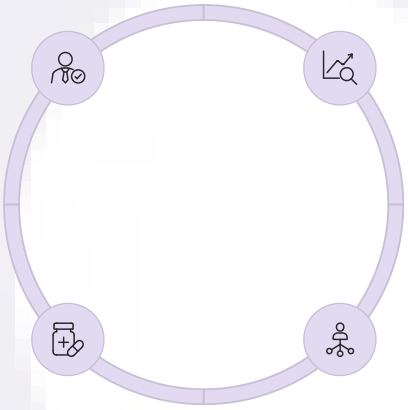
A Comprehensive Clinical Practice Model

Industry Experts

Respected professionals shaping field standards

Clinical Practitioners

Influence real-world adoption and best practices



Academic Researchers

Publish studies and provide evidence-based insights

Industry Influencers

Drive awareness through networks and platforms

Jasmine Sinha, MD
Chair

James Buxbaum, MD

Jennifer Moffett, MD

Patrick Murphy, MD

Mike Ujiki, MD

Steven Shamah, MD

This publication produced by EndoscopyNow was financially supported by Boston Scientific. This publication was the result of the industry collaboration of Jasmine Sinha, MD, James Buxbaum, MD, Jennifer Moffet, MD, Patrick Murphy, MD, Michael Ujiki, MD, and Steven Shamah, MD, within the CPM initiative. Although Boston Scientific provided limited input in connection with the CPM initiative, EndoscopyNow and the physician authors retained sole editorial control over this published content.

Executive Summary

Gallstone disease affects **10-15% of adults** in developed countries, with **10-20%** developing choledocholithiasis. Traditional two-stage management involving preoperative ERCP followed by cholecystectomy is associated with complications, increased costs, and longer hospital stays.

01

The Problem

Traditional two-stage approach exposes patients to multiple procedures, anesthesia rounds, and ERCP complications (5-10% risk)

02

The Solution

Surgery-first paradigm with routine IOC and LCBDE offers comparable outcomes with reduced costs and complications

03

The Goal

Standardized approach improving outcomes, enhancing cost-effectiveness, and reducing procedural variation

This CPM was developed by a KOL team across academic and private practice settings to ensure relevance for gastroenterologists, general surgeons, acute care surgeons, minimally invasive surgeons, and hepatobiliary surgeons.

Limitations of the Traditional Two-Stage Model

The prevailing model separates ERCP for duct clearance and cholecystectomy into two procedures, exposing patients to additional tests, multiple anesthesia rounds, and increased adverse events.

Multiple Procedures

Separate ERCP and cholecystectomy sessions require duplicate anesthesia and recovery time

ERCP Complications

5-10% risk of pancreatitis, bleeding, and perforation

Delayed Surgery

Increased readmissions and patient morbidity during waiting period

MRCP availability and accuracy vary between practices, leading to poor resource utilization. Many ERCPs are performed that turn out to be normal, exposing patients to unnecessary ERCP-related pancreatitis risk.

Advocacy for a Surgery-First, Single-Stage Model

Advancements in surgical techniques now allow definitive intraoperative management of choledocholithiasis at the time of laparoscopic cholecystectomy. IOC confirms stone presence during LC, enabling immediate LCBDE when indicated.

Single Session Treatment

Definitive management during one operation reduces patient burden and hospital stay

Comparable Outcomes

Duct clearance rates match ERCP while avoiding endoscopic risks

Cost Effective

Reduces procedural redundancy and aligns with value-based healthcare goals

This single-session strategy demonstrates comparable duct clearance rates while reducing length of stay, cost, and procedural redundancy. More recent data from the LIBERTI Trial suggest single-stage Lap cholecystectomy with LCBDE can significantly reduce length of stay and overall cost. The surgery-first model emphasizes timely intervention, minimizes care fragmentation, and can greatly reduce "diagnostic" ERCP volume.

Despite these advantages, limitations include lack of standardized training in IOC and LCBDE and concerns regarding reimbursement.

Objective of This Clinical Practice Model

This document proposes a standardized, evidence-informed Clinical Practice Model for gallstone and choledocholithiasis management based on expert consensus, best available evidence, and implementation science.

Guide Transition

Support physicians transitioning toward surgery-first protocols

Foster Collaboration

Enable multidisciplinary teamwork across specialties

Ensure Quality

Deliver reproducible, high-quality care across all settings

This model targets gastroenterologists, surgeons managing gallstone disease, and health system administrators with a goal to optimize management in both elective and emergent settings.

Diagnostic Framework and Risk Stratification

Clinical Presentation and Laboratory Evaluation

Patients with suspected choledocholithiasis typically present with right upper quadrant or epigastric pain, jaundice, or pancreatitis. Thorough clinical assessment is essential to differentiate between uncomplicated biliary colic, acute cholecystitis, and choledocholithiasis-related complications.

Liver function tests (LFTs) including ALT, AST, alkaline phosphatase, and total/direct bilirubin help risk stratify patients. Elevated transaminases or bilirubin increase suspicion for ductal obstruction or cholangitis.

Imaging Modalities

1

Transabdominal Ultrasound

First-line modality; 50-70% sensitivity for choledocholithiasis; operator dependent

2

MRCP

Highly sensitive (>90%) and specific (near 100%); may miss stones impacted at ampulla

3

Endoscopic Ultrasound

95% sensitivity, 97% specificity; direct visualization of small stones possible

4

Intraoperative Cholangiogram

75-100% sensitivity and specificity; can advance to LCBDE if positive

Risk Stratification Models

2019 ASGE Guidelines

Categorize patients into low, intermediate, or high risk for choledocholithiasis presence:

High Risk

Clinical cholangitis, CBD stone on imaging (73% sensitivity, 91% specificity), bilirubin >4 mg/dL with dilated duct

Intermediate Risk

Abnormal LFTs, age >55, gallstone pancreatitis, dilated CBD without clear stone

Low Risk

Normal LFTs, no ductal dilation, absence of risk factors

While these categories guide decision-making between expectant management, preoperative imaging, or direct-to-surgery pathways, recommendations for intermediate-risk patients present multiple options, leading to considerable treatment heterogeneity.

2021 SAGES Guidelines

Categorize patients into low, intermediate, or high risk. Management depends on timing of choledocholithiasis diagnosis relative to cholecystectomy but includes variability based on available expertise.

2025 SAGES Guidelines for IOC

- Panel suggests performing IOC in adult patients undergoing laparoscopic cholecystectomy for benign biliary disease
- Panel suggests performing IOC routinely rather than selectively

Integrating Risk with Pathway Selection

Patients at intermediate or high risk for choledocholithiasis are typically candidates for a surgery-first approach with IOC and common bile duct exploration.

Intermediate/High Risk

Surgery-first with IOC and LCBDE when indicated

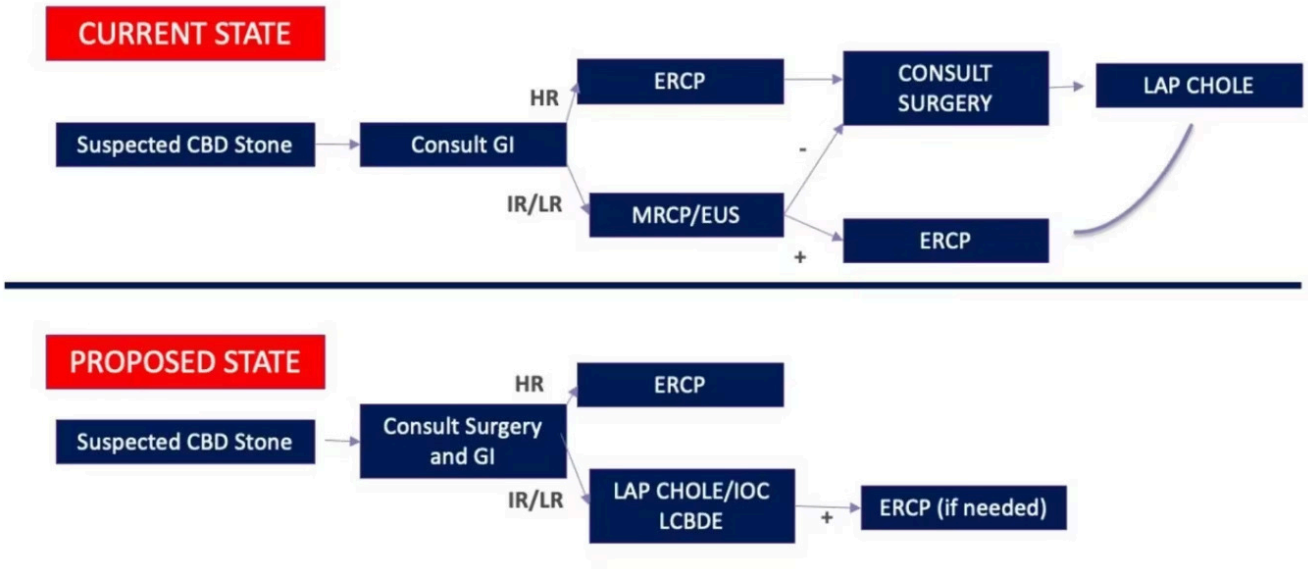
Low Risk

Direct to LC with or without IOC depending on operative findings

Relative Contraindications

Mirizzi Syndrome, concern for malignancy, aberrant anatomy

Management Pathways and Procedural Options



Institutions should implement structured diagnostic pathways to reduce management variation and ensure timely triage and disposition.

Comparing Management Approaches

ERCP + LC: Traditional Two-Stage Model

This widely used approach separates duct clearance (ERCP) and cholecystectomy into two sessions, each with anesthesia and recovery time, increasing costs and patient burden.

ERCP Complications

Post-ERCP pancreatitis risk (5-10%) results in readmissions and increased resource utilization. Additional risks include:

- Duodenal perforation (0.08-0.6%)
- Bleeding (0.3-2.0%)
- Cholangitis (0.5-3.0%)
- Stent complications

Delays Cholecystectomy

Patients waiting for surgery may develop interval complications:

- Recurrent biliary colic
- Acute cholecystitis
- Pancreatitis

This increases readmissions and patient morbidity.

LC with IOC and LCBDE: Single-Session Treatment

Performing LC + IOC and managing choledocholithiasis in the same operation reduces exposure to multiple procedures and shortens total length of stay.

High duct clearance rates

Experienced centers achieve >90% clearance via LCBDE, matching ERCP outcomes while avoiding endoscopic risks

Negative IOC benefit

Patients with negative IOC maximally benefit from direct-to-surgery approach by avoiding multiple procedures

Infrastructure requirements

Success requires C-arms, cholangioscopes, retrieval tools, and trained staff

Time considerations for IOC range from 10-90 minutes, with LIBERTI trial suggesting an additional 45-50 minutes on average.

Rendezvous Technique

This hybrid technique allows surgeons to pass a guidewire through the cystic duct to facilitate ERCP cannulation, reducing post-ERCP pancreatitis risk. Requires interdepartmental coordination and synchronized scheduling, which limits scalability.

Current Literature: Evidence Supporting Surgery-First

Multiple randomized controlled trials, systematic reviews, and retrospective studies demonstrate the efficacy and safety of the surgery-first approach.

Study (Year)	Type	Comparison	Outcomes	P-value	Summary
LIBERTI: VnaDruff v et al. (2024)	Simulator based Multicenter	n/a	Simulator-based training in LCBDE results in higher utilization rates, shorter LOS, and comparable safety to ERCP plus cholecystectomy.		LCBDE is a viable option with proper training and supports the single-stage surgery first approach
Sung et al. (2010)	RCT (n=122)	LC+LCBDE vs ERCP+LC	Similar clearance; LCBDE shorter discharge (55h vs 98h), lower fees	p<0.001	Similar efficacy, faster discharge, lower cost
Havana RCT (2011)	RCT (n=134)	Intra-op ERCP vs LCBDE vs pre-op ERCP	All arms similar clearance (~97%)	NS	All equally effective; intra-op more efficient
Cochrane Review (2013)	Systematic Review (5 RCTs)	Single-stage LCBDE+LC vs two-stage ERCP+LC	Similar clearance and morbidity; fewer retained stones with LCBDE	-	Comparable safety, potentially fewer retained stones

Evidence Supporting Surgery-First (Continued)

Study (Year)	Type	Comparison	Outcomes	P-value	Summary
Oude Elferink et al. (2017)	Retrospective (n=671)	LCBDE vs pre-/post-ERCP	LCBDE lowest morbidity (minor: 5.2%; major: 6.1%) and mortality (0.5%)	p<0.001	LCBDE safest; pre-op ERCP highest complications
Guan et al. (2018)	Retrospective (n=128)	ERCP vs LCBDE	100% clearance LCBDE+LC vs 75% ERCP+LC; shorter hospitalization (4.1 vs 8.4 days)	p<0.05	Single-stage advantages over ERCP+LC
ElGeidie et al. (2020)	Meta-analysis (n=2181)	LCBDE vs ERCP	No difference clearance/mortality; ERCP more pancreatitis; LCBDE more bile leaks	-	Similar outcomes; each has specific complications
Moffett et al. (2024)	Retrospective (n=154)	Single stage vs double stage	Shorter LOS (3.9 vs 5.1 days), fluoroscopy time (70.3s vs 151.4s), radiation (23.0 vs 40.3 mSv)	p<0.05	Shorter clearance time, LOS, less radiation

The evidence consistently demonstrates that LCBDE offers comparable or superior outcomes to traditional ERCP-based approaches while reducing complications, hospital stays, and costs.

Proposed Algorithmic Pathway: "Surgery-First" Approach

Risk Stratification

Employ validated criteria (ASGE or SAGES) based on labs, imaging, and clinical presentation to guide initial triage

Intermediate/High Risk

Surgery for cholecystectomy with IOC. Bypass ERCP and proceed to LC where IOC is routinely performed

LCBDE Failure

If LCBDE fails → intraoperative or separate session ERCP

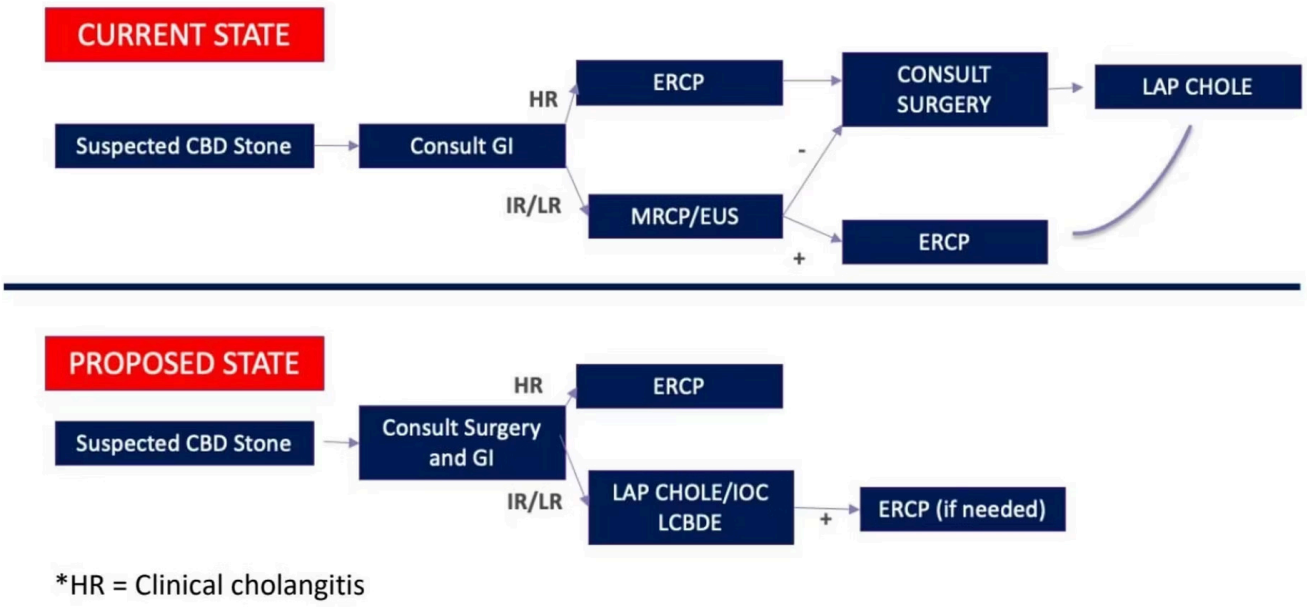
Low Risk for Choledocholithiasis

Surgery for cholecystectomy with or without IOC depending on intra-operative findings

IOC Results and Management

IOC negative → complete LC IOC positive → LCBDE with transcystic or transcholedochal approach

When to Consider ERCP First: Patients with clinical cholangitis may benefit from ERCP with biliary stenting prior to LC.



*HR = Clinical cholangitis

Institutional Infrastructure and System Implementation

Technology Needs Assessment

Successful implementation requires specific equipment and infrastructure investments.

C-arms for Fluoroscopy

Essential for IOC and intraoperative visualization of the biliary tree;

Must be mobile, available, and supported by trained radiologic technologists.

Requires forethought regarding seamless integration with OR setup and equipment (ie laparoscopic vs robotic setup.

Wire-ready cholangiogram setups facilitate ease of progressing to wire-based transcystic interventions if cholangiogram is positive for choledocholithiasis.

Procedural Devices

Guidewires, dilation balloons, and pressure-based inflation devices are needed to maintain duct access, for dilation of the cystic duct when needed, and for balloon dilation of the ampulla.

Cholangiosocpes with additional imaging towers are required for visualization of stones within the common bile duct.

Familiarity with the various types of retrieval baskets available to ensure optimal selection depending on the type of stones needing retrieval.

Options for fragmentation of large stones will improve success rates. Lasers and electrohydraulic lithotripsy may be employed, but additional equipment including power sources and appropriate safety equipment (for lasers) must be employed.

Equipment Maintenance

Regular maintenance and high-level disinfection are required for non-disposable equipment including cholangiooscopes.

Institutions must ensure inventory availability and sterile processing capability.

Workflow Integration

Preoperative Patient Identification

Triage patients with cholelithiasis for IOC/LCBDE suitability using guidelines embedded in pre-op workflows.

Streamlined OR Booking and Equipment Setup

Implementation of routine IOC into LC practice ensures availability of required equipment, standardizes set up for each LC case and promotes surgeon and staff familiarity with equipment and procedural process.

LCBDE Use

LCBDE equipment should be available and quickly accessible for positive IOC cases; this can be achieved by creating a cart with LCBDE-specific equipment. Inclusion of QR codes linking videos that outline setup of the equipment may also facilitate efficient intraoperative transition from IOC to LCBDE. We need consensus on definition of LCBDE and the various approaches (e.g. transcystic, transductal and what are the steps to a desired outcome).

Assessment of Nursing and OR Teams: Is there training and guidance we can establish for robotic and non-robotic cases.

EHR Integration Details

Risk Stratification Templates

Built into pre-operative notes to determine low, intermediate, or high risk with documented rationale

Order Sets for Cholelithiasis

Bundle relevant labs (LFTs, INR) and imaging findings (CBD diameter, stone presence)

IOC Order Sets

Prompt automated orders for fluoroscopy and equipment at OR case request

Building a "Surgery First" Approach

Governance, Training, and Metrics

Multidisciplinary Governance

Surgeons, GI, anesthesia, radiology, nursing collaboratively define escalation triggers, imaging algorithms, and handoff protocols. Hospital quality committees track performance indicators. Defining prerequisites of training, credentialing, and documentation

Training and Education

Start w collaborative training in performance and interpretation of IOC. Simulation labs and proctorship for LCBDE training. Onboarding of surgical teams with hands-on equipment training. Institutions should invest in dry labs and arrange simulation days with expert mentors.

Pilot Phases

Start with high-volume centers and acute care surgery units as early adopters. Expand as capacity and training mature through stepwise implementation.

Tracking Key Metrics

90%+

Duct Clearance Success

Track primary and rescue success rates to benchmark performance

<5%

Complication Rates

Monitor bile duct injuries, retained stones, re-operations, delayed ERCPs

IOC

Utilization Tracking

Proxy for pathway adoption; identify variance between teams

Additional metrics include bed utilization, healthcare costs, total hospital costs, length of stay comparisons, and patient satisfaction surveys regarding care coordination.

Cost Modeling, Reimbursement, and Economic Impact

Direct Costs

Value-based care models favor the “surgery first” model. Fewer procedures = lower anesthesia, OR, and hospital stay costs. One-stop approach avoids duplicate preps and PACU stays.

Complication Avoidance

Post-ERCP pancreatitis often results in multi-day stays and ICU admissions, driving up costs substantially.

Reimbursement

Correct CPT coding for IOC and LCBDE supports advanced procedural codes. Avoid bundling errors through staff training.

Reduced Readmissions

Definitive treatment during index admission improves outcomes and reduces downstream cost burdens.

$3,000+

Estimated Savings Per Patient

Based on…

- reduced bed days
- repeat imaging
- ERCP-related complications with the "Surgery First" pathway

Payer Engagement

- Advocate for value-based incentives demonstrating improved outcomes at lower costs
- Support inclusion of LCBDE pathways in alternative payment models and bundled care initiatives

Training, Outcomes, Barriers, and Future Directions

Training Pathways and Credentialing Standards

Residency and Fellowship

- Standardized modules for IOC/LCBDE including biliary anatomy and procedural decision-making
- Simulation and case volume benchmarks with hands-on training
- Fluoroscopy licensing preparation in states where required

Proctorship for Practicing Surgeons

- Short courses and mentorship utilizing simulation labs
- Regional centers of excellence providing recurring courses and live-case observations
- Fluoroscopy operator/supervisor licenses where required

Credentialing Standards

Defined Case Numbers

Specify volume thresholds and proctor attestations for LCBDE privileges

Competency Verification

Use checklists and skill assessments to ensure readiness before independent practice

Outcomes and Quality Metrics

Clinical

- Standardizaton of IOC is an important first step. Requires collaborative efforts between GI and surgery.
- Stone clearance >90%
- Conversion to open <5%
- Complications tracking
- NSQIP participation

Operational

- OR times assessment
- ERCP/MRCP/EUS avoidance
- Post-op ERCP monitoring

Patient Experience

- Satisfaction surveys
- Fewer hospital visits

Barriers to Adoption and Facilitators for Change

Barriers

Skill and Equipment Gaps

Many community hospitals lack fluoroscopy, choledochoscopy, and trained staff

ERCP-Centric Culture

Longstanding reliance on gastroenterologists may create concerns regarding procedural territory or productivity loss

Technical Limitations

Large or complex stones may be difficult or impossible to remove laparoscopically

Real World Adoption

Requires surgical leadership and OR committee approval, capital funding, and full administrative support

Facilitators

Institutional Champions

Motivated surgeons lead by example, mentor peers, and liaise with administration

Demonstrated QI Data

Sharing metrics like reduced complications, cost savings, and high clearance rates promotes buy-in

GI-Surgery Collaboration

Cross-disciplinary protocols and shared governance models ease transitions and reduce resistance

Policy Recommendations and Future Directions

Guidelines and Training

SAGES, ACS, ASGE endorsement adds legitimacy. Inclusion in clinical quality pathways drives compliance. Training course(s) taught by collaborative faculty of surgeons and interventional GIs teaching standardized techniques and operational workflows.

Payment Models

Align payer incentives with single-session care. Support bundled payments for LCBDE pathways.

Research/Education

Cost-effectiveness trials, AI-based cholangiogram tools, combined GI/surgical training initiatives.

Global Impact and Future Vision

Global/Community Health

Promote LCBDE in resource-limited settings where ERCP is unavailable. Surgical management offers a durable solution for underserved populations.

Technology Innovation

Investment in durable, low-cost scope innovations including reusable/disposable choledochoscopy platforms may enhance global access.

> The surgery-first approach represents a paradigm shift in gallstone and choledocholithiasis management—one that prioritizes patient outcomes, reduces healthcare costs, and aligns with value-based care principles.

Evidence-Based

Supported by robust clinical data demonstrating comparable or superior outcomes

Patient-Centered

Prioritizes patient outcomes, reduces healthcare costs, and aligns with value-based care principles

References

1) Stinton LM, Shaffer EA. Epidemiology of gallbladder disease: cholelithiasis and cancer. Gut Liver. 2012;6(2):172-187. doi:10.5005/jp-journals-10018-1146.

2) Barie PS, Eachempati SR. Gallstone disease. N Engl J Med. 2010;362(14):1365-1373. doi:10.1056/NEJMra0901547.

3) Shaffer EA. Gallstone disease: epidemiology of gallbladder stone disease. Best Pract Res Clin Gastroenterol. 2006;20(6):981-996. doi:10.1016/j.bpg.2006.07.006.

4) Merck Manual Professional Version. Choledocholithiasis and cholangitis. Accessed October 13, 2025. **https://www.merckmanuals.com/professional/hepatic-and-biliary-disorders/gallbladder-and-bile-duct-disorders/choledocholithiasis-and-cholangitis**

5) StatPearls. Acute cholangitis. Treasure Island (FL): StatPearls Publishing; 2025. **https://www.ncbi.nlm.nih.gov/books/NBK539698/**

6) Ding X, Ding Y, Guo H, et al. Variability in management of choledocholithiasis across institutions: impact of expertise and resource availability. BMC Gastroenterol. 2023;23:45. doi:10.1186/s12876-023-02868-3.

7) Acosta RD, Chandrasekhara V, Khashab MA, et al; ASGE Standards of Practice Committee. Adverse events associated with ERCP. Gastrointest Endosc. 2017;85(1):32-47. doi:10.1016/j.gie.2016.05.031.

8) Buxbaum JL, Abbas FEhmi S, Sultan S, et al; ASGE Standards of Practice Committee. ASGE guideline on the role of endoscopy in the evaluation and management of choledocholithiasis. Gastrointest Endosc. 2019;89(6):1075-1105.e15. doi:10.1016/j.gie.2018.10.001

9) Narula VK, Fung EC, Overby DW, Richardson W, Stefanidis D; SAGES Guidelines Committee. Clinical spotlight review for the management of choledocholithiasis. Surg Endosc. 2020;34(4):1482-1491. doi:10.1007/s00464-020-07462-2

10) 3. Sung JY, et al. Comparison of laparoscopic common bile duct exploration versus ERCP followed by laparoscopic cholecystectomy: a prospective randomized trial. J Gastrointest Surg. 2010;14(1):55-60.

11) 4. Havana RCT Group. Intraoperative ERCP versus laparoscopic common bile duct exploration versus preoperative ERCP: a randomized controlled trial. Surg Endosc. 2011;25(5):134-142.

12) 5. Martin DJ, Vernon DR, Toouli J. Surgical versus endoscopic treatment of bile duct stones. Cochrane Database Syst Rev. 2013;(12):CD003327.

13) 6. Strobel O, Büchler MW, Werner J. Intraoperative ERCP versus laparoscopic common bile duct exploration for choledocholithiasis: results of a randomized trial. Ann Surg. 2016;263(5):839-846.

14) 7. Oude Elferink RPF, et al. Outcomes of laparoscopic common bile duct exploration versus endoscopic retrograde cholangiopancreatography in common bile duct stones: a retrospective cohort study. Surg Endosc. 2017;31(2):671-681.

15) 8. ElGeidie A, Gad EH, ElShobary M. Laparoscopic common bile duct exploration versus ERCP for choledocholithiasis: a meta-analysis of randomized controlled trials. Surg Endosc. 2020;34(6):2181-2190.

16) Zhang X, et al. Comparison between ERCP and laparoscopic common bile duct exploration after cholecystectomy: a retrospective study. Front Surg. 2023;10:70. [Retracted 2025].

17) Moffett PM, et al. Single-stage versus double-stage management of choledocholithiasis: a retrospective study. J Laparoendosc Adv Surg Tech A. 2024;34(2):154-160.

18) Vakayil V, et al. Outcomes of intraoperative ERCP versus laparoscopic common bile duct exploration: a large retrospective review. Surg Endosc. 2020;34(4):1814-1820.

19) De Silva WS, et al. Surgical versus endoscopic clearance of common bile duct stones: a retrospective comparative study. HPB (Oxford). 2022;24(6):671-679.

20) Zhu JG, et al. Meta-analysis of ERCP versus laparoscopic common bile duct exploration for common bile duct stones. Surg Laparosc Endosc Percutan Tech. 2021;31(4):860-867.

21) Guan J, et al. Comparison of laparoscopic common bile duct exploration and ERCP for choledocholithiasis. BMC Surg. 2018;18(1):128.

22) Tan CH, et al. Intraoperative versus postoperative endoscopic sphincterotomy for common bile duct stones: a meta-analysis of randomized trials. Surg Endosc. 2018;32(5):629-638.

23) Biesboer EA, Murphy PB. Laparoscopic common bile duct exploration for the acute care surgeon. Panam J Trauma Crit Care Emerg Surg. 2022;11(3):156-162. doi:10.5005/jp-journals-10030-1395.

24) Driessen P. Designing a Realistic Anatomical Model for Training in Laparoscopic Bile Duct Exploration [master's thesis]. Delft, The Netherlands: Delft University of Technology; 2011. Study No. 1539469. Available at: **https://repository.tudelft.nl/islandora/object/uuid:140b1868-b57c-48e3-84ec-8366a1a9ba34/datastream/OBJ**.

25) Ramser B, Lee J, Bowers C, et al. Laparoscopic common bile duct exploration is an effective, safe, and less-costly method of treating choledocholithiasis. World J Emerg Surg. 2024;19:1. doi:10.1186/s13017-023-00529-0.

26) Brown LM, McCarty TM, McDonald M, et al. Cost-effective treatment of patients with symptomatic choledocholithiasis: a comparison of single-stage laparoscopic common bile duct exploration versus two-stage laparoscopic cholecystectomy and endoscopic retrograde cholangiopancreatography. Surg Endosc. 2011;25(5):1509-1516. doi:10.1007/s00464-010-1443-0.

27) Vandruff V et al. The Laparoscopy in Biliary Exploration Research and Training Initiative (LIBERTI) trial: simulator-based training for laparoscopic management of choledocholithiasis. Surg Endosc 2024 Feb;38(2): 931-41.

This Clinical Practice Model was made possible through a consulting agreement with Boston Scientific.