

Risk Management Observations From Litigation Involving Laparoscopic Cholecystectomy

Thomas R. McLean, MD, JD

Hypothesis: Limited information exists on the outcome of laparoscopic cholecystectomy (LC) litigation.

Design: A retrospective review of a public malpractice database was compared with previously published reviews of LC litigation by K. A. Kern, MD, and the Physician Insurers Association of America.

Setting: Private surgery practice.

Selection: The database was searched for cases containing the terms *laparoscopy*, *bile*, or *gall* between August 1, 1999, and August 31, 2004. Identified cases were further reviewed to select only the unique cases that concerned elective biliary surgery.

Main Outcomes Measures: Surgical technique, injuries, and incidence of conversion to open procedures.

Results: In Kern's study, injuries triggering litigation involved the bile duct in 61%, bowel in 16%, vascular system in 9%, and miscellaneous events in 14%; in the present study, injuries involved the bile duct in 78%, bowel in 2%, vascular injury in 7%, and miscellaneous injuries in 13%. Missed injuries occurred in 86% in the present study and 83% of the Physician Insurers Association of America cases. Although 15% of cases in the present study were converted to open procedures, in 53% of these cases conversion was performed to repair an injury.

Conclusions: Despite residency training, injuries triggering litigation after LC remain largely unchanged. The nature of the bile duct injuries suggests that routine intraoperative cholangiography is unlikely to make LC safer. To minimize the risk of litigation after LC, it is recommended that the threshold for conversion to open procedures be lowered.

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A DECADE OF EXPERIENCE with laparoscopic cholecystectomy (LC) has resulted in the liberalization of the indications for the procedure.^{1,2} Despite this experience, the incidence of injury to the extrahepatic biliary tree (approximately 1 injury per 200 cases), remains almost twice as high as that for an open procedure.^{3,4} This should concern surgeons, because when LC litigation data are compared with litigation data for open cholecystectomy (OC), it appears patients are much more willing to sue for an adverse

vascular (4 cases [9%]), and miscellaneous (6 cases [14%]) injuries. The mortality rate associated with these events was 16%. Claims in the study by Kern⁶ were closed in 25 cases (57%) and in the plaintiff's favor for an average of \$438 000. In the second study, the Physician Insurers Association of America (PIAA)⁵ reviewed 324 LC claims. The PIAA, which represents

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more than 50 malpractice insurance companies that provide coverage for 60% of physicians,⁷ found that 67% of the claims filed after LC involved an injury to the biliary tree and that 83% of these injuries were not recognized at the time of surgery. Moreover, the PIAA observed that 50% of claims were settled in the plaintiff's favor for an average of \$236 384.

The data by Kern⁶ and, to a lesser degree, those of the PIAA⁵ reflect the "learning curve" years of LC, and thus may not be applicable to today's surgeons, who were formally trained in the laparoscopic technique. Neither of these studies at-

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Author Affiliations: Third Millennium Consultants, LLC, Shawnee, Kansas; Department of Surgery, University of Kansas School of Medicine, Kansas City; and Surgical Service, Dwight D. Eisenhower Veterans Administration Medical Center, Eastern Kansas Veterans Affairs Health Care System, Leavenworth.

outcome after LC.⁵ Regrettably, only 2 studies have examined the outcome of litigation involving LC.

In the first study, Kern⁶ reviewed LC litigation data in a public database containing malpractice verdicts and settlements. He found 44 legal abstracts that demonstrated the distribution of adverse events that trigger litigation after LC were bile duct (27 cases [61%]), bowel (7 cases [16%]),

Table 1. Summary of Why Surgeons Who Perform a Cholecystectomy Are Sued

Type of Procedure	No. of Procedures
LC	104
Open	8
OC	6
CBD exploration	2
LC vs OC not distinguishable	7
T-tube removal	2
Failure to operate	1
Total	122

Abbreviations: CBD, common bile duct; LC, laparoscopic cholecystectomy; OC, open cholecystectomy.

Table 2. Plaintiff Demographics

	Present Study	Kern ⁶
No. of plaintiffs	104	44
Patient age, y, mean \pm SD	45.2 \pm 6.7	NA
Female, No. (%)	94 (90)	NA
Adverse events, No. (%)		
Bile duct injury	81 (78)	27 (61)
Bile duct leak	61 (68)	
Cystic duct leak	10 (10)	
Clip	21 (20)	
Stricture	1 (1)	
Retained stone	1 (1)	
Bowel injury	2 (2)	7 (16)
Vascular injury	7 (7)	4 (9)
Miscellaneous injury	14 (13)	6 (14)
Injury not identified, No. (%)	89 (86)	83*
Mortality, No. (%)	14 (13)	7 (16)
Average payout, \$	508 341	438 000

Abbreviation: NA, data not available.

*Indicates data taken from Physician Insurers Association of America data.⁵ Given as a percentage.

tempted to correlate litigation outcome with mechanism of injury. Accordingly, the present study was undertaken to address these weakness.

METHODS

The methodology used herein is virtually identical to that used by Kern,⁶ and it has been detailed elsewhere.⁸ Briefly, the Lexis-Nexis database "Jury Verdict and Settlements, Combined" was searched for all cases containing the terms *laparoscopy*, *bile*, or *gall* between August 1, 1999, and August 31, 2004. Abstracts of each unique biliary surgery case identified were reviewed for patient demographics (age and sex) and type of injury (which were classified according to Kern's system). Bile duct injuries (BDIs) were then subclassified by the following mechanisms of injury: bile duct laceration (lacerations recognized intraoperatively, non-cystic duct bile accumulations, or leaks that presented postoperatively); ductal clippings (including traction or tent injuries of the confluence of the cystic, hepatic, and common bile ducts, as well as direct clip application to the right hepatic duct or the common bile duct [CBD]); cystic duct leaks; strictures of the extrahepatic biliary tree; and retained stones.

Bile duct lacerations occurred with and without major vascular injuries. These injuries were distinctly different from vas-

cular injuries that result from trocar insertion. For purpose of this analysis, when a vascular injury occurred in association with a bile duct laceration, it was classified as bile duct laceration. The remaining vascular injuries, which were all due to trocar insertion, were classified as vascular injuries.

The bowel injury group consisted of injuries to the duodenum, and in all of these cases the actual mechanism of injury (eg, trocar or cautery) could not be determined. The miscellaneous group contained the remaining cases that were not otherwise classified. Thus, included in this group are 1 case of a preoperative error in judgment as well as intraoperative and postoperative complications that were not directly related to bile duct, vascular, or bowel injury. The miscellaneous group also includes 2 cases where the sole basis for the litigation appeared to be a prolonged postoperative course without a major adverse event related to negligence and 1 case where there was insufficient information for classification.

Wherever possible, the data collected for the present study were compared with data published by Kern⁶ or the PIAA.⁵ Data are expressed as mean \pm SD or mean (range). Finally, cases were classified according to intent to treat. Thus, LC cases that were converted to open procedures were analyzed as LC cases. Exploration of the CBD, which was always performed as an open procedure, was classified as an open procedure.

RESULTS

One hundred twenty-two unique cases of elective biliary surgery litigation form the basis of this report (**Table 1**). Most of the cases involved LC; with only 8 cases involving the open technique (6 OCs and 2 CBD explorations). In 7 additional cases, there was insufficient information to determine whether the surgeon used the open or the laparoscopic technique. These 7 cases were classified as open. Surgeons were also named in 2 suits for T-tube removal and in 1 suit for failing to operate.

Focus was then directed toward the 104 suits filed after LC (**Table 2**). Plaintiffs' demographics tended to reflect the demographics of patients who undergo elective LC in the private sector, ie, plaintiffs who sue their physicians tend to be middle-aged women. The most common event precipitating litigation was a BDI (61% in the Kern study⁶ vs 78% in the present study). However, BDIs were caused by multiple mechanisms, including laceration, inappropriate clip application, and failure to secure the cystic duct. Not infrequently, BDI occurred because it was mistaken for the cystic duct. Miscellaneous misadventures were the second most frequent trigger for litigation (14% in the Kern study⁶ vs 13% in the present study). Experience with LC has led to a decrease in the incidence of bowel and vascular injuries as litigation triggers (bowel injuries, 16% in the Kern study⁶ vs 2% in the present study; vascular injuries, 9% in the Kern study⁶ vs 7% in the present study). However, intraoperative injuries associated with LC continue to be frequently missed (86% in the present study vs 83% in the PIAA study⁵). These missed injuries were associated with a high mortality rate (which was frequently related to sepsis) in patients who file suit (16% in the Kern study⁶ vs 13% in the present study).

Two miscellaneous cases did not appear to have any specific adverse event to trigger litigation other than a prolonged hospital course. Regardless, being sued can be expensive. Kern⁶ found that 57% of cases resulted in an average payment being made to plaintiffs of \$438 000,

which was echoed in the findings of the present study, where 60% of plaintiffs received \$508 341 to end litigation, against single surgeon defendants.

Because of the high prevalence of missed injuries, the decision to convert to an open procedure (hereafter referred to as convert-to-open) was reviewed in greater detail (**Table 3**). Overall, only 15% of the cases reviewed mention the decision to convert-to-open. In the 10 patients who received compensation (average, \$570 956) despite the surgeon's decision to convert-to-open, in 60% of these cases the decisions to convert-to-open was made because of the need to fix an injury. Only 40% of convert-to-open decisions in this series were based on the surgeon's discretionary judgment that more exposure was necessary. A similar finding is observed in the 5 cases where a verdict favorable to the surgeon was returned (ie, litigation ended without any payment being made). In this group, there were 2 cases (40%) where the decision to convert-to-open was made only after an injury was recognized; in the remaining 3 cases (60%), the decision to convert-to-open was made to improve exposure.

COMMENT

Risk management has been defined as "a provider-based effort designed to reduce preventable injuries resulting from errors."⁹ That is, risk management should be viewed as a process by which surgeons can improve their outcomes. Information collected in this study can be formulated into 5 risk management observations that could aid surgeon in avoiding being sued.

OBSERVATION 1: MALPRACTICE SUITS ARE UNCOMMON AFTER OC

Litigation after OC is uncommon, if not rare. As the gold standard for the management of biliary calculi,¹⁰ OC appears to be associated with a 50% lower incidence of BDIs.^{3,4} Moreover, the apparent lower incidence of BDIs after OCs compared with LCs is corroborated by the rising incidence of remedial biliary operations in many tertiary care centers.^{11,12} Such data suggest that OC is a safer operation. Therefore, it is not surprising that the only report of OC litigation in the literature could identify only 68 cases in a 20-year period.¹³

Similarly, the present study, using similar methodology to the study by Kern,⁶ found that in a 5-year period, only 15% of medical malpractice suits arising after cholecystectomy occurred after an open procedure. One could argue that this finding reflects the fact that LC has been the preferred surgical approach.^{1,4} However, such an argument would not explain the data from the studies by PIAA⁵ or Kern.⁶ (In particular, Kern's review of 44 cases of LC litigation identified during a 5-year period was performed in the early 1990s, when LC had not yet asserted its hegemony in the surgical armamentarium.) Thus, if a surgeon's sole goal is to minimize the risk of litigation after cholecystectomy, OC should be preferred over LC. (Admittedly, such a consideration may be incompatible with market realities and patients' desires.)

Table 3. Conversion to Open Procedures

	Finding
Plaintiffs' outcome	
No. of cases	10
Indication, No. (%)	
Discretion	4 (40)
Fix a recognized injury	6 (60)
Average payout, \$	570 956
Surgeons' outcome	
No. of cases	5
Indication, No. (%)	
Discretion	3 (60)
Fix a recognized injury	2 (40)

OBSERVATION 2: FORMAL RESIDENCY TRAINING HAS NOT DECREASED THE PREVALENCE OF BDI IN LC LITIGATION

In his seminal work on LC litigation, Kern⁶ was optimistic about the future. Because most LC misadventures are the result of "preventable iatrogenic trauma or technical mishaps,"¹⁴ Kern hoped that LC misadventures would decrease over time because his data represented the "beginning of the laparoscopic learning curve." Unfortunately, this hope seems to have only partially come true; despite more than a decade of formal residency training in LC, BDIs remain twice as common after LC than after OC.

This observation suggests that systematic factors are operative in LC misadventures. Hugh¹⁵ opined that the surgeon's spatial disorientation during LC was an important systematic factor that contributed to misadventures. Because of this misrecognition, Hugh noted that the traditional maxims for performing LC safely (the biliary structures must be adequately exposed; no structure is to be clipped or divided until it is clearly identified; and intraoperative cholangiography [IOC] should be routine) were not adequate to keep a surgeon out of trouble. Hugh¹⁵ found that LC misadventures could be substantially reduced if the operating surgeons would (1) always proceed from a fixed point of reference; (2) know their location at all times (by zooming the camera in and out); and (3) have a clear bearing on where the next several steps will take them. It is hard to truly know whether these recommendations, if incorporated into formal resident training, will improve the safety of LC. After all, Hugh's hospital is a high-volume tertiary care practice, and therefore his excellent results actually reflect his expertise.

Still, Hugh¹⁵ is to be congratulated for attempting to rethink how LC is taught and performed. Systematic analysis of surgical misadventure is an idea whose time has come, and all surgeons will soon benefit from ongoing research in system error reduction strategies.¹⁶ Other factors that, if incorporated into formal residency training, may decrease LC misadventures include the use of true stereoscopic vision afforded by a commercially available robotic surgical instrument (da Vinci surgical system; Intuitive Surgical, Mountain View, Calif)¹⁷ and increasing the use of automation.^{18,19} Admittedly, cost may be a barrier to implementing these techniques.

OBSERVATION 3: ROUTINE IOC WILL NOT ELIMINATE LC LITIGATION

The debate over whether IOC should be performed routinely or selectively during cholecystectomy was raging long before the laparoscopic technique was available. This report will not end the debate, but it will contribute to it by adding a legal slant. First, some commentators have stated that routine laparoscopic IOC “yields very little useful clinical information over what is obtained by selective policies.”²⁰ Unfortunately, the studies used to support this conclusion focused on the use of IOC to eliminate retained stones and not on the identification of intraoperative BDIs. Second, in the present study, retained stones only rarely served as a litigation trigger. Thus, because the end point of IOC studies is the incidence of retained stones and because surgeons are rarely sued for retained stones, most of the literature on IOC is not relevant evidence when contemplating litigation.

On the other hand, after reviewing Medicare’s data on 1.6 million cholecystectomies, Flum et al²¹ opined that “the routine use of IOC may decrease the rate of CBD injury.” However, that article never said that the routine use of IOC would or could eliminate (or even substantially reduce) the number of BDIs that occur during LC. The reason Flum et al²¹ did not make the latter statement was pointed out by the accompanying editorial by Talamini²²: Many BDIs occur when the CBD is confused with the cystic duct. Accordingly, BDIs often occur before a routine IOC would have been performed. Talamini’s conclusion²² is supported by the present study, because many of the BDIs reported in the legal literature occurred because of misidentification of the CBD as the cystic duct, thereby resulting in the CBD being divided or clipped in preparation for an IOC.

Still, routine performance of IOCs is not without potential value. A common denominator in LC litigation is that intraoperative injuries often go unnoticed. Intraoperative injuries were missed in 83% of cases in the PIAA study⁷ and 86% of those in the present study. Because the vascular injuries are almost always readily recognized, the missed injury data suggest that virtually all BDIs are associated with a delay in diagnosis. Thus, if IOC were performed more frequently than 40% of LC cases,²¹ perhaps the number of cases that end up in court would decrease.

Unfortunately, litigation avoidance is not so simple because, after an injury is recognized, the bile duct still needs to be repaired. However, because 75% of BDIs that are repaired at the time of the initial LC require subsequent revision,²³ most patients with BDIs, even if recognized intraoperatively, require a remedial operation. Although patients may have some misgiving toward their surgeon when they learn that the surgeon had to repair a BDI during an elective LC, it is likely that these same patients will be very unhappy when they learn that the BDI will require a remedial operation. This unhappiness is something that drives litigation, especially because from the patient’s point of view, a remedial operation is strike 3.

For some time, it has been recognized that patients rarely sue their physicians after an adverse outcome.²⁴ Generally, to be sued, a surgeon needs more than a single mistake and an adverse outcome; something more is required

to get most people to file suit against their physicians. The “something else” could be a suboptimal interpersonal relationship with a patient, a devastating adverse event (eg, unanticipated paralysis), or the presence of multiple mistakes. Based on this review, many patients view conversion-to-open with dissatisfaction. That is, having forgotten that they were told that conversion-to-open was a possibility, plaintiffs often view conversion-to-open as strike 1 against the surgeon. A BDI would have been strike 2, and a suboptimally performed primary repair would therefore be strike 3. (Alternatively, the failure to identify injury intraoperatively could be strike 3.) Given that patients perceive BDIs as occurring because of a string of mistakes, it is not surprising that many of these patients become plaintiffs. In short, unless a BDI is expertly repaired so as to avoid a third strike, it is not clear that routinely performing an IOC will mitigate the potential for litigation.

OBSERVATION 4: ROUTINE USE OF A DRAIN WILL NOT ELIMINATE LC LITIGATION

As with IOC, the debate on mandatory drainage of the gallbladder fossa is not new, and this report is not going to provide the definitive answer. Still, one case abstract was interesting because a prominent biliary surgeon testified for the plaintiff that the failure to leave a drain constituted a deviation from the standard of care. This plaintiff’s expert was willing to concede that a bile duct laceration was a recognized complication; however, the failure to place a drain, so as to detect the leak early, was substandard care. In this particular case, which was resolved in the plaintiff’s favor, the diagnosis of a bile duct leak was delayed for several days. So even if the drain had been used and the leak detected sooner, the patient still would have required a remedial operation. From the patient’s perspective, strike 1 was sustaining the injury, strike 2 was the surgeon’s failure to recognize the injury during the procedure, and strike 3 would be the need for reexploration to treat the bile leak. Thus, as with the performance of a routine IOC, it is not clear that routinely leaving a drain after an LC will avoid litigation because it is likely that, from the patients’ point of view, a remedial operation only arises after the surgeon has made several errors.

OBSERVATION 5: LIBERALIZATION OF THE DECISION TO CONVERT-TO-OPEN MAY AVOID SOME LC LITIGATION

In this series, the operating surgeon elected to convert-to-open in only 15% of the cases. This figure for conversion-to-open is certainly in the range of 1% to 30% that is reported in the literature.²⁵ However, such statistics do not seem to tell the entire story. In more than half of the cases that underwent conversion-to-open in this series, the decision to convert was not made until the surgeon had recognized an injury. Thus, the decision to convert-to-open was mandated by intraoperative events and was not a discretionary decision to obtain better exposure or facilitate mobilization of the right upper quadrant.

The textbook by the American College of Surgeons, however, states:

Ideally, the surgeon should wish to convert before any complication occurs. It must be emphasized that conversion to open surgery should not be considered a failure or a complication. Rather, it should be considered a prudent maneuver for achieving the desired objective—namely, safe removal of the gall bladder.^{26(p467)}

This seems like prudent advice. If the trigger to open a patient during surgery were liberalized (ie, the threshold to convert-to-open was lowered), it is reasonable to conclude that fewer BDIs would occur. Whether this is because the 2-dimensional view of the typical laparoscopic imaging system is suboptimal, or because Hugh¹⁵ is correct that the laparoscopic technique is associated with increased spatial disorientation of the surgeon, the fact remains that fewer BDIs occur during OC. For surgeons who perform LC and wish to avoid litigation, the trick appears to be to make the decision to convert-to-open before an injury occurs and a bile duct needs to be repaired. True, some patients may perceive conversion-to-open with dissatisfaction. However, patients who are only dissatisfied rarely sue their surgeons.²⁷ Thus, if a surgeon converts-to-open and the rest of the case proceeds well, such that the surgeon avoids adverse strikes 2 (iatrogenic injury) and 3 (remedial operation), it is much less likely that the surgeon will be sued.

LIMITATIONS

Observations are only as good as the data on which they are built. A *Wall Street Journal* article²⁷ observed that finding quality data on medical malpractice litigation is difficult. The reason that quality malpractice data are lacking is multifactorial. Although the *Journal* is correct that “corporate shield” clauses compromise the data within the National Practitioner Data Bank by concealing the identity of wayward physicians, it is equally true that the National Practitioner Data Bank data are skewed because they only contain information on physicians’ adverse outcomes.^{25,28}

In addition, there are 3 other limitations to reviewing medical malpractice limitation from legal data banks. First, legal data banks, such as used by Kern⁶ and herein, contain only a small sample of all LC malpractice claims. Second, legal data banks have 2 levels of case selection bias: selection bias at the submitter level and at the journal level for cases that are newsworthy. Thus, reported cases tend to be those cases where one side was perceived to have achieved a clear victory. Third, legal database studies included negotiated settlements and verdict awards. A negotiated settlement is a hard figure that is not ordinarily subject to further change. On the other hand, jury awards are an elusive figure. After a trial is over, many procedural avenues are available for physicians to challenge an excessive jury award.

CONCLUSIONS

Litigation is much more common after LC than OC. There appear to be 2 reasons for this finding. First, BDIs are more common with LC; second, intraoperative injuries are missed in most litigated LC cases. How to improve the outcomes associated with LC is not obvious, because it appears that formal residency training and routine use of IOC do not

eliminate a substantial number of BDIs. Accordingly, it is recommended that surgeons lower their threshold to convert-to-open during LC. In particular, if a surgeon wishes to avoid litigation, the decision to convert-to-open should be made early in the procedure to prevent an intraoperative misadventure and not to repair an injury.

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Correspondence: Thomas R. McLean, MD, JD, Surgical Service, Eastern Kansas Veterans Affairs Health Care System, 4101 S Fourth St Trafficway, Leavenworth, KS 66048 (tmclean@dnmail.com).

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Invited Critique

Among the figures given by McLean, one number cited by him stands out by its sheer enormity. It is the number of BDIs incurred during LC, quoted at the rate of 1 injury per 200 cases. Given the large number of cholecystectomies performed annually in the United States (500 000-750 000), we should expect more than 15 000 cases of BDI in a 5-year period. McLean draws his conclusions from an analysis of only 104 cases, derived from litigation statistics. This is a very small fraction of the total case incidence. Can his observations be valid based on that small sample?

There is no disputing his first observation that the landscape of litigation concerning BDI has been changed radically by LC. His second observation that formal training has not decreased the prevalence of litigation is less evident, in my opinion, in this small heterogeneous sample. His third observation that routine intraoperative cholangiography will not eliminate LC litigation is probably true, but the implications can be misleading. Intraoperative cholangiography is useful for disclosure of residual stones, but it is equally important for delineation of biliary tract anatomy and detection of operative injury.¹⁻³ I believe the preponderance of evidence is that intraoperative cholangiography is useful in lessening BDI and in identifying it once it has occurred. It would be the height of folly to discourage intraoperative cholangiography merely because it does not appear to influence litigation.

I heartily agree with his fifth observation on timely conversion of LC to an open procedure. Better exposure in difficult situations can not only avert BDI but also detect those injuries amenable to repair. On both counts, it is a way out when "the going gets rough." I once dubbed the hesitancy to convert in timely fashion "surgical hubris."

I applaud McLean's assiduous quest for the root causes of BDI in LC. His small case sampling points out an inherent defect in our reporting system. Information from current data banks is woefully inadequate, an ironic defect in this age of informatics.

Laparoscopic cholecystectomy is here to stay, despite BDI and litigation risks. Good practice demands training, competence, evidence-based techniques, judgment, and recognition of risks, probably the least of which should be litigation.

Leon Morgenstern, MD

Correspondence: Dr Morgenstern, Department of Surgery, Cedars-Sinai Medical Center, 8700 Beverly Blvd, Becker Building, Suite 216, Los Angeles, CA 90048 (morgenstern@cshs.org).

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