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Diagnosis and treatment of common bile duct stones (CBDS)

Results of a consensus development conference

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Abstract
Background: Common bile duct stones (CBDS) are a frequent problem (10–15%) in patients with symptomatic cholecystolithiasis. Over the last decade, new diagnostic and surgical techniques have expanded the options for their management. This report of the Consensus Development Conference is intended to summarize the current state of the art, including principal guidelines and an extensive review of the literature.
Methods: An international panel of 12 experts met under the auspices of the European Association of Endoscopic Surgery (EAES) to investigate the diagnostic and therapeutic alternatives for gallstone disease. Prior to the conference, all the experts were asked to submit their arguments in the form of published results. All papers received were weighted according to their scientific quality and relevance. The preconsensus document compiled out of this correspondence was altered following a discussion of the external evidence made available by the panel members and presented at the public conference session. The personal experiences of the participants and other aspects of individualized therapy were also considered.
Results: Our panel of experts agreed that the presence of common bile duct stones should be investigated in all patients with symptomatic cholecystolithiasis. Based on preoperative noninvasive diagnostics, either endoscopic retrograde cholangiopancreaticography (ERCP) or intraoperative cholangiography should be employed for detecting CBDS. Eight of the 12 panelists recommended treating any diagnosed CBDS. For patients with no other extenuating circumstances, several treatment options exist. Stones can be extracted during ERCP, or either before or (in exceptional cases) after laparoscopic or open surgery. Bile duct clearance should always be combined with cholecystectomy. Evidence for further special aspects of CBDS treatment is equivocal and drawn from nonrandomized trials only.
Conclusions: The management of common bile duct stones is currently undergoing some major changes. Many diagnostic and therapeutic strategies need further study.

Key words: Common bile duct stones — Gallbladder — Bile duct calculi — Laparoscopic cholecystectomy — Endoscopic retrograde cholangiopancreaticography

During the last decade, laparoscopic techniques for abdominal surgery have changed the options for the diagnosis and treatment of many abdominal pathologies. Laparoscopic cholecystectomy has now become the standard procedure

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for removing symptomatic gallbladder stones. New techniques have also been developed for the removal of common bile duct stones (CBDS), which accompany symptomatic gallbladder stones in 10–15% of patients.

A number of different strategies have emerged that combine laparoscopic cholecystectomy with bile duct clearance. There has been a proliferation of publications in this search for a superior or ideal technique. The European Association for Endoscopic Surgery (EAES) recognizes the need to discuss and summarize these controversial developments and to provide practical guidelines based on the current state of knowledge. Bearing in mind the experience of previous consensus development conferences, we decided to use the joint meeting of the EAES and the ELSA (Endoscopic and Laparoscopic Surgeons of Asia) to bring together an international panel of experts in Istanbul.

Methods

In 1996 the EAES decided to hold a consensus development conference (CDC) on CBDS. The Cologne group was authorized by the EAES to organize the CDC according to general guidelines. Twelve internationally known experts were nominated by the Scientific Committee of the EAES. The criteria for selection were clinical and scientific expertise and activity in the diagnosis and/or treatment of CBDS. In order to balance the interests of experts in the areas of surgery, internal medicine, and radiology, panelists from all three specialities were selected.

Prior to the conference, all panelists were asked to survey the literature, list all relevant articles, and estimate the strength of evidence for every article cited. Referring to these articles, the panelists were asked to address the major open questions concerning the management of CBDS. For the five most relevant therapeutic options, they were also asked to comment on the status of each therapy. In regard to the question of laparoscopic common bile duct revision versus endoscopic retrograde cholangiopancreaticography (ERCP) with stone extraction, each panel member was instructed to indicate which technique is superior for several specific situations. All panelists received detailed information on how to answer each section, including a basic description of the CDC process, a scale for ranking the strength of the evidence of medical articles, and a description of levels of technology according to Mosteller [105] and Troidl [164].

In Cologne, all answers were analyzed and subsequently combined into a provisional preconsensus statement. This text was mailed to all panelists a month prior to the Istanbul meeting. The panel members were also informed about the identity of the other members, which had not been previously disclosed.

In Istanbul, all panel members convened for a first meeting on June 18, 1997. Here the provisional statement was scrutinized word by word. The following day, the modified statement was presented to the conference audience for public discussion. During a postconference meeting on the same day, all suggestions made by the audience were discussed by the panelists. Because not all of these questions could be resolved at this time, the chairmen were asked to provide additional literature that would address some of the critical issues. When these points had been cleared and altered in the text, the whole statement was mailed to all the panelists for agreement (Delphi process). In October 1997, the following statement was finalized.

Consensus statement on the diagnosis and treatment of common bile duct stones

General comment

Options for the management of common bile duct stones (CBDS) are increasing with the development of new technologies for diagnosis and treatment. While intraoperative cholangiography and open CBD exploration have comprised the applied technology for decades, the introduction of ERCP with endoscopic stone extraction in the 1970s and the more recent introduction of laparoscopic cholecystectomy led to a reappraisal of the situation. For each management policy, numerous publications—from case reports to prospective controlled clinical trials—are available, but evidence-based conclusions an rarely be achieved yet.

In terms of predictors for CBDS, the crucial issue is perhaps not which indicators should best be applied to detect CBDS, but whether we should favor a high rate of negative examinations or a high rate of retained stones, with all their sequelae. The consequences of either strategy are currently not well understood and are often dependent on the local medical and nonmedical conditions.

Nowadays, new imaging techniques in medicine (e.g., magnetic resonance cholangiopancreaticography [MRCP]) have opened up new options for the diagnosis of CBDS. Furthermore, any debate about procedure and timing of diagnosis of CBDS leads to this question: Should they all be diagnosed?

Any discussion of an optimal therapy for common bile duct stones must take into account the rare but grave complications that each treatment option, may entail.

In general, the optimal diagnostic and therapeutic strategy seems to be dependent on local circumstances and the experience and expertise of the medical team, since there is still no evidence-based gold standard. In addition, ethical and socioeconomic considerations have an important impact on the controversy. For example, the costs of several techniques are prohibitive in some parts of the world.

Question 1. The diagnosis of CBDS

What are good indicators or predictive symptoms/signs for CBDS?

At the time of cholecystectomy for symptomatic cholelithiasis, 8–15% of patients under the age of 60 years and 15–60% of patients over the age of 60 years have CBDS. This prevalence reflects the prior probability of any patient harboring CBDS before any discriminating test. The prevalence of CBDS has a decisive influence on the predictive value of any indicator. The prevalence of CBDS and the threshold for investigating CBDS vary among individual clinicians.

Among the many parameters investigated, no single indicator is completely accurate in predicting CBDS before cholecystectomy. The indicators can be grouped as follows: symptoms and signs, biochemical parameters, and imaging techniques. Although acute pancreatitis or cholecystitis are associated with a higher prevalence of CBDS, there is no good evidence that a history of pancreatitis is an indicator for CBDS.

Table 1 lists the predictive values for the main indicators of CBDS. These data were combined from several primary studies with a meta-analysis [1]. For each individual indicator, the lowest abnormal value is considered to be the threshold. Within a hypothetical population with symptomatic cholelithiasis, a 10% probability (prevalence) of harboring CBDS is assumed. As shown in the example in the table footnote, an individual patient's risk factors can be established by multiplying the relevant positive or negative likelihood ratios.

Table 1. Predictive values of preoperative indicators of CBDs[a]

Indicator	Sensitivity (95%- Cl)	Specificity (95%- Cl)	LR+[b]	LR–[c]
Cholangitis	0.11 (0.02–0.19)	0.99 (0.99–1.00)	18.3	0.93
Preop jaundice	0.36 (0.26–0.45)	0.97 (0.95–0.99)	10.1	0.69
Cholecystitis	0.50 (0.11–0.89)	0.76 (0.45–1.00)	1.6	0.94
Bilirubine ↑	0.69 (0.48–0.90)	0.88 (0.84–0.92)	4.8	0.54
Alkaline Phosph ↑	0.57 (0.46–0.69)	0.86 (0.78–0.94)	2.6	0.65
Amylase ↑	0.11 (0.02–0.20)	0.95 (0.93–0.98)	1.5	0.99
CBDS on US	0.38 (0.27–0.49)	1.00 (0.99–1.00)	13.6	0.70
Dilated CBD on US	0.42 (0.28–0.56)	0.96 (0.94–0.98)	6.9	0.77

Data can be read as follows (line 1, cholangitis):
From 2% to 19% of patients *with* CBDS have cholangitis (defined as the triad pain-fever-jaundice). Nearly all patients who do *not* have CBDS also do *not* have cholangitis (column 2). A patient with CBDS is 18.3 times more likely to have cholangitis. If we assume prior odds to be 1 to 9 (i.e., 10% prevalence), we multiply 1/9 × 18.3 to get 2.03. So the posttest odds are about 2 to 1, which is a 66% probability. However, on the other hand, in a patient without CBDS (column 5), cholangitis is still not unlikely. We receive 1/9.67 posterior odds, or a 9.4% probability.
[a] Data from Abboud et al. [1], reprinted with permission
[b] LR+ = positive Likelihood Ratio
[c] LR– = negative Likelihood Ratio

A cystic duct found to have a diameter >4–5 mm at operation was associated with an increased probability of CBDS (sensitivity, 0.34; PPV, 0.52) in a population of 319 patients with a CBDS prevalence of 12% [59, 61].

In the clinical setting, several groups of patients can be identified, as follows: (a) a *high-risk* group, which fulfills a series of predictive factors resulting in a global probability of CBDS >90% based on the data in Table 1; (b) a *medium-risk* group, or group of uncertainty, which fulfills one or several prognostic factors listed in Table 1 but for whom the resulting posttest probability (although higher than the pretest probability of 10%) does not reach 90%; (c) a *low-risk* group, which has no signs or symptoms. Although their probability of harboring CBDS is below average, in clinical practice unsuspected CBDS are found in ⩽5% of patients with symptomatic gallbladder stones.

Question 2. Diagnostic procedures

Which diagnostic tools are useful in the detection of CBDS?

In what order should they be applied?

Preoperative ultrasonography (US) misses two of three patients with common bile duct stones. However, it is a useful screening tool for the diagnosis of CBDS because of its noninvasiveness, easy availability, and low costs. Of all tools it should be applied as first. It has a reasonable predictive value if the CBD diameter is dilated as an indirect sign for CBDS. According to the literature, the sensitivity of preoperative US is 0.14–0.40, depending on the investigator's experience, the defined threshold value, and the general prevalence. The diagnosis of CBDS is more frequently achieved exclusively in patients with dilated CBD (diameter >8–10 mm). Furthermore, liver or pancreas pathologies are also detectable by this means.

Preoperative intravenous cholangiography (PIC) does not play a major role in the diagnosis of CBDS anymore. PIC has been reevaluated in patients without jaundice, using a new contrast reagent (meglumine iotroxate) with a reported risk of <1% adverse reactions. Infusion yields a satisfactory bile duct opacification in 90–95% of patients. The negative predictive value (NPV) of a normal PIC is 0.98–1. The positive predictive value (PPV) of PIC for CBDS diagnosis was 0.94 for stones demonstrated at PIC but only 0.31 for stones suspected at PIC [16, 57]. Previous studies showed that PIC missed CBDS in an average of 40% of cases (range, 22–90% sensitivity). Therefore, it is not recommended as a routine procedure. It may be an option based on the local circumstances of a center.

Endoscopic retrograde cholangiopancreatography (ERCP) is a valid diagnostic tool (high sensitivity, specificity, accuracy in experienced hands). It should only be applied with the intention to treat in patients with a high probability of CBDS who are eligible for ES. It has to be recognized that the procedure is invasive and inconvenient for the patient. It requires sedation and has defined morbidity (5–10%) and mortality (<1% for diagnostic purpose) rates. The success rate for ERCP is 95%. The sensitivity is 0.84–0.89. Specificity is 0.97–1. PPV is 1 and NPV is 0.88.

Endoscopic ultrasonography (EUS) is another exclusively diagnostic procedure with a high accuracy rate, but currently there is no indication for its routine use in diagnosing CBDS. The sensitivity of endoscopic ultrasound is 93%; specificity is 97%. PPV is 98% and NPV is 88%.

Intraoperative cholangiography (IOC) and *laparoscopic ultrasound* are reliable diagnostic tools (>90% accuracy). Modern equipment and the use of fluoroscopy is required and may increase the accuracy in general practice. However, routine performance for the detection of symptomatic CBDS is questionable, although some of our panelists did recommend it. No final consensus was achieved regarding this point. The decision to perform routine or selective IOC during cholecystectomy depends both on the physician's personal beliefs regarding asymptomatic CBDS and his or her individual strategy for treatment. Reasons other than detection of CBDS for performing IOC, such as clarification of biliary anatomy, were considered outside the scope of the consensus. Invasive preoperative diagnostic tests should be avoided in patients scheduled for elective cholecystectomy.

Magnetic resonance cholangiopancreaticography (MRCP) seems to be an excellent diagnostic tool with high accuracy rates, so it might supersede other invasive diagnostic procedures such as ERCP. Disadvantages include inconvenience for the patient, low availability, and high costs. Furthermore, it is not applicable in every case (morbid obesity, pacemaker, etc.). In a first study from Italy [89], MRCP showed 91.6% sensitivity, 100% specificity, and an overall diagnostic accuracy of 96.8%.

Computer tomography (CT) has been evaluated only in biased populations. It plays no role in routine management.

All patients with symptomatic gallbladder stones need to be assessed for CBDS, and the treatment of all diagnosed CBDS is mandatory (eight of 12 panelists were in favor of it). There are three options:

- Routine IOC requires no preoperative screening for CBDS. The rate of useless examinations is in correspon-

Table 2. Results of six prospective randomized trials comparing preoperative ERC/ES with open surgery alone for CBDS

	Surgery	Preop ERC/ES
Total number of patients	302	283
Endoscopic failures		15 (5%)
Successful primary extraction	275 (91%)	233 (82%)
Complications (range)		
Major	8% (4–15%)	8% (4–10)
Minor	15% (8–15%)	10% (6–17)
Total	23% (18–31%)	19% (12–26)
Deaths	4 (1.3%)	8 (2.8%)
Residual stones (range)	4.9% (2–12)	3.4% (0–12)

[a] See Neoptolemos et al. [107], Stain et al. [151], Stiegmann et al. [154], Hammarström et al. [56], Targarona et al. [160], and Association universitaire de recherche en chirurgie [6]

dence with the prevalence of CBDS in the population scheduled for cholecystectomy.

- Selective contraindication for IOC is based on the negative predictive value of indicators for CBDS. It allows a 30–50% reduction in the number of IOC and yields a 2–3% rate of missed CBDS [61, 70].
- Selective indication for IOC is based on the positive predictive value of preoperative indicators for CBDS. It limits its diagnosis and treatment to preoperatively symptomatic CBDS. Limitations are related to the information provided by the predictors and uncertainty regarding the natural history of asymptomatic CBDS.

Question 3. Timing of diagnostics

When should CBDS by diagnosed?

The timing of diagnostics should be dependent on the status of the patient and the preferred treatment modality of the center—pre- or intraoperatively. A routine policy of postoperative diagnoses of patients with preoperative suspicion for CBDS is not advisable, since it entails the risk of a second operative intervention.

Question 4. Timing of treatment

Should CBDS be treated before, during, or after cholecystectomy?

Depending on the clinical status of the patient, treatment can be performed before or during surgery. The policy of the specific center, as well as the experience and expertise of the medical team, may affect the choice of treatment modalities yet yield similar results (Table 2). Postoperative treatment of CBDS is only necessary if intraoperative clearance of the common bile duct fails or if patients develop symptoms of retained stones.

Question 5. Standard treatment

Which is the best treatment for CBDS and what is the appropriate surgical procedure for CBDS with gallbladder in situ?

There is no standard treatment today. In principle, three treatment regimens are available: endoscopic stone extraction during ERCP, laparoscopic bile duct exploration, and open bile duct exploration (Table 3). There is no strong evidence from controlled trials that one procedure is superior to another in experienced hands (Table 4). The majority of panel members saw no advantages to laparoscopic surgery over ERCP in terms of intraoperative safety, postoperative complications, mortality, pain, hospital stay, return to work, or cosmesis.

Laparoscopic bile duct exploration or a combination of endoscopic stone removal and laparoscopic cholecystectomy might be better than open surgery in terms of such aspects as less pain and faster recovery.

The laparoscopic transcystic approach and laparoscopic choledochotomy are feasible. For ASA I/II patients, they might be preferable to preoperative ERCP and endoscopic sphincterotomy (ES) followed by laparoscopic cholecystectomy, since they shorten the duration of hospital stay.

Question 6. Treatment in special situations

Should asymptomatic CBDS be treated?

Because of the impredictibility of the occurrence of symptoms or complications, diagnosed stones should be treated in all cases. It is additionally an ethical problem to knowingly leave stones behind. However, an expectant management for CBDS is acceptable in high-risk patients (ASA III/IV) and patients unfit for surgery. These patients may benefit from endoscopic treatment alone.

What is the appropriate treatment for large and/or impacted CBDS?

Large and/or impacted stones are a rare and ill-defined condition. Their treatment is usually difficult and depends on individual expertise. Options include:

- Endoscopic treatment (with the adjunct of lithotripsy)
- Primary surgery (laparoscopic or open approach with the adjunct of intraoperative lithotripsy and/or hepaticojejunostomy)
- Extracorporeal shockwave lithotripsy (ESWL) with or without ES

How should CBDS in cholecystectomized patients be managed?

All such patients should be first treated by endoscopy, if feasible, including lithotripsy as required. There is as yet no evidence that endoscopic sphincterotomy or dilation of the sphincter performed in younger patients has a long-term negative outcome with higher rates of cholangitis, papillary stenosis, or other sequelae.

Question 7. Cholecystectomy

Is cholecystectomy always compulsory in patients with CBDS?

Available data suggest that cholecystectomy should be recommended in patients with CBDS. In patients with major risk factors for surgery or in elderly patients, an individual management policy—e.g., leaving the gallbladder in situ—

Table 3. Evaluation of the status of CBDS therapy in 1997: strength of evidence[a]

Stages in technology assessment[b]	ERCP	Open surgery	Laparoscopic surgery	ESWL	Transhepatic approach
Feasibility	III	III	III	III	0–I
Benefit for patient	III	III	III	III	0
Benefit for surgeon	III	III	I–III	0–III	0
Effectiveness	II	III	II	0–I	0–I
Costs	III	0–I	0–II	0–I	0
Ethics	III	III	III	I–III	0
Recommendations	yes	yes	yes	no	no

[a] Grading of scientific evidence was done using the scale explained in Table 4 (III = strong evidence, 0 = no evidence)
[b] See Mosteller [105] and Troidl [164]

Table 4. Ratings of the literature on CBDS: strength of evidence

Study design	Strength of evidence	References
Clinical randomized controlled trial with power and relevant endpoints	III	5, 6, 14, 24, 28, 35, 37, 44, 49, 52, 56, 60, 61, 77, 79, 81, 83, 86, 91, 103, 106, 107, 108, 109, 110, 112, 113, 118, 127, 134, 135, 141, 143, 146, 149, 150, 151, 152, 154, 157, 159, 160, 168
Prospective studies with parallel or historical controls	II	2, 3, 4, 7, 8, 10, 11, 13, 15, 16, 17, 18, 19, 20, 21, 23, 25, 26, 27, 29, 30, 31, 32, 33, 34, 36, 38, 39, 40, 41, 42, 43, 45, 46, 47, 48, 50, 51, 53, 54, 55, 57, 58, 59, 62, 63, 64, 65, 66, 67, 68, 69, 71, 72, 73, 74, 75, 76, 79, 80, 84, 85, 87, 88, 89, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 104, 114, 115, 116, 117, 119, 120, 121, 122, 123, 124, 125, 126, 128, 129, 130, 131, 132, 133, 134, 136, 137, 139, 140, 142, 143, 144, 145, 147, 148, 153, 155, 156, 158, 161, 162, 163, 165, 166, 167, 169, 170, 171, 172, 173, 174, 175
Case-control studies		
Cohort studies with literature controls	I	numerous, not evaluated
Database analyses		
Reports of expert committees		
Uncontrolled trials	0	numerous, not evaluated
Case reports, case series		
Belief		

can be justified. In Oriental cholangitis and in patients without gallbladder stones, cholecystectomy is usually not indicated after clearance of the common bile duct.

Question 8. Consequences of therapy

What are the long-term results and sequelae of therapeutic interventions?

For both endoscopic sphincterotomy and open surgical common bile duct exploration, the long-term complication rates are reported to be in the same range (<10%), and the procedures have a high success rate in experienced hands. There are no data on the long-term complication rate of laparoscopic bile duct exploration.

Closing remarks

The closing remarks were delivered by J. Périssat, of France:

- The emerging success of MR cholangiopancreaticography, which has provided an excellent roadmap for the surgeon, should help to stem the debate over the diagnostic purpose of ERCP.
- The general population of surgeons should be brought up to date about the technology of laparoscopic bile duct exploration; furthermore, additional research is urgently needed.
- There should be a follow-up on the results of this conference in the year 2000.

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