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GUIDELINES

Prevention and treatment of bile duct injuries during laparoscopic cholecystectomy: the clinical practice guidelines of the European Association for Endoscopic Surgery (EAES)

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Abstract
Background Laparoscopic cholecystectomy is one of the most common surgical procedures in Europe (and the world) and has become the standard procedure for the management of symptomatic cholelithiasis or acute cholecystitis in patients without specific contraindications. Bile duct injuries (BDI) are rare but serious complications that can occur during a laparoscopic cholecystectomy. Prevention and management of BDI has given rise to a host of publications but very few recommendations, especially in Europe.

Methods A systematic research of the literature was performed. An international expert panel was invited to appraise the current literature and to develop evidence-based recommendations. Statements and recommendations were drafted after a consensus development conference in May 2011, followed by presentation and discussion at the annual congress of the EAES held in Torino in June 2011. Finally, full guidelines were consented and adopted by the expert panel via e-mail and web conference.

Results A total of 1,765 publications were identified through the systematic literature search and additional

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submission by panellists; 671 publications were selected as potentially relevant. Only 46 publications fulfilled minimal methodological criteria to support Clinical Practice Guidelines recommendations. Because the level of evidence was low for most of the studies, most statements or recommendations had to be based on consensus of opinion among the panel members. A total of 15 statements and recommendations were developed covering the following topics: classification of injuries, epidemiology, prevention, diagnosis, and management of BDI.

Conclusions Because BDI is a rare event, it is difficult to generate evidence for prevention, diagnosis, or the management of BDI from clinical studies. Nevertheless, the panel has formulated recommendations. Due to the currently limited evidence, a European registry should be considered to collect and analyze more valid data on BDI upon which recommendations can be based.

Keywords Guidelines · Laparoscopy · Bile duct injury · Cholecystectomy

Laparoscopic cholecystectomy is one of the most common surgical procedures in Europe (and worldwide). It has become the standard procedure for the management of symptomatic cholelithiasis or acute cholecystitis in patients without specific contraindications.

Bile duct injuries (BDI) are rare but serious complications that can occur during a laparoscopic cholecystectomy. BDI are associated with high postoperative morbidity and mortality as well as with reduced quality of life, especially when they are unrecognized.

Prevention, diagnosis, and management of BDI have given rise to a host of publications but very few recommendations, especially in Europe. For these reasons, the European Association for Endoscopic Surgery (EAES) decided to develop statements and recommendations regarding the prevention, diagnosis, and management of BDI. Clinical Practice Guidelines (CPG) are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options [1].

Materials and methods

The EAES scientific committee commissioned a methodological expert team (EN, ME, DP, TJ) to analyze the current evidence and coordinate the guideline development process with the intention to develop recommendations. An international expert panel consisting of surgeons and research scientists was constituted. Experts were selected according to their scientific and clinical expertise as well as their geographical localization.

The methodological expert team was responsible for the literature search, the critical appraisal of literature, the data extraction, the moderation of the consensus conference, and writing of guidelines. Furthermore, the methodological experts designated the selection of topics and key questions. Based on their clinical knowledge and experience, the clinical experts' contribution involved further selection of topics and key questions, a complementary literature review, the submission of additional relevant evidence, the discussion and formulation of the recommendations, the presentation and discussion of the recommendations, and the review and comments on the draft version of the guidelines before consenting to the final version, presented herein.

Selection of topics and research questions

The list of key clinical issues derived according to a formal consultation process was presented to the expert panel. A set of 15 key questions was developed and consented by the panel members. Where appropriate, the key questions were refined once the evidence had been searched or additional questions were generated.

Systematic literature search

An initial scoping search for published guidelines, systematic reviews, and health technology assessments was performed to identify current relevant guidelines and to identify relevant words and terms for the search strategy in the following databases as well as on websites: Guidelines International Network (GIN), National Guidelines Clearinghouse (NGC), Cochrane Database of Systematic Reviews (CDSR), Health Technology Assessment Database (HTA), and MEDLINE.

A systematic literature search was conducted in the electronic databases: MEDLINE (via PubMed) and Cochrane Library. No restrictions regarding the publication date were applied to the search. The initial search was conducted on February 18, 2011, an updated search on June 21, 2011. Further details of the search strategy are provided in "Appendix 1" section.

Literature selection

Publications (primary studies and secondary literature) identified during the literature searches were reviewed to exclude duplicates and identify the most appropriate data to address the key questions.

The remaining publications were selected for inclusion in the guideline adopting the following inclusion criteria:

1. Population: adult patients with BDI during laparoscopic cholecystectomy
2. Population (for single-arm cohort studies): less than 20 % of the patients had an open procedure and a subgroup analysis was done for the laparoscopic group
3. Language: English or German
4. Publication type: systematic review, randomized controlled trial, controlled clinical trial, cohort study, case control studies, case series $\geq$6 patients
5. Full text of the publication is available

The selection process was performed in a two-step procedure. First, the titles and abstracts of the retrieved citations were scanned to exclude all publications that were clearly not relevant to the guideline topic or the key questions. The remaining abstracts were checked against the inclusion criteria. Next, full versions of the potential eligible studies were acquired for assessment and checked against the inclusion criteria. Two reviewers performed the selection process independently. Any discrepancies regarding the inclusion were resolved in a discussion. In the case of insolvable inconsistency, a third reviewer was involved in the discussion.

Critical appraisal of literature

The study quality of relevant publications was assessed using the study-type-specific methodology checklists for primary studies by NICE [2] and the AMSTAR-instrument for systematic reviews [3, 4]. Two reviewers independently assessed the studies. Any disagreements were resolved in a discussion. In the case of insolvable inconsistency, a third reviewer was involved in the discussion. Based on the assessment of study quality, the levels of evidence (LoE) were determined by using the Oxford Centre for Evidence-based Medicine (CEBM) LoE-table (Version 2009).

Formulating recommendations and consensus process

All recommendations were graded according to the quality and quantity of the underlying scientific evidence, the risk–benefit balance, and the values expressed by the panelists. The grades of recommendations ranged from A to D:

A Consistent level 1 studies
B Consistent level 2 or 3 studies or extrapolations from level 1 studies
C Level 4 studies or extrapolations from level 2 or 3 studies
D Level 5 evidence or inconsistent or inconclusive studies of any level

In case of limited or lacking data to support a recommendation, the panel decided that the grade of recommendation could be higher than the evidence would ordinarily allow for. Furthermore, for some recommendations, there was a need to modulate and weigh the evidence locally according to value judgments, priorities, and local conditions.

Based on the identified studies and the assessment of study quality, the expert panel formulated statements and draft recommendations. The statements and recommendations were discussed and consented in a consensus conference (May 20–21, 2011) and thereafter presented by members of the panel at the annual congress of the EAES in Torino, June 16, 2011 in a 90-min plenary session. Comments were taken from the audience after discussion and considered in the further process.

The strength of consensus was classified according to the percentage of agreement (Table 1). After drafting the final consensus of the statements and recommendations, the full guideline was consented and adopted by the expert panel via e-mail and web conference.

Results

A total of 1,735 publications were identified through the systematic literature search, 30 further publications were identified through an additional database research and the submission by panelists. After exclusion of duplicates and screening of titles, abstracts, and full texts 671 publications were selected as potentially relevant. Most of these trials were observational studies without control group. Only 46 publications fulfilled minimal methodological criteria to support Clinical Practice Guidelines recommendations: 5 systematic reviews [5–9]; 18 randomized controlled trials (RCT) [10–27]; 10 nonrandomized, controlled, clinical trials (CCT) [28–37]; and 13 two-armed cohort studies [38–50]. Furthermore, 625 studies (mostly single-arm cohort studies and case series) were analyzed for additional information for guideline development (see "Appendix 2" section). A detailed flow chart of the systematic literature search and the selection process is given in Fig. 1.

As a result of the systematic literature search and the appraisal of the literature, we concluded that there is only limited evidence from clinical studies to support CPG recommendations. Most of the publications had

Table 1 Classification of consensus

Strength of consensus	Percentage of agreement
Strong consensus	>95 % of participants
Consensus	75–95 % of participants
Majority	50–75 % of participants
No consensus	<50 % of participants

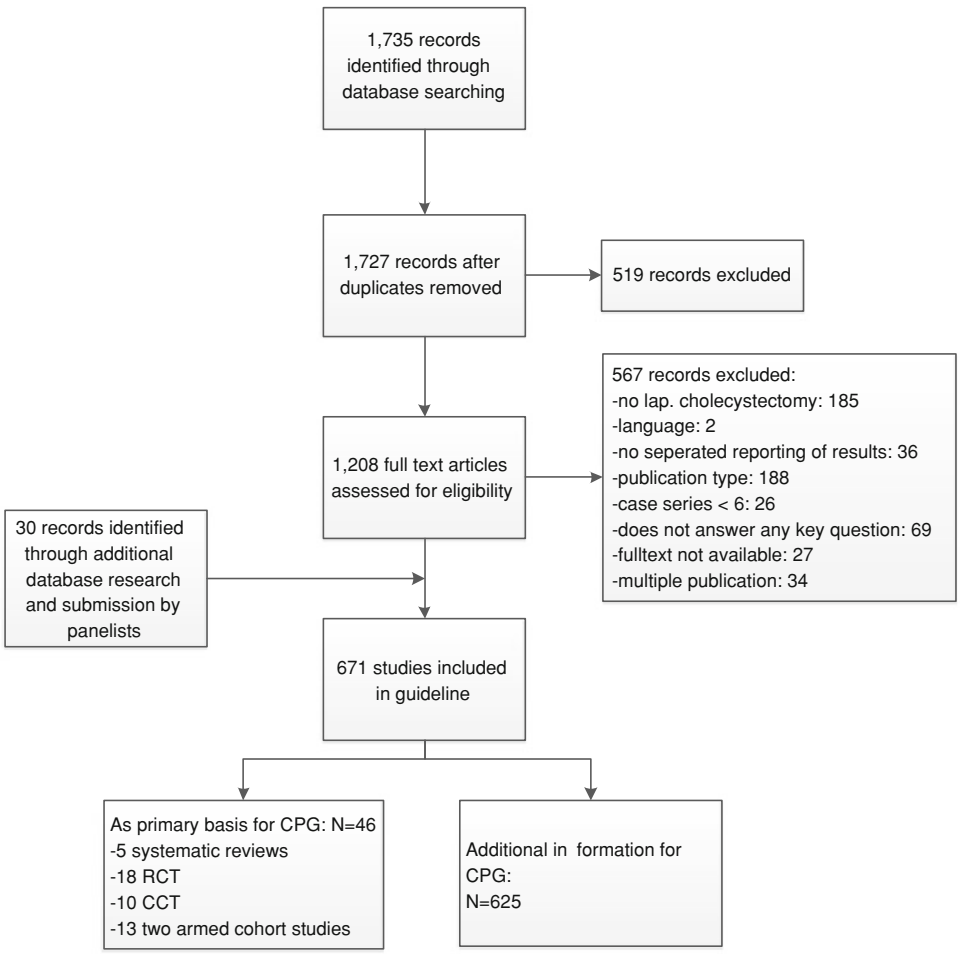

Fig. 1 Flow chart: literature search and selection process

shortcomings regarding the methodological quality. For a number of key questions, no single publication could be identified. As in other areas of low or absent evidence, this led to rely heavily on expert opinion in formulating the recommendations.

Recommendations and statements

Classification of injuries

Various classification schemes have been used to classify BDI. They reflect anatomical type, type of division, vascular involvement, detection (intraoperative, postoperative leak, stricture), and etiopathogeneses to different degrees. All of the classifications have strong positive points but also weaknesses. Therefore, the panel decided to formulate a new comprehensive classification scheme, based on the existing classifications.

According to the EAES-classification BDI are graded on the basis of the following criteria:

(1) Anatomical location on biliary tree (1 to 6)

- Type 1: main bile duct injury ≥2 cm distal to inferior border of superior hepatic confluence
- Type 2: main bile duct injury <2 cm distal to inferior border of superior hepatic confluence
- Type 3: main bile duct injury involving superior hepatic confluence but communication left right preserved
- Type 4: main bile duct injury involving superior hepatic confluence but communication left right interrupted
- Type 5: left or right hepatic duct without lesion of the superior confluence
- Type 6: non-main bile duct injury including hepatic bed, aberrant, accessory ducts

(2) Type of division: complete (C), major (M) (>25 % of diameter) vs. partial (P) (minor (m) <25 % of diameter)

(3) According to whether a concomitant vascular lesion occurred (V +, V −)

(4) According to whether loss of substance (length) occurred LS +, LS−

Table 2 Comparison of BDI classification schemes

	Anatomical type	Type of division (C, M, P, LS)	Vascular	Detection (intraoperative postoperative leak, stricture)	Pathogenesis
Bismuth	+	–	–	–	–
McMahon	±	+	–	–	–
Strasberg	+	+	–	–	–
AMA (Bergman)	+	+	–	–	–
Neuhaus	+	+	–	±	–
Csendes	+	±	–	±	+
Stewart-Way	+	+	+	+	+
Lau	+	+	+	–	–
EAES	+	+	+	+	+

(5) According to time of detection: during operation (Ey), early postoperative bile leak (E), late (S = stricture)
(6) According to etiopathogenesis: mechanical division (e.g., scissors) (M), energy driven (e.g., electric (E), ischemic (whether secondary to vascular injury or energy-related) (I)
(7) According to whether occlusion (O) (ligation, clip) or leak (L)

In Table 3, a matrix for the classification of bile duct injuries according to the EAES scheme is shown. Table 2 summarizes the classification criteria of the most common classification schemes compared with the new EAES classification.

Epidemiology

Key question 1.1 What is the event rate for BDI during laparoscopic cholecystectomy (LC) (compared with an open approach)?

The risk of BDI in LC has drawn wide attention from the beginning of the laparoscopic era.

In the present systematic literature search, the authors identified only two small, randomized, controlled trials [14, 19] with data on BDI. Furthermore, a number of case series and—mostly retrospective—cohort studies were identified. Due to the study design and/or small populations, the information on event rates of BDI of these studies was not considered valid.

A systematic review consisting of 45 studies with 2,626 patients identified a BDI rate of 0.72 % for single incision laparoscopic cholecystectomy performed in the absence of acute cholecystitis (90.6 %) [51].

In addition, data from registries are available. In Germany, the Institute for Applied Quality Improvement and Research in Health Care GmbH (AQUA) is commissioned by the Federal Joint Committee to collect and analyze data for quality assurance and publishes the "German Hospital Quality Report" annually [52]. In 2010, 172,368 cholecystectomies were reported for reasons other than malignant diseases of the gallbladder or bile ducts, approximately 90 % of all cases were performed laparoscopically. Overall (laparoscopic and open approach) an "Occlusion or transection of the CHD" was registered in 177 operations (0.1 %), the reintervention rate for all reasons (including BDI) was 0.9 %. The rate of at least one intervention-specific complication requiring treatment after laparoscopically initiated surgery in 2010 was 2.4 %.

According to data from the Danish Cholecystectomy Database in Denmark, 28,379 patients underwent a cholecystectomy between 2006 and 2009, with complete registration data in 24,240 patients [53, 54]. A laparoscopic

Table 3 EAES classification matrix for bile duct injuries

Anatomical type	Type of division				Vascular		Detection			Pathogenesis			Type of injury	
	C	M	P (m)	LS	Yes	No	D	Ey	S	M	En	I	O	L
1														
2														
3														
4														
5														
6														

procedure was started in 23,672 patients (97.7 %). In 21,626 patients the procedure was completed laparoscopically (92.6 %). A reconstructive bile duct surgery within 30 days had to be conducted in 0.1 % (2007) to 0.25 % (2008), another bile duct surgery within 30 days had to be conducted in 0.11 % (2009) to 0.19 % (2007).

In a large retrospectively analyzed Finnish cohort [55], 75 BDI were encountered in a total of 8,349 cholecystectomies (1,616 open and 6,733 laparoscopic cholecystectomies), which means an overall BDI incidence of 0.9 %. Twenty BDI occurred in open cholecystectomy (incidence rate: 1.24 %) and 55 in laparoscopic cholecystectomies (incidence rate 0.82 %). For the open approach, most injuries were minor (15/20): during laparoscopic cholecystectomies 26 of 55 injuries were classified as minor, and 29 of 55 as major BDI (14 of them with complete transection or excision of common bile duct). In conclusion, OC was associated with a higher number of BDI but mostly classified as a minor BDI. LC was associated with less but more severe BDI [55].

In a recent publication medical record from Kaiser Permanente Northern California (KPNC), data from 83,449 patients who underwent laparoscopic cholecystectomy (LC) between 1995 and 2008 were analyzed retrospectively. The incidence rates were contrasted with the results from the Nationwide Inpatient Sample (NIS). In the KPNC patient sample, a cumulative BDI rate of 0.04 % was found, for the NIS a cumulative BDI rate of 0.11 %. For the KPNC sample, types of injuries were analyzed. The authors found a trend toward more major injuries approaching the hilum and fewer distal or minor injuries but no significant differences [56].

Today, the laparoscopic approach has become the standard procedure and the open approach more often is used for difficult patients.

Statement 1.1 Following the introduction of laparoscopic cholecystectomy, the literature pointed out to an increase in the incidence of BDI.

(Strong consensus)

Key question 1.2 What is the event rate for BDI during conventional laparoscopic cholecystectomy compared to alternative endoscopic techniques?

Recently developed techniques in laparoscopic surgery as "Single Incision Laparoscopic Surgery" (SILS) or "Natural Orifice Translumenal Endoscopic Surgery" (NOTES) are performed in selected patients. In particular, NOTES is an endoscopic surgical technique for which only limited evidence from clinical studies [9, 22] or small registries [57] regarding the event rates of BDI is available until now. Therefore, no conclusions could be made regarding this question.

Statement 1.2 Because there is currently no high-quality clinical evidence, the EAES cannot conclude that the incidence of BDI in alternative endoscopic techniques is less or greater than conventional laparoscopic cholecystectomy.

(Strong consensus)

Key question 1.3 Do alternative endoscopic techniques increase the risk for BDI?

As stated in the key question, no data from high-quality clinical studies for alternative endoscopic techniques are available. In the German Hospital Quality Report 2010, it is stated: "The risks of more recent procedures wherein surgical access is gained by natural orifice translumenal endoscopic surgery (NOTES), for instance, through the vagina, cannot yet be estimated with certainty" [9].

There is some evidence for needlescopic, miniport, or 3-port laparoscopic cholecystectomy compared with 4-port technique [8, 20, 27], but the study populations and therefore the rates of BDI were too small to answer the key question under consideration.

Statement 1.3 Because there is currently no high-quality clinical evidence, the EAES cannot conclude that the incidence of BDI in NOTES and single-port cholecystectomy is less or greater than conventional laparoscopic cholecystectomy.

(Strong consensus)

Prevention

Key question 2.1 What are the patient risk factors for BDI?

Key question 2.2 Which factors (related to surgical technique) can decrease the risk for BDI?

Key question 2.3 What are the indications for the conversion to an open approach to avoid BDI?

Studies differ for the reported patient or local risk factors for BDI. Age, sex, acute cholecystitis, impacted gallstone within the Hartman pouch or a short or inexistent cystic duct, anatomical variations of biliary or vascular system, thickened gallbladder wall and dilated common bile duct, severe chronic scarring of the gallbladder, bleeding in the Calot triangle obscuring the operative field, previous (upper) abdominal surgery and adhesions, and duration of the operative procedure have been mentioned as risk factors for BDI. Nevertheless, due to the small number of cases, it is not possible to provide clear data for the relevance of these factors for BDI. Data from the registry of the Swiss Association of Laparoscopic and Thoracoscopic Surgery

(SALTS) showed no significant difference in risk of BDI for acute versus chronic inflammation. An increased risk was found in male compared with female patients. However, the participation in the study was voluntary and only 65 % of surgeons contributed [58].

Although there is only limited evidence from clinical studies to back this technique, the panel recommends performing the critical view of safety as follows [59–61]:

- The critical view of safety can be achieved with the 0°, 30°, or 45° optics. However, the common bile duct (CBD) is more difficult to see with the 0° telescope, because it lies parallel to the scope and it is partly hidden behind the duodenal bulb. Moreover, 360° rotation of the 30° or 45° scope provides different angles of visualization of the surgical field and offers the surgeon more information for safe dissection throughout the procedure. Therefore, the use of an angled forward oblique viewing telescope is recommended.
- Firm cephalic traction on the fundus of the gallbladder toward the patient's right shoulder to reduce redundancy in the infundibulum of the gallbladder.
- Lateral and caudal traction on Hartmann's pouch to place the cystic duct perpendicular to the CBD.
- Visual identification of the supraduodenal CBD without dissection, Dissection starts with an incision on the peritoneum of the infundibulum of the gallbladder, *not directly on what is presumed to be the cystic duct*, either on the lateral or more commonly on the medial aspect of the infundibulum near its reflection on the liver parenchyma.
- Dissection then proceeds alternately on the lateral and medial aspects of the gallbladder toward the cystic duct, with an alternate movement exerted on Hartmann's pouch by the grasper holding it on either side (flag technique).
- Dissection may be accomplished by any instrument according to surgeon's preference (hook, scissors, dissector, ultrasonic dissection).
- To avoid thermal damage, monopolar electrocautery should be used sparingly, and with short bursts (1-2 s).
- Attention is warranted not to place the active blade of alternative energy sources, such as ultrasonic dissection, in contact with the bile duct structures, again to avoid thermal damage.
- Dissection continues until the infundibulum is completely lifted off the liver bed.
- The next step is to clear the triangle of Calot of fat, small vessels, and lymphatics, bridging the gap between the cystic duct and artery. Achievement of the CRITICAL VIEW of SAFETY is completed when only two tubular structures—the cystic duct and artery—are identified joining the gallbladder. Cloquet's node may be used as a landmark for the cystic artery.
- The surgeon should always be aware of the possible existence of a variety of ductal and vascular aberrations.

If at this step of the surgical procedure the surgeon does not achieve the critical view of safety, it is advisable:

1. To reevaluate the anatomical landmarks
2. To proceed with further dissection of the gallbladder body off the liver bed
3. To reexplore Calot's triangle closer to the infundibulum in an attempt to achieve the critical view
4. Intraoperative cholangiography or laparoscopic ultrasonography both provide valuable anatomic information. They should be employed liberally whenever the surgeon has any doubt about the anatomy and to provide permanent documentation
5. Consider fundus-first dissection
6. Consider subtotal cholecystectomy, in cases with an important scarring and difficult dissection
7. Consider conversion.

The surgeon should proceed with ligation only when the cystic duct and artery are clearly identified and encircled. The use of metal clips, absorbable clips, or ties is up to the individual preference of the surgeon. Once the artery and cystic duct are divided, the surgeon should rule out the presence of further tubular structures before proceeding with the separation of the gallbladder from the liver bed. During dissection of the gallbladder from the liver bed, the surgeon should carefully look for accessory (Luschka) ducts. These ducts should be ligated and not just divided with electrocautery to avoid postoperative bile leakage. Any open subvesicular duct should be treated with sutures. Any thin continuous tubular structure running on the liver bed should be opened. If it bleeds, it can be diathermed. If it is of biliary origin (Luschka duct), it should be ligated.

Statement 2.1 Surgeons should be aware that anatomical biliary tract and vascular variations are frequent. Such variations are considered risk factors if they cannot be properly identified and dealt with.
Pathological risk factors include the impacted Hartmann's pouch stone, impacted cystic duct stones, the Mirizzi syndrome or inflammatory changes that make identification of the anatomy difficult.

(Strong consensus)

Recommendation 2.2 Optimal exposure to reach the critical view of safety is highly recommended. GoR A

(Strong consensus)

Recommendation 2.3 Inability to reach the critical view of safety and/or to identify the source and safely control bleeding are indications for conversion. GoR A

(Strong consensus)

Key question 2.4 Is the surgeon's experience a risk factor for BDI?

Key question 2.5 Can structured training reduce the rate of BDI?

Shortly after the introduction of laparoscopic cholecystectomy, the rate of BDI were more commonly reported early in each surgeon's experience [62]. Studies have been performed to evaluate the effect of training programs to the complication rate in laparoscopic cholecystectomy, especially BDI [37, 63]. Since this time, the laparoscopic approach has become the standard procedure, and young surgeons become familiar with this approach from the beginning of their education. The rate of BDI seems to have decreased and remains apparently constant. The authors could not identify more current clinical studies dealing with the influence of surgeon's experience on the complication rate or the impact of training programs. Therefore, no current evidence exists for the role of surgeons experience or the impact of training programs. Data from the registry of the Swiss Association of Laparoscopic and Thoracoscopic Surgery (SALTS) showed no significant difference in risk of BDI according to surgeon's laparoscopic experience [58].

Statement 2.4 Although BDI can occur even in the hands of expert surgeons, inadequate experience is a risk factor.

(Strong consensus)

Recommendation 2.5 EAES recommends supervised structured training starting with skills courses. GoR B

(Majority)

Key question 2.6 Can intraoperative cholangiography prevent BDI?

IOC allows efficient clarification of bile duct anatomy.

For the patients analyzed for the registry of the Swiss Association of Laparoscopic and Thoracoscopic Surgery (SAL TS), IOC was performed in 36.6 % of the patients. The frequency of IOC decreased from 37.1 % (1995) to 30.1 % (2005), whereas IOC was less commonly used in the group of surgeons with an intermediate level of experience. There was no significant difference in incidence of BDI in the groups with or without the use of IOC [58]. A systematic review consisting of eight RCT did not demonstrate any benefit in preventing BDI by using IOC [64]. In contrast, another systematic review based on five trials showed a protective effect of IOC on BDI during cholecystectomy [65].

Recommendation 2.6 The use of routine IOC in the prevention of BDI is controversial; therefore, the panel cannot recommend routine IOC based on the current literature. However, the panel strongly agreed that IOC allows early identification of BDI as long as it is correctly interpreted. GoR B

(Consensus for the first, strongly for the second)

Key question 2.7 Can intraoperative laparoscopic ultrasound prevent BDI?

The effect of intraoperative laparoscopic ultrasound (IOUS) on the rate of BDI was evaluated in several studies [38, 66–70]. Due to limitations in study design and/or only a small event rate the evidence is not sufficient to base any recommendations on it. Therefore, the panel only formulated a statement.

Statement 2.7 Laparoscopic ultrasound can be helpful in clarifying bile duct anatomy.

(Strong Consensus)

Diagnosis

Patients with BDI can present with the injury intraoperatively, soon after the cholecystectomy or delayed, weeks to months after the injury.

Key question 3.1 Which diagnostic investigations are indicated to confirm a suspected BDI intraoperatively?

No evidence was identified from clinical studies regarding the diagnostic value or the diagnostic or therapeutic impact of different diagnostic procedures.

The panel recommends suspecting a BDI whenever bile is observed in the operative field.

Recommendation 3.1 In case of suspected BDI, whether or not there is a bile leakage, IOC must be performed.

If an IOC cannot be accomplished safely, a subhepatic drain must be inserted and the patient must be referred to an expert of a hepatobiliary unit.
GoR A

(Strong Consensus)

Key question 3.2 How is suspected BDI after surgery handled?

Key question 3.3 Which diagnostic investigations/interventions are indicated postoperatively in case of suspected BDI?

Symptoms that are associated with leakage of bile into the abdominal cavity are: persistent pain, fever or hypothermia, nausea, vomiting, rigidity, or abnormal liver function (jaundice, laboratory parameters) after laparoscopic cholecystectomy. Patients who continue to complain about symptoms that do not improve should be suspected to have BDI. Standard laboratory parameters of cholestasis can be elevated in both partial or total occlusion of the bile duct. They remain elevated in case of total occlusion (>10 days) but can decrease to normal ranges after 10 days in case of partial occlusion of the bile duct.

Ultrasonography or computed tomography is the primary investigation method to detect intra-abdominal fluid in case of BDI. Both methods can be combined with guided drainage. Endoscopic retrograde cholangiography (ERC) should be performed as an emergency procedure to evaluate the biliary tree. ERC offers the possibility of simultaneous therapy, such as stenting or dilation, and can be the definitive therapy in more than half of the cases. In the case of complete obstruction, the proximal part of the biliary tree may be visualized by percutaneous transhepatic cholangiography (PTC). MRCP can give valuable information on intrahepatic biliary tree, not visible by ERC or PTC. Adequate mapping is essential before any therapeutic action.

Recommendation 3.2 Any deviation from an uneventful postoperative course, even after discharge or after 30 days postoperative must be investigated.
GoR A

(Strong Consensus)

Recommendation 3.3 Primary investigation methods are ultrasound and contrast enhanced computerized tomography to detect intra-abdominal fluid.

Whenever found, intra-abdominal collections should be drained immediately and analyzed.

If bile contents are found, ERCP should be done as an emergency procedure to evaluate the biliary tree. Simultaneous therapy, such as stenting or dilatation, is feasible and could possibly be the definitive therapy in half of the cases. Sphincterotomy should not be performed.

If complete obstruction is found, the proximal part of the biliary tree may be visualized by percutaneous transhepatic cholangiography or magnetic resonance cholangiography.
GoR A

(Strong Consensus)

Management

Key question 4.1 What are the indications for conversion to an open approach in case of BDI?

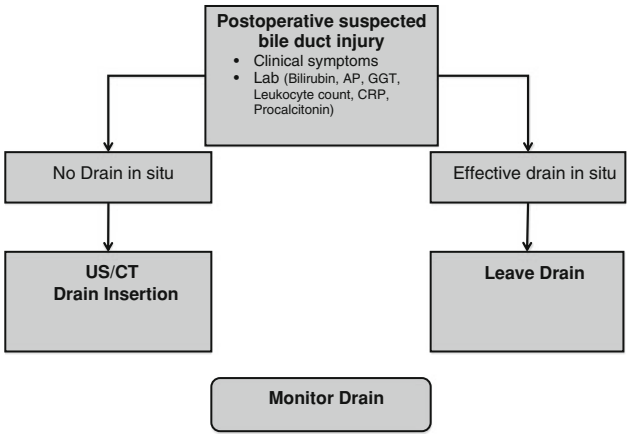

Fig. 2 Algorithm 1 suspected BDI

No high-quality evidence dealing with this question was identified from clinical studies.

Recommendation 4.1 BDI may be an indication for conversion. However, it is strongly recommended that this must only be done by a surgeon with experience in reconstructive hepatobiliary surgery, once the BDI has been confirmed and the indication for open reconstructive surgery established. Otherwise, in all other cases the panel strongly recommends not to convert; insert a subhepatic drain and refer to a unit with experience in this type of injuries.
GoR A

(Strong Consensus)

Key question 4.2 What is the recommended management for minor/major BDI (early/late detection)?

No high-quality evidence dealing with this question was identified from clinical studies. The management of BDI should be performed by surgeons who are experienced in

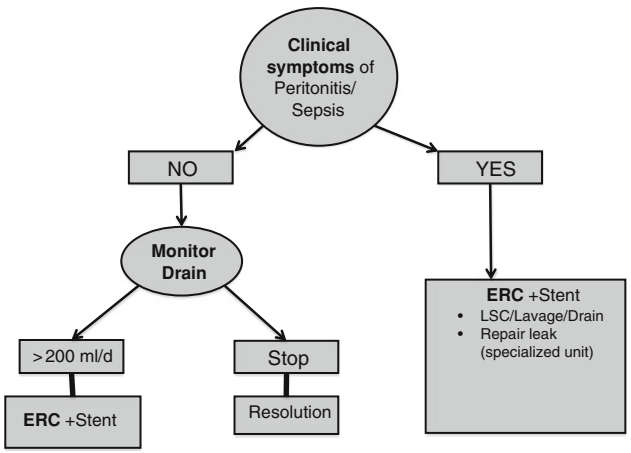

Fig. 3 Algorithm 2 suspected BDI

this field. The algorithms for the management of BDI are presented in Figs. 2 and 3.

Recommendation 4.2 The specific management of BDI must be left to units with experience in this type of injuries.

Apart from confirmed leakage from cystic ducts or subvesicular ducts (liver bed leakage) that can be treated endoscopically, all other injuries must be referred to specialized unit or experts.
GoR A

(Strong Consensus)

Conclusions

BDI is a rare but serious complication of cholecystectomy. In the beginning of laparoscopic cholecystectomy, the event rates increased. Nowadays, it seems that the event rates have decreased and are stabilized.

Because it is a rare event, it is difficult to generate evidence for prevention, diagnosis, or management of BDI from clinical studies. We identified nearly 700 clinical studies dealing with BDI, but only little information can be used as an evidence base for recommendations. Even though a systematic literature search and an appraisal of the literature were performed, most statements or recommendations had to be based on consensus of opinion between the panel members with only limited information from clinical studies.

Nevertheless, the panel has formulated recommendations for the prevention, diagnosis, and management of BDI. Due to the currently limited evidence, a European registry should be considered to collect and analyze more valid data on BDI upon which recommendations can be based.

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Appendix 1: search strategy

Search strategy Medline via Pubmed

(((((Laparoscop* OR Celioscop* OR Coelioscop* OR Abdominoscop* OR Peritoneoscop* OR lap) AND (cholecystectom* OR colecystecto* OR chole) OR "Cholecystectomy, Laparoscopic" [Mesh]) AND ((((injur* OR bile leak* OR biliary leak* OR transection* OR occlusion* OR stricture* OR stenosis* OR obstruct* OR laceration* OR damage*) OR (harm* OR convers* OR "Peritonitis"[MeSH] OR peritonitis OR "Cholestasis"[Mesh] OR Cholestas*) OR (peritone* AND inflamma*) OR ((biliary OR bile) AND stas*)) AND (bile duct* OR biliary tract*)) OR "Biliary Tract/injuries"[Mesh])) AND (German [LA] OR English [LA]))) NOT (animals [MeSH] NOT (humans [MeSH] AND animals [MeSH]))

Search strategy Cochrane Central Register of Controlled Trials (Central; Clinical Trials) via Cochrane Library

((((Laparoscop* OR Celioscop* OR Coelioscop* OR Abdominoscop* OR Peritoneoscop* OR lap) AND (cholecystectom* OR colecystecto* OR chole)) OR "Cholecystectomy, Laparoscopic"[Mesh])) AND ((injur* OR bile leak* OR biliary leak* OR transection* OR occlusion* OR stricture* OR stenosis* OR obstruct* OR laceration* OR damage* OR harm* OR convers* OR "Peritonitis"[MesH] OR peritonitis OR "Cholestasis"[Mesh] OR Cholestas* OR (peritone* AND inflamma*) OR ((biliary OR bile) AND stas*)) AND ((bile duct* OR biliary tract*) OR "Biliary Tract"[Mesh]))

Appendix 2: additional information for guideline development

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