

Safety and Efficacy of Laparoscopic Cholecystectomy

A Prospective Analysis of 100 Initial Patients

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Laparoscopic cholecystectomy quickly emerged as an alternative to open cholecystectomy. However its safety, efficacy, and morbidity have yet to be fully evaluated. During the first 6 months of 1990, we performed 100 consecutive laparoscopic cholecystectomies with no deaths and a morbidity rate of 8% (8 of 100 patients; 4 major, 4 minor). There were 81 women and 19 men, with a mean age of 46.1 years (range, 17 to 84 years). All patients had a preoperative history consistent with symptomatic biliary tract disease, and most had proved gallstones by sonography. This included four patients with acute cholecystitis. Mean operating time improved significantly from month 1 to month 6 (122 ± 45.4 minutes *versus* 78.5 ± 30 minutes, respectively), indicating a rapid learning curve. Mean hospital stay was 27.6 hours, reflecting a policy of overnight stay. Postoperative narcotic requirements were limited to oral or no medications in more than 70% of patients. A regular diet was tolerated by 83% of the patients by the morning following the procedure. Median time of return to full activity was 12.8 ± 6.8 days after operation. In addition analysis of the hospital costs of these 100 cases demonstrates a modest cost advantage over standard open cholecystectomy ($n = 58$) (mean, $\$3620.25 \pm \1005.00 *versus* $\$4251.76 \pm \988.00). There was one minor bile duct injury requiring laparotomy and t-tube insertion, two postoperative bile collections, and one clinical diagnosis of a retained stone that passed spontaneously. Four patients required conversion to open cholecystectomy because of technical difficulties with the dissection. Although there is a significant learning curve, laparoscopic cholecystectomy is a safe and effective procedure that can be performed with minimal risk. Laparoscopic cholecystectomy should be performed by surgeons who are trained in biliary surgery and knowledgeable in biliary anatomy, and, as with all operations, it should be performed with meticulous attention to technique.

THE MANAGEMENT OF calculus disease of the biliary tract has undergone significant change during the last decade and clearly is still evolving. Recent years have seen the investigation and development of al-

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ternative methods for the management of biliary lithiasis, including gallstone dissolution therapy,¹ endoscopic and percutaneous methods of stone extraction,^{2,3} biliary lithotripsy,⁴ and the advocacy of gallstone removal *via* a 'minilaparotomy.'⁵ Yet, despite these technologic 'advances,' most surgeons have continued to manage most patients with gallstone disease with standard operative 'open' procedures. Open cholecystectomy, having now been performed in a similar fashion for more than 100 years,⁶ has been an effective method of treating gallstone disease and has been demonstrated to have acceptably low morbidity and minimal mortality rates.⁷ Thus open cholecystectomy represents an acceptable risk-benefit ratio for patients and should be regarded as the gold standard against which new therapies are compared. The recent advent of the ability to remove the gallbladder in a fashion identical to open cholecystectomy *via* the laparoscope,⁸⁻¹⁰ without formal laparotomy, represents a further advance in the management of biliary disease that seems to have significant merit. This report details an experience with 100 'laparoscopic cholecystectomies' in an effort to study the feasibility and safety of the technique as well as its short-term efficacy in controlling symptoms associated with cholelithiasis.

Clinical Material

One hundred consecutive patients with symptomatic gallstone disease referred to us between December 1989 and June 1990 were included as the initial study population. All patients were evaluated by one of the authors, the need for cholecystectomy was established, and standard laboratory and radiographic tests were obtained. De-

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mographic data, including indications for cholecystectomy, weight, height, previous history of jaundice or pancreatitis, and previous surgery, were recorded. All patients underwent preoperative laboratory testing, including complete blood count (CBC), electrolytes, bilirubin, alkaline phosphatase, alanine aminotransferase (ALT), aspartate aminotransferase (AST), and abdominal sonogram. The presence of symptomatic gallstones was required for entry into the study. The initial 50 patients were restricted to elective procedures for chronic cholecystitis and cholelithiasis. After this initial experience, the indications were broadened to include acute cholecystitis, as defined by emergency admission with acute right upper quadrant pain, fever, elevated white blood count (WBC), and gallstones on sonography. Known choledocholithiasis was considered a contraindication in this study population.

All patients, with the exception of those presenting with acute cholecystitis, were admitted to the hospital the day of surgery. Oral and intramuscular pain medications were ordered routinely and left to the discretion of the patient. Liquids were provided the night of surgery and a regular diet was resumed the next morning. Most patients were admitted for overnight observation. Follow-up examination was performed as close as possible to postoperative days 7 and 90. Follow-up laboratory studies on these days included CBC, bilirubin, alkaline phosphatase, AST, and ALT. Symptomatic follow-up of the first 50 patients was obtained by telephone more than 3 months after procedure. A standardized questionnaire was used to analyze postoperative pain, nausea, and vomiting, scaled from 1 to 4+ (1 = never had symptom after operation, 2 = occasionally, 3 = frequently, and 4 = daily symptoms). In addition patients were asked if they believed they were cured, improved, or worsened by the procedure and if they would undergo the surgery again under the same circumstances.

Technique

Nearly all patients were operated on in the supine position, although a few were placed in the lithotomy position, with the operating surgeon standing between the patient's legs, to allow one surgeon to manipulate both sets of instruments. The advantages of the supine position is that it facilitates performance of a cholangiogram and it is easier to proceed to standard cholecystectomy from this position should this become necessary. In addition, as our experience grew, we found that the supine position often allowed a single surgeon to manipulate instruments for both exposure and dissection. Nasogastric tubes and Foley catheters were placed routinely for gastric and urinary bladder decompression, although recently simple straight catheterization of the bladder has been used to avoid an indwelling Foley catheter.

The patients were placed in a 15- to 20-degree head-down position, a small infraumbilical incision was made, and a Verres needle directed toward the midline pelvis was placed into the abdominal cavity for initial CO₂ insufflation. Recently we used an open technique (similar to 'open' peritoneal lavage) for insertion of the trochar because it facilitates both initial insufflation and removal of the gallbladder at the conclusion of the procedure. Two to three liters of CO₂ were used to insufflate the abdomen while maintaining an intra-abdominal pressure less than 15 mmHg. A standard 10-mm laparoscopic trochar was placed in the subumbilical position. The video laparoscope was introduced into the abdomen through the subumbilical trochar and the pelvic retroperitoneum was inspected for any evidence of hematoma indicating trochar injury. The laparoscope then was directed cephalad and the liver and gallbladder were visualized.

Occasionally intra-abdominal adhesions were encountered, but the laparoscope usually can be maneuvered around the adhesions to the right upper quadrant (RUQ). Additional trocars were placed with video visual control to prevent intra-abdominal injury. An 11-mm trocar was placed in a subxiphoid, midline position, entering the abdominal cavity just to the right of the falciform ligament. This trocar customarily was placed 4 to 5 cm below the xiphoid process, but varied according to the position of the liver. A preliminary inspection of the level of the liver edge and position of the gallbladder allowed for more precise placement. We found it best to keep the skin incisions as small as possible to prevent CO₂ leakage around the trocar. A screwing-type motion rather than a direct puncture allowed a more controlled entry into the abdomen. Two 5-mm trocars were placed, one in the right subcostal midclavicular line (MC) and one in the right subcostal anterior axillary line (AA) near the level of the umbilicus (Fig. 1). Grasping forceps were placed in the two lateral trocars and dissecting forceps into the subxiphoid port (SX). Ratched-type self-clamping instruments were preferred in the MC and AA ports so the assistant did not have to squeeze the instrument during the entire case. Initial retraction of the gallbladder was provided by grasping the fundus with the AA forceps (or alternatively the MC grasper), lifting the gallbladder ventrally, and pushing the gallbladder and liver toward the patient's head and right shoulder. This exposed the gallbladder, subhepatic space, and porta hepatis. The neck of the gallbladder above the cystic duct (Hartmann's pouch) was grasped with the MC forceps and pulled toward the AA trocar exposing the porta (Fig. 2).

Occasionally adhesions from the gallbladder to the transverse colon were taken down. The surgeon, standing at the patient's left side, inspected the anatomy, identified the cystic and bile ducts, and began the dissection. Because the common hepatic duct typically courses posteriorly

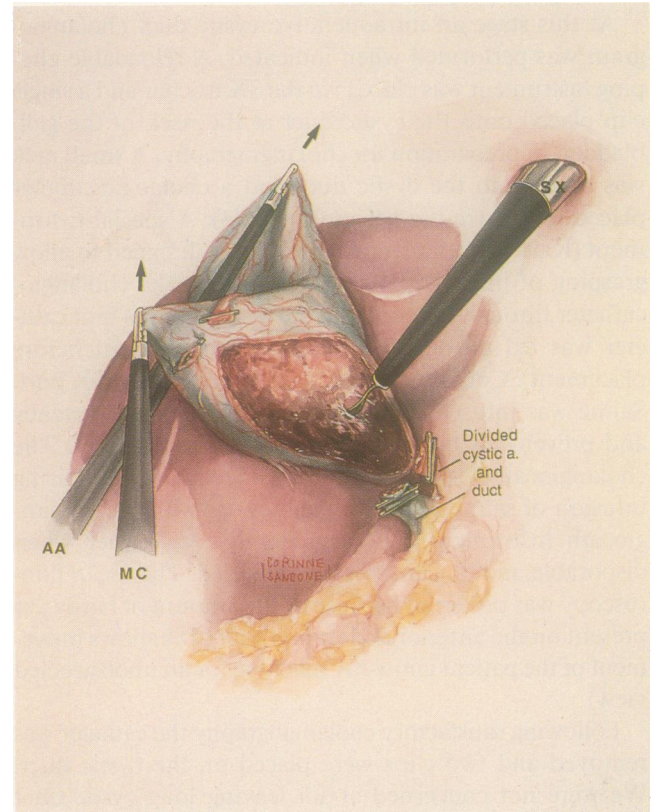
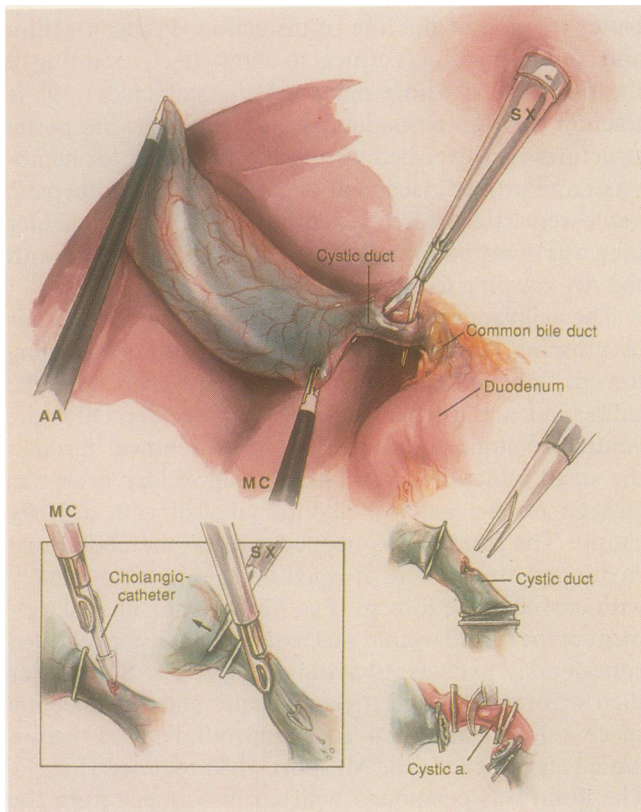
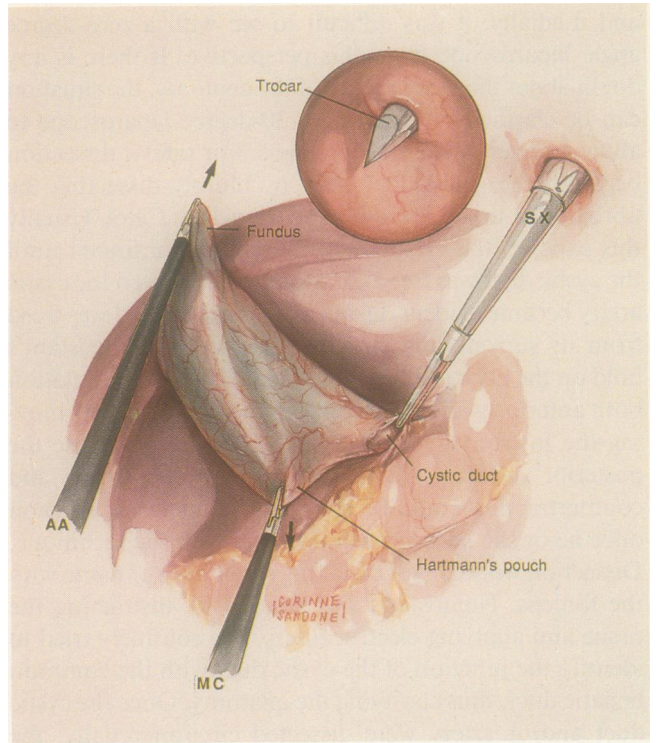
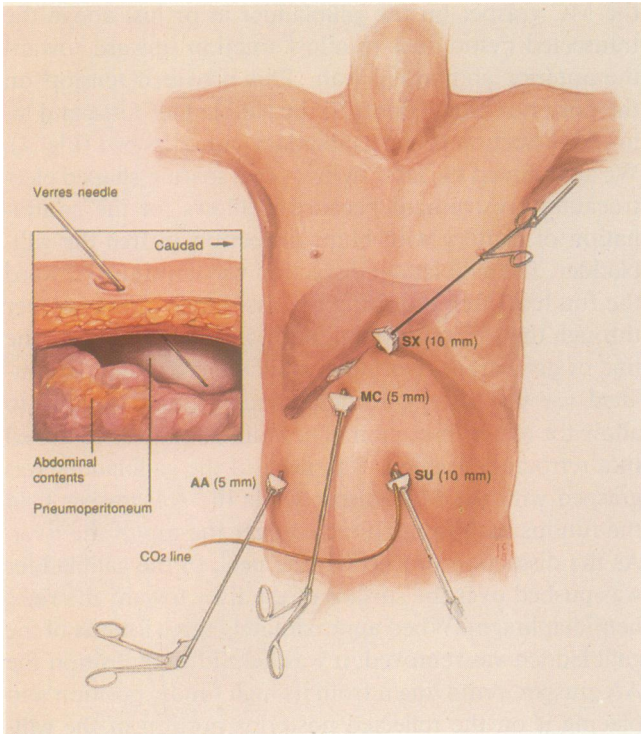
and medially, it was difficult to see with a zero-degree angle laparoscope from this perspective. If there is any doubt about the exact nature of the anatomy, the situation can be clarified by inserting a 30-degree laparoscope to allow an alternative viewing angle. For safety, dissection began at the gallbladder neck by bluntly dissecting the fibroareolar tissue overlying the triangle of Calot. Usually this exposed the cystic duct. Dissection continued until the cystic duct was freed circumferentially. Often the cystic artery became evident during this dissection and was freed from its surrounding structures as well. The assistant's hold on the neck of the gallbladder allowed manipulation both anteriorly and posteriorly to the cystic duct by moving the instrument medially and upward to expose the posterior surfaces. Alternatively this maneuvering and countertraction could be done by the operating surgeon once he or she becomes comfortable with the technique. Dissection worked best by taking small bites of tissue with the forceps. Hemostasis was assured by distracting the tissue and applying electrocautery. We routinely tried to identify the junction of the cystic duct with the common hepatic duct, thus clarifying the anatomy. Once the cystic duct and/or artery were dissected circumferentially, the anatomy was inspected again.

At this stage an intraoperative cystic duct cholangiogram was performed when indicated. A reloadable clipping instrument was placed *via* the SX trochar and a single clip placed onto the cystic duct at the neck of the gallbladder, in preparation for cholangiography. A small nick was made into the cystic duct and a cholangiocatheter placed into it *via* the MC port (Fig. 3). A special instrument (Karl Storz, Culver City, CA) was designed to allow grasping of the cystic duct while feeding the cholangiocatheter through the center of the instrument (a taut catheter was fed retrograde through the instrument before placement). Countertraction was applied *via* the SX port. Saline was infused during placement to ensure patency and prevent air bubbles in the common bile duct. The cholangiocatheter was secured with a clip applied during infusion of saline to assure patency, or with the cholangiocath instrument. Cholangiography was easier when disposable, radiolucent trocars were used. The use of fluoroscopy was preferred because of the amount of hardware present on the anterior abdominal wall (this allows movement of the patient and x-ray machine for an unobstructed view).

Following satisfactory cholangiography the catheter was removed and two clips were placed on the cystic duct. We were not concerned about leaving long cystic duct remnants and erred on the gallbladder side to avoid common duct injury. The cystic duct was divided with scissors. The cystic artery was dissected free circumferentially, two clips were placed proximally, one distally, and the vessel was divided. At this point it was usually best to reposition

the MC grasper on the gallbladder at or just above the transected cystic duct to allow traction upward toward the anterior abdominal wall. This provided tension on the posterior attachments to the gallbladder fossa and allowed dissection of the gallbladder out of its bed (Fig. 4). We abandoned the laser in favor of a spatula-shaped electrocautery instrument because it allows for the combination of cautery with blunt dissection to free the gallbladder. The gallbladder dissection was continued toward the fundus, often requiring the assistance of the grasper through the MC port to maintain optimal tension on the line of dissection. Again the gallbladder can be manipulated *via* the MC instrument medially and laterally to allow for easier dissection. The gallbladder was removed in a retrograde fashion. The neck of the gallbladder was grasped with the MC grasper while the AA grasper held the fundus with forces directed over the top of the liver. As the dissection proceeded, the neck of the gallbladder was pushed over the surface of the liver toward the right hemidiaphragm. When approximately three fourths of the gallbladder was removed, it was helpful to reposition the AA grasper, removing it from its high fundic position and placing it on the reflected posterior portion of the gallbladder just above the line of dissection. This allowed better traction at the line of dissection. Proper traction and countertraction is critical to allow effective cutting of the tissues. Just before removing the gallbladder, while traction can still be maintained on the liver, the portal structures and liver bed were again inspected for hemostasis and proper placement of the clips. The subhepatic space were irrigated free of debris (Fig. 5). The gallbladder then was removed from the liver, maintaining a hold with the AA grasping forceps.

The gallbladder was removed through the SX trochar by grasping the cystic duct with large 10-mm grasping forceps and pulling it into the trochar. Then both the gallbladder and trochar were removed together. Often the volume of stones prevented complete removal through the small puncture site. If so, the gallbladder neck was grasped on the anterior abdominal wall with a Kelly clamp. The fundus was opened outside the abdominal cavity and stones were crushed and removed manually with curved stone forceps (Fig. 6). Occasionally enlargement of the fascial wound was required. This step required considerable patience to avoid spillage. The SX trochar then was replaced and the subhepatic and suprahepatic space were irrigated. A 4- to 5-mm round closed suction drain was placed *via* the MC port when required (Fig. 7). The drain was positioned with an instrument from the SX port, following which the MC trocar was withdrawn over the drain. The CO₂ was evacuated and all wounds were closed with a subcuticular suture. Fascial sutures were used only when the fascial incisions at the SX or SU ports were enlarged.



Results

Demographic data for these 100 patients are demonstrated in Table 1. There were 81 women and 19 men

whose average age was 46.1 years (range, 17 to 84 years). All patients had symptomatic biliary tract disease. All but two patients had gallstones demonstrated by preoperative sonography, one patient having had previous lithotripsy

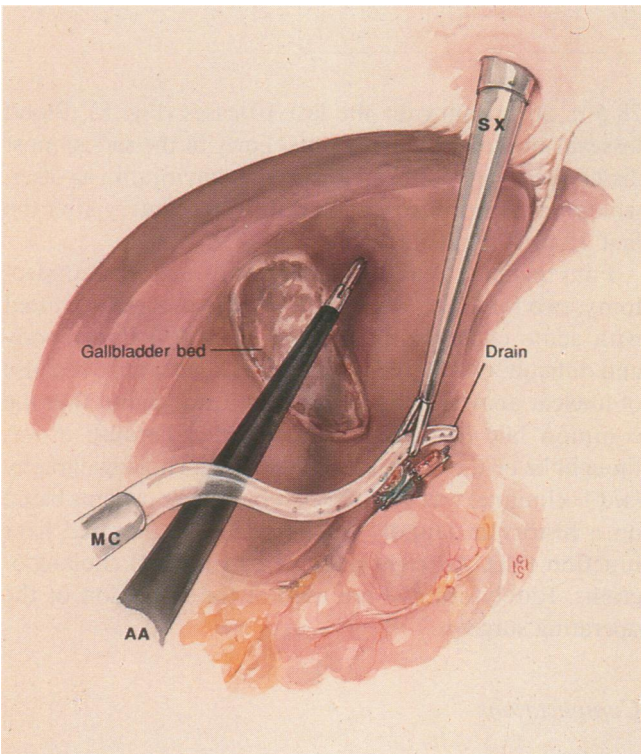
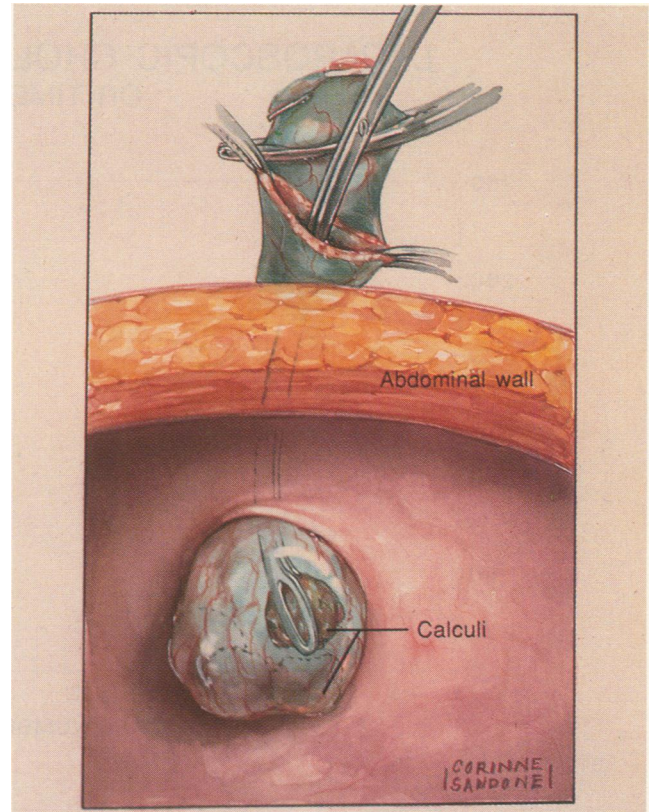
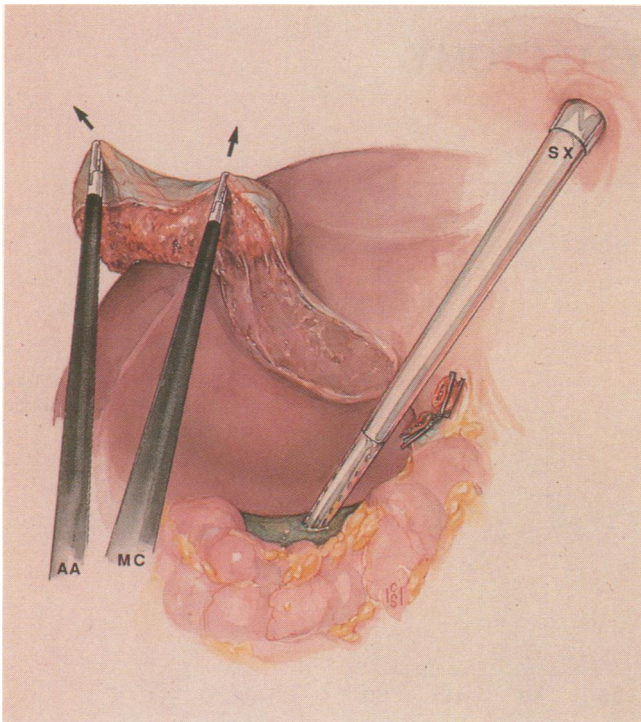


FIG. 1. Facing page, top left. Trochar placement on anterior abdominal wall. SU, subumbilical, SX, subxiphoid; MC, midclavicular line; AA, anterior axillary line. Inset: Insufflation through verres needle placed subumbilically and directed toward the pelvis. **FIG. 2.** Facing page, top right. Initial exposure of the gallbladder and porta hepatis. Note that the SX instrument is the surgeon's port, the AA instrument is commonly used to retract the fundus of the gallbladder toward the head and right shoulder. The MC instrument is used to manipulate the portal exposure via a grasp on Hartmann's pouch. **FIG. 3.** Facing page, bottom left. Illustration of cystic duct dissection and cystic duct cholangiography, followed by transection of the cystic duct and artery. Cystic duct dissection and cystic duct cholangiography (inset), followed by transection of the cystic duct and artery. Note the clips that have been placed. A single clip is placed distally to prevent flow into the gallbladder during cholangiography, and two clips proximally before transection of the duct. **FIG. 4.** Facing page, bottom right. The cystic duct and artery have been transected and the gallbladder is being removed from its bed via blunt dissection with a spatula-shaped electrocautery instrument. Tension is maintained on the plane of dissection via the MC instrument. **FIG. 5.** This page, top left. Just before complete removal of the gallbladder, the liver bed and porta hepatis structures are irrigated clean and inspected for hemostasis. The integrity of the cystic duct and artery clips also are inspected and the anatomy is reviewed. **FIG. 6.** This page, top right. The gallbladder is commonly removed via the SX port after grasping it with large forceps and pulling the portal end into the trochar. Under direct vision, both outside and inside the abdomen, the stones then often need to be removed manually to allow removal of the gallbladder through the small incision. **FIG. 7.** This page, bottom left. Drains are introduced via the AA lateral port. The MC port instrument is used to retract the liver while the SX instrument places it in the subhepatic space.

and one having biliary colic in the absence of gallstones. Four patients were admitted 2 to 5 days before surgery with the diagnosis of acute cholecystitis. All four had fever, elevated WBC, and RUQ pain associated with gallstones demonstrated sonographically. One had a previous history

of biliary pancreatitis. One had previous history of jaundice.

Laboratory studies for the 100 patients performed before operation, 1 week after operation, and 3 months after operation are shown in Table 2. Thirteen patients had

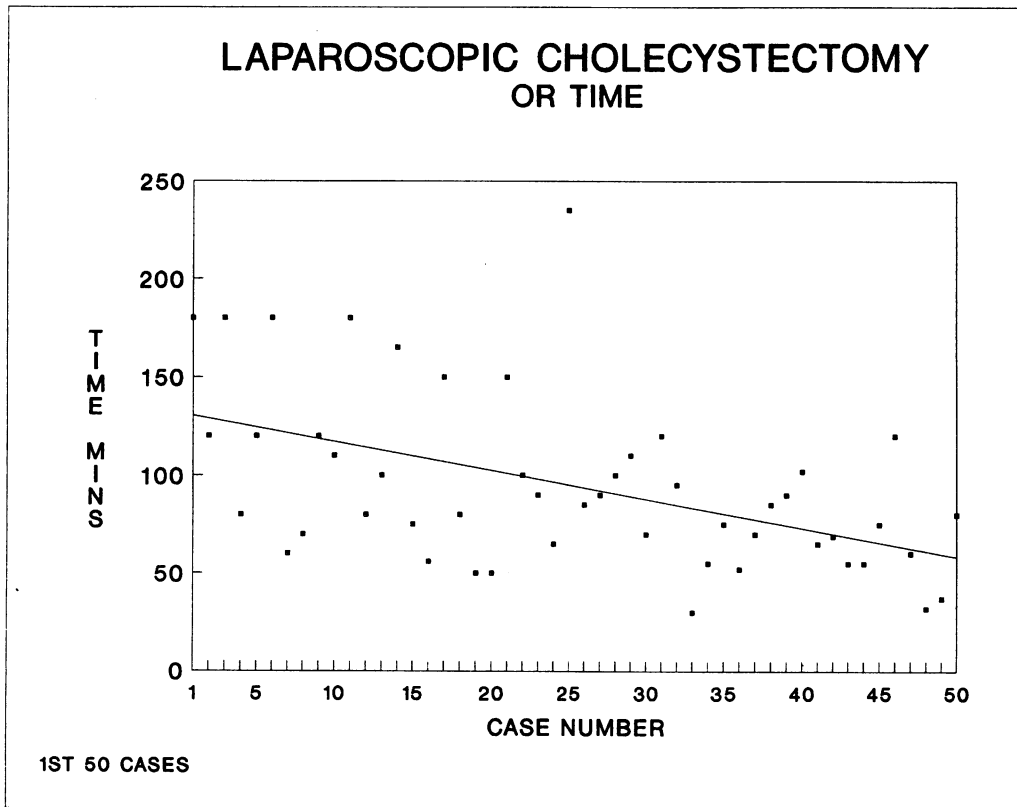


FIG. 8. Trend toward decreased operative time in the first 50 cases.

elevated alkaline phosphatase levels before operation, and four patients had elevated bilirubin levels (1.3, 1.9, 1.1, and 1.1, respectively).

Operating Room Data

All patients underwent general anesthesia with Foley catheters and nasogastric tubes in place. Initial procedures were performed with two attending surgeons and a single consistent camera operator. As our experience grew, the senior resident acted as the operating surgeon, and a scrub nurse as the camera operator. Five attending surgeons participated in the study. Operative time decreased from an average of 122 ± 45 minutes for the first 10 cases to

78.5 ± 30 minutes for the last 10 cases (Fig. 8). Blood loss was minimal in all patients. Early in the series, most dissections were performed with a neodymium:yag laser, which was abandoned in favor of electrocautery after the first 25 to 30 patients.

Four patients required laparotomy and cholecystectomy, two for acute inflammation (one of these admitted with acute cholecystitis), making the dissection bloody and difficult. One patient underwent laparotomy because of unclear anatomy. In this patient it was found that the common bile duct had been dissected because it was thought to be the cystic duct. Cystic duct cholangiography (see Technique) was used selectively in eight patients based on a history of jaundice, pancreatitis, or elevated liver function tests. All eight patients had normal cholangiograms. Rarely drains were used at the discretion of the operating surgeon.

TABLE 1. Patient Characteristics

Characteristic	Mean	Median	Range
Age (years)	46.1	45	17-84
Duration Sxs (days)	131.7 ± 184	78	2-1059
Weight (pounds)	178.6 ± 48.8	167	85-320
Sex F:M	81:19		
Previous surgery*	45		
Acute cholecystitis	4		
Hx of jaundice	1		
Hx of pancreatitis	0		

\pm Standard deviation.

* All lower abdominal surgery.

Sxs, Symptoms.

Hx, History

Complications

There were no deaths (Table 4). A single intraoperative common bile duct tear occurred in a patient with an inflamed gallbladder. The common duct was dissected through the laparoscope because it was thought to be the cystic duct. Laparotomy revealed a small tear in the anterior common bile duct that was treated by t-tube insertion. Four months after the procedure, this patient's t

TABLE 2. Laboratory Data

Data	Preop (n = 97)			POD 7 (n = 80)			POD 30 (n = 23)		
	Mean	Median	Range	Mean	Median	Range	Mean	Median	Range
Bilirubin	0.54 ± .57	0.5	0.1-1.9	0.42 ± .29	0.4	0-2	0.44 ± .2	0.4	0.2-1
#Abnormal Bilirubin		4			3			0	
Alkaline Phosphatase	82 ± 31.5	78	30-245	83.9 ± 40.2	83.5	0-288	81.3 ± 31.4	78	33-175
# Abnormal Alk Phos		13			12			3	
ALT	27.8 ± 20.	22	10-153	35.7 ± 56.9	24	0-457	311.5 ± 22.9	25	
# Abnormal ALT		14						1	12-121
AST	24.6 ± 8.5	23	11-61	35.2 ± 13.7	22	0-459	28. ± 13.7	23.55	
# Abnormal AST		14						0	16-82

± Standard deviation.

Normals: T Bili; 0.2-1.0, Alk Phos; 37-107, SGPT (ALT); 7-40, SGOT

(AST); 12-45.

POD, postoperative day.

tube has been removed and cholangiography and alkaline phosphatase levels are normal. Five patients were readmitted to the hospital from 3 to 10 days after operation. One patient was readmitted with a clinical diagnosis of a retained stone after demonstrating acute biliary colic and elevated bilirubin and alkaline phosphatase levels. By the morning after admission, the patient's pain had resolved, the hyperbilirubinemia abated, and an endoscopic retrograde cholangiogram (ERCP) was normal. It was presumed that she had passed the stone spontaneously. Two patients were readmitted several days after operation with acute RUQ pain and were found to have bile extravasation from the gallbladder bed by biliary scintigraphy (Technetium-HIDA). In both cases ERCP demonstrated bile leakage from small biliary radicles entering the gallbladder fossa. Both were treated with endoscopic placement of 10 french biliary stents across the offending duct. Both resolved within 3 to 5 days. Two patients were readmitted with nonspecific abdominal pain that resolved rapidly.

One patient complained of severe pain localized to his right subcostal area and was thought to have right-sided costochondritis. There were no significant pulmonary complications. There was one urinary tract infection. We observed two instances of infection in the subumbilical wound. Shoulder pain was encountered relatively frequently (in 14 of 100 patients, or 14%), usually in the first week after surgery. Of note gallbladder perforation and

bile leakage occurred frequently. An effort was made in each case to remove the spilled stones laparoscopically and irrigate the subhepatic space liberally. Neither early nor late clinical sequelae could be identified in these patients.

Postoperative Characteristics

Postoperative characteristics are shown in Table 5. Nasogastric tubes and Foley catheters were removed in the recovery room. Patients routinely were kept overnight, given clear liquids the evening of surgery, a regular diet the next morning, and prescribed intramuscular meperidine or oral oxycodone as needed for pain. Three patients were discharged the evening of surgery; 80 the following day; and 7 patients were discharged on postoperative day 2, including the 4 patients with acute cholecystitis; and 3 patients were discharged on postoperative day 3. Eighty-three per cent of patients were able to tolerate a regular diet by the next morning. Most patients took oral narcotics (71%) until discharge. Twenty-five per cent of patients required no narcotic medication for pain. Patients returned to full activity an average of 12.8 days after surgery (range, 3 to 34 days).

Cost Analysis

Mean hospital charges for the 93 patients admitted the day of surgery for elective cholecystectomy was \$3620.25

TABLE 3. Operating Room Data

Data	Mean	Median	Range
Time, all cases (min)	85.27 ± 39	75	25-235
Time first 10 cases (min)	122 ± 45.4	120	60-180
Time last 10 cases (min)	78.5 ± 30.2	65	50-145
Laparotomies	4		
Laser	38		
Electrocautery	62		
Introp. cholangiogram	8		

± Standard deviation.

TABLE 4. Complications

Complication	Number
Bile duct injury	1
Bile leak	2
Retained stones	1
Wound infection	2
Costochondritis	1
Urinary tract infection	1
Readmission	5
Shoulder pain	14

TABLE 5. *Postoperative Characteristics*

Characteristic	IV	IM	PO	None	
Narcotic requirement (n = 96)	2 DOS	30 POD 1	71 POD 2	25 POD 3	POD 4
Hospital stay (n = 93)	3	80	7	3	
Regular diet (n = 95)	6	77	9	2	1
Return to full activity†	12.8 ± 6.8 days (range 3–34)				

* IV, intravenous morphine; IM, intramuscular meperidine; PO, oral oxycodone; POD, postoperative day.

† Mean ± standard deviation.

± \$1004.00 (Table 6). For comparison mean hospital charges for the previous 58 cholecystectomies (1988 to 1990) that the same group of five surgeons performed in the same hospital was \$4251.76 ± \$988.00, yielding an average of more than \$600.00 savings per case. No attempt was made to evaluate the savings achieved in earlier return to work and increased productivity.

Follow-up

At completion of the trial, an attempt to contact the first 50 patients by telephone was made. For all of these patients, more than 3 months had passed since their procedures. Table 7 demonstrates the results of this survey. Most patients had resolution of their biliary symptoms. All indicated that they were satisfied with the procedure and would undergo it again under similar circumstances. Most patients were eating an unrestricted diet.

Discussion

Laparoscopic cholecystectomy rapidly emerged as an established method for the treatment of symptomatic gallstone disease. Although a few isolated centers studied the feasibility of the procedure for several years, the fall and winter of 1989 to 1990 brought an explosion of this technique.¹⁰ Reports of its safety, efficacy, complication rate, learning curve, and applicability to the spectrum of biliary tract disease are only now beginning to emerge. Anecdotal reports abound, but little published information exists. The advent of this procedure has raised several issues.

The Safety of Laparoscopic Cholecystectomy

This initial experience with 100 patients demonstrated to us that this is a feasible procedure that the general surgeon and resident can perform safely. The four major complications in the first 100 patients argues for its safety and compares favorably with recent series of open cholecystectomies. Traverso et al.¹¹ evaluated the 'modern' morbidity of cholecystectomy performed for chronic

cholecystitis under elective circumstances. In a series of 671 elective standard cholecystectomies, there were no deaths and a major complication rate of only 4.5%, including three bile duct injuries (0.2%). A morbidity rate of 8% with one bile duct injury (1%) for laparoscopic cholecystectomy compares favorably. There were no complications related to the insertion of the laparoscopic trochar. Whether the morbidity and/or biliary injury rate will change substantially with increasing experience remains to be seen. It also seems clear that laparoscopic cholecystectomy may not be universally applicable to the entire spectrum of gallstone disease. With increasing experience the question becomes not if one **can** perform the procedure under difficult circumstances, but if one **should** perform the procedure given a potentially dangerous situation. It seems that this procedure can be performed as safely as a standard cholecystectomy, as long as patients are selected properly and appropriate caution is exercised.

Comparison of Laparoscopic Cholecystectomy Complications with Those of Open Cholecystectomy

If laparoscopic cholecystectomy is to represent a significant advance in the management of cholelithiasis, morbidity and mortality rates superior to those of standard cholecystectomy should be the goal. Whether this can be achieved awaits a study with larger numbers and a larger variety of patients. Clearly the most significant complication of laparoscopic cholecystectomy is bile duct injury. Anecdotal reports, presentations, and our experience indicate that biliary injury is a real possibility, varying between 0% and 7% in most initial series. Whether this represents an initial learning curve or an inherent hazard of the procedure remains to be proved; however most surgeons would agree that this is a preventable injury. Our single patient who sustained a ductal injury did so under circumstances of chronic cholecystitis, with a contracted short gallbladder and a very short, wide cystic duct that made delineation of the anatomy difficult. The common bile duct was dissected mistakenly for the cystic duct. An

TABLE 6. *Cost Analysis*

Procedure	Mean	Median	Range
Laparoscopic (n = 93)	\$3620.25 ± 1005	\$3436.70	\$1391.80–6091.0
Standard (n = 58)*	\$4251.76 ± 988	\$3938.00	\$2591.40–6400.00
Acute laparoscopic (n = 4)†	\$6197.25 ± 1156	\$5946.10	\$5199.00–7697.00

± Standard deviation.

* Standard cholecystectomies done over 2-year period before to laparoscopic era.

† Acute laparoscopic, acute cholecystitis with laparoscopic cholecystectomy.

TABLE 7. *Follow-up (n = 52)*

Query	Cured	Improved	Same	Worse
Overall Status (n = 52)	40 (77%)	12 (23%)	0	0
Would have surgery again	Yes	No		
	52 (100%)	0		
Abdominal pain Nausea* Vomiting*	Never	Occasional	Frequent	Daily
	43 (83%)	8 (15%)	0	1 (2%)
	37 (80%)	9 (20%)	0	0
	36 (92%)	3 (8%)	0	0
Diet	Unrestricted	Avoid Fat	Severe Restrict	
	36 (71%)	13 (25%)	2 (4%)	

* Some patients did not have these preoperative symptoms.

injury caused by the grasping forceps on the anterior common bile duct was recognized after the abdomen was opened. Such injuries can be prevented by a liberal attitude toward early abandonment of the laparoscopic procedure in favor of an open cholecystectomy. Indeed our threshold for laparotomy has decreased with increasing experience rather than increased, as we learn which patients will prove difficult despite all efforts.

Two instances of symptomatic bile leakage and subhepatic bile collections occurred. Both patients in the early postoperative period developed acute RUQ pain and were shown easily by radionuclide biliary scanning and ERCP to have leaked bile from small accessory ducts entering the gallbladder bed. One patient required percutaneous drainage of the bile collection accompanied by insertion of a 10 french endoscopic biliary stent and quickly resolved her bile collection and symptoms. The stent was removed after 6 weeks with complete healing. The second patient had a very small collection and rapidly improved after stent insertion. She did not require drainage. Whether these stents were necessary and how long to leave them remains unknown. A retrospective review of the operative videotapes revealed no obvious cause of the leaking accessory ducts. In addition we noted that neither a laser technique nor electrocautery seemed to be responsible because the patients were divided between the two techniques. Luschka¹² first demonstrated these small biliary radicles entering directly into the gallbladder bed nearly 100 years ago. Cadaver dissections demonstrated these ducts to be present in 25% to 30% of patients and that significant injury can be avoided by dissection close to the gallbladder wall.¹³ We speculate that injury of these small ducts results from the combination of a tearing type of dissection in and around the porta hepatis, along with a dissection where it may be more difficult to maintain directly on the gallbladder wall. What the true incidence

is of this complication and whether it can be prevented remains a topic of further study.

A single patient returned with recurrent biliary colic, elevated alkaline phosphatase level, and a bilirubin level of 2.2. A clinical diagnosis of a retained stone was made, she was admitted to the hospital, and ERCP was scheduled the following day. However, by early morning, her symptoms had completely resolved and it was suspected that she passed her stone. Results of the ERCP were normal. Retained common duct stones remain a problem for standard cholecystectomy as well as for laparoscopic cholecystectomy.^{14,15} Known choledocholithiasis is considered a contraindication to this procedure. We advocate an attitude of laparotomy and common duct exploration when intraoperative cholangiography demonstrates common duct involvement. The standard of care for common bile duct disease should be no different from how one would manage such disease under the circumstances of open cholecystectomy. However other options exist. The most attractive options are preoperative papillotomy and stone extraction or intraoperative choledoscopic and laparoscopic common duct exploration. Both procedures have their shortcomings, however. Preoperative identification of common duct stones remains imprecise, leaving a large number of patients with normal (and thus unnecessary) ERCP exams. The techniques of laparoscopic common bile duct exploration are only beginning to emerge, require specialized equipment, significant time to perform, and can be technically difficult. These options should be investigated; however until such time as alternatives to standard care are demonstrated to be efficacious, an attitude toward laparotomy and common duct exploration would seem the most prudent alternative.

Intraoperative and postoperative bleeding represents a theoretical concern. Arterial injury (hepatic or cystic) during the dissection, as well as failure to adequately clip

the cystic artery, can result in the need for laparotomy or, of greater concern, the possibility of bleeding after discharge from the hospital. Because of the possibility of cystic arterial bleeding, we usually observed patients in the hospital for 24 hours, although experience may show that this is not necessary.

We observed no significant incidence of major or minor cardiovascular or thrombotic complications. It is unclear whether laparoscopic cholecystectomy differs in this regard or whether it represents a safer alternative in patients with preoperative cardiovascular risk factors. It requires general anesthesia and similar operative times to standard open cholecystectomy, thus one might not expect a significant advantage. Minor complications included two instances of wound infection in the subumbilical wound and a single patient with a urinary tract infection. Right shoulder pain occurred relatively frequently but usually was mild and self limiting. This has been well described in the gynecologic literature and has been attributed to retained CO₂.

Unresolved Issues

Many issues remain unresolved with regard to laparoscopic cholecystectomy. There are several major issues. 1) In what clinical setting is this procedure most useful and in which is it difficult and dangerous, *i.e.*, can it, or should it, be applied in the setting of acute cholecystitis, biliary pancreatitis, and choledocholithiasis? Most centers restrict laparoscopic cholecystectomy to chronic cholecystitis and cholelithiasis. This would seem appropriate, especially during the initial learning curve of the procedure. As experience is gained, however, many centers are expanding the indications to include attempts at laparoscopic cholecystectomy in acute cholecystitis, and biliary pancreatitis. Further study is necessary to delineate the spectrum of disease for which laparoscopic cholecystectomy would be the option of choice. 2) Can this procedure be performed safely by the average general surgeon in a community and/or rural hospital? 3) What are the advantages and disadvantages of selective *versus* routine cholangiography in this setting? It seems apparent that the consequences of a false-positive cholangiogram (unnecessary laparotomy or ERCP) tip the balance even further toward a policy of selective cholangiography. 4) What is the optimal method of management of common duct disease when considering or performing this procedure? Opinions vary regarding the proper management of common duct stones with this procedure. As discussed above, options include preoperative ERCP and stone extraction in patients suspected to be at high risk for choledocholithiasis, postoperative performance of the same in those

with positive intraoperative cholangiograms, laparotomy and common duct exploration, and laparoscopic common duct exploration *via* choledocopy. Definitive answers require further study. 5) Will laparoscopic cholecystectomy afford a means of decreasing morbidity and mortality in high-risk groups of patients requiring elective cholecystectomy? Again proper study of this population of patients is required.

It is clear that laparoscopic cholecystectomy is a useful procedure that has significant, although perhaps not dramatic, advantages over open cholecystectomy. It can be performed safely by experienced surgeons in properly selected patients and it represents a significant and permanent advance in the management of biliary tract disease.

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