

The Standard of Care in Laparoscopic Cholecystectomy

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I. Introduction

Laparoscopic cholecystectomy is the treatment of choice for gallstone disease. It is estimated that between 1.5 and 2 million laparoscopic cholecystectomies have already been performed. The incidence of cholecystectomies has increased since the introduction of the laparoscopic procedure. Over 500,000 cholecystectomies are performed annually in the United States. (N.J. Soper et al., *Laparoscopic General Surgery*, 330 N. ENG. J. MED. 409 (1994).)

II. Training And Credentialing

Laparoscopic cholecystectomy should be performed only by surgeons who are qualified to perform open cholecystectomy. (SAGES, GUIDELINES FOR THE CLINICAL APPLICATION OF LAPAROSCOPIC BILIARY TRACT SURGERY (1994).) As current surgical residents enter private practice, the debate over credentialing will become moot. Most of these residents will have actually performed far more laparoscopic cholecystectomies than open cholecystectomies. The individual surgeon's expertise with this procedure is usually developed after performing between 10 and 20 cases. A general consensus has developed that surgeons who finished their residency before 1990 and were not exposed to laparoscopic cholecystectomy should attend a didactic course of instruction offered by a recognised teaching body. They should be exposed to hands-on laboratory activity, allowing them to perform all parts of the operative procedure, with the training evaluated by their own institution. These surgeons should observe a small number of laparoscopic cholecystectomies performed by an experienced surgeon and experienced operating team. The surgeon's initial 10 to 15 cases should then be proctored by an experienced laparoscopic surgeon prior to full credentialing in this procedure.

III. Equipment

Laparoscopic cholecystectomy should be performed in an operating room with appropriate equipment and personnel for both laparoscopic and open operations. The operating room team should

be well trained in the use of all equipment necessary to perform either procedure. Equipment should be up-to-date and designed to perform laparoscopic cholecystectomy. Every member of the operating team must be able to observe the operation comfortably. (SAGES)

IV. Indications And Contraindication

The indications for laparoscopic cholecystectomy are no different than for open cholecystectomy except as agreed upon by the Consensus Development Panel at the National Institutes of Health in September 1992. The exceptions included in this group were carcinoma of the gallbladder, septic shock from cholangitis, severe acute pancreatitis, generalised peritonitis, coagulopathy unresponsive to treatment, cirrhosis with portal hypertension, and patients unable to tolerate general anesthesia. (*Gallstones and Laparoscopic Cholecystectomy*, 10(3) NIH CONSENSUS STATEMENT 1-26 (Sept. 1992)) Pregnancy was once thought to be a relative contraindication, but the procedure has now been performed safely many times during the second trimester and early third trimester.

The indications for cholecystectomy, as always, include not only symptomatic gallstones, the primary cause for surgery, but also symptoms of biliary colic and a positive hepatobiliary scan with reproduction of pain after injection of CCK or poor function of the gallbladder. Another small group of patients for whom cholecystectomy is appropriate would be patients with symptoms of biliary colic on whom the other diagnostic studies were unremarkable, but who have positive cholesterol crystals visible within fluid collected within the first and second portions of the duodenum near the ampulla of Vater.

V. Technique

The principles of laparoscopic cholecystectomy have been well established and extensively documented. (H.J. Asbun & R.L. Rossi, *Techniques of Laparoscopic Cholecystectomy: The Difficult Operation*, 74 SURG. CLIN. N. AM. 979-84 (1994); SAGES). The following points should be emphasised in any description of the procedure.

1. Pneumoperitoneum may be established using either closed or open technique. (SAGES) The Verres needle is still the most common method performed today. It is a fast and relatively safe method, although it does offer the chance of causing intestinal or vascular injury. The author of this paper has performed over 1,500 Verres needle insertions without complication. The open technique to obtain pneumoperitoneum avoids the morbidity related to blind puncture and is probably best used by the

inexperienced laparoscopist. It should also be used in patients who have had extensive prior abdominal surgery.

2. Maximum cephalad traction on the gallbladder should be obtained to reduce redundancies in the gallbladder infundibulum. (J.G. Hunter, *Avoidance of Bile Duct Injury During Laparoscopic Cholecystectomy*, 162 AM. J. SURG. 71-76 (1991).)

3. Traction of the gallbladder infundibulum should be lateral rather than cephalad. This manoeuvre creates a more distinct angle between the cystic and common ducts and permits better identification of both structures. (J.G. Hunter; SAGES; E.J. Reddick et al., *Safe Performance of Difficult Laparoscopic Cholecystectomies*, 161 AM. J. SURG. 377-81 (1991).)

4. Meticulous dissection of the cystic duct and cystic artery is essential. (SAGES) The dissection should be started high in the neck of the gallbladder and carried from a lateral to medial direction. All dissection should be kept close to the gallbladder until the anatomy is defined. (Asbun and Rossi; D.O. Olsen et al., *Laparoscopic Cholecystectomy for Acute Cholecystitis*, 8 PROBL. GEN. SURG. 426-31 (1991)). Posterior lateral dissection near the infundibulum is helpful in identifying the junction of the neck of the gallbladder with the cystic duct. (Asbun and Rossi) The cystic duct must be identified at its junction with the gallbladder. (SAGES)

5. After accurate anatomic dissection has been obtained, clips can be placed as close to the gallbladder as possible under direct vision. The clips should be seen in their entirety crossing the duct completely.

6. Liberal use of operative cholangiograms is desirable to discover surgical anomalies, clarify difficult anatomy, and detect unsuspected common bile duct stones. (SAGES) Operative cholangiography is not mandatory but should be done when the anatomy cannot be clearly identified or when there are structures present that cannot be accounted for. The use of cholangiography to detect stones is indicated when the patient is found to have elevated liver function studies, a history of pancreatitis, or a dilated common duct on preoperative ultrasound. If preoperative ERCP has been performed, cholangiography is usually not performed.

7. Keep all dissection close to the gallbladder and do not use excessive energy in close proximity to the hilum of the liver. (Asbun and Rossi) All energy sources, including laser, can cause occult injury. (SAGES)

8. Do not hesitate to convert to an open cholecystectomy if there are technical difficulties, anatomic uncertainties or anomalies, or especially in the case of acute cholecystitis. (SAGES)

9. Gallstones which escape from the gallbladder should be retrieved whenever possible and, if they are seen in association with purulent bile, must be removed to prevent the development of abscess and fistula formation. (J.G. Hunter, *Commentary*, 74 SURG. CLIN. N. AM. 777-80 (1994).)

VI. Morbidity And Mortality

Mortality associated with laparoscopic cholecystectomy has been reported to range from 0 to 0.15 percent. (D.J. Deziel, *Complications of Cholecystectomy*, 74 SURG. CLIN. N. AM. 809-23 (1994).) A significant proportion of operative deaths have been the result of technical complications with injury to the bile ducts, viscera, or vascular structures. (D.J. Deziel et al., *Complications of Laparoscopic Cholecystectomy: A National Survey of 4,292 Hospitals and Analysis of 77,604 Cases*, 165 AM. J. SURG. 9-14 (1993).) Major retroperitoneal vascular injury usually occurs during placement of trochars and has been associated with a nine percent mortality rate. Intestinal injury is associated with a mortality rate of approximately five percent and is most commonly seen in the small intestine followed by the colon, duodenum, and stomach. Significant bile duct injuries are associated with a mortality rate of at least two percent. (D.J. Deziel et al., *Complications of Laparoscopic Cholecystectomy: A National Survey of 4,292 Hospitals and Analysis of 77,604 Cases*, 165 AM. J. SURG. 9-14 (1993).)

Major complications have been reported in approximately two percent of all patients undergoing laparoscopic cholecystectomy, with half of those patients requiring laparotomy for management of the complication. (D.J. Deziel, *Complications of Cholecystectomy*, 74 SURG. CLIN. N. AM. 809-23 (1994).) Overall, the morbidity rate associated with laparoscopic cholecystectomy is approximately five percent.

Wound problems have been reported to be minimal after laparoscopic cholecystectomy. A wound infection rate of from 0.3 to 1 percent has been reported. The most significant wound problem has to do with incarceration of small intestine leading to Richter's hernia with bowel obstruction (D.W. Crist & T.R. Gadacz, *Complications of Laparoscopic Surgery*, 73 SURG. CLIN. N. AM. 265-89 (1993)) This is an infrequent complication and has led to the recommendation that all fascial defects greater than 10 mm. be closed after the procedure. Other less frequently seen complications include

postoperative respiratory problems and deep venous thrombophlebitis. Pneumothorax and gas embolism have been reported as rare complications associated with this procedure. (D.J. Deziel, *Complications of Cholecystectomy*, 74 SURG. CLIN. N. AM. 809-23 (1994).)

Major bile duct injury is the most significant complication related to laparoscopic cholecystectomy. Its incidence has been reported as anywhere from two to four times that of open cholecystectomy. The most common mechanism is misidentification of the common bile duct as the cystic duct. (G. Branum et al., *Management of Major Biliary Complications After Laparoscopic Cholecystectomy*, 217 AM. J. SURG. 532-41 (1993); A.M. Davidoff et al., *Mechanisms of Major Biliary Injury During Laparoscopic Cholecystectomy*, 215 AM. J. SURG. 196-202 (1992).) A multicenter review of these injuries has revealed that the primary surgeon often fails to recognise the injury at the original operation, fails to obtain or correctly reinterpret an operative cholangiogram, and fails to convert to an open procedure when indicated. It has also been shown that initial attempts to repair these injuries are inadequate. (D.J. Deziel, *Complications of Cholecystectomy*, 74 SURG. CLIN. N. AM. 809-23 (1994).)

A cystic duct stump leak accounts for approximately half of bile leaks after laparoscopic cholecystectomy. (D.J. Deziel et al., *Complications of Laparoscopic Cholecystectomy: A National Survey of 4,292 Hospitals and Analysis of 77,604 Cases*, 165 AM. J. SURG. 9-14 (1993).) This may be related to improper clip placement, secondary necrosis, or inadequacy of the clips to secure large cystic ducts. Bile leakage can lead to biloma formation and/or bile ascites, bile peritonitis, or bile fistula.

Bleeding is a common problem associated with laparoscopic cholecystectomy, but as a significant complication only occurs 0.5 percent of the time. (D.J. Deziel, *Complications of Cholecystectomy*, 74 SURG. CLIN. N. AM. 809-23 (1994).) This can occur with needle or trochar placement as well as dissection of tissue. Bleeding that cannot be controlled laparoscopically automatically dictates open procedure.

VII. Discussion

Not all injuries associated with laparoscopic cholecystectomy represent negligence. (K.A. Kern, *Medicolegal Perspectives on Laparoscopic Bile Duct Injuries*,

74 SURG. CLIN. N. AM. 979-84 (1994).) Each case has to be evaluated on its own merit and the circumstances surrounding the procedure. If the surgeon has failed to follow the standard techniques recognised to prevent possible complications, then negligence may indeed be considered. Other issues that might indicate negligence include failure to recognise an injury in a timely fashion and improper or inadequate attempt at correction of this problem.

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