Chapter 20
Bile Duct Injuries and the Law

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Bile duct injury during laparoscopic cholecystectomy has led to numerous malpractice claims; many more than in the era of open cholecystectomy [1]. For the patient and family, bile duct damage sustained during surgery is a potentially devastating injury with lifelong consequences. Surgeons must be aware of the legal issues surrounding cholecystectomy. The possibility of bile duct injury should be a part of the informed consent process. The operating surgeon may be obligated to disclose the facts of such injuries. Lastly, the surgeon may be legally liable to the patient and family for damages caused by bile duct injury.

The Necessity of Informed Consent

For a definition of informed consent, the US Supreme Court held the following:

> We are content to accept, as the meaning, the giving of information to the patient as to just what would be done and as to its consequences [2]

Surgeons have a duty to discuss with patients the risks of the planned operation so that the patient can give informed consent. Individual autonomy when making a decision on health-care treatment has been a priority of the law. Requirements for consent have been codified in statutes of most states and litigated in the common

The information contained in this chapter is not legal advice. Due to the complexity and variability of federal, state, and local statutes and regulations, as well as case law, consult attorneys licensed in your jurisdiction for specific questions or in response to complaints.

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E. Dixon et al. (eds.), *Management of Benign Biliary Stenosis and Injury*, DOI 10.1007/978-3-319-22273-8_20

law. National accrediting bodies and most if not all professional societies also require written, signed informed consent of the patient prior to performance of a variety of medical procedures, but particularly surgery (Table 20.1).

Informed consent should be thought of as an event and a process [3]. Informed consent is documentation that permission is obtained usually by a patient's signature on a consent form (the event). However informed consent is also a process by which, through a variety of means, information is imparted to patients which allows them to give an informed consent (the process). Both are necessary from a legal standpoint. In addition to being a legal requirement, informed consent should also be considered a good opportunity for strengthening the physician-patient relationship through communication. Where studied, poor communication between physicians and patients is a common source of malpractice claims [4]. Poor communication skills increase the likelihood of lawsuits after medical injury whether or not due to error [5].

Table 20.1 Elements of informed consent

The Joint Commission [10]
1. The nature of the proposed care, treatment, services, medications, interventions, or procedures
2. Potential benefits, risks, or side effects, including potential problems related to recuperation
3. The likelihood of achieving care, treatment and service goals
4. Reasonable alternatives to the proposed care, treatment, and service goals
5. The relevant risks, benefits, and side effects related to alternatives, including the possible results of not receiving care, treatment, and services
6. When indicated, any limitations on the confidentiality of information learned from or about the patient
American College of Surgeons [44]
1. The nature of the illness and the natural consequences of no treatment.
2. The nature of the proposed operation, including the estimated risks of mortality and morbidity.
3. The more common known complications, which should be described and discussed. The patient should understand the risks as well as the benefits of the proposed operation. The discussion should include a description of what to expect during the hospitalization and post hospital convalescence.
4. Alternative forms of treatment, including non-operative techniques.
American Medical Association [45]
1. The patient's diagnosis, if known.
2. The nature and purpose of a proposed treatment or procedure.
3. The risks and benefits of a proposed treatment or procedure.
4. Alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance).
5. The risks and benefits of the alternative treatment or procedure.
6. The risks and benefits of not receiving or undergoing a treatment or procedure.

When informed consent has not been given the physician may be open to the tort of battery or unauthorized, unwanted touching. In battery, proof of damages is not necessary, but recovery is limited. The majority of cases involving informed consent issues have also alleged negligence which will be discussed in detail below. One analysis of negligence claims against doctors showed that disputes over informed consent involved allegations that particular complications were not fully discussed [6]. A full consent discussion lets the patient appreciate the fact that their physician has thought carefully through the proposed procedure, will take the necessary steps for the patient's safety and can also enhance the patient's sense of well-being. Patients who receive thorough informed consent understand the reasons for treatment more completely, are alerted to potential complications, and can notify health-care providers when more can be done to mitigate injury [7].

With respect to laparoscopic cholecystectomy, the need to fully disclose the procedure, alternatives, anticipated benefits and possible risks is especially important. Standardized, printed consent forms have been advocated [8]. In addition to the laparoscopic cholecystectomy and possible conversion to an open cholecystectomy, tube cholecystostomy and intraoperative cholangiogram should be added when appropriate. The inclusion of such material imparts to the patient the possible need for these adjuncts and further, should the case proceed to litigation, that such maneuvers were considered. The possibility of bile duct injury in its several forms should be explicit. Given the deficiencies in recall, it is helpful to the patient to receive a copy of the consent form after signing has occurred.

Disclosure of Bile Duct Injuries

How, when, and what to disclose about medical injuries—such as bile duct damage—has become complicated and requires conscientious deliberation. Essentially all ethicists and policy makers encourage disclosure of medical injury whether or not due to error [9]. The Joint Commission requires physicians to inform patients about unanticipated outcomes related to certain *sentinel* events [10]. Although not binding, a number of organizations also advocate disclosure. The National Quality Forum has identified timely, transparent, clear communication of serious unanticipated outcomes as a safe practice [11]. The Institute of Medicine has also framed disclosure as a patient safety concern [12]. Malpractice insurers have begun to appreciate that proper disclosure of medical injuries may also reduce claims.

Disclosure may also be a legal requirement; some states require disclosure of medical injuries to patients and families. As one example, the Pennsylvania legislature enacted the Medical Care Availability and Reduction of Error (MCARE) Act that requires health-care providers to send written reports of *serious events* (death or unanticipated injury requiring incremental health-care services) to the patient or family [13]. Finally, just as proper processes of informed consent may improve communication between patient and surgeon, proper disclosure may also have a positive impact in terms of trust, satisfaction, and whether to switch physicians [14, 15].

But policy mandates do not provide guidance to surgeons on how or when to disclose injuries such as those of the bile duct. Such disclosures must be carefully considered; apologies, or statements like "I made a mistake," are not a good idea. There is empirical support in some circles for apology as a possible way to decrease the number and size of settlements in malpractice cases [16, 17]. The law is not so forgiving; an apology is a statement of remorse, regret, and responsibility, and essentially proves a case for medical negligence [18]. Physicians who must disclose bad outcomes—such as bile duct injuries—need to know how to conduct themselves, and generally would be advised to contact risk management and seek legal advice. Statements constituting admission of liability also open the healthcare organization to possible vicarious liability and may void malpractice insurance contracts.

Reduction of medical liability claims and costs by implementation of a carefully constructed disclosure program has growing support. Several institutions have reported a reduction of claims and costs with implementation of robust communication and resolution programs (CRP). However, early adoption successes required strong health-care system champions, clinician communication to break down resistance to cultural change, and persistent patience during implementation [19]. Further, CRPs require that liability insurers must agree, leadership must advocate that disclosure will occur for all adverse events, disclosure protocols must be easy to understand, and opportunities should be provided for physicians to practice what to say to patients.

Significant infrastructure investments are also required, a system for rapid adverse event reporting, causation analysis teams, and coordinators for the disclosure. Lastly, consideration of what other members of a team might disclose should be managed. A recent study showed that 25 % of residents who disclosed a medical error made an admission of negligence and were told in debrief that general expressions of empathy or support are about as far as they should go [20]. In short, surgeons are at the "sharp" end of injuries such as might happen to patients' bile ducts but are necessarily only one of many individuals involved in managing proper disclosure.

Bile Duct Injury and Malpractice Claims

Introduction

Medical malpractice is a specialized form of the tort (injury) of negligence. "[I]njury alone is insufficient to prove negligence in medical malpractice cases" [21]. Surgeons cannot guarantee the outcome of a patient's condition, and, medical injuries occur without fault. But surgeons have a duty to their patients to apply knowledge, skill, and care possessed and used by their peers under like circumstances and conditions. If patients are injured and the surgeon fails to meet (breaches) a professional standard of surgical care, the surgeon may be liable to the patient in a court

of law. There are four elements required to prove a case of negligence: a duty of the defendant to the plaintiff; a breach of that duty; a finding that the breach of duty was an actual and proximate cause of the injury; and that the plaintiff suffered damages that can be monetary or non-monetary. In a medical malpractice action, the second element—breach—is defined as a deviation or departure from an accepted standard of care.

As applied to the special case of bile duct injury, the element of duty is generally clear; a surgeon who operates on a patient has a duty to meet the professional standard of care. Similarly, the question of causation—did the bile duct injury cause the damages for which the patient has sued—is generally not at issue. The two main points that are litigated are whether the standard of care was breached, and the magnitude of the damages for which the surgeon is liable.

Medical Malpractice: The Scope of the Problem

Physicians have compared medical malpractice lawsuits to Ahab's nemesis; "… evil, ubiquitous, and seemingly immortal" [22]. But from a patient's perspective, when a medical injury occurs, someone should be held accountable and the injured patient may seek legal counsel. Although not directly relevant to bile duct injuries, a short review of the literature of medical malpractice claims is instructive. Negligent medical injury has been considered morally wrong, but if such negligence does not result in a claim and compensation the malpractice system has failed [23]. In one study of malpractice claims, 97 % of patients felt to be victims of negligence did not file claims and conversely a high rate of claims were filed for non-negligent injuries [24].

Two basic strategies have been used to analyze malpractice claims; patient chart reviews and closed claims reviews. The California Medical Association reviewed over 20,000 medical charts and showed that 17 % of patients sustaining medical injury would be eligible for compensation [25]. The Harvard Medical Practice Study (HMPS) of over 30,000 charts noted 28 % of injuries were due to negligence [26]. A similar study in Utah and Colorado validated the HMPS; the rates of negligent contributing injuries were 38 % and 28 % respectively [27]. A sample taken from some 31,000 medical charts and statewide data on medical malpractice claims found a ratio of negligence to malpractice claims of about 8 to 1 [28]. The negligent adverse event to claims ratio was 5.1:1 and 6.7:1 in Utah and Colorado, respectively [24]. The data are clear; most individuals who suffer negligent medical injury do not sue.

Closed claims analyses have several advantages compared to chart reviews; physician fears of disclosure and subsequent litigation are past, most of the claims involve serious injuries, and more detailed information about the injury exists. Smaller in scope, surgery closed claims data are similarly useful. A follow-up to the Utah and Colorado study showed that 66 % of all injuries were surgical [29].

Two research groups have analyzed surgery closed claims data from different vantage points; Harvard-affiliated Departments of Surgery, and the American College of Surgeons' (ACS) Committee on Patient Safety and Professional Liability [30, 31]. The Harvard group looked at contributions of human and systems factors to errors in surgical care [32]. The ACS group asked whether injuries by individual surgeons were preventable [33].

The Harvard group reviewed 444 closed surgery claims, 422 involved injuries, 61 % were attributed to error, and 39 % were error-free [30]. Errors were found to occur most often in commonly performed operations by experienced surgeons where system failures or patient complexity were also present [34]. The ACS study collected data from five malpractice insurance companies; a total of 460 closed surgical claims; injuries thought to have met standard of care (no negligence) were present in 36 % of cases, care that fell below the standard were present in 50 % of claims [31]. Thus, the incidence of closed claims in which no breach of the standard of care was identified was remarkably similar between the Harvard and ACS studies (39 % and 36 %, respectively). A separate study of over 1400 closed claims showed that 40 % of claims were for non-negligent or no medical injury and accounted for 10 % of total liability costs in the system [35]. In summary, the available data suggest that meeting the standard of care will not prevent a claim from being filed. In the studies cited, serious injuries were present in the vast majority of cases and bad outcomes—not negligence—are more likely to predict lawsuits.

The data for bile duct injury-related claims are not as robust as for surgical malpractice claims in general, but are nonetheless useful. Since laparoscopic cholecystectomy was widely adopted in the late 1980s, litigation claims resulting from injuries to the bile ducts surpassed by 20 times that of similar litigation for open cholecystectomy. A 20-state survey from national jury verdict reporting services identified 44 cases of laparoscopic cholecystectomy injury, 21 settled out of court for a mean payment of $469,711 [36]. Twenty-three cases went to trial, with 19 verdicts for the defendant, and 4 for plaintiffs with a mean payment of $188,772 [36]. Biliary injury is reputed to be the most common cause for litigation in gastrointestinal surgery; bile duct injury represents 20 % of all general surgery claims, 50 % of laparoscopic claims and about 15 % of total general surgery indemnity (the dollars paid by insurers) is for biliary injuries [37].

One study of 46 closed bile duct injury claims documented that 72 % of injuries occurred in elective cases without acute inflammation. Eleven of 16 cholangiograms, when done, were misinterpreted. With 86 % of cases resolved at the time the study was published, the plaintiff won 21 settlements and 5 jury verdicts with mean awards of $221,000 and $214,000, respectively [38]. In a second study, 324 claims were collected by the Physician Insurers Association of America (PIAA) encompassing more than 50 malpractice insurance companies providing coverage for 60 % of physicians, 67 % of the claims filed after laparoscopic cholecystectomy involved an injury to the biliary tree and 83 % of the injuries were not recognized during the operation. Further, 50 % of the claims were settled for the plaintiff with an average of $236,384 [1]. A literature review of 122 laparoscopic cholecystec-

tomy claims involved injuries to the bile ducts in 78 % that were missed 86 % of the time. Fifteen percent of cases were converted to open but in just over half, conversion was required to repair an injury [1].

Breach of the Professional Standard

In malpractice cases involving bile duct injuries, the question of whether or not the standard of care was breached is usually determinative. Plaintiff's attorneys will argue that common bile duct injury is entirely preventable if proper surgical technique is used. Said another way, the question often put before the court is: if the operation had been performed competently would the patient's injury have occurred? The standard of care for surgeons in in most states is said to be objective, centering on professional care, skill, and knowledge usually exercised and possessed. In determining whether the standard of care was breached, what the surgeon actually did or did not do is the relevant issue; not what the surgeon may have been thinking (the subjective standard).

Ultimately, whether the standard of care was breached is a matter for the finder of fact—usually a jury but sometimes a judge—in a civil trial. The fact finder usually hears testimony from expert witnesses employed by the plaintiff or the defendant. Specifically, bile duct injury malpractice cases usually require testimony from expert witnesses to establish whether the standard of care for cholecystectomy was breached. Courts generally have decided that medical malpractice facts are too technical for juries to understand without help.

The rules regarding who may qualify as an expert witness are complex. Presiding judges allow experts to testify depending on qualifications offered by the attorney. Qualifications of expertise might include the necessary experience and training, academic as well as practical experience, and board certification. In some states, an expert witness' opinion is required to initiate a lawsuit; in others, a peer specialist may be required for specialized medical disciplines; expert's opinion might be needed to initiate a lawsuit; lastly, there may be rules designed to prevent "career" experts. Juries are not required to adopt expert opinions, but may be required to use them to consider the facts.

Elements that may be considered—and put forth by expert witnesses—have been the subject of various commentators over the years. One comprehensive report suggests nine important considerations [39]. Position the gallbladder with maximum cephalic traction. Obtain lateral and inferior retraction of Hartmann's pouch of the gallbladder. Dissect lateral to medial high in the neck of the gallbladder. Posterolaterally dissect Hartmann's pouch to identify the gallbladder neck–cystic duct junction. Free the neck of the gallbladder from the liver circumferentially. Place clips only under direct vision and as close to the gallbladder as possible. Liberally use intraoperative cholangiography to define the anatomy and mitigate severity of any injury. Dissect close to the gallbladder. Lastly, the surgeon must know when to convert to open cholecystectomy. Another commentator additionally

adds caution in interpretation of cholangiogram images and avoidance of blind attempts to control hemorrhage [40].

Notwithstanding the fact that patients give informed consent, they do not consent to negligence like a surgeon's failure to properly recognize anatomy, a decision not to convert the procedure to open, or a failure to use IOC when indicated. Lack of attention or excessive speed is an additional theory put forward in efforts to make out a negligence claim. As with any surgical procedure, there are certain risks and potential complications that are known to occur, and such complications do not necessarily constitute a deviation from the standard of care. Studies on bile duct injuries that resulted in litigation have shown that the main reasons for lawsuits are inadequate dissection of the triangle of Calot, confusion of normal anatomy, misidentification of Common Bile or Hepatic Duct (CD) as cystic duct, clips impinging on CD, blind clipping or cauterization near hilar structures, and failure to recognize a Luschka's duct [38]. If the operation was dictated as "straightforward, with minimal inflammation, easy dissection of the gallbladder, and unremarkable pathologic findings", the lack of intraoperative findings to suggest a difficult dissection might constitute a deviation from the standard of care.

The decision not to do an intraoperative cholangiogram (IOC) may also be advanced as evidence of breach. Misinterpretation of cholangiography, by not visualizing a hepatic duct, noting extravasation of uncertain origin, or not completing the procedure may also be a ground for a negligence claim. Under certain circumstances, the plaintiff may offer into evidence scholarly papers which may be offered as evidence of standard of care [41, 42]. Further, cholangiography itself does not prevent duct injuries. In litigation concerning CD injury in which an intraoperative cholangiogram was not performed, surgeons often state that there was no doubt about the anatomy. However, the plaintiff's attorney will question how the injury occurred in the first place if there was no doubt. If significant inflammation and scarring were present, an IOC should probably have been performed, or at least attempted. If the inflammation was so severe that the IOC could not be performed, but was at least attempted (and documented), it would be harder to prove a breach of the standard of care.

There are, however, times when a decision to perform the IOC becomes a judgment call of the surgeon to prevent undue risk to the patient. If the gallbladder is severely inflamed, making dissection difficult, an IOC should be attempted. If the surgeon, despite all best attempts, is unable to technically place the catheter into the cystic duct due to the inflammation, it is not below the standard of care to abort the IOC and simply remove the gallbladder, assuming the anatomy is understood. Another option would be to convert to an open procedure, although this does not necessarily protect against a CD injury. Once a bile duct is injured, improper management or delayed recognition might also breach standard of care. If the surgeon has minimal experience with bile duct reconstruction, intraoperative consultation from a colleague, a surgeon more experienced in HPB surgery, or transfer—even from operating room to operating room—might be the best option. Lastly, in a teaching hospital setting, letting an inexperienced surgical resident persist in attempting the procedure in the face of distorted anatomy, bleeding, or inflammation may be judged negligent.

Evidence

Bile duct injuries happen in the operating room, and although there may be corroborating evidence in the case of delayed diagnosis, for the bile duct injury itself, only the operative note and depositions are likely to be admitted at trial. Op notes should be concise and without speculation. They should not be retroactively changed and are best dictated, edited and signed at the time of the procedure. Relatively little has been published on how to dictate an operative note. In one report 250 actual operative notes were compared to a model note developed through cognitive task analysis. Using such an analysis, the following elements were judged to be important: (1) cephalic traction of the gallbladder, (2) dissection of the gallbladder neck bordering the triangle of Calot; (3) identification of the cystic duct–gallbladder neck junction, (4) details of ligation and division of the cystic duct and cystic artery, (5) dissection of the gallbladder from the hepatic bed, and (6) findings to include inflammation, any difficulties in dissection, bleeding, and other irregular cues. Key elements were present in 25 % of routine operative reports, but none in bile duct injury cases, respectively. Further, irregularities such as perceived anatomic or other deviations correlated with bile duct injury operative reports [43].

Depositions are question and answer sessions under oath, which result in a written and possible video transcript. In most states, the questions are generally about the surgeon's treatment of the patient but can be about any subject matter relevant to the case. In most states, deposition testimony can be read to a jury even if the physician does not take the stand. Plaintiff's counsel (representing the injured patient) hopes to get an admission of negligence (see apology discussion above), lock in statements to prevent the physician from telling a different story at trial (impeachment), or create conflicting testimony amongst treating physicians.

As the subject of a deposition, the surgeon's obligation is to answer questions accurately. The deposition is not a conversation but part of an important formal legal proceeding. Prior to sitting in a deposition, the surgeon's attorney will generally give advice on preparation. It is important to be serious, business-like, and courteous. Understand and answer only the question asked, a process that should be simple but not easy. If the question is not understood, it cannot be answered, and it is appropriate to ask that the question be repeated or even rephrased. Records should be referred to if appropriate. A general rule of thumb is that the surgeon should be able to give any answer in two sentences or less and preferably with a yes or no. Medical literature is generally not allowed at trial; however if the surgeon acknowledges a source as "authoritative," she may be questioned as to anything in that source.

Damages

Patients are more likely to sue the surgeon who performed the cholecystectomy if bile duct reconstruction results in complications and the patient's recovery is protracted. These complications include anastomotic stricture of the

hepaticojejunostomy, cholangitis, cirrhosis, or liver failure. If the patient does well for the first 5 years after reconstructive surgery, then the patient most likely will continue to do well. However, in those years of recovery, damages both monetary and non-monetary will be alleged.

To be awarded damages, the patient must show that the surgeon's malpractice caused the injury, and a price in dollars can be put on the damages. Damages can be broadly separated into monetary and non-monetary categories. Monetary damages are generally easier to quantify. Monetary damages cover expenses caused by the malpractice, including medical bills, lost time from work, and future missed work often including anticipated promotions and raises. There is inevitably guesswork involved, especially when it comes to future medical expenses. Experts are generally employed to assist in the calculation of these damages.

Non-monetary damages refer to costs of the patient's suffering that are real but do not have a definite price. Probably the most common example is pain and suffering; the physical or emotional distress resulting from the malpractice and resulting injury. The patient seeks compensation in dollars as the only viable substitute for the experiences sustained as a result of the injury. The price the defendant owes for pain and suffering is calculated separately from the amount owed for monetary expenses, such as medical bills, time lost from work, and loss of future earning capacity.

Often, relatives will also file claims for injuries such as loss of consortium and loss of services. The dollar value is generally arrived at by the fact finder—judge or jury. The patient and others will give evidence about the patient's pain and suffering, and other non-monetary damages. Experts often testify about the usual outcome of the patient's injury. Some states—California being the most prominent—place a cap on the maximum amount of non-monetary damages the patient can recover. Some states cap all damages. Some states reduce the damages the surgeon must pay by the amount the injured patient receives from insurance or other sources (the collateral source rule). Lastly, some states limit the contingency fees an attorney can charge for a malpractice representation (although the usual fee is about one-third of the award, plus expenses).

Conclusion

Should a bile duct injury occur, the likelihood of a patient's claim of malpractice against the surgeon depends on a number of factors. Good communication and a thorough informed consent process may help defuse anger, as well as insure that the patients are aware of the possibility of such injuries. Once a bile duct injury is sustained, the patient should be told the facts as known, and such disclosure must be done according to any relevant state laws and regulatory requirements. Apologies are ill-advised; such conversations are best had after deliberation with legal counsel. The documentation of the operation should be thoughtful and limited to the facts of the case.

The medical malpractice system is not efficient; many patients who are injured by negligence never file a claim. Conversely, when serious injuries occur, some claims are filed in the absence of negligence. Laparoscopic cholecystectomy cases are more likely to generate lawsuits than open procedures. Lack of timely conversion, failure to consider or misinterpretation of cholangiograms, delay in diagnosis of the injury and inadequate repair in the event of recognition are all common sources of litigation. Lastly, many lawsuits are settled out of court; those cases that go to trial are split with verdicts for both the plaintiff and defendant. The decision to go to trial is often one of the most difficult a surgeon must face in a career of difficult decisions and reinforces the need to work closely with counsel throughout what is always a harrowing experience.

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