Role of Intraoperative Cholangiography in Avoiding Bile Duct Injury

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Each year, over 750,000 patients undergo cholecystectomy in the United States, making it the most frequently performed abdominal surgical procedure.[1] Common bile duct (CBD) injury during cholecystectomy occurs with relative infrequency (~ 1 in 200 to 400)[1,2] but ranks among the leading sources of medical malpractice claims against surgeons.[3] Between 34% and 49% of surgeons are expected to cause such an injury during their career.[4,5] Repair of such injuries is often complex and requires multiple procedures.[4,6,7] Major CBD injury also has a substantial impact on quality of life, functional status,[8-10] and survival. Among Medicare beneficiaries young and old in the 1990s, after CBD injury there was a nearly threefold increase in risk of short-term death compared with uninjured patients.[11]

Routine intraoperative cholangiogram (IOC) during laparoscopic cholecystectomy (LC), a radiologic contrast-based examination of the bile duct, can represent a system-level approach to avoiding CBD injury. Mirizzi[12] first described IOC in 1937, to help delineate the anatomy of the biliary tree in case of advanced biliary disease. As biliary surgery was refined and elective cholecystectomy became more common in the mid to late 20th century, this use for IOC diminished and was relegated to detection of stones in the CBD. Before the use of IOC for this purpose, diagnostic ultrasonography, serologic testing for liver enzyme elevation, and palpation of the CBD during open exploration were the only ways to detect CBD stones.

With the advent of LC, and the subsequent surge of associated CBD injuries in the late 1980s and early 1990s, a new use for IOC appeared—as a "road map" of the biliary system that could potentially help avoid major injury (Fig. 1). When the cystic duct/gallbladder junction is inadequately exposed, or if excess traction is being applied to the cystic duct/CBD junction, the CBD can be mistaken for the cystic duct. This can lead to clipping and, if not recognized, division of the CBD. This mistake is more likely to occur, and harder to detect, with the laparoscopic approach. This can be attributed to diminished tactile feedback and loss of three-dimensional perspective inherent to laparoscopy.

Despite the reported use of IOC in preventing transection of the CBD, its routine use has been, and remains, a matter of surgeon preference. Those surgeons who use IOC selectively (or not at all) suggest it is unnecessary to visualize the biliary system during every operation because prudent surgeons can avoid CBD injury without using IOC. Selective IOC users believe it changes management in relatively few cases and apply it only in situations where choledocholithiasis is considered likely or among those they describe as "high risk" for CBD injury. Selective users highlight the added cost of IOC and the relatively small group of patients who would benefit from either the protective effect of the IOC or detection of small CBD stones (1.1% to 11.4% of patients might have stones, but their clinical significance is unknown).[13-16] Routine IOC users argue it is impossible to predict who is at highest risk for injury, making routine IOC the safer method.[17]

Recent evidence has emerged evaluating the link between IOC and bile duct injury. This review is intended to evaluate the body of evidence about the use of IOC and to help clinicians and other stakeholders determine if it represents a system-level opportunity to protect patients against CBD injury. All studies pertinent to the topic were gathered, evaluated for their contribution to the question of routine or selective IOC use, and are discussed in this article.

CLINICAL DATA

When performing an IOC, the gallbladder is retracted laterally and the fat and peritoneum overlying the cystic duct and artery (in an area called Calot's triangle) is dissected. The surgeon identifies the cystic duct at its

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Abbreviations and Acronyms
CBD = common bile duct
IOC = intraoperative cholangiogram
LC = laparoscopic cholecystectomy

junction with the gall bladder neck, makes a small ductotomy, and threads in a cholangio catheter, which is subsequently fixed in place by a clamp, clip, or balloon. Radiographic contrast is then infused through the catheter and fluoroscopic images are obtained (Fig. 2). These images help the surgeon confirm the catheter is in the cystic duct (rather than the CBD) and identify obstructing stones in the biliary tree. The most common type of major biliary injury is caused by misidentification of the CBD as the cystic duct (Fig. 3). By using IOC as a road map, the surgeon can theoretically confirm the adequacy of the operative dissection, clarify assumptions made about the anatomy, and identify the location of the CBD before division of any biliary structures.

Several prospective studies have tried to evaluate the usefulness of IOC in preventing CBD injury. Drawing meaningful conclusions about the use of IOC has been difficult because these reports include relatively small numbers of patients. CBD injury is a relatively uncommon event, whether IOC is used or not (0.002% to 0.5%).[1,2] Sample size calculations using basic statistical software reveal that to identify a 50% reduction in such an infrequent event, a study would need to include $>$ 30,000 patients to be sufficiently powered. Studies failing to demonstrate a difference in IOC effectiveness are susceptible to type II error (failure to reject a false null hypothesis). For example, Hauer-Jensen and colleagues performed a randomized, prospective evaluation of 280 patients who had a cholecystectomy either with or without IOC.[18] Despite their study being underpowered, the authors concluded IOC could be safely applied selectively. Several other authors have either concluded selective IOC or routine IOC is acceptable based on a low or absent rate of CBD injury in relatively small series (n = 514 to 2,538).[16,19-22] Given this sample-size issue, none of these series offers adequate assessment of the effect of using IOC on the rate of CBD injury.

In an effort to address the issue of sample size, a meta-analysis of 40 case series detailing 327,523 LCs and 405 major injuries was performed in 2002.[23] In reports detailing 103 of these injuries, case-specific information

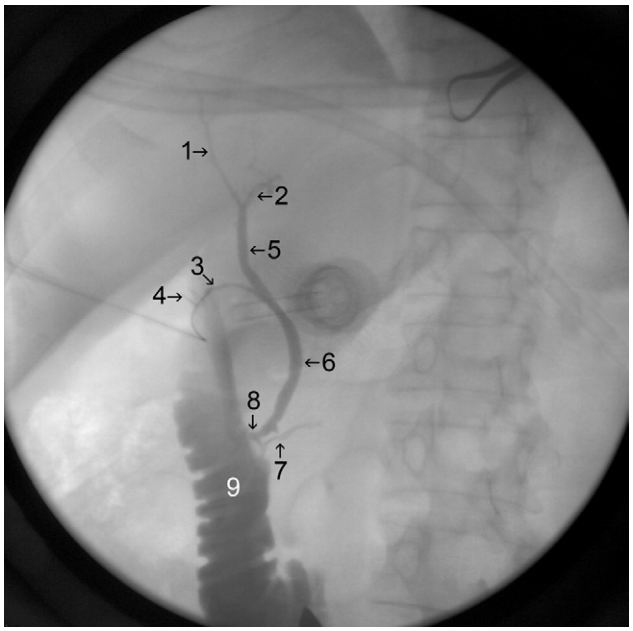

Figure 1. Normal intraoperative cholangiogram. (1) Right hepatic duct; (2) left hepatic duct; (3) cystic duct; (4) two surgical clips holding the cholangio catheter in the cystic duct; (5) common hepatic duct; (6) common bile duct; (7) pancreatic duct; (8) ampulla of Vater; (9) duodenum.

was available to determine the association of IOC and injury. Rate of injury was halved in the routine IOC group (0.21%) as compared with the selective group (0.43%)—a statistically significant difference ($p < 0.05$). In addition, in the selective group, only 21.7% of CBD injuries were detected intraoperatively. The heterogeneous nature of the aggregate reports in this series precluded advanced metaanalytic approaches. Nonetheless, this work suggests routine IOC use is safer.

Nuzzo and colleagues[24] recently performed a survey analysis of the heads of 184 Italian surgical units. Respondents self-reported on 56,591 LCs, recording if the surgical unit routinely or selectively used IOC. Although the authors reported the difference in CBD injury rate to be nonsignificant (0.32% versus 0.43%, $p = 0.25$), they included 7 bile duct injuries in the routine group that were, in fact, recognized or suspected before the IOC was performed. In these patients, IOC was not performed to prevent injury but rather to confirm it. If these 7 patients were removed from the analysis, the resulting risk of CBD injury in the routine group would be 0.23%, representing a near halving of the rate reported in this survey and consistent with other, more rigorously performed analyses.

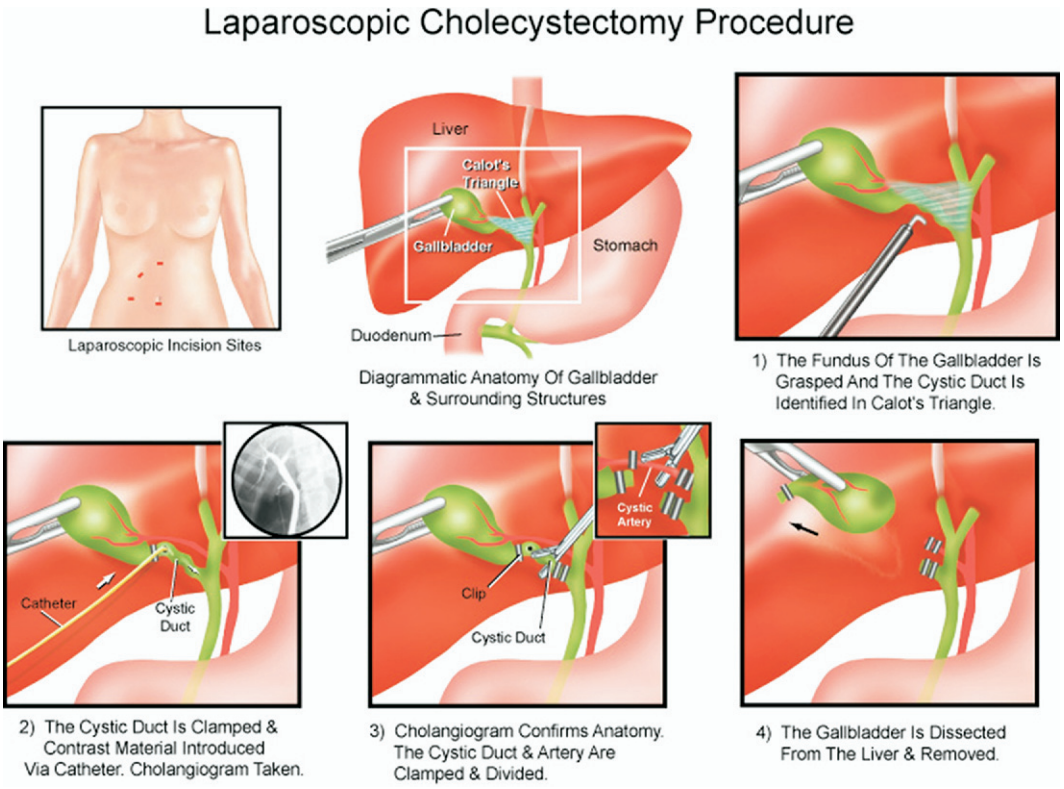

Figure 2. A laparoscopic cholecystectomy with intraoperative cholangiogram. Reprinted with permission of the artist, Katherine M Reilly.

POPULATION-LEVEL DATA

Population-based registry data from Western Australia supports routine IOC use. Using electronic records Fletcher and colleagues[25] identified all cholecystectomies (open and laparoscopic) performed in the region from 1988 to 1994 and demonstrated a 50% protective effect of IOC on the rate of all injuries (bile duct injury, bowel or blood vessel injury, or clinically significant bile leak). There were too few cases of bile duct injury to analyze as separate outcomes. These data were recently updated by the same group to include patients through 1998 (n = 33,309; LC = 19,414 and open cholecystectomy = 13,895) and again demonstrated a substantial reduction in the rate of all injuries when IOC was used.[26]

Our group used the State of Washington's abstract discharge database to evaluate the same issue.[2] Using ICD-9 procedure codes, we identified 30,630 LCs performed from 1991 to 1998. There is no reliable ICD-9 code for CBD injury,[27] so we defined CBD injury by identifying a CBD repair operation (ie, choledochojejunostomy) within 90 days after cholecystectomy. When IOC was not used, we found the rate of CBD injury to be 60.6% higher. In addition, use of IOC was associated with an even greater risk reduction among surgeons early in their experience with LC. Inexperienced surgeons were 2.2 times more likely to cause a CBD injury when not using IOC, as compared with more experienced colleagues who did use IOC. This study was not designed to determine if the effect on CBD injury was the result of IOC use or another "protective" effect inherent in routine IOC users. If the latter were true, this might suggest IOC use is a marker for some other component of clinical practice protective of the CBD.

To address this issue, our group evaluated all nationwide, fee-for-service Medicare beneficiaries undergoing cholecystectomy in the 1990s. This study included nearly 1.6 million patients undergoing cholecystectomy and identified over 7,000 with major bile duct injury. After adjusting for patient and surgeon characteristics, this series demonstrated the risk of injury increased by 71% when IOC was not used.[1] Surgeons who were classified as "routine cholangiographers" had the lowest rates of CBD injury, but these low rates were only noted when IOC was used. Routine cholangiographers who did not use an IOC were at similar,

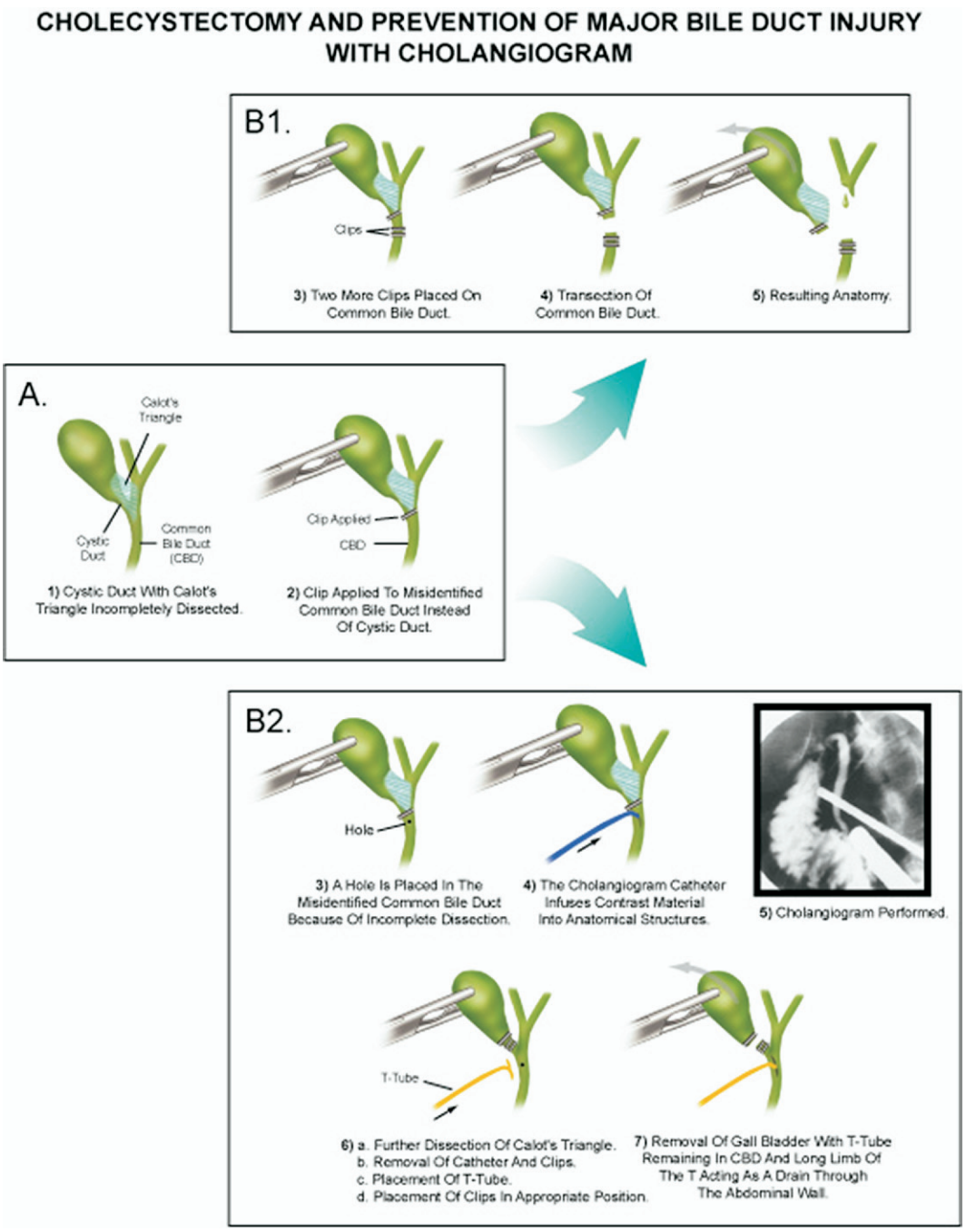

Figure 3. Two possible sequences when the common bile duct is misidentified. (A) The common bile duct is misidentified and a surgical clip is applied. (B1) The misidentified common bile duct is transected. (B2) A cholangiogram detects the misidentification and the small defect in the common bile duct is stented. Reprinted with permission of the artist, Katherine M Reilly.

if not greater, risk of damaging the CBD as an infrequent IOC user. The association between IOC use and bile duct injury appeared to be independent of other qualities inherent to routine cholangiographers.

These types of studies have important limitations. Administrative data could not be used to determine if IOC was being used for CBD stone detection, anatomic information before duct transaction, or to confirm a

suspected injury. Interestingly, in the Medicare study, infrequent users had a slightly higher rate of injury in cases when they used IOC. This might suggest these surgeons were using the IOC after a CBD injury (perhaps to confirm an injury), rather than before transecting ductal structures to prevent injury. An alternative explanation is infrequent cholangiographers might have caused injury in performing IOC. Another important limitation to studies using administrative data is that they only recognize major bile duct injuries (those requiring bilioenteric anastomoses). These studies thereby undercount all CBD injuries by overlooking less clinically relevant, but potentially important, bile duct injuries. These could include cystic duct leaks (or small common duct openings, such as those made for the cholangiogram catheter) treated with a T tube or an endoscopic approach.

LIMITS OF ROUTINE CHOLANGIOGRAPHY: INJURY PREVENTION OR MINIMIZATION?

One argument against cholangiography is if the CBD is misidentified while an IOC is being performed, the ductotomy created for placement of the IOC catheter is itself a CBD injury. Once contrast is injected and no flow to the upper hepatic radicals is visualized, the error should be apparent. When the catheter is removed, a defect measuring 1 to 2 mm remains. This common duct opening, a form of low-grade duct injury, can usually be addressed by placing a T tube (Fig. 3B2). This T tube generally allows the CBD to heal without stricture formation and is removed nonoperatively several weeks after the cholecystectomy. Although T-tube placement is not without consequences (with leaking and stricture in a small percentage [$<$ 0.05%] of patients[28,29]), the alternative is worse. In this scenario, if an IOC was not performed and incorrect assumptions about the anatomy were not corrected, the CBD would have been clipped on both ends and completely transected (Fig. 3B1). Complete transection is a much more grave injury and requires an open bilioenteric anastomosis for repair—a procedure associated with considerable morbidity and mortality. In this way, the true value of IOC might be with regard to injury minimization rather than prevention.

In several case series, these minor ductotomies (repairable laparoscopically) have been grouped along with major CBD injuries, thereby biasing the results against IOC.[30-32] For example, in a 3-year prospective study of 10,174 patients undergoing laparoscopic cholecystectomy in Switzerland, an overall CBD injury rate of 0.31% was found, with similar injury rates for those with and without IOC.[31] The authors included these minor injuries in their assessments. Sixteen percent of these injuries were repaired laparoscopically, suggesting that some of the injuries in this analysis were not complete transections but rather simple ductotomies that have little effect on patients.

ARGUMENTS AGAINST IOC

IOC is not always effective

There are situations when IOC is impractical or can even cause injury (other than the type already mentioned). A shortened, fibrotic, or valve-filled shortened duct can make ductal catheterization extremely difficult or even impossible. If the cystic duct is short or absent (as in Mirrizzi's syndrome), use of IOC can actually cause injury through puncture of the back or front wall of the CBD by the cholangio catheter.[33] Alternatively, an IOC will be ineffective if it is misinterpreted. For example, occlusion of the CBD with the balloon tip of the cholangiogram catheter that migrates too far beyond the cystic duct can mimic CBD injury and must be anticipated as a possibility when using this type of catheter.[34] Interpretation of the IOC requires appropriate training. In an analysis of 252 bile duct injuries during cholecystectomy, Way and colleagues[35] reported that 43 IOCs demonstrated a bile duct injury, but only 9 were correctly interpreted at the time of operation. In retrospect, more than half the time, abnormal IOC findings were simply overlooked. These scenarios stress the importance of appropriate training in both performing and interpreting an IOC.

Cost

The cost effectiveness of IOC was first considered in the 1980s when IOC was used as an alternative tool for evaluating CBD stones. Given the relatively low rate of CBD stones, when compared with preoperative blood tests and ultrasonography, routine IOC use was not found to be cost effective for the average patient.[36-38] In an informal cost analysis done based on a single center's experience with IOC for CBD injury prevention, routine use was not considered cost effective because of the low absolute risk of bile duct injury and a relatively high number needed to treat to avoid a single CBD injury ($\sim$ 500).[39] More formal cost evaluations (using decision

models and sensitivity analysis based on previously demonstrated rates of risk reduction) demonstrate routine IOC use is cost effective across a wide range of estimated costs for this test.[40] The cost of a cholangiogram ranges between $77 and $738 (with a best estimate of $122). At this cost, and with a near halving of the risk of CBD injury with IOC, the authors concluded routine use of IOC costs approximately $13,900/quality life-year. Using the standard benchmark of < $50,000/quality life-year, IOC appears to be quite cost effective.[40]

An alternative way of considering IOC cost effectiveness is to compare it with the cost of bile duct injury. In the same study, the cost for avoiding a CBD injury ranged from $60,983 to $87,100. When all costs of medical care after injury were considered, the incremental cost for managing 10,000 patients with IOC was an additional $100/patient.[40] These costs include the resources needed for an IOC program (fluoroscopy machines and personnel), but did not explicitly consider the price of litigation because it is also generally considered to be dollar averaged in hospital costs. Given that more general surgeons get sued for bile duct injuries than any other cause, and the average settlement ranges from $250,000 to $500,000, this incremental cost might be reasonable. A more global cost analysis of IOC considered the estimated cost of CBD injury and subsequent duct repair in 1 hospital ($500,000) and showed routine IOC would cost considerably less.[41]

TIME FOR IOC

The length of time required to perform IOC is frequently cited as a barrier to its broader use. When evaluated prospectively, IOC adds an additional 16 minutes to the procedure.[17] This added time should be considered in the context of other safety interventions aimed at protecting the patient from harm, including "time-outs" for avoiding wrong-site operations and instrument counts and cavitary x-rays to avoid retained instruments.

ALTERNATIVE METHODS TO AVOID CBD INJURY

There are other intraoperative methods available to evaluate the biliary tree. In cystocholangiography, the cholangiogram catheter is inserted directly into the gall bladder, allowing access to the biliary system and minimizing the risk of injury to the CBD.[42] According to at least one report, this technique has a similar rate of successful completion without any substantial difference in complication rate when compared with standard IOC.[43] More contrast material might be needed to effectively perform this technique, and it is certainly not practical when the cystic duct is obstructed (not an unusual finding in acute cholecystitis). Alternatively, intraoperative ultrasonography is less invasive (essentially eliminating the risk of damage to biliary structures by avoiding placement of an IOC catheter), yet still offers an adequate evaluation of the biliary tree, allowing diagnosis of CBD stones and determining anatomic abnormalities.[44-46] Another benefit of ultrasonography can be in avoiding use of contrast material or radiation (adverse reactions to cholangiogram contrast material have been reported, albeit rarely[47]). Although advocates of intraoperative ultrasonography compare it favorably with IOC and ERCP, the average surgeon's lack of familiarity with the equipment and its interpretation can limit its use.

Some argue IOC would not be necessary if better operative technique were applied. Many surgeons still advocate for open cholecystectomy performed through "mini" incisions because of the problems associated with CBD injury. Others have offered variations on the laparoscopic operative technique, including: beginning the dissection on the gall bladder rather than the cystic duct/CBD junction;[48,49] avoiding blood in the operative field and early identification of an operative "safety zone";[50] use of a 30-degree−angled laparoscope;[51] having a low threshold for conversion to the open procedure.[52] All these should be considered best practices, based on conventional wisdom, but there remains a lack of high-level evidence to demonstrate their injury-preventing effect.

BEYOND ROUTINE VERSUS SELECTIVE: ALTERNATIVE PERSPECTIVES ON BILE DUCT INJURY

IOC and heuristics

Way and colleagues[35] recently attempted to understand why bile duct injuries occur despite use of IOC. They determined that a combination of limited sensory input during laparoscopy and reliance on heuristics ("rules of thumb"), underlies most injuries. They reviewed 252 CBD injuries that included detailed retrospective analyses and reviews of intraoperative videotapes and IOCs. The investigators concluded that heuristics about the identification and isolation of the cystic duct too often guide decision making in the presence of incomplete visual or tactile data, and inevitably lead to bile duct

injury. Although these heuristics can result in injuries when there is incomplete confirmatory data (such as a visual hint of a duct seeming to enter the gall bladder), this theory does not address the issue of clear disconfirmatory data (such as an abnormal IOC). In 79% of the cases of bile duct injury when an IOC had been performed, the injury occurred despite the cholangiogram being abnormal and disconfirmatory—the abnormal test was simply overlooked by the surgeon. With such disconfirmatory data, a surgeon might be expected to challenge the adopted heuristics, much in the way a road map would help a traveler avoid a false turn at a seemingly familiar (but mistakenly identified) roadside landmark. The failure of this disconfirmatory information to be incorporated into decision making might reflect an opportunity for better education among surgeons, rather than a reliance on heuristics.

SOCIETAL PERSPECTIVES

Although legalistic definitions of the medical standard of care vary between states, the common theme is that care delivered reflects what a reasonable physician would do—often interpreted to mean what the average surgeon would do in a given surgical situation. Applying this legal definition to the past decade, routine IOC use was not the standard of care in the United States during the 1990s, as only approximately 20% of surgeons could be classified as routine IOC users and only 40% of patients nationwide had IOC during cholecystectomy.[1] What is considered standard of care and what is considered best practice are not always the same.

The debate over IOC use can also be considered in the context of other public health interventions aimed at improving safety. For example, given a common procedure known to have a small risk of serious injury (eg, 1:100 or 1:200), if a simple intervention were identified that could reduce that risk by half at a reasonable cost, the social interest would likely insist it become standard. This scenario is typified by the fatality rate caused by automobile accidents and the risk-reduction effect of seatbelt use. Although seatbelts do not confer absolute protection from fatalities (40% to 70% reductions), community laws have made routine seatbelts mandatory because society largely believes the benefits outweigh the costs.[53-55] As expected, use of seatbelts has increased dramatically with the widespread enactment of such laws.[56] Given the high rate of associated morbidity and mortality with CBD injury and the risk-reduction profile of IOC and its low cost, from a public health perspective, a compelling argument can and should be made for its routine use.

Given the effect of CBD injury on patients, its medicolegal impact, and the growing demands on the medical community to reduce medical errors, perhaps another approach to this argument should be considered—that the protective effect of IOC on major CBD injury should be assumed legitimate until adequate evidence to the contrary is identified. Although exposing several hundred patients to IOC to prevent grievous injury in one might seem unreasonable, this might represent the only evidence-based approach available to improve patient safety during this commonly performed procedure.

In conclusion, the evidence supporting use of IOC is strong but comes from observational cohorts rather than from randomized trials. Despite this limitation, the compiled evidence in support of IOC does appear to meet many of the standard epidemiologic metrics used to ascribe a cause-and-effect relationship to observational data. The studies detailed within this review demonstrate a similar robust effect of IOC on injury reduction. As this effect is almost identical in magnitude across all studies and is clinically plausible, the likelihood of this representing a statistical fluke is unlikely. These data suggest the use and correct interpretation of IOC decreases the rate of CBD injury and that its broader use will improve patient safety. Like the surgical "time-out" to prevent wrong-site operations and the recent emphasis on the appropriate timing of prophylactic antibiotics and deep vein thrombosis prophylaxis, IOC should be considered a system-level approach to avoiding important adverse outcomes during this commonly performed operative procedure.

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