

Intraoperative cholangiography in the laparoscopic cholecystectomy era: why are we still debating?

F. Ausania · L. R. Holmes · F. Ausania ·
S. Iype · P. Ricci · S. A. White

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Abstract Laparoscopic cholecystectomy is now one of the most frequently performed abdominal surgical procedures in the world. The most common major complication is bile duct injury, which can have catastrophic repercussions for patients and it has been suggested that intraoperative cholangiography may reduce the rate of bile duct injury. Whether this procedure should be performed routinely is still an active subject of debate. We discuss the available evidence and likely implications for the future.

Keywords Hepato... (Liver)

The first laparoscopic cholecystectomy (LC) was performed in September 1985 by Erich Muhe [1]. Although the surgical community was initially unconvinced about the significance of this new technique, it is now the most frequently performed abdominal surgical procedure, and one of the most common operations in Europe and the United States [2].

Morbidity has been reported as 2–4 %, whereas the incidence of major complications that require urgent operative management is much lower [2, 3]. The most common major complication is bile duct injury (BDI), with published rates as high as 1.4 %, although the literature

more commonly reports incidence as 0.15–0.6 %, approximately one per 200 procedures [2–9]. In contrast, the incidence of BDI after open cholecystectomy (OC) is reported as 0.1–0.3 %, an equivalent nearer to one per 500 cases [10, 11]. Traditionally, surgeons opt for operations with lower complication rates, and the “learning curve” was one of the arguments to account for the increased incidence of BDIs during LC [12]. However, further publications have reported that this incidence remains higher even when “learning curve” is accounted for [4, 13, 14], even in light of technological advances that have improved visualization and instrumentation [14–18]. Despite this evidence, LC remains the treatment of choice for symptomatic gallstones, a fact most likely attributable to the benefits of less postoperative pain, shorter hospital stay, better cosmetic result, and increased patient satisfaction [12, 19–22]. In fact, the number of cholecystectomies in the United Kingdom has nearly doubled during the past decade (Fig. 1).

Bile duct injury: mechanism, classification, and consequences

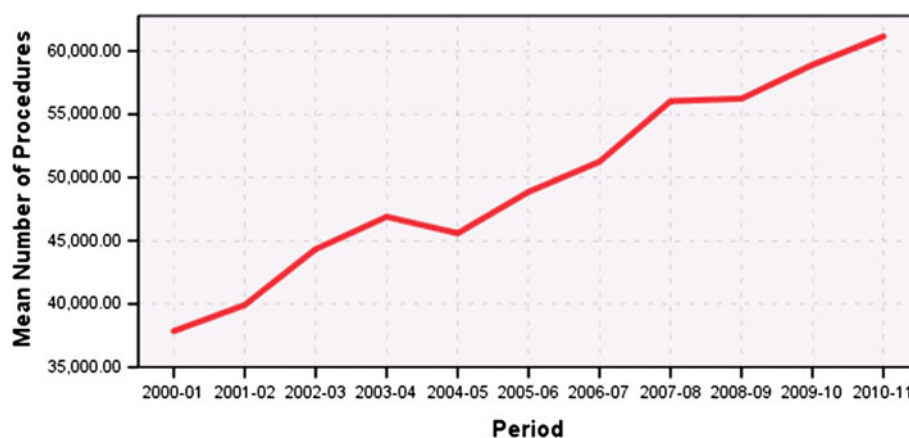
Davidoff et al. described “classical laparoscopic BDI” as misinterpretation of the common bile duct (CBD) or hepatic duct, as the cystic duct, resulting in clipping and division [23]. Several mechanisms for laparoscopic ductal injury can be identified, including tenting and diathermy injuries [7]. Dissection of the hilum of the liver can result in injury of more proximal hepatic ducts; nonetheless, the causes leading to BDI often are multifactorial. These causes include excessive bleeding, poor visualization of the field, inflammation, poor illumination, lack of awareness

F. Ausania (✉) · L. R. Holmes · S. A. White
HPB Surgery, Freeman Hospital, Newcastle Upon Tyne
NE77DN, UK
e-mail: f.ausania@googlemail.com

F. Ausania · P. Ricci
Forensic Medicine, Magna Graecia University, Catanzaro, Italy

S. Iype
Upper GI Surgery, Ipswich Hospital, Ipswich, UK

Fig. 1 Number of total cholecystectomies in the United Kingdom (Source: Hospital Episode Statistics)



about the orientation of bile duct anatomy, anatomical abnormalities, and surgical incompetence.

There are several classifications for BDI. Bismuth's classification (Type I–V) of BDI/stricture precluded the advent of LC but helped surgeons to choose the type of repair and correlated well with outcome [24, 25]. McMahon et al. [26] then further subdivided the type of BDI into laceration, transection, or excision, while retaining Bismuth's classification to grade the level of the stricture. Minor and major injuries also were distinguished for the purposes of management; minor required a simple suture repair and/or insertion of a T-tube, whereas a hepaticojejunostomy was recommended to treat a major injury [26]. Strasberg's classification (Type A–E) is a comprehensive modification of Bismuth's classification that includes various other types of laparoscopic extrahepatic BDIs [11]. Various other systems have since been proposed by Bergman et al. [27], Neuhaus et al. [28], Csendes et al. [29], Stewart et al. [30], and Lau et al. [31] in an effort to describe all possible lesions (Table 1). Recently Cannon et al. [32] have reported criteria to aid in predicting the financial cost of a particular insult and when referral to a tertiary hepatobiliary center is appropriate.

BDI causes serious consequences for the patient, which is compounded by any delay in the recognition of an insult or if a repair is attempted by an inexperienced surgeon [33]. Several authors have reported alarming outcomes for BDI repair, and in some series, mortality and morbidity for biliodigestive reconstruction after injury are as high as 8.6 % and 42 % respectively [34]. Even in the event of a successful repair, subsequent morbidity is significant and the sequelae include symptomatic adhesions, recurrent cholangitis, abscess, strictures, secondary biliary cirrhosis, and chronic liver disease [3, 35–40]. In extreme cases, a liver transplant may be required as a direct result of BDI complications [41–43]. As well as these physical complications, BDI also has been shown to impact a patient's quality of life and life expectancy significantly, often even

after successful repair [44, 45]. The poor outcome after BDI often is determined by the severity and level of the injury during LC. Ludwig et al. found that the most common lesions are type C and D according to the Neuhaus classification, injuries that often can require a biliodigestive anastomosis, which confers significant morbidity and mortality [9]. Lillemoe et al. [46] also compared BDIs sustained during LC versus OC and found that the injuries associated with LC tended to be more complex, with more than 60 % classified as Bismuth 3 or higher compared with only 40 % of this severity as a result of OC.

Role of intraoperative cholangiogram (IOC): a literature overview

In the past many attempts have been made to reduce the rate of BDI. Among these, IOC is probably the most commonly used, as well as the most debated. This technique, originally described by Mirizzi in 1931 [47], involves endoscopic cannulation of the cystic duct to visualize the bile duct. This allows the identification of any bile duct stones or preexisting anatomic abnormalities, as well as highlighting iatrogenic injuries that may have occurred [2].

IOC was historically utilized in open procedures to aid CBD stone detection and its routine use was debated long before the birth of LC [48]. However, IOC during LC provides the additional benefit of providing a “road map” for operative dissection. Some institutions use IOC routinely to identify CBD stones, provide extra evidence for anatomical decisions during dissection, training purposes, and to highlight biliary injury should it occur. The selective use of IOC is based on individual surgeon/institution policy, because no reliable standardized criteria exist [49], and often is used to help clarify difficult anatomy or highlight CBD stones if they are suspected. If stones are highlighted, they can be treated at the time in a single operation, which

Table 1 Different biliary injury classification system

Bismuth [24]	Strasberg et al. [11]	AAMC [27]	Neuhauser et al. [28]	Csendes et al. [29]	Stewart et al. [30]	CUHK [31]	Cammon et al. [32]
1 Low CHD stricture, with a length of common hepatic duct stump of >2 cm	A Cystic duct leaks or leaks from small ducts in the liver bed	A Cystic duct leakage from aberrant or peripheral hepatic radicles	A Peripheral bile leak (in communication with the CBD) A1 Cystic duct leak A2 Bile leak from the liver bed	I A small tear of the hepatic duct or rt hepatic branch caused by dissection with the hook or scissors during the dissection of Calot's triangle	I CBD mistaken for cystic duct, but recognized cholangiogram incision in cystic duct extend	I Leaks from stump or small ducts in liver bed	I Leaks from the cystic duct stump, duct of Luschka, or accessory rt hepatic ducts
2 Proximal CHD stricture-hepatic duct stump <2 cm	B Occlusion of part of biliary tree, almost invariably the aberrant rt hepatic	B Major bile duct leaks with or without concomitant biliary strictures	B Occlusion of the CBD (or rt hepatic duct, i.e. clip, ligation): B1 Incomplete B2 Complete	II Lesions of cysticohepatocholel jct. due to excessive traction, use of a Dormia catheter, section of the cystic duct very close or at jct. with CBD, or burning by electrocautery of cysticocholel jct.	II Bleeding, poor visibility Multiple clips placed on CBD/CHD	2 Partial CBD/CHD wall injuries: 2A without tissue loss 2B with tissue loss	II All other levels of biliary injury, including those to the CBD or intrahepatic bile ducts
3 Hilal stricture, no residual CHD, but the hepatic ductal confluence is preserved	C Transsection without ligation of the aberrant rt hepatic ducts	C Bile duct strictures without bile leakage	C Lateral injury of CBD C1 Small lesion (<5 mm) C2 Extended lesion (>5 mm)	III A partial or complete section of the CBD	III CBD mistaken for cystic duct, not recognized CBD, CHD, or rt or lt hepatic ducts transected &/or resected	3 CBD/CHD transection: 3A without tissue loss 3B with tissue loss	III All combined vascular and biliary injuries
4 Hilal stricture, with involvement of confluence & loss of communication between rt & lt hepatic duct	D Lateral injuries to major bile ducts	D Complete transsection of the duct with or without excision of some portion of the biliary tree	D Transsection of CBD (or rt hepatic duct not in communication with CBD) D1 Without structural defect D2 With structural defect E Stenosis of the CBD E1 CBD with short stenosis (<5 mm) E2 CBD with long stenosis (>5 mm) E3 Confluence E4 Rt hepatic duct or segmental duct	IV Resection of more than 10 mm of the CBD	IV Rt hepatic duct (or rt sectorial duct) mistaken for cystic duct Rt hepatic artery mistaken for cystic artery Rt hepatic duct (or rt sectorial duct) & rt hepatic artery transected	4 R/Lt hepatic duct or sectorial duct injuries: 4A without tissue loss 4B with tissue loss	
5 Involvement of aberrant rt sectorial hepatic duct alone or with concomitant stricture of the CHD	E Subdivided as per Bismuth's classification into E1 to E5	E					

decreases the use of unnecessary, nontherapeutic, endoscopic retrograde cholangiopancreatography (ERCP) [50, 51].

The role of IOC has been extensively investigated, and several national surveys have been published (Table 1). The results are controversial, often biased by retrospective data collection, poor data quality (mostly based on questionnaires or data codes), and impossibility to determine the intent of IOC use at the time (routine or to protect against injury, to detect CBD stones, or for suspected injury). Whether this procedure should be performed routinely is still an active subject of debate, but several of the larger retrospective studies associate a decrease in the frequency and severity of CBD injuries when an IOC is performed (Table 2) [2, 6, 52].

Several prospective studies have tried to evaluate the usefulness of IOC [53–55]; however, because BDI is such a rare event during LC (0.15–0.6 %), to demonstrate a 50 % reduction in CBD injuries, more than 26,000 patients need to be included in such a trial [56]. This sample size clearly renders previously published studies inadequate in terms of assessing the effect of IOC.

The limiting factors often mentioned when debating the routine use of IOC are local resource availability, expertise to interpret cholangiograms, additional operating time, and the infrequency of BDI [61]. The incorrect interpretation of cholangiograms is probably the most important of these considerations [62, 63], and a recent evaluation of IOC found that correct biliary anatomy could only be conclusively documented in 57 % of cases [64], a feat that is rendered even more difficult in the presence of cholecystitis. Conflicting reports exist about the usefulness of IOC for the identification of biliary anatomy when there is significant scarring or inflammation in the triangle of Calot [61, 64]. Adequate resolution of the anatomy is imperative so that injuries can be identified to permit successful repair. Stewart et al. [65] reported that 69 % of repairs were not

successful when the cholangiographic data were incomplete. In contrast, the initial repair was successful in 84 % of patients when IOC data was complete. This required level of competence, in technique and interpretation, might be linked to why surgeons performing IOC routinely have more favorable opinions about its usefulness and have a corresponding lower incidence of BDI [2, 66].

Performing IOC means an increased operative time, which has been reported in the literature as 8, 10, 16, and 20 min respectively [9, 58, 67, 68]. However, studies have indicated that despite the increased time in operative procedure and materials, routine IOC is cost-effective by reducing the severity of bile duct injury and the cost of treatment of patients with retained stones who did not receive IOC [56, 61, 69].

Importance of intraoperative detection of BDI

Despite variation on opinions about the routine or selective use of IOC, it has demonstrated a reduction in the incidence of major BDI and expeditiously identifies insults at the time of surgery [2, 13, 52, 59, 70–73]. Archer et al. [13] reported that routine use of IOC increased detection of BDI from 45 % to 85 %, which is similar to the increased detection described by Ludwig et al. [9] from 45 % to 90 %. Intraoperative detection of a ductal injury should decrease the technical difficulty of a repair, because there is no infection, inflammation, or fibrosis in the operating field compared with a delayed repair. This will greatly reduce the subsequent morbidity that is experienced compared with delayed BDI detection, which can be catastrophic for patients. It has been described that once an injury occurs, a patient's possible mortality increases to near 18 % [2, 3]. In addition to this significant mortality, the monetary cost of BDI repair can be 26 times that of an uncomplicated procedure, which is directly related to the increased

Table 2 Population level data showing LC use and impact of IOC on BDI incidence

Ref. no.	Source	Inclusion period	Country	No. of pts undergoing LC	No. of BDI (%)	Approx. BDI risk reduction if using IOC during LC
[57]	Regöly-Mérei J	1991–1994	Hungary	26,440 ^a	148 (0.56)	No effect observed
[58]	Z'graggen K	1992–1995	Switzerland	10,174	32 (0.31)	Did not reduce risk of BDI but improved diagnosis of intraoperative BDI
[59]	Fletcher D	1988–1994	Australia	7,675	25 (0.33)	>50 % ↓risk, eightfold if complex case
[6]	Flum DR	1991–1997	USA	30,630	76 (0.25)	40 % ↓risk
[2]	Flum DR	1992–1999	USA	1,570,361 ^b	7911 (0.5)	50–70 % ↓risk
[60]	Nuzzo G	1998–2000	Italy	56,591	235 (0.42)	No significant risk reduction observed between routine and selective IOC
[52]	Waager A	1987–2001	Sweden	152,776 ^c	613 (0.4)	34 % ↓risk

^a IOC in only 6.9 % of cases; ^b >75 % were LCs; ^c LCs and OCs were not differentiated

morbidity, mortality, length of hospitalization, and number of outpatient care days [46, 74].

Medicolegal implications

More than half a million LCs are performed each year in the United States as standard treatment of gallbladder disease, whereas more than 55,000 are undertaken annually in England, making it one of the most commonly performed surgical procedures [75, 76]. Complications are relatively rare; however, this volume of patients mean that a significant number of people suffer an iatrogenic injury at the time of the procedure (Table 2). BDI is the most common of these to involve litigation; most studies indicate that it accounts for 60–72 % of all claims following LC (Table 3). In the United States, BDI injury is the leading cause of medical negligence claims against general surgeons and LC is associated with 20-fold more litigation compared with OC [77, 78]. It also is a significant reason for litigation in Europe [79, 80]; in England alone during the past 15 years, legal action has cost the NHS in excess of 20 million GBP [81]. Data from the National Health Service Litigation Authority (NHSA) on clinical negligence indicate that, as a whole, the organization is receiving more claims each year and 2009/2010 recorded an annual increase of 31.6 % [82]. This corresponded to a 12 % increase in total expenditure on claims from 651 to 729 million GBP [82].

Three main reasons have been previously outlined that not only contribute to a claim being made but also to a large monetary sum being awarded [78, 81, 85]: high earnings loss, patient disability or death, and a feeling by the patient that negligence is responsible. Delay in diagnosis of BDI contributes to both of these latter issues and is reported to occur in more than 80 % of cases, therefore strongly correlating with an increased risk of litigation [16, 18, 79, 83–85]. IOC allows early identification of a BDI as

discussed, so it can significantly ameliorate patient morbidity and mortality, as well as have a protective effect against malpractice litigation [78].

Final considerations

It is clear that IOC is not a fail-safe technique against BDI. Surgeons must understand the nuances of interpretation if they are going to perform the technique and obtain an experienced opinion when unsure [63, 88]. Whether IOC in LC should become routine will continue to remain a contentious issue. The statement that “no persistently reliable intraoperative criteria” upon which a selective IOC policy can be based adds weight to the argument for routine [49]. Also, the collective weight of evidence from several large, observational studies that IOC reduces BDI should not be ignored. This is coupled with good evidence that IOC decreases the need for reoperation and patient morbidity/mortality if a BDI does occur by significantly reducing the degree of the insult. This evidence suggests that arguments against IOC, such as lack of resources and technical expertise, should not act as a deterrent. Rather they should be used as an argument for centralization of services and the inclusion of cholangiogram interpretation in LC training. However, a truly causal relationship between IOC and reduced BDI has yet to be conclusively established, which leaves the issue unresolved, probably forever.

A consideration in the argument for the implementation of routine IOC that is gaining weight is its use as a weapon in the arsenal of defensive medicine. Society is becoming increasingly litigious, and the volume of medical negligence claims is rising each year, especially in the United Kingdom [82]. Currently, it is estimated that 16 % of BDIs in England result in malpractice claims, but this number continues to close on the United States’ rate of $\approx 30\%$ [85]. These rising figures and large settlements mean that routine IOC has been reported to be cost effective due to its

Table 3 Comparison of litigation data following LC

Ref. no.	Source	Period	Country	No. cases	% BDI	% Vascular injury	% bowel injury	Av. payout (USD to nearest thousand)
[78]	Kern	1989–1992	USA	44	61	9	16	438
[86]	Chandler	1989–1993	USA	306	66	6	8	160–223
[83]	PIAA	1990–1993	USA	324	70	9	11	136
[18]	McLean	1999–2004	USA	104	78	7	2	508
[87]	Griffen	2004–2006	USA	88	≈ 60	N/A	N/A	N/A
[81]	Alkhaffaf	1995–2009	England	418	43	10	11	168
[85]	Roy	2000–2005	England	133	72	3	9	84
[79]	De Reuver	1994–2006	Holland	210	62	N/A	N/A	18

early detection of BDI as discussed [56, 61]. A recent study investigating medicolegal claims following laparoscopic cholecystectomy in the United Kingdom and Ireland concluded that BDI is “almost indefensible” [89]. This statement means that although the protective effects of IOC against BDI continue to be debated in the absence of definitive evidence, the undeniable fact that IOC does reduce the cost of litigation will likely gain increasing gravitas with time, culminating in health organizations instigating routine IOC during LC for economic reasons.

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