Biliary Injury in Laparoscopic Surgery: Part 1. Processes Used in Determination of Standard of Care in Misidentification Injuries

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Biliary injury is a major cause of patient morbidity and litigation. Many surgeons have a poor understanding of the issues involved when litigation follows biliary injury. The purpose of Part 1 is to familiarize surgeons with concepts about the standard of care in misidentification injuries. The first section of Part 1 outlines legal concepts that form the basis for how claims are considered. The second section of Part 1 describes the range of expert opinion that the author has encountered in regard to misidentification injury.

There are no precise current statistics, but based on information received from risk management sources,[1] (and Anderson RA. CEO, The Doctors Company, personal communication, 2004.) it seems that biliary injury is by far the most common cause for litigation in gastrointestinal surgery. Claims arising from laparoscopic surgery represent 20% of all general surgery claims, and 50% of laparoscopic claims are for bile duct injury. In terms of indemnity (dollars paid out by insurers), the situation is even more serious because 33% of general surgery indemnity arises from laparoscopic procedures, and half of that is for biliary injury. So, about 15% of all general surgery indemnity is from biliary injuries (Anderson RA. CEO, The Doctors Company, personal communication, 2004).The percentage of biliary injuries litigated is very high. There are no current reliable statistics on the incidence of biliary injury. The latest high quality studies relate to operations performed in the last decade.[2,3] Biliary injury has probably declined,[2] but it seems still to be greater than during the period of open cholecystectomy.

Most major biliary injuries are from misidentification, either misidentification of the common bile duct as the cystic duct or misidentification of an aberrant bile duct as the cystic duct. I have treated patients with this type of injury, studied its pathogenesis,[4,5] and acted as an expert witness in such cases. This experience convinced me that many surgeons have a poor understanding of the issues involved when litigation follows biliary injury. The purpose of this article is to familiarize surgeons with concepts about the standard of care in misidentification injuries. I believe that such knowledge can promote safe practice, which will help protect patients from such injury, and coincidentally protect surgeons from litigation. The presentation is a simplified overview of a complex subject using a number of sources as guides.[6–9] It is not intended to set forth guidelines for determining whether the standard of care has been met in biliary injury patients, nor is it specific to a particular locality; this is an important caveat because unlike medical concepts, the details of legal concepts vary from state to state and these nuances can be very important. The article has two parts. The first section outlines legal concepts that form the basis for how claims are considered. The second section describes the range of expert opinion that I have encountered in regard to misidentification injury. In a companion article, injury prevention and litigation prevention are considered together more broadly than just misidentification injury. Although the discussion is directed toward biliary injury, the concepts described in the first section of this article apply broadly to the practice of surgery.

LEGAL CONCEPTS

Negligence, standard of care, and the responsible person

The key concept of the section of law relating to negligence is that a person injured through careless actions of another person(s) has a moral right to compensation from that person(s), even though the injury was unintentional. The basic idea is the careless person has an obligation to return the injured person to their original state.[6] But unintentional injury may sometimes result from actions that are not careless, and such actions are

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not negligent. The simple justice of these concepts is intuitive and may be illustrated through examples using automobile injuries. In the first instance a driver who is intoxicated and driving at a high rate of speed on a city street ignores a stop sign and strikes a pedestrian, causing injury. In the second instance, the same type of injury is caused by a driver who, although traveling within the speed limit, strikes a pedestrian darting out from behind a truck when the car is only a few feet from the point of impact. Note that in both cases, injury was caused by a car striking a pedestrian; there is no question of causation. Also note that in both cases, the injury was unintentional; there is no question of intention to injure. The difference lies in that the driver in the first case behaved carelessly and the driver in the second did not. So, when confronted with an unintentional injury, the central question is whether the injury was caused by carelessness. To answer this question, *care* must be defined, as must the concept, "standard of care."

Standard of care is defined as the care that a reasonable person would take to prevent injury to another. Note that standard of care is a broad concept that applies to nonmedical and medical injuries. Returning to the examples, it is clear that a reasonable person would not drive when intoxicated or drive at a high rate of speed on a city street. So the actions of this driver are below the standard of care. The difference in the second case, which is an example of actions not below the standard of care, is that the accident occurred even though the driver was behaving as reasonable people do. Most, if not all drivers, given the same circumstances as in the second case, would have the same outcomes. The reasonable person, then, is an individual with normal intelligence who would be expected to foresee the risk of actions in respect to the possibility of injury to others and to avoid them to the extent that other ordinary persons do. The risk of injury to others consequent to driving while impaired is foreseeable and avoidable; injury to others while driving safely is unexpected, and in this sense, unforeseeable and unavoidable. Another important concept is that the reasonable person is the ordinary citizen and not one possessed of extraordinary braking reflexes or other exceptional abilities. Of course, most cases are not as clear cut as our examples. There is no objective measure of foresight and there are well described biases[6] when determining in retrospect whether adequate degrees of foresight were applied by an individual.

Negligence in medicine

The preceding concepts apply to professional behavior, but are adjusted to account for the fact that the interaction is between a trained professional (the physician), and a lay person (the patient). For instance, instead of a determining what a reasonable person would do to avoid injury to another person, the bar is usually set at what a reasonable physician would do to avoid injury to a patient. In most circumstances, four conditions must pertain in medical negligence. The physician must have accepted care of the patient; practice below the standard of care must be present; injury must have occurred; and the injury must be due to the substandard care. In the case of a misidentification injury at cholecystectomy, three of these conditions are almost always present. The surgeon, by virtue of operating on the patient, has assumed care, the injury has happened, and if it can be shown that misidentification occurred because of actions below the standard of care, then the link between failure to meet the standard of care and misidentification injury is established. So in the context of misidentification injury, the crux of arriving at an opinion about whether negligence has occurred is the determination of whether the standard of care has been met.

There is not a universal definition of standard of care as it applies to the medical profession. A basic definition as it applies to surgery would be: the degree of care a reasonable surgeon would take to prevent harm to a patient. In some definitions, adjectives such as *prudent* and *skilled* are added, as in: the degree of care a reasonably prudent and skilled surgeon would take to prevent harm to a patient. Some consider the modifiers irrelevant because they believe that prudence and skill are already contained within the definition of what a reasonable surgeon is. Others approve of the modifiers, believing that they refine and clarify the definition of a professional standard of care as opposed to the definition of standard of care as it applies to ordinary activities such as driving. When dissected, the professional standard of care seems to involve two elements: the type of care and the quality of care.

Quality of care

Prudence, derived from *providere* (Latin: to provide), is an important quality of care descriptor for the reasonable practitioner. The story of the ant and the grasshopper is the lesson of prudence. The ant has foresight and wisely provides for the future. Foresight is a central ele-

ment to standard of care in both lay and professional activities. Prudence also involves judgment. Skill, for the surgeon, usually means the technical ability expected of the reasonable surgeon. There are other descriptors that are sometimes used to flesh out qualities of the reasonable practitioner. These indicate that the care delivered must be uninterrupted (continuous, attentive) and that it must be on the lookout for problems (heedful). Such additional terms may be summarized by the term *diligent*. Their use is an attempt to define more precisely what is expected of the professional.

The preceding might make the reasonable practitioner or surgeon seem like an unachievable paradigm, but that is not the case. Akin to the standard for nonprofessional negligence, the bar is set at the level of the ordinary practitioner. The standard of care requires professional qualities to the degree that they exist in the ordinary practitioner of the specialty and not to the extent that they reside in an exceptionally gifted practitioner. Extraordinary foresight and extraordinary skill are not the standards, nor is *average* a good descriptor because it implies that one-half of the profession would be below average. Stated otherwise, the professional is judged against ordinary peers.

Type of care

Standard of care also examines whether the actual type of care selected for the patient is reasonable, ie, would be selected by the reasonable practitioner. In almost all cases, courts leave the decision of whether care is acceptable to the profession. Care is acceptable if it falls within norms of practice, which are established by professional authorities in writings and recorded electronic communications. Different approaches to diagnosis and treatment are within the standard of care if they fall within current norms of practice. In some cases, there may be only one acceptable approach, and in other instances, there may be two or more. For instance, in acute cholecystitis, early and interval cholecystectomy are generally both acceptable. Similarly, there are several acceptable ways of wound closure. The operative term in this regard is *reasonable minority*. When a reasonable minority of the profession recommends a technique, it usually is judged as acceptable in terms of standard of care. For care to be acceptable, it must be within current norms of practice. Also, when judging standard of care in retrospect, the care provided must be examined against the norms of practice at the time that the care was tendered and not at the time the judgment is made. Similarly, acceptable care is what the norms of practice are and not what they ought to be. Although quality and type of care have been separated in this discussion, there is considerable overlap, eg, the surgeon exhibiting ordinary levels of prudence would be expected to recommend procedures that fall within current norms of practice.

Locality

Acceptability of care is judged by the profession as a whole as opposed to a group practicing in one locality. When an alternative to generally accepted care is practiced by a reasonable minority, that minority should exist broadly across the profession and not only in one locality.[7] This is to avoid the possibility that a substandard treatment might exist within a locality and be deemed acceptable, or even worse, that one practitioner in that locality whose care was good could be judged as negligent because his care was different from a local pattern of substandard care. But locality is taken into consideration in the sense that the care given may be judged against care under similar circumstances, for instance, size of institution and degree of subspecialization available. Locality is an area in which there are differences from state to state. The general trend is away from locality rules, in part because they seem to suggest that there are levels of acceptable care.

Opinions about negligence in misidentification injury

There is a wide range of opinion among experts about what constitutes a breach in the standard of care in misidentification injuries. I have grouped these opinions into three categories: misidentification is always negligent, misidentification is sometimes negligent, and misidentification is never negligent. The "always" and "never" should be taken as "almost always" and "almost never." The full range of opinion that I have met during 12 years in depositions and trial testimony is presented, and it likely represents the range of opinion among experts. But I am not suggesting that this approach can objectively quantify how many experts fall into one or another category.

Misidentification injury is always negligent

This set of expert witnesses holds that misidentification injury is always or nearly always negligent. Generally, their view is that the reasonable surgeon has methods at his disposal that should always result in correct identifi-

cation of the cystic duct, even in difficult or unusual circumstances. To them, misidentification injury is always foreseeable and avoidable. So when a biliary injury from misidentification occurs, it is, by definition, negligent, in their opinion. Sometimes such experts express the opinion that although identification of the ducts under certain difficult conditions may not be possible laparoscopically, the surgeon has the responsibility to recognize a need for conversion to an open procedure before injury occurs. Then the surgeon should be able to correctly identify the cystic structures at the open procedure. These witnesses frequently express the opinion that intraoperative cholangiography should be done routinely to identify biliary anatomy. Some of these experts are highly experienced biliary surgeons. But in my experience, most of these individuals acting as experts and expressing these views have little or no personal experience in laparoscopic cholecystectomy, although they frequently have experience in open cholecystectomy. Sometimes they are not trained in gastrointestinal surgery or are nonsurgeons.

Misidentification injury is sometimes negligent

The opinions of most expert witnesses I have encountered fit into this category. Their view of the problem of misidentification might be best illustrated by analogy: identification of an enemy by the military during combat. Every branch of the military has a set of rules for identifying the enemy. The goal is positive or conclusive identification of the enemy. The main purpose is to avoid injury to one's own or allied troops. Positive identification is a key element in the rules of engagement, which govern whether an enemy shall be attacked. This system for protection of friendly troops works well in most circumstances, but it can fail. When failure occurs, it seems to be for one of three reasons. The first is that the system is not used or not used as instructed. In some cases this will be due to carelessness and an action below the standard of care will have occurred. The second is that the battle conditions are so severe that even with proper application of the rules, the system will sometimes fail. And the third possibility is that there is an unforeseen flaw in the rules, possibly because of changing conditions of war such that under certain conditions, the system will fail. The second and third conditions result in injuries, which are not from negligence because they can happen as a result of activity of the reasonably prudent soldier. To extend the analogy to cholecystectomy, the cystic duct is the enemy to be correctly identified and the other bile ducts are friendly. This set of experts holds the following opinions.

1. There are several approved methods of identification of the cystic duct—approved in the sense that they are accepted practice as defined previously. A surgeon should use one of these accepted methods with the goal of obtaining positive identification of the cystic duct. I am aware of four methods for ductal identification of this type. These are intraoperative cholangiography, the infundibular technique, the critical view technique, and identification by display of the confluence of the cystic duct with the common hepatic duct to form the common bile duct. Support for the use of the first three during laparoscopic cholecystectomy can readily be found in the literature, and the fourth was a common means of ductal identification in the open cholecystectomy era.
2. Under difficult or unusual operative conditions, even when an approved method has been used appropriately and it appears to the operator that positive or conclusive identification has been achieved, misidentification may still occur in the hands of reasonably prudent and skilled surgeons. Some of the operative difficulties pointed to are inflammation, anomalies, large body size or unusual habitus, previous operations causing adhesions, or concomitant disease in the area of dissection. Inflammation may be acute or chronic. Anomalies may be from aberrancy (abnormal location) or unusual size or number of structures. Anomalies may be very common or very rare. Several of these problems can coexist, and their coexistence may contribute to the degree of difficulty. For instance, the coexistence of acute and chronic inflammation may add to operative difficulty. Also, one can readily appreciate how much easier it is to damage an aberrant duct that is caught up in chronic scar than one that is not, or how body habitus can contribute to operative difficulty. The greater the degree of difficulty the more likely it is that experts of this type will agree that reasonably prudent surgeons following the rules of ductal identification, and reaching what they believed was positive or conclusive identification will still misidentify ducts as the cystic duct and injure them. There is a range of opinion among these experts as to what the threshold is for saying that the requisite degree of difficulty was present. This is not surprising because the variables (inflammation, anomalies, and so forth) are not readily quantifiable and weighting these factors will be a matter of judgment.

In the analogy, the third cause for failure was a problem with the system or plan. We have shown that the infundibular technique is prone to failure in the pres-

ence of severe acute or chronic inflammation, and when the cystic duct is hidden or effaced by a large stone, or hidden because of difficulty in retracting the gallbladder.[5] These conditions tend to cause a visual deception when this technique is used. Even when the technique is carried out properly, as a result, the common bile duct will be perceived as the cystic duct. So the problem in this case is not one of individual error but an error in a system for identification of the cystic duct. This was the first of several articles that have focused on visual deception as a cause of injury in this operation,[10,11] although the others focused on Reason's models[12] of human error as they relate to cholecystectomy[10,11] as opposed to the failure of a specific technique of ductal identification.[5] We recommended that the infundibular technique ought to be abandoned or if used, that a confirmatory cholangiogram be obtained. But judging from responses at continuing surgical education courses at national meetings, the infundibular technique is still in wide use around the country, so its use would still seem to be within the current norms of practice.

Actually, none of the four methods of ductal identification is perfect, although in our experience, the infundibular technique has the greatest chance of failing. Operative cholangiography is currently an unreliable method of detecting some aberrant bile ducts.[4,13] Dissection of the cystic duct to the confluence with the common hepatic duct risks injury to the common duct during the process of obtaining identification and is discouraged by many teachers of laparoscopic cholecystectomy because of the possibility of injuring the common duct during dissection.[10] The same criticism might be made of the critical view technique, ie, that it requires considerable dissection, although dissection near the common bile duct is discouraged.

Misidentification injury is never negligent

This set of experts holds that misidentification injury is never negligent, perhaps with rare exceptions. Their view is that misidentification injury is a complication of laparoscopic cholecystectomy that "just happens one in awhile" and that it is unavoidable. Asked what the exceptions to the rule are, ie, when misidentification injuries are from negligence, examples provided are of a type that would be considered reckless behavior, such as operating while intoxicated or under the influence of drugs, ie, activity bordering on or actually criminal in nature.

The view of this set of experts is attractive because there are complications of operations that occur in a small percentage of operations that all would agree are usually unavoidable by reasonable surgeons. Wound infections, incisional hernias, and postoperative bowel obstruction from adhesions are examples. These and other types of complications will indeed happen once in awhile in the hands of virtually all reasonably prudent surgeons. In terms of ductal misidentification, these experts also see visual deception as an important element in pathogenesis, but do not necessarily relate it to a specific technique or set of conditions. Instead, they believe that reasonably prudent surgeons can become disoriented by the visual information they are receiving, even in the absence of risk factors such as inflammation and anomalies and with any of the methods of ductal identification. Once they form a visual hypothesis that a duct is the cystic duct, subsequent information is incorrectly processed around the false hypothesis. Indeed, their argument is that visual disorientation must have occurred because no surgeon would purposefully misidentify and cause injury. To them, this is an unavoidable and unforeseeable form of human error that will just happen once in awhile to reasonable surgeons.

In conclusion, the broad range of opinion among experts about what constitutes breech of standard of care in misidentification injuries may be surprising and somewhat disconcerting. In the future, it might be valuable for a national surgical society to convene a consensus conference in an attempt to define the standard of care for laparoscopic cholecystetcomy. For now, it is the milieu in which we work. When litigation is in progress, the plaintiff's lawyer will seek expert opinion and likely find experts of the first or second type. With an expert of the first type it is very likely that the litigation will proceed. But with the second type, litigation is often stopped when the expert states that a conclusive or positive method of identification was used but failed because of conditions. Conversely, when it seems that the surgeon did not use an accepted method of identification or used one inappropriately, then the litigation may proceed. The implications for practice and avoidance of litigation are obvious; an accepted method of ductal identification should always be used and followed to its end point, at which it is supposed to provide positive identification and the steps documented. Routine proper application of accepted methods increases the safety of the operation for the patient, which is our primary goal. This theme of

fulfilling our primary goal of safe practice while avoiding litigation will be carried forward in the companion article, which looks at biliary injury in laparoscopic cholecystectomy more broadly.

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