J Hepatobiliary Pancreat Sci (2017) ••:••–••
DOI: 10.1002/jhbp.491

GUIDELINE

IRCAD recommendation on safe laparoscopic cholecystectomy

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DOI: 10.1002/jhbp.491

Abstract An expert recommendation conference was conducted to identify factors associated with adverse events during laparoscopic cholecystectomy (LC) with the goal of deriving expert recommendations for the reduction of biliary and vascular injury. Nineteen hepato-pancreato-biliary (HPB) surgeons from high-volume surgery centers in six countries comprised the Research Institute Against Cancer of the Digestive System (IRCAD) Recommendations Group. Systematic search of PubMed, Cochrane, and Embase was conducted. Using nominal group technique, structured group meetings were held to identify key items for safer LC. Consensus was achieved when 80% of respondents ranked an item as 1 or 2 (Likert scale 1–4). Seventy-one IRCAD HPB course participants assessed the expert recommendations which were compared to responses of 37 general surgery course participants. The IRCAD recommendations were structured in seven statements. The key topics included exposure of the operative field, appropriate use of energy device and establishment of the critical view of safety (CVS), systematic preoperative imaging, cholangiogram and alternative techniques, role of partial and dome-down (fundus-first) cholecystectomy. Highest consensus was achieved on the importance of the CVS as well as dome-down technique and partial cholecystectomy as alternative techniques. The put forward IRCAD recommendations may help to promote safe surgical practice of LC and initiate specific training to avoid adverse events.

Keywords Bile duct injury · Cholecystectomy · Consensus · Laparoscopy · Recommendations

Introduction

Laparoscopic cholecystectomy (LC) is one of the most frequently performed surgical procedures with more than half a million cholecystectomies per year in the USA and 55,000 per year in the UK [1, 2]. LC compared to open approach is the treatment of choice for symptomatic cholelithiasis with the proven benefits of less postoperative pain, shorter hospital stay, improved cosmesis, and increased patient satisfaction [3].

While LC has been shown to be safe, the most feared complication of LC is iatrogenic bile duct (BDI) or vascular injury, with a reported incidence ranging from 0.15 to 0.6% [1]. In open cholecystectomy the rate of BDI has been reported to be approximately 0.1 to 0.3% [4]. Although relatively rare, given the high volume of LC, the societal burden of BDI is significant and the resulting effect on patients' outcomes of iatrogenic BDI may be severe, ranging from intraoperative repair, liver transplant or even death, depending on the type of lesion and whether the injury was recognized intraoperatively [5]. Therefore, common BDI during LC is a serious intraoperative event that must be avoided as it leads to increased risk of serious morbidity, mortality, and length of stay [6], in addition to reduced quality of life [7] and long-term survival [8].

The major causes of BDI are related to three factors: (1) technique – related to surgeon's experience and performance; (2) pathology – extent of hilar inflammation; and (3) anatomy – presence of anomalies of the bile ducts. All these factors may lead to judgment error with resulting damage to the biliary tree. Surprisingly, despite improvements in surgical training in LC and the parallel developments in optics with High Definition cameras, the rate of BDI remains stable over time [9].

Given the clinical challenge as outlined above, the Institut de Recherche contre les Cancers de l'Appareil Digestif (IRCAD) decided to convene an expert recommendation meeting (ERM) to generate practical recommendations for safe LC.

Material and methods: Expert Recommendation Meeting (ERM) organizational model

In April 2015, the IRCAD Hepatobiliary and Pancreatic surgical experts convened to organize an ERM with the aim of compiling IRCAD recommendations on safe laparoscopic cholecystectomy (SLC). The IRCAD facilitator assigned three expert-IRCAD affiliated members to an organizational committee and 16 to a Scientific Committee. The Scientific Committee developed seven key questions highlighting relevant technical points in SLC (reported in Table 1). Each member of the committee was asked to provide the structured results of an electronic search of PubMed and EMBASE, to specifically develop practical recommendations for SLC.

The ERM on SLC was held in Strasbourg, France, on 21 September 2016, and used a nominal group technique to achieve consensus. First, each member presented key issues and corresponding expert recommendations, along with literature supporting each statement. Modifications were carried out when needed, based on the feedback and comments of the other experts. The audience then voted on each statement and the level of agreement was assessed on a Likert scale of "totally agree," "partially agree," "partially disagree" and "totally disagree." Using an electronic voting system, the degree of agreement was recorded and comments were collected for each statement (Table 1). In case of disagreement greater than 20%, the statement was further discussed and adapted until agreement was achieved. The revised statements were then presented again to the experts and voted on.

The approved statements were then presented for vote to a group of international HBP surgeons (n = 71). Following this assessment by specialized HPB surgeons, the relevance and practicality of the recommendations was tested among a group of general surgeons (n = 37).

None of members of the expert panel declared any direct or indirect conflicts of interest.

Results

IRCAD recommendations on SLC were structured in seven main statements, which were derived from 26 key items. The key topics ranged from exposure of operative field, appropriate use of energy device and establishment of the critical view of safety (CVS), to systematic preoperative imaging, intraoperative cholangiography (IOC) and alternative techniques, or role of partial and dome-down (fundus-first) cholecystectomy. Two statements were voted on twice due to a disagreement greater than 20% among the experts members. These were statement 1b (number of ports), and statement 4 (necessity of systematic preoperative imaging) (Table 1).

The highest consensus was achieved on the importance of the CVS, and dome-down (fundus-first)/partial cholecystectomy as acceptable alternative techniques.

No recommendation could be achieved on patient positioning, entry method, number of ports or type of energy source for dissection. Preoperative imaging with ultrasound was considered routine while other preoperative imaging modalities were considered optional. Additional key concepts for improvement in training, assessment, and research were discussed.

Statement 1. Exposure of operative field and gallbladder

Pneumoperitoneum

(1) The method of entry should be tailored to the patient characteristics (obesity, thin patients, adhesions, etc.).
(2) Open trocar insertion is a safe technique.

Establishment of pneumoperitoneum is an essential step in laparoscopic surgical procedures including LC. Although it may seem routine, its inherent risks should be emphasized. Although relatively rare, abdominal entry-related complications are estimated to account for about one-fifth of all laparoscopy medical liability insurance claims [10–12]. Despite the relative safety of laparoscopic techniques, inadvertent serious injuries to bowel, bladder

Table 1 Vote results of the IRCAD statements on safe laparoscopic cholecystectomy

Statements	Number of experts votes	Experts agreement $n = 19$	IRCAD HBP attendants $n = 71$	IRCAD general surgeon attendants $n = 37$
How to expose the operative field and the gallbladder?				
1. Pneumoperitoneum				
Totally agree	1	100%	76%	73.5%
Partially agree			18.3%	23.5%
Partially disagree			4.2%	0%
Totally disagree			1.5%	3%
1-2 Surgeon positioning				
Totally agree	1	94.7%	67.2%	81%
Partially agree		5.3%	31.2%	19%
Partially disagree			1.6%	0%
Totally disagree			0%	0%
1-3 Number of ports				
Totally agree	2	100%	85.7%	81.6%
Partially agree			9.5%	18.4%
Partially disagree			4.8%	0%
Totally disagree			0%	0%
1-4 Exposure of the Calot's triangle				
Totally agree	1	89.5%	90%	94.4%
Partially agree		10.5%	10%	2.8%
Partially disagree			0%	2.8%
Totally disagree			0%	0%
Appropriate use of energy devices				
Totally agree	1	100%	80.9%	97.3%
Partially agree			15.9%	6.7%
Partially disagree			3.2%	0%
Totally disagree			0%	0%
How to establish the critical view?				
Totally agree	1	100%	93.4%	75.7%
Partially agree			6.6%	24.3%
Partially disagree			0%	0%
Totally disagree			0%	0%
Necessity of a systematic preoperative imaging before laparoscopic cholecystectomy?				
Totally agree	2	100%	67.1%	70.3%
Partially agree			14.3%	29.7%
Partially disagree			15.7%	0%
Totally disagree			2.9%	0%
Place of intraoperative cholangiography and alternative technique				
Totally agree	1	100%	79.6%	78.4%
Partially agree			18.4%	21.6%
Partially disagree			2%	0%
Totally disagree			0%	0%
Place of partial cholecystectomy				
Totally agree	1	100%	88.7%	97.3%
Partially agree			8.1%	6.7%
Partially disagree			0%	0%
Totally disagree			3.2%	0%

Table 1 *Continued*

Statements	Number of experts votes	Experts agreement $n = 19$	IRCAD HBP attendants $n = 71$	IRCAD general surgeon attendants $n = 37$
Statement for dome-down cholecystectomy				
Totally agree	1	100%	83.9%	84.6%
Partially agree			12.5%	15.4%
Partially disagree			1.8%	0%
Totally disagree			1.8%	0%

and vascular structures do occur [13, 14]. It has been recognized that the most common cause of serious laparoscopic complications is related to primary trocar insertion [15].

Several techniques and devices are available for safe laparoscopic entry. Entry techniques include the non-insufflated open (Hasson) technique, the conventional closed entry technique with Veress needle CO_2 pre-insufflation, and the optical entry method. The latter includes visual Veress needle system, disposable optical trocars and trocarless reusable threaded visual cannula system. A recent Cochrane review of laparoscopic entry techniques failed to demonstrate any evidence of benefit in terms of safety of one technique over another [15]. However, the open entry technique has been reported to be associated with a decreased risk of minor complications and failed entry [15, 16].

Surgeon positioning

(1) A specific patient position is not considered as being superior (French vs. American).
(2) Optimization of eye – hand – target – monitor axis is recommended.

During a laparoscopic procedure, the surgeon may have to work in an oblique angle to the working field and line of vision. This can create awkward static postures including rotation of the spine, extension of the neck, and unnatural elevation of the upper extremities that might compromise surgical task performance [17–20]. Ergonomic studies suggest that balance should be maintained between comfort and safety on one hand and effectiveness and efficiency on the other hand [21]. This balance can be achieved through optimization of the surgeon's eye-hand-monitor axis.

Regarding patient positioning, more research is needed to assess the safety and quality between the two main positions used today: (1) In the French position, the patient is placed in lithotomy position with the perineum at the edge of the table, the hips and knees flexed, and the left arm or both arms in abduction. The operating surgeon stands between the legs and the assistant is positioned on the right side of the patient and the scrub nurse on the left. (2) In the American position, the patient is placed supine, with the left arm or both arms abducted. The operating surgeon stands to the left side of the patient, with the scrub nurse and assistant on the right side. Only very few studies compared the ergonomics of the surgeon's body posture and positional changes during LC between French and American position. It has been reported that body posture of the neck and trunk and the orientation of the head do not differ significantly between the French and American position [22].

Number of ports

(1) The number of ports should allow adequate triangulation and exposure.
(2) Reduced number of ports (including single-port) may require specific training.

In recent years, LC with the four port standard technique is being challenged as newer techniques are introduced. The idea behind reducing the number and size of ports is to reduce postoperative pain and provide better cosmesis [23]. In this context, surgeons have successfully performed mini-, three-, two-, and single-port LC. In particular, single incision laparoscopic cholecystectomy (SILC) has been gaining increased attention with reportedly improved cosmetic results, faster recovery, less postoperative pain, reduced incidence of port-site hernia and superficial wound infection [24]. However, the restrictions applied to number and degree of freedom of instruments during the single incision leads to limitations in triangulation and to instrument conflicts. Further, while several systematic reviews and meta-analysis of randomized controlled trials (RCTs) comparing single-incision versus conventional LC found SILC to be associated with improved cosmetic satisfaction, SILC is associated with longer operative time, increased need for additional ports and possibly a higher incidence of serious adverse events [25, 26].

Therefore, surgeons should keep in mind that decreasing the number of access ports and/or the use of smaller instruments may create technical challenges, due to more difficult retraction and triangulation. However, optimal retraction and triangulation during the dissection is needed to safely expose the surgical field and obtain the CVS [27–30].

Exposure of the Calot's triangle

(1) The gallbladder should be retracted superiorly by the fundus and laterally by the Hartmann's pouch to create an optimal angle between the cystic and the common bile duct.

In order to establish the CVS, cephalad retraction of the gallbladder fundus and lateral retraction of Hartmann pouch are required to visualize Calot's triangle or the hepatocystic triangle [31]. Retraction of the Hartmann pouch laterally and inferiorly is usually achieved with the graspers inserted through the two 5-mm lateral ports. Alternate techniques, such as port number reduction or smaller/alternate devices may create technical challenges related to triangulation [27–30]. Lateral retraction of the Hartmann pouch facilitates the creation of a distinct angle between the cystic duct and the common bile duct (CBD) to safely obtain the CVS (discussed later).

Statement 2. Appropriate use of energy devices

(1) There is low level of evidence to recommend a source of energy compared to another with respect to safety.
(2) Bipolar, monopolar and ultrasonic devices are appropriate sources of energy for safe cholecystectomy.
(3) Surgeons should be familiar with the specific complications associated with each type of energy.

Energy devices are applied to tissue for cutting, coagulation, desiccation, or dissection and are commonly used during LC. The most important energy sources used during LC are: (1) monopolar electrosurgery (the electrical circuit is completed by the passage of current from the active electrode at the surgical site to the dispersive electrode fixed to the patient's body); (2) bipolar electrosurgery (both active and return electrodes are located in the same tool and the electrical circuit is closed by the small area of tissues that are grasped or manipulated by the tool; the voltage required is lower); and (3) ultrasonic energy (low-frequency mechanical vibrations in the range of 20–60 kHz).

The traditional method described for LC uses a monopolar electrosurgical probe for the dissection of Calot's triangle and the separation of the gallbladder from the liver bed. The cystic duct and artery are usually secured by the application of surgical clips. However, bile duct, intestinal or vascular injuries can occur from energy source trauma, and may not always be recognized intraoperatively.

There are few data on the comparison between different energy devices in LC with respect to safety. In order to recommend a source of energy, the best endpoint to assess safety may be the incidence of bile duct, intestinal and vascular injuries. While some authors reported the number of bile leaks after LC, the definition of bile leak was heterogeneous among studies and its value as a surrogate marker of safety ill-defined. Nevertheless, there was no significant difference between the use of ultrasonic or electrocautery energy with respect to postoperative bile leakage [32–37].

Most literature comparing different energy sources for LC focus on operative time and not safety as the primary outcome. One meta-analysis on dissection for LC with ultrasonic energy versus monopolar electrosurgical energy reviewed seven prospective randomized studies including a total of 695 patients, and found operative time to be significantly shorter in the ultrasonic energy group [38]. A secondary outcome measure in these studies was incidence of gallbladder perforation. All studies found lower gallbladder perforation rates with ultrasonic (from 7 to 16.7%) compared to electrocautery dissection (18.3 to 63%) [32, 33, 39–42]. A randomized trial by Catena et al. comparing ultrasonic dissection to electrocautery surgery in LC for acute cholecystitis found a significant lower conversion rate in the ultrasonic group (1/21 vs. 7/21), with two conversions in the electrocautery group occurring due to the operative time exceeding 2 h [43]. While all energy devices carry inherent risk for thermal injuries the surgeon should be familiar with the specific complications associated with the type of energy used. While traditionally monopolar energy is used for dissection during LC, ultrasonic energy devices may achieve safe LC with shorter operative time.

Statement 3. Establishment of the critical view of safety (CVS)

(1) The CVS is endorsed for achieving adequate exposure, as previously described by Strasberg et al.
(2) The three elements of CVS are: (1) hepatocystic triangle is cleared of fat and fibrous tissues; (2) the lower one-third of the gallbladder is separated from the liver to expose the cystic plate; and (3) two and only two structures should be seen entering in the gallbladder.
(3) If it cannot be achieved, alternative options should be explored such as intraoperative imaging,

consultation with another surgeon, subtotal cholecystectomy, etc.

(4) The CVS should be described in the operative report.

The CVS, as previously established by Strasberg et al., involves identification of the cystic duct and artery with their complete dissection off the cystic plate: Calot's triangle is cleared of fat and fibrous tissue and only two structures should be connected to the lower end of the gallbladder following this step. The lowest part of the gallbladder attachment to the liver bed should be exposed. Once this has been achieved, the two structures entering the gallbladder can only be cystic duct and artery [31]. This clinically applicable approach mimics the approach of identifying the CBD that has been used in open surgery prior to the advent of laparoscopic approach.

The key consideration of early establishment of CVS prior to division of any structure is that the CBD would not be divided if any of the key conditions for the CVS is not met: cystic duct/artery is not identified, and/or the Calot's triangle is not cleared, and/or cystic plate is not displayed; however, the CBD could still be mistaken as cystic duct during tunneling in case of severe inflammation [44]. If the rigorous target identification with the CVS cannot be properly achieved, the result should be aborting the surgery or the use of complimentary methods for ductal identification to avoid a CBD injury [45]. Any difficulty in achieving the CVS should prompt consideration for alternative approaches such as IOC/intraoperative ultrasonography (IOUS), conversion to open approach, or solicitation of help from a colleague. Alternative approaches if the establishment of the CVS is unsuccessful are various forms of subtotal cholecystectomy (SC). SC has been redefined and recently described as "reconstructive" and "fenestrating" types [45], as discussed in statement 6. While establishing the CVS cannot entirely protect against CBD injury, this technique is applicable to daily clinical practice and may have advantages over traditional approaches in case of significant inflammation [46].

The reviewed literature suggests that judicious establishment of CVS could decrease bile duct injury rate, from an average 0.4% [1] to nearly 0% [47–50]. Examples of large institutional retrospective series that have demonstrated efficacy of CVS include Yegiyants et al. (3,042 laparoscopic cholecystectomies without BDI), or Avgerinos et al. (1,046 laparoscopic cholecystectomies with CVS achievement in 95.4% of patients and no BDI) [49, 50]. Establishment of CVS has been adopted by large societal organizations such as the Dutch Society of Surgery [51]. Despite encouraging data, there is no Level I evidence that CVS reduces bile duct injury. However, this may not be necessary or even achievable: a 4-fold increase in bile duct injury rate (from 0.1 to 0.4%) would require 4,500 patients per arm in a RCT to detect a statistically significant difference; logistics and cost of such RCT would be overwhelming [1, 52].

In addition to aiming at establishing the CVS early during every LC supplemental measures are photo documentation of CVS [53], CVS quality audit [52], and formal education and training of residents on safe cholecystectomy with CVS [54]. While CVS is a milestone in reducing BDI, limitations of CVS establishment exist: they include low achievement rate [55, 56] and insufficient critical self-assessment. Case series of biliary injuries have not found that CVS was used as the method of ductal identification [57–59], and a Dutch study analyzing 800 BDI cases reports that almost no biliary injuries were associated with the proper use of CVS [60]. Some of these limitations can be overcome by template documentation of CVS in operative reports [61]: template operative reports could not only improve the quality of operative notes themselves but also foster critical self-assessment.

In summary, CVS has most likely contributed to a reduction in bile duct injury rate based on large single institution series. Adequate audit (by photo documentation, template operative reports etc.) is essential in maintaining CVS quality. Especially in challenging cases with severe inflammation, failure to establish CVS should lower the threshold for utilizing alternative approaches such as conversion or use of complimentary measures such as IOC.

Statement 4. Systematic preoperative imaging before laparoscopic cholecystectomy

(1) There is no evidence that preoperative imaging can prevent BDI, however routine ultrasound is recommended prior to LC.
(2) In countries where magnetic resonance cholangiopancreatography (MRCP) is cost-effective, a MRCP prior to LC may be of benefit particularly in patients at high risk for CBD stones.
(3) MRCP is recommended if a CBD stone is suspected.
(4) If gallbladder polyp or cancer is suspected on the basis of an ultrasonography (US), staging imaging including a CT and/or MRI of the abdomen is recommended.

The main indications for LC include gallbladder/CBD stones and polyps/tumors in the gallbladder. In all cases, it is recommended to perform preoperative abdominal US to affirm the diagnosis and assess the level of inflammation of the gallbladder [62]. The accurate assessment of the severity of gallbladder inflammation will determine the therapeutic approach and the timing for surgery [62].

A preoperative radiological assessment for bile duct anatomical abnormalities, either by MRCP or endoscopic retrograde cholangiopancreatography (ERCP), may be a preventive measure in BDI avoidance. In the last decade, MRCP has been found to have equivalent diagnostic utility as ERCP [63] and to be more cost-effective [64]. However, while many studies investigate the role of IOC to prevent BDI, there is currently not enough evidence to support the use of systematic preoperative MRCP or other specific bile duct imaging to prevent BDI, not even mentioning the costs of such routine use of MRCP.

In case of preoperative suspicion for CBD stones, MRCP is a safe and effective imaging modality to image the bile duct [65]. In this context, it has been reported that 10–20% of patients undergoing LC have asymptomatic CBD stones without any clinical symptoms or laboratory abnormalities [66]. Therefore, routine MRCP prior to LC could be considered if MRCP imaging is cost effective.

In cases where suspicious lesions (usually polyps) are found on preoperative US, further imaging studies are required [67]. Contrast-enhanced dynamic studies, such as computerized tomography or magnetic resonance imaging exam of the abdomen are useful for the differential diagnosis and detection of invasion and metastasis [68], and help to determine the treatment strategy [69–72].

Statement 5. The role of intraoperative cholangiography (IOC) and alternative techniques

(1) There is no evidence that IOC could prevent BDI.
(2) IOC is recommended to define unclear anatomy.
(3) Fluorescence cholangiography is an investigational technique that may prove beneficial in the future.

Despite an abundant literature on the association between IOC and the prevention of BDI, the results of population-based studies using administrative and hospital data are conflicting. Some studies report higher odds of BDI in patients who did not undergo IOC [73–78], whereas other report no difference in BDI rates between patients undergoing routine IOC or not, the latter including several randomized clinical trials [9, 79–81]. Further, IOC is associated with increased surgical time and cost [82]. Moreover, population-based studies are prone to bias and confounders (e.g. routine vs. selective) such as indication for surgery or the level of surgical expertise [83].

Two systematic reviews of RCT published in 2012 failed to demonstrate evidence to support the routine use of IOC to prevent BDI [84, 85]. A recent RCT in patients with low risk of CBD stones showed no statistically significant association between IOC and postoperative morbidity [80]. Therefore, currently there is no evidence to support the use of routine IOC to prevent BDI.

Near-infrared fluorescence cholangiography (NIRF-C) is a real-time, radiation-free method to enhance the visualization of the biliary tree anatomy. It has been recently applied to minimally-invasive cholecystectomy [86]. To obtain a fluorescence cholangiogram, a near-infrared fluorescence camera is required to excite a fluorophore substance that is administered to the patient and eliminated through the bile, such as indocyanine green (ICG), which is the most commonly used fluorophore. The current literature shows a low level of evidence with heterogeneous parameters such as clinical context, surgical approach, ICG dose and timing, or fluorescence-enabling devices. No adverse events related to the administration of the fluorophores have been reported. A recent review of the literature concluded NIRF-C to be sensitive and safe for the detection of biliary structures [87]. NIRF-C has also been associated with faster and more cost-saving procedures when compared to traditional IOC [82].

A RCT protocol is currently underway to establish the clinical efficacy of NIRF-C and to help clarify optimal dosing and time interval between injection and visualization [88]. However, establishing the clinical efficacy of NIRF-C for BDI prevention shares the same problems as IOC. Considering the relatively low rate of BDI, the number of patients required for a RCT to prove that NIRF-C can reduce the rate of BDI would be overwhelming. As a result, the majority of trials use surrogate markers of efficacy, which is the rate of visualization of important biliary structures, before and after the triangle of Calot dissection, or, the time required to reach the CVS. In summary, NIRF-C remains an investigational technique that might prove to be beneficial in the future. The current level of evidence in published studies is low and well-designed prospective trials should be encouraged.

Statement 6. Role of partial cholecystectomy

(1) In case of difficult dissection, partial cholecystectomy is a safe alternative.
(2) During partial cholecystectomy, removal of all gallbladder stones should be attempted.

(3) If partial cholecystectomy has been performed, it should be described in the operative report and the patient informed that a portion of the gallbladder is in place.

While obtaining the CVS [31] is recommended as the safest way to complete a cholecystectomy, in case of biliary inflammation with tissue fusion and gallbladder contraction, it may be challenging to identify the cystic duct and artery safely. A key concept when performing a difficult cholecystectomy is to promptly recognize that change in surgical strategy may result in lowering the risk of BDI. Pushing on with blind dissection could lead to vascular or bile duct injury [89].

In the past, difficult cholecystectomy was strongly associated with conversion to open surgery. More recently, due to increasing experience in laparoscopic surgery along with decreasing experience in open surgery, alternative approaches and techniques are considered over conversion. In these cases, a partial or subtotal removal of the gallbladder has been largely demonstrated as a safe procedure. In the literature, "partial," "subtotal," "insufficient," "incomplete" and "completion" are different terms used to define the same concept. Strasberg et al. suggested that the term "subtotal" is preferred since it expresses the nearly-complete removal of the gallbladder. Two types of subtotal cholecystectomy have been described: (1) subtotal fenestrating cholecystectomy (no full thickness gallbladder remnant existing); and (2) subtotal reconstituting cholecystectomy (existence of a gallbladder remnant) [45]. The latter, due to the persistence of a gallbladder remnant, may result in new stone formation, and expose the patient to the risk of recurrent cholecystitis with a possibly challenging reoperative cholecystectomy [90].

Although a SC is a valid alternative in case of a difficult dissection due to inflammation, it should not be considered as an alternative to total cholecystectomy (TC) when feasible. Elshaer et al. reviewed 1,231 patients undergoing laparoscopic (73%), open (19%) or converted (8%) SC. They found low rates of postoperative hemorrhage (0.3%), subhepatic collection (2.9%) or BDI (0.08%), but higher rates of bile leak (18%), especially in open procedures (OR = 5.3) [91]. Henneman et al. analyzed 625 patients with acute cholecystitis undergoing PC, and found that in case of difficult LC, only 10% was converted to open surgery, highlighting that conversion is infrequently used to manage difficult LC [92]. Higher bile leak rates (10.6%) were successfully managed with ERCP in 7.5% of cases. Of note, the formation of gallstone in the remnant gallbladder was symptomatic in only 2.2% of cases, with only one patient undergoing completion of the cholecystectomy.

In conclusion, laparoscopic SC is feasible and safe and represents a valid alternative to conversion to reduce the risk of BDI in difficult cases. Future prospective studies may indicate which method is optimal in the treatment of the remnant stump and avoids bile leaks and recurrent cholecystitis.

Statement 7. Statement for dome-down cholecystectomy

(1) Requirements for a safe dome-down (fundus-first) technique are:
   a. Clear understanding of the anatomy of the cystic and hilar plates is mandatory.
   b. The dissection should be maintained along the SS-inner layer to avoid vascular and/or biliary injury.
(2) Dome-down (fundus-first) technique is an alternative when the triangle of Calot is severely inflamed.

LC can be performed either by retrograde caudal approach or antegrade cranial approach. The retrograde caudal approach begins with Calot's triangle dissection, allowing for a favorable caudal view [93] for CVS achievement. Performing the dissection of the Calot's triangle to achieve CVS before dividing the cystic duct and cystic artery is recommended to avoid BDI [94]. Therefore, the retrograde caudal approach for LC is has been preferred and adopted worldwide [95].

However, in case of diffuse inflammation of Calot's triangle, continued dissection to obtain the CVS might result in BDI [96], and an antegrade cranial approach may represent an alternative [97–99]. The antegrade cranial approach starts with dissection of the fundus and has been also described as "dome-down," "fundus-first," "fundus-down," or "retrograde" cholecystectomy [97–99]. "Dome-down" is an intuitive description and "fundus-first" is most commonly used in the literature. Dome-down (fundus-first) LC is a valid alternative if the CVS cannot be achieved due to severe inflammation or fibrosis of Calot's triangle. In several case-control studies, dome-down (fundus-first) LC showed satisfactory results in terms of both safety and reliability in patients with severe inflammatory disease [100–102], and has the potential to decrease conversion in difficult cases [103].

However, significant vasculobiliary injuries can occur during dome-down (fundus-first) LC [59]. Avoiding serious injuries requires a clear understanding of the anatomy of the cystic and hilar plates [104]. When dome-down (fundus-first) LC is performed, the dissection should be close to the gallbladder wall as much as possible and be maintained along the subserosal-inner (SS-inner) layer to avoid vasculobiliary injury [105]. If the SS-inner layer cannot be exposed around the Calot's triangle, further dissection should be abandoned and a subtotal cholecystectomy may be preferred to prevent vasculobiliary injury [106].

Conclusion

Despite an overall low incidence of adverse event during LC, the high rate of LC leads to a significant absolute number of patients who suffer from long-term adverse events, with one of the most significant being BDI. For this reason, expert laparoscopic HPB surgeons convened to put forward recommendations for surgeons performing LC to reduce the number of BDI and other adverse events. Table 1 highlights the consensus achieved by HPB surgeons and contrasts them to responses of general surgeons who both attended courses at IRCAD. Interestingly, while there was a significant agreement on most recommendation statements, discrepancy was found regarding the value of establishment of the CVS. While laparoscopic HPB surgeons considered the CVS as a crucial component for safe LC with 93% total agreement, only 76% of general surgeons agreed totally on the need to establish the CVS. This is reflective of the literature as was discussed in the recommendation section on CVS above. This survey result may indicate to the community of laparoscopic HPB surgeon and to organizers of future meetings on safe LC, that the general concepts of safe LC and the CVS specifically need to be promoted further. Establishment of CVS to reduce BDI has one of the highest level of evidence among all measures to reduce BDI. The authors hope that the put forward recommendations are practical and will help to promote safe surgical practice of LC, initiate specific training in the areas such as single access cholecystectomy and highlight novel approaches such as near-infrared fluorescence cholangiography that can be considered for safe LC practice.

Acknowledgment We would like to thank Professor Steven Strasberg for the critical review of the statement on CVS.

Conflict of interest None declared.

Appendix 1: author's affiliations

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Appendix 2: IRCAD recommendations statements

Topic	
Statement 1. How to expose the operative field and the gallbladder?	
Pneumoperitoneum	(1) The method of entry should be tailored to the patient characteristics (obesity, thin patients, adhesions, etc.). (2) Open insertion seems to be a safer technique.
Surgeon positioning	(1) A specific patient position is not considered as being the superior (French vs. American). (2) Optimization of eye – hand – target monitor axis is recommended.
Number of ports	(1) The number of ports should allow adequate triangulation and exposure. (2) Reduced number of ports (including single-port) should not be performed without specific training.
Exposure of the Calot's triangle	(1) The gallbladder should be retracted superiorly by the fundus and laterally by the Hartmann's pouch to create an optimal angle between the cystic and the common bile duct.
Statement 2. Appropriate use of energy devices	(1) There is low level of evidence to recommend a source of energy compared to another with respect to safety. (2) Bipolar, monopolar and ultrasonic devices are appropriate sources of energy for safe cholecystectomy. (3) Surgeons should be familiar with the specific complications associated with each type of energy.
Statement 3. How to establish the critical view?	(1) The critical view of safety (CVS) is endorsed for achieving adequate exposure, as previously described by Strasberg et al. (2) The elements of CVS are: a. hepatocystic triangle is cleared of fat and fibrous tissues; b. the lower one-third of the gallbladder is separated from the liver to expose the cystic plate; c. two and only two structures should be seen entering in the gallbladder. (3) If it cannot be achieved, alternative options should be explored such as intraoperative imaging, consult with another surgeon, subtotal cholecystectomy, etc. (4) The CVS should be described in the operative report.
Statement 4. Necessity of systematic preoperative imaging before laparoscopic cholecystectomy?	(1) There is no evidence that preoperative imaging can prevent a BDI, however a routine ultrasound is recommended prior to LC. (2) In countries where MRCP is cost-effective, a routine MRCP prior to LC may be of benefit particularly in patients at high risk for CBD stones. (3) MRCP is recommended if a CBD stone is suspected. (4) If gallbladder polyp or cancer is suspected on the basis of an US, a CT of the abdomen and/or a full MRI of the abdomen is recommended.
Statement 5. The role of intraoperative cholangiography and alternative techniques	(1) There is no evidence that intraoperative cholangiography could prevent BDI. (2) Intraoperative cholangiography is recommended to define unclear anatomy. (3) Fluorescence cholangiography is an investigational technique that may prove to be beneficial in the future.
Statement 6. The role of partial cholecystectomy	(1) In case of difficult dissection, subtotal cholecystectomy is a safe alternative and is recommended. (2) During subtotal cholecystectomy, removal of all gallbladder stones should be attempted. (3) If subtotal cholecystectomy has been performed, it should be described in the operative report and the surgeon should inform the patient that a portion of the gallbladder is still in place.
Statement 7. Safe dome-down cholecystectomy	(1) Requirements for a safe dome-down (fundus-first) technique are: a. Clear understanding of the anatomy of the cystic and hilar plates. b. The dissection should be maintained along the SS-inner layer to avoid vascular or/and biliary injury. (2) Dome-down (fundus first) technique is an alternative when Calot's triangle is severely inflamed.

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