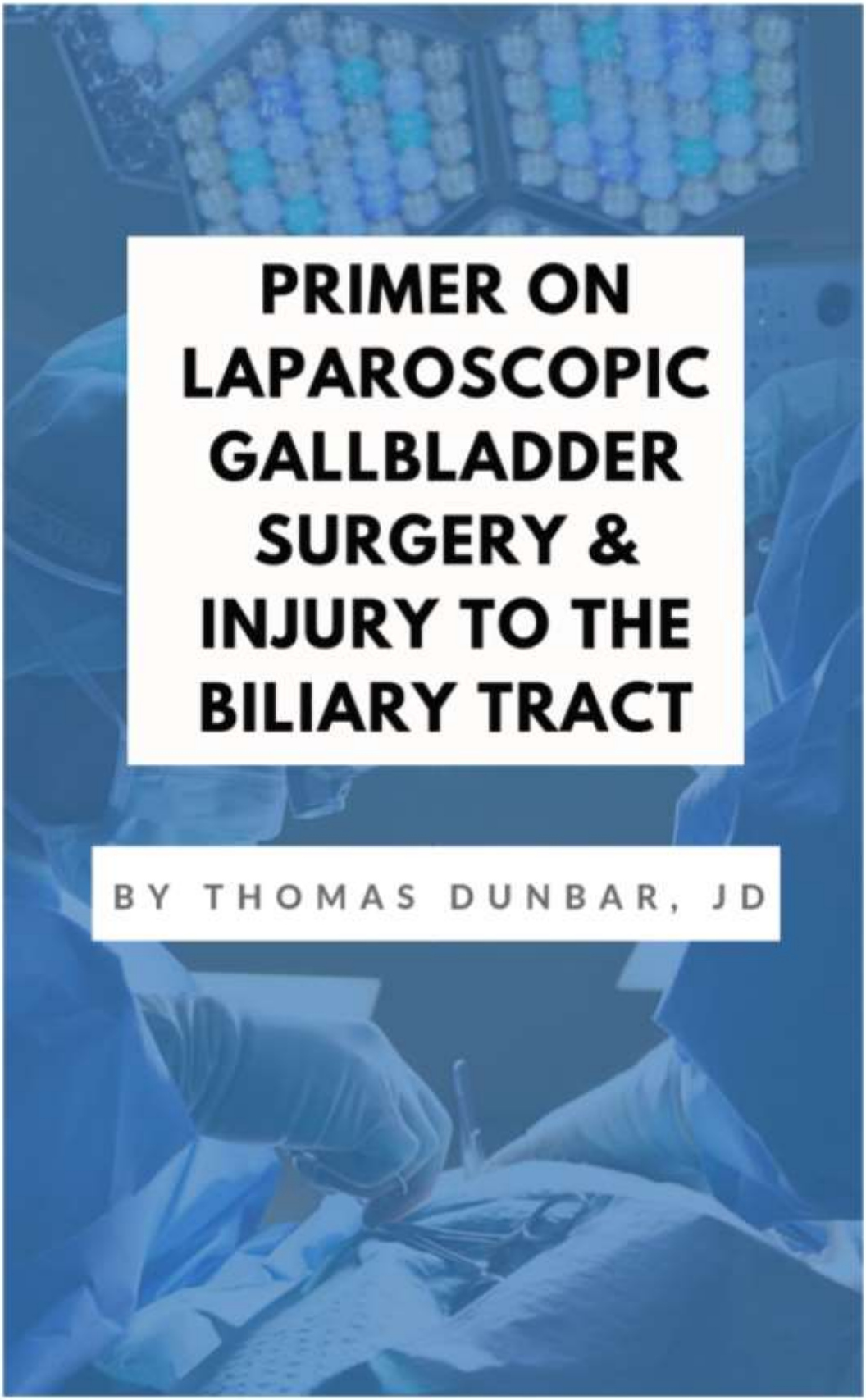

PRIMER ON LAPAROSCOPIC GALLBLADDER SURGERY & INJURY TO THE BILIARY TRACT

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Primer on Laparoscopic Gallbladder Surgery and Injury to the Biliary Tract

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This medico-legal article explains the laparoscopic gall bladder surgery and the proper technique to avoid injury. An injury can be chronic and devastating. Both laymen and legal practitioners should be aware of the future risks prior to resolving a claim of medical negligence causing bile duct injury. (A glossary of terms can be found at the end of this article.)

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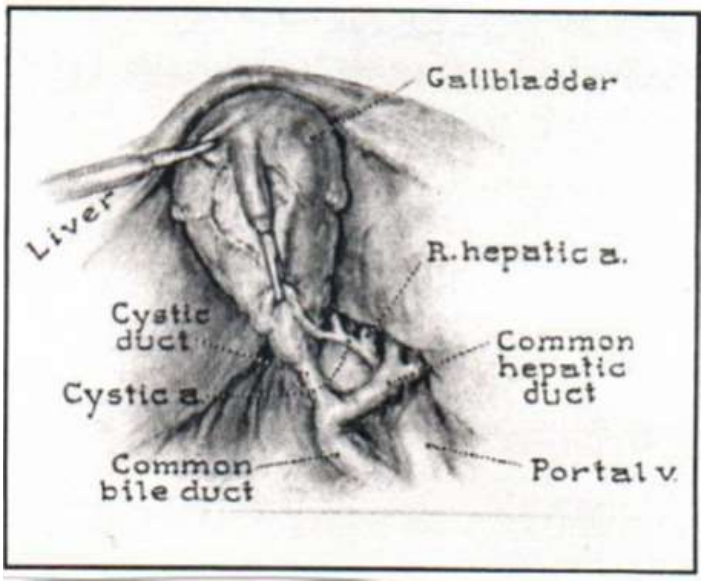
I. INTRODUCTION - ANATOMY

The biliary ducts carry bile from the liver to the small intestine. Bile aids in the digestion of fatty foods. The biliary tract begins as the left lobe duct and the right lobe duct which descend from the liver. These two liver ducts form at their bifurcation the common hepatic duct. As the hepatic duct descends toward the small intestine, the cystic duct which leads from the gallbladder joins the hepatic duct to form the common bile duct. The common bile duct descends into the small intestine. The ampulla of vater is the sphincter of tissue that controls the flow of bile from the common bile duct into the small intestine.



Cholecystectomy is the removal of the gallbladder due typically to gallstones or sludge formation. Most often a cholecystectomy is an elective or planned procedure though emergency cases occur. The gallbladder is removed surgically by clipping and transecting the cystic duct and the cystic artery so as to allow the gallbladder to be removed. The gallbladder is not a vital organ and if gallstones or sludge formation have occurred, it can be readily removed without a change in lifestyle or liver or biliary tract function.

Earlier, a surgical procedure was used to open the patient's abdomen and the biliary tract was examined in a traditional manner by the surgeon. In the late 1980s, laparoscopic surgery became the method of choice to remove the gallbladder. Laparoscopic surgery was touted as causing less pain to the patient and a shorter recuperative period.

II. LAPAROSCOPIC TECHNIQUE

Preceding removal of the gallbladder during laparoscopic surgery, "trocars" are introduced into the patient's abdomen. Trocars are sharply pointed instruments used to puncture a cavity so as to remove fluid, blood, or introduce laparoscopic instruments. The trocars allow for

lighting, video camera illustration, surgical instruments and carbon dioxide insufflation. The abdomen is insufflated with carbon dioxide initially and video camera and surgical instruments are used to scan the abdomen for any abnormalities. The liver is lifted and the gallbladder is exposed. The gallbladder is grasped and a process of meticulous dissection begins to remove tissue and/or adhesions from the gallbladder and cystic duct so that accurate identification of the anatomy occurs. The better practice is to pull the base of the gallbladder to the patient's right so that the cystic duct is perpendicular to the common bile duct. When the base of the gallbladder is not pulled to the patient's right side, sometimes the cystic duct aligns parallel to the common bile duct which can lead to misidentification.

Because there are variations in the biliary anatomy, most surgeons agree that the safest practice is to perform a cholangiogram before a transection of any duct. A cholangiogram is a test where dye is introduced into the biliary system and outlines the system so that the anatomy is more readily identified. A cholangiogram is a safeguard for the patient. It confirms that the surgeon has properly identified the anatomy and also the lack of any ductal injury. It also confirms that a gallstone is not obstructing the biliary tract thereby eliminating a possible problem requiring re-invasive treatment at a later time.

Many surgeons in active practice in the late 1980s went through training which included early monitoring at their hospitals by qualified and experienced laparoscopic surgeons. At the same time, medical students began receiving laparoscopic training in medical school and were qualified prior to graduation

Surgical journals reveal that many iatrogenic ("physician-caused") injuries during laparoscopic cholecystectomies are due to lack of experience. The Southern Surgeon's Club reported that the new laparoscopic technique resulted in a learning period.[1] The learning curve reflected a higher incidence of bile duct injury. The Southern Surgeon's Club's study found that within the first 13 cases of any participant's experience, the bile duct injury rate was 2.2%, compared with 0.1% after the 13" case. During the initial 12-13 procedures the surgeon is on his "learning curve". Another cause for injuries is the surgeon's overconfidence or lack of careful dissection resulting in failure to meticulously dissect and conclusively identify the biliary anatomy prior to transection. (The law generally requires that the surgeon operate “carefully”. Defense attorneys wrongfully and deceptively claim at trial that the Plaintiff must prove that the surgeon acted “carelessly”.)

III. INJURY AND REPAIR EFFORTS

Injuries include clipping and/or cutting of common bile duct, hepatic duct, or other anatomy. Clipping of the improper duct may prevent the flow of bile which backs up in the liver

[1] *"The Southern Surgeon's Club. A prospective analysis of 1,518 laparoscopic cholecystectomies performed by southern U.S. surgeons."* N. Engl. J. Med. 1991; 324:1073-1078.

leading to jaundice. If the hepatic/common duct is cut, bile will leak into the abdominal cavity resulting in possible infection. If not identified and repaired within a short time, the odds increase that the patient may face a lifetime of chronic troubles. Since the biliary ducts do not have profuse blood circulation, scar tissue may form at the site of a repair causing a stricture or narrowing that blocks the flow of bile. The stricture may be repaired (or managed) via a catheter needle introduced (through the skin) into the liver. Then a deflated balloon is guided down into the stricture where it is inflated to open up the stricture (as occurs in angioplasty). The risks of significant bleeding, infection and other complications of the balloon dilatation procedure are approximately 11%. Further, repeated balloon dilatations efforts and other necessary gastrointestinal studies increase the risk of scar tissue within the ductal anatomy at the anastomosis and at other locations where friction occurs. A second option that may be required to repair a stricture is re-operation and re-attachment of the remaining hepatic duct with a loop of the bowel. A Roux-en-Y hepaticojejunostomy is a surgical procedure often used to attempt to repair bile duct lesions or injuries high (towards the liver) on the bile duct. A hepaticojejunostomy involves removing a 8-10 inch loop of bowel from the small intestine, suturing one end closed, suturing a top portion of the loop to the remaining bile duct, and resuturing the lower end into the intestine. Strictures also occur at the site of the anastomosis or the location where the remaining duct is sutured to the loop of intestine. A stricture at the anastomosis or connection between the biliary duct and the bowel loop may require continued management via balloon dilatation. This repair may fail requiring re-attachment at a higher level of the biliary tree. Ultimately, a patient is transformed via a biliary injury from a relatively healthy individual to a patient who, at a minimum, must have her liver enzymes regularly monitored for possible obstruction. Cholangitis (infection), liver damage, liver transplantation are possibilities.

Injuries to the biliary tract can have a devastating impact on a patient's life. Injuries that are discovered during surgery or post-operatively should be referred to a specialized center with expertise in hepatobiliary surgery because the first attempt at repair is critical. Studies show there is an increased risk of stricturing if an initial stricture occurs. The mortality risks also increase if the first repair is not successful."[2]

When a stricture occurs following an injury, one effect is "back flow" pressure in the liver since the bile no longer flows to the intestine. If this pressure is not relieved, liver damage can result. One of the effects of prolonged stricture formation is dilation and/or scarring of the intrahepatic ducts. (The extra-hepatic ducts are the ducts that flow out of the liver towards the intestine. The intra-hepatic ducts are the ducts within the liver.)

Cholangitis is infection or inflammation of the bile ducts. Since the ampulla of vater no longer is present in the injured patient, the sphincter of tissue that normally control the flow of

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[2] *"Iatrogenic Injury to the Bile Duct, Who, How, Where?"* A. R. Moossa, M.D., FRCS, et al. Arch. Surg, Vol. 125, August 1990, Pages 1028–1031.

bile from the common bile duct to the small intestine is no longer present. Therefore, the bacteria and other matter present in the small intestine can flow up the previously "sterile" biliary duct to cause infection possibly extending into the liver. Antibiotics are used to treat the cholangitis which is then usually resolved but may re-appear intermittently. Severe cases of cholangitis can be life-threatening particularly after several episodes due to the effect on the ducts and possibly the liver.

IV. STANDARD OF PRACTICE

The Society of American Gastrointestinal Endoscopic Surgeons (hereinafter "SAGES") sets forth well-established principles for the prevention of injury during laparoscopic biliary tract surgery:

1. the cystic duct should be identified at its junction with the gallbladder;

2. traction on the gallbladder infundibulum (lower portion or “neck” of organ) should be lateral rather than cephalad (towards the "head");

3. meticulous dissection of the cystic duct and cystic artery is essential;

4. gallbladder holes should be closed to prevent loss of stones;

5. the surgeon should not hesitate to convert to an open operation for technical difficulties, anatomic uncertainties or anatomic anomalies, especially in cases of acute cholecystitis (infection of the gallbladder);

6. liberal use of operative cholangiography is desirable to discover surgically important anomalies, clarify difficult anatomy and to detect unsuspected common bile duct stones;

7. all energy sources (electro-cautery or laser which is used to dissect gallbladder off liver bed) can cause injury. An injury may be difficult to detect immediately?[3]

Correct dissection exposes the cystic artery and the entire gallbladder infundibulum but not the common bile duct. The steps of dissection that will avoid confusing the common bile duct for the cystic duct are:

1. retraction of the infundibulum laterally;

2. initiation of dissection on the gallbladder (dissection should begin on the gallbladder and proceed along the cystic duct towards the common bile duct rather than vice-versa);

3. opening up all folds in the gallbladder;

4. stopping medial (towards the patient's middle) dissection when a sufficient portion of the cystic duct has been cleaned for cholangiography and clipping; and

[3] Society of American Gastrointestinal Endoscopic Surgeons, 2716 Ocean Park Blvd., Suite 300 Santa Monica, CA 90405

5. application of the first clip to the base of the pedunculated gallbladder where it begins to taper to its stalk (where cystic duct begins)."[4]

Because the cystic duct and cystic artery are the structures to be divided, it is these structures only that must be conclusively identified in every laparoscopic cholecystectomy. Accordingly, the cystic duct and artery should not be clipped or cut until conclusively identified. To achieve conclusive identification, Calot's Triangle must be dissected free of fat, fibrous and areolar tissue and the lower end of the gallbladder dissected off of the liver bed. (The latter is an essential measure that precludes the possibility of injury to an aberrant duct.) At the completed dissection, there should only two structures seen to be entering the gallbladder, and the bottom of the liver bed should be visible. While it is not necessary to see the common duct, it is at this point that the surgeon has achieved the critical view of safety and the cystic structures may be occluded because they have been conclusively identified. Failure to achieve the critical view of safety because of difficulty of dissection as a result of inflammation or any other cause is an absolute indication for cholangiography or conversion to open cholecystectomy to define ductal anatomy."[5]

If an injury is recognized early, odds increase that a specialist's repair attempt may succeed. Therefore, the standard of practice requires the surgeon to search for potential injuries prior to completing the surgery. The omission of cholangiography increases the odds of an injury failing to be recognized.

After a repair surgery, stricturing (an abnormal narrowing) and re-stricturing occurs unfortunately. Some studies reflect that only 10-28% patients undergoing hepaticojejunostomy in these circumstances experience a stricture of the ductal anatomy. However, these studies arguably include "selection bias" of the reporting physicians in choosing their patients and the studies do not involve long periods of patient history review. Further, re-stricturing is more likely after an initial stricture. Strictures may occur as late as 20 years after the initial repair surgery. A minimum of 5–7 years is required in follow-up of the patient before a patient's chances of stricture following a repair surgery diminish significantly.

In one patient's case presently in litigation, the repair surgeon wrote in the Operative Notes that there was a 90% chance that the patient would completely recover from the repair surgery. Four months later, the patient experienced a stricture of the anastomosis or repair site, cholangitis, a balloon dilatation sequence involving two dilatations and repeated episodes of an apparent continuing peptic ulcer. Another result of the hepaticojejunostomy repair is that stomach acids no longer neutralize the bile as before. Rather, the bile acids directly flow into the

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[4] *"Exposure, Dissection and Laser Versus Electrosurgery in Laparoscopic Cholecystectomy",* John G. Hunter, M.D., FACS, American Journal of Surgery, Vol. 165, April 1993, Pages 492-496.

[5] *"An Analysis of the Problem of Biliary Injury During Laparoscopic Cholecystectomy,"* Steven M. Strasberg, M.D., FRCS, FACS, et al., Journal of the American College of Surgeons, January, 1995, Vol. 180, Pages 101-125.

intestinal loop and this can cause an ulcer as the acids inflame the intestinal tissue.

Another client's experience began in 1990 when her bile duct was divided during laparoscopic cholecystectomy. A cholangiogram was not performed and the injury was not diagnosed nor repaired until approximately 14 days later. This patient's management has included two major surgeries (re-attachments) and numerous balloon dilatations of recurrent stricture (all within three years).

Therefore, the author suggests that an attorney practicing in this field of medical malpractice should not resolve his or her client's case without an understanding of the significant and chronic risks facing the injured patient.

Glossary of Terms:

aberrant: abnormal; usually applied to a blood vessel or nerve that does not follow its normal course

ampulla of vater: the dilated part of the common bile duct where it is joined by the pancreatic duct

anastomosis: a communication between two vessels or ducts without any intervening capillary network

anomalies: any deviations from the normal

areolar: binds the skin to underlying muscles and forms a link between organs while allowing a high degree of relative movement

bifurcation: the point at which division into two branches occurs

Calot's Triangle: triangle exposed upon dissection and retraction of gallbladder; it is formed by alignment of cystic duct, cystic artery and common duct

catheter: a flexible tube for insertion into a narrow opening so that fluids or instruments may be introduced or removed

cholangiography: X-ray examination of the bile ducts, used to demonstrate the site and nature of any obstruction to the ducts or to show the presence of stones within them

cholangitis: inflammation of the bile ducts which usually occurs when the ducts are obstructed, especially by stones, or after operations on the bile ducts

cholecystectomy: surgical removal of the gallbladder

common bile duct: the duct that conveys bile from the liver; it is formed when the hepatic duct and cystic duct join

cystic artery: the artery supplying blood to the gallbladder

cystic duct: the duct connecting the gallbladder to the common bile duct

dilatation: the state of being distended or stretched

dissection: the cutting of tissues in an orderly manner so as to distinguish and separate anatomical parts from one another

gallbladder: a hollow, pear-shaped organ located beneath the liver in the right upper portion of the abdomen, it stores and concentrates bile

gallstones: stones in the gallbladder

gastrointestinal: relating to the stomach and intestines

hepaticojejunostomy: operation attaching a loop of intestine directly to ducts at base of liver; a bypass of hepatic/common ducts

hepatobiliary: referring to the liver, gallbladder and bile ducts

infundibulum: a stalk or funnel-shaped structure; the portion of the gallbladder near the cystic duct junction

insufflated: blow a vapor or powder into a part of the body

jaundice: yellow discoloration of the skin and eyes due to bile pigments in the blood

lateral: out to the side, rather than toward the midline

medial: toward the midline of the body, the opposite of lateral

pedunculated: attached by a narrow stalk