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Biliary duct injuries caused by surgeons can be devastating--and sometimes fatal--to people who undergo gallbladder surgery. Biliary injury is the greatest problem besetting one of the greatest advances in biliary operation during this century, the laparoscopic cholecystectomy. The key to this problem is not in complicated repairs at tertiary centers but in prevention. Prevention requires commitment to perform meticulous dissection so that only structures that have been unequivocally and conclusively identified are divided.(1)

This year, more than 1 million people in the United States will learn they have gallstones. They will join the estimated 20 million Americans who have previously been diagnosed with this condition. Most people with gallstones are asymptomatic, typically remain symptom free for years, and require no treatment. However, each year more than 700,000 Americans develop symptomatic stones, requiring some form of intervention. While there are alternative nonsurgical forms of treatment, these remain palliative rather than curative.

Cholecystectomy--the surgical removal of the gallbladder--is the standard method for treating symptomatic gallstones and gallbladder disease. Until the end of the 1980s, this surgery was done as an "open" procedure, requiring a six-inch incision, a three-to four-day hospital stay, followed by a three-to six-week convalescence.

In 1989, the world of gallbladder surgery underwent a revolution with the introduction of laparoscopic cholecystectomy, or fiber optic surgery performed through the abdominal cavity wall. Developed in the United States by Dr. Eddie Joe Reddick, the procedure was enthusiastically embraced by both the surgical community and the public, because it resulted in less postoperative pain, shorter hospital stays, and more rapid return to normal activity when compared to the open procedure.

Currently, 90 percent of cholecystectomies are done laparoscopically, and the procedure is the most common one performed in a general surgery practice. Yet, the benefits of the procedure have been attained against the backdrop of an alarmingly increased number of iatrogenic injuries, or those inadvertently induced by the surgeon. While many errors can arise during laparoscopic cholecystectomy, the focus of this article is on the most devastating complication--iatrogenic injury to the bile duct system.

THE ANATOMY

To understand the mechanism of bile duct injury, it is necessary to be familiar with the anatomy of the biliary structures. The liver is a large organ in the upper right part of the abdomen. One of its functions is to produce bile. Bile, which is a combination of digestive enzymes and waste products, plays an important role in the digestion of fats in the intestinal tract. The bile is delivered from the liver to the intestines through a series of ducts, or tube-shaped structures. Collectively, the gallbladder and these ducts are called the biliary system.

From the liver, the bile initially passes into the right and left hepatic ducts. These then coalesce into one duct called the common hepatic duct. Merging into this duct is the cystic duct, coming from the gallbladder. After this merger, the tube is then called the common bile duct, which feeds on down to the small intestine.

The gallbladder itself is a pear-shaped sac that lies on the undersurface of the liver. It connects to the biliary ductal system through the cystic duct. The primary job of the gallbladder is to collect and concentrate bile, which is secreted continuously by the liver, until the bile is needed to aid in digestion.

After fatty food is eaten, the gallbladder contracts and sends its stored bile into the small intestine by way of the biliary ducts. When digestion of the meal is completed, the gallbladder relaxes and once again begins to store bile. The bile is then recirculated in the digestive tract by being absorbed in the intestine and returning to the liver in the bloodstream.

Gallstones are formed when the components of bile (particularly cholesterol and bilirubin) solidify and form crystals. These stones can range from the size of a grain of sand to the size of a golf ball. The gallbladder may contain anywhere from one stone to hundreds.

The consequences of gallstones may be severe, ranging from brief episodes of biliary pain to potentially life-threatening complications. It is thought that gallstone pain results from a blockage of the cystic duct by a stone. If stones become lodged in this duct and block the flow of bile for several hours, they can cause acute cholecystitis, an inflammation of the gallbladder. Blockage of the cystic duct is a common complication caused by gallstones.

Occasionally a gallstone can move through the cystic duct from the gallbladder and slip into the common bile duct. The stone can then potentially lodge at the outlet of the common bile duct (a condition known as choledocholithiasis) and block the flow of bile completely. If this occurs, the bile accumulates in the blood stream, causing the patient to become yellow or jaundiced. If this blockage is associated with infection of the bile, a life-threatening condition known as cholangitis (inflammation of the bile ducts) results. A prolonged blockage of any of the biliary ducts can cause severe damage to the gallbladder, liver, or pancreas.

Once a patient with gallstones begins having pain in the upper abdomen for which there is no more likely explanation, elective cholecystectomy is indicated. An urgent cholecystectomy is performed if the patient is experiencing more severe gallbladder problems, such as acute cholecystitis, choledocholithiasis, and cholangitis.

THE PROCEDURE

The only true cure for gallstones is removal of the gallbladder itself. Fortunately, the gallbladder is not an organ necessary for our existence. Once it is removed, minor digestive problems may occur, but the primary functioning of the digestive system

remains undisturbed. Surgeons now consider laparoscopic cholecystectomy to be the "gold standard" when removal of the gallbladder is necessary.

Laparoscopic cholecystectomy is performed using video-telescopic visualization of the gallbladder and surrounding vital structures. The patient is placed under general anesthesia. One of the common techniques for performing this procedure is begun by making a small incision near the navel and inserting a needle into the abdominal cavity. The cavity is then inflated with carbon dioxide gas. This distention allows for easier viewing and creates a work space for the surgery to be performed. The needle is then removed and a sharp, hollow metal cylinder called a trocar is inserted into the now insufflated abdominal cavity. A laparoscope is then placed through the trocar.

The laparoscope is equipped with a camera that allows a magnified view of the inside of the abdominal cavity to be projected onto video monitors located on either side of the operating table. Once the laparoscope is in place, the abdomen is examined to ensure no injuries resulted from the placement of the trocar.

Three additional trocars are then placed into the abdomen through small incisions under direct observation through the laparoscope. It is through these ports that various surgical instruments are inserted for manipulation and dissection. The surgeon then watches the monitor and performs the operation by manipulating the inserted surgical instruments.

In the typical procedure, the end of the gallbladder is pulled upward toward the diaphragm. This allows the cystic duct, the cystic artery, and the common bile duct to be seen. Once these structures have been clearly identified and dissected away from the surrounding tissue, the cystic duct is sealed with a clip placed near its junction with the gallbladder. The surgeon then places two more clips near the point where the cystic duct joins the common bile duct. The cystic duct is cut and separated between the clips. The cystic artery, which provides the main blood supply to the gallbladder, is then divided in the same way.

In performing this procedure, the surgeon must be meticulous for the cardinal rule of cholecystectomy is that no anatomic structures are clipped or cut until the surgeon is unequivocally certain that they have been properly identified.(2)

Once the ducts have been divided, the gallbladder is separated from the liver bed and the gallbladder neck is pulled through the port at the navel. The neck is then cut open and the stones and bile are expressed. The deflated gallbladder is then removed through the incision near the navel. The abdominal cavity is irrigated to prevent any irritation from spilled bile. The instruments are removed, and the carbon dioxide is allowed to escape. The half-inch incisions are then closed with small sutures, if necessary, and bandaged. The procedure should last between 40 and 60 minutes.

Early on in the procedure, if there is any doubt as to the identification of the biliary structures, the surgeon may perform an intraoperative cholangiogram. This procedure may also be done if it is suspected that a stone has lodged in the common duct.

Cholangiography is also especially helpful in detecting any unusual anatomy--a typical defense raised by the surgeon.

During this procedure, a small incision (ductotomy) is made in the cystic duct just below the clip placed at the junction of the cystic duct and the gallbladder. The cut is made before the placement of any of the remaining clips and before any division of the structures. A catheter is then slipped into the cystic duct and a radiopaque contrast solution--which shows up clearly as a light area on the X-ray--is injected into the biliary duct system.

The injected material is then monitored with a device called a fluoroscope as it travels through the biliary ducts, and the surgeon obtains an image similar to a real-time X-ray. Failure of the various ducts to fill with the contrast solution should alert the surgeon to a problem requiring immediate attention before continuing with any cutting of the biliary system.

Many surgeons perform cholangiograms routinely, and some have described the procedure as creating a "safety zone."(3) It has been a matter of great controversy among biliary surgeons whether a cholangiogram is the standard of care during gallbladder surgery. The consensus at this time appears to be that the procedure is not necessary; however, a surgeon should not hesitate to order it if there is any question as to the identity of the biliary anatomy. Cholangiography is also useful in detecting unrecognized iatrogenic injury to the bile duct at a time when it can most easily be effectively repaired.

Those who argue against routine cholangiograms say the procedure may actually increase the chance of ductal injury as a confused surgeon may mistake the common bile duct for the cystic duct and cut into the common bile duct for catheter placement. This has occurred; however, the subsequent cholangiogram, if properly read, will show the injury and allow immediate repair during the primary procedure.

An additional problem may arise if the cholangiogram is performed and simply misread. This occurred in the first case handled by the author, where the defendant physician, in the face of severe inflammation, properly decided to perform a cholangiogram. The physician then failed to appreciate that the ductal structures were not filling with the contrast material due to her improper placement of a clip on the common bile duct itself.

MECHANICS OF BILE DUCT INJURY

The classic injury that can occur during cholecystectomy is the cutting of the common bile or common hepatic ducts. As recognized in the medical literature, this injury results in the unfortunate patient becoming a "biliary cripple."(4) The recurrent strictures, or narrowing of the bile duct, caused by the bile duct injury may require multiple operations, accompanied by an increased risk of secondary biliary cirrhosis and liver failure.

A surgical dictum--"the only cardinal sin in biliary tract surgery is injury to the common bile duct"--is premised on the devastating effects of this type of injury.(5) This is one of the driving forces behind laparoscopic cholecystectomy litigation as patients, due to no fault of their own, incur enormous medical bills--hundreds of thousands of dollars--as a result of the injury. The future medical expenses easily surpass that if the liver becomes so cirrhotic as to require a transplant.

Typically, injury to the bile duct occurs when the surgeon cuts the common bile duct, mistaking it for the cystic duct and thereby violating the cardinal axiom of biliary surgery that every structure be clearly identified before cutting. A similar duct injury is known to occur with the open procedure but not with the same frequency or extent of ductal damage as seen with laparoscopic cholecystectomy. Injuries may also be caused by compromising the blood supply to the duct during the dissection process, causing an ischemic stricture --a constriction or narrowing of the duct usually due to scarring.

Injury may also occur when part of the bile duct is pinched due to an improper application of the clips to the cystic duct. This may lead to partial or complete severance of the bile duct and also predispose the bile duct to stricture formation.

Depending on where the common bile duct is injured, effecting a lasting repair can be an impossible task. The "higher" the laceration occurs on the biliary tree, the worse the prognosis. The height of the injury is usually referenced by using the Bismuth scale, which gauges an injury based on its location in relationship to the confluence of the right and left hepatic duct. The lower the Bismuth number, the greater the chance of good repair and full recovery.

Unfortunately, bile duct injuries occurring during laparoscopic cholecystectomy are usually ranked high on the Bismuth scale, creating a poor prognosis for a good outcome. These injuries are associated with increased risk of failure of the repair.

The standard operation to repair a high bile duct injury is the Roux-en-Y hepaticojejunostomy. In this procedure, a part of the small intestine, the jejunum, is looped up and adjoined to the hepatic ducts, allowing the flow of bile from the liver directly into the intestine.

In a large number of cases, particularly when the injury is high on the Bismuth scale, strictures occur at the point of attachment of the ducts into the intestine. This can result in a failure of the Roux-en-Y procedure and require additional operations to open up the ducts. Eventually, these strictures may cause such a stagnant flow of bile and increased biliary pressure that the liver itself becomes cirrhotic, necessitating a liver transplant.

The fundamental cause of iatrogenic injury to the common bile duct during laparoscopic cholecystectomy is anatomic misidentification by the surgeon, because he or she cannot clearly see the biliary structures. This may be caused by acute inflammation or chronic scarring, both of which are present in most reported bile duct injury cases.(6) Excessive bleeding or large amounts of fat may also impair the surgeon's view. Excessive cauterization or blind placement of hemostatic clamps in an attempt to control the bleeding has also contributed to a large number of iatrogenic injuries.

Part of the problem leading to this anatomic confusion is the surgeon's experience level--the "learning curve" effect discussed later in this article. In addition, there are several technical factors inherent in a laparoscopic approach that contribute to the increased error rate.

Surgeons operating through a laparoscope experience a reduction in their depth perception to a two-dimensional view on the video monitor. This is coupled with the loss of touch due to the use of the various surgical instruments.

Another possible reason for iatrogenic injury, typically asserted as a defense in laparoscopic cholecystectomy cases, is that of anomalous anatomy. The surgeon and defense experts will claim that the cystic duct and common bile duct were in such an unusual relationship anatomically that it was not below the standard of care for the surgeon to have misidentified and cut the common bile duct. This is easily rebutted by showing that there is no "normal anatomy" of the biliary tract. A common pattern of several anatomic variants exist, and it is the surgeon's responsibility to recognize these normal variations when they occur.(7)

INJURY PREVENTION

It has been noted that it is "far better to prevent a duct injury than to repair an avoidable injury."(8) There are a number of strategies that, if incorporated, would allow a surgeon to prevent iatrogenic injury. From the author's experience in laparoscopic cholecystectomy malpractice cases, the defendant physician usually could have averted catastrophic injury to the patient had these techniques been adopted.

First and foremost, the procedure should only be performed by experienced, well-trained surgeons. Even the experienced surgeon should be ready to convert to an open procedure (laparotomy) if there is any question as to identification of the biliary anatomy, if the case is too difficult due to inflammation, or if the view is obscured by excessive bleeding.

While the surgeon's ego may dictate plowing ahead laparoscopically, conversion to an open technique is not considered a negative outcome but rather good surgical judgment with a successful outcome for the patient. Indeed, the American College of Surgeons's Statement on Laparoscopic Cholecystectomy sets forth its requirement that laparoscopic cholecystectomy only be performed by surgeons who are qualified to perform an open cholecystectomy.(9)

There are numerous surgical approaches that can be employed to prevent iatrogenic injury. These include performing an intraoperative cholangiogram; using a 30-degree telescope (rather than a zero-degree one) that provides a superior angle of visualization of the ductal anatomy; maneuvering the gallbladder in such a way as to maximize the exposure of the cystic duct and common bile duct; and beginning the dissection of the cystic duct at the gallbladder neck and moving toward the junction at the common bile duct. All these areas should be covered in the defendant's deposition.

DISCOVERY

In addition to the usual discovery conducted in every medical malpractice case, plaintiff attorneys bringing these cases should cover two other areas. First, many times the physician has videotaped the complete procedure. Attorneys should obtain the tape through a request for production immediately.

The videotape can be immensely useful for experts to analyze and pinpoint the negligent act or omission. The videotape, when viewed with the experts, may also serve as a starting point for the attorney learning about the procedure. Additionally, it can be used during the deposition of the defendant to establish the exact moment at which the bile duct injury occurred. Finally, the videotape may also be edited down for a trial exhibit.

On occasion, the videotape made during the procedure is erased once the defendant becomes aware of the injury he or she has caused. This action not only gives rise to damaging cross-examination but may also create the independent cause of action of spoliation of evidence in jurisdictions where that tort is recognized.

The second area to develop during discovery is the training that the defendant obtained to perform laparoscopic cholecystectomies. Although virtually every surgical residency now offers formal training in this area, many surgeons who completed their residencies before the early 1990s did not learn the technique in a formal setting. Most of these surgeons have attended a "quickie" weekend course in the procedure, often promoted and produced by the manufacturers of the laparoscopic instruments.

These courses typically begin with lectures on the instrumentation, followed by surgery on pigs. Finally, the attendees observe the procedure on a human patient. The surgeons are then expected to associate with a surgeon more experienced in laparoscopy to serve as a proctor during the first few cases they perform on their own.

Early in the discovery process, plaintiff lawyers should obtain the course materials used by the defendant. They are useful in many ways. First, they can be used to establish the standard of care required in the procedure as they typically set forth the proper method of performing the operation. Second, they make great cross-examination reference points as the physician can be confronted with the training materials to emphasize the departure from the training protocols. Finally, the attorney should obtain the original materials, not just copies, as the originals typically contain beautifully drawn renderings of the procedure and make great trial exhibits when blown up to chart size.

Not surprisingly, this practice of a weekend education followed by a few proctored procedures has created what some authors have referred to as a "learning curve" effect. This means physicians performing their first 13 laparoscopic procedures experience a dramatically higher morbidity rate compared with the rate on later patients.(10)

If the duct injury in litigation occurred during the physician's learning curve, several issues pertaining to informed consent are raised. Did the defendant inform the patient that the procedure was to be part of his or her learning curve? Did the defendant inform the patient of the increased error rate associated with the learning curve? Not surprisingly, the answer to these questions is often "no."

An additional cause of action that should be explored if the duct injury occurred during the learning curve is that of negligent credentialing. While this cause of action has been virtually abolished in Texas, many jurisdictions still allow such a claim. Many hospital credentialing committees only require proctoring for as few as four cases, giving rise to corporate liability as the excessive learning curve morbidity has long been recognized in the medical literature.

Interestingly, recent studies have shown that while the bile duct injury rate is greater during the surgeon's learning curve, it continues to be greater than the injury rate for open cholecystectomies even after the surgeon has gained considerable experience with the procedure.(11) It has been stated that the rate for duct injury with the laparoscopic procedure is as high as 3 percent.(12)

This gives rise to more informed consent issues. Did the physician advise the patient of the greatly increased chance of such a devastating injury if the procedure is done laparoscopically? Most of the informed consent forms examined by the author simply state that one of the risks of laparoscopic cholecystectomy is bile duct injury. There is no mention of the statistically significant increased risk of this injury when compared to an open procedure. Patients contemplating the procedure are rarely informed of this and certainly have a right to know this information.

Iatrogenic injury to the bile duct is avoidable if the surgeon adheres to proper surgical methods. A patient who experiences this injury can be faced with a life of pain, loss of quality of life, ongoing surgical interventions, and enormous medical expenses.

Trial lawyers can assist these patients in getting relief from the monetary side of their misfortune. An attorney who is called on to assist a client who has suffered such a catastrophic injury should remember the words of Dr. George Grey Turner, who over half a century ago, wrote, "Injuries to the main ducts are nearly always the result of misadventures during operations and are therefore a serious reproach to the surgical profession. They cannot be regarded as just an ordinary risk.(13)

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Notes

(1.) Steven M. Strasberg et al., An Analysis of the Problem of Biliary Injury During Laparoscopic Cholecystectomy, 180 J. AM. C. SURGEONS 101, 125 (1995).

(2.) Id.; see A.R. Moossa et al., Iatrogenic Injury to the Bile Duct: Who, How, Where? 125 ARCHIVES OF SURGERY 1028, 1029 (1990).

(3.) K. Ido et al., Confirmation of a "Safety Zone" by Intraoperative Cholangiography During Laparoscopic Cholecystectomy, 10 SURGICAL ENDOSCOPY 798 (1996).

(4.) Jonathan M. Sackier et al., The Role of Cholangiography in Laparoscopic Cholecystectomy, 126 ARCHIVES OF SURGERY 1021, 1023 (1991).

(5.) K.D. Horvath, Strategies for the Prevention of Laparoscopic Common Bile Duct Injuries, 7 SURGICAL ENDOSCOPY 439 (1993).

(6.) Id. at 440.

(7.) David B. Adams, The Importance of Extra-hepatic Biliary Anatomy in Preventing Complications at Laparoscopic Cholecystectomy, 73 SURGICAL CLINICS OF N. AM. 861, 870 (1993).

(8.) Leonard Caputo et al., Iatrogenic Bile Duct Injuries: The Real Incidence and Contributing Factors--Implications for Laparoscopic Cholecystectomy, 58 AM. SURGEON 766, 770 (1992).

(9.) Statement on Laparoscopic Cholecystectomy, 75 BULL. AM. C. SURGEONS 23 (1990).

(10.) The Southern Surgeons Club, A Prospective Analysis of 1,518 Laparoscopic Cholecystectomies, 324 N. ENG. J. MED. 1073, 1076-77 (1991).

(11.) Gallstones and Laparoscopic Cholecystectomy, 10 NIH CONSENSUS STATEMENT 1 (1992).

(12.) Ricardo L. Rossi et al., Laparoscopic Bile Duct Injuries: Risk Factors, Recognition, and Repair, 127 ARCHIVES OF SURGERY 596, 598 (1992).

(13.) George Grey Turner, Injuries to the Main Bile Ducts, 1 LANCET 621 (1944).

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