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An External Audit of Laparoscopic Cholecystectomy in the Steady State Performed in Medical Treatment Facilities of the Department of Defense

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Objective

This study provides the first objective assessment of a complete patient population undergoing laparoscopic cholecystectomy in the steady state. The authors determined the frequency of complications, particularly bile duct, bowel, vascular injuries, and deaths.

Summary Background Data

This retrospective study, conducted for the Department of Defense healthcare system by the Civilian External Peer Review Program, is the second complete audit of laparoscopic cholecystectomy. Data were collected on 9130 patients undergoing laparoscopic cholecystectomy between January 1993 and May 1994.

Methods

The study sample consisted of clinical data abstracted from the complete records of 9054 (99.2%) of the 9130 laparoscopic cholecystectomies performed at 94 military medical treatment facilities.

Results

Of 10,458 cholecystectomies performed in the Military Health Services System, 9130 (87.3%) were laparoscopic and 1328 (12.7%) were traditional open procedures. Seventy-six medical records were incomplete; however, there was sufficient data to determine mortality and bile duct injury rates. Of the remaining 9054 cases, 6.09% experienced complications, including bile duct (0.41%), bowel (0.32%), and vascular injuries (0.10 percent). The mortality rate was 0.13%. Access *via* Veress technique was used in 57.6% and Hasson technique in 42.4% of patients. Intraoperative cholangiograms were performed in 42.7% of the cases with a success rate of 86.2%. Eight hundred ninety-two (9.8%) patients were converted to open cholecystectomies.

Conclusions

In the steady state, despite an increase in the percentage of laparoscopic cholecystectomies performed for nonmalignant gallbladder disease, there continues to be minimal complications and low mortality.

After the introduction of laparoscopic cholecystectomy by Mouret in 1987, the procedure became the standard of care for gallbladder disease by 1992.[1,2] Early reviews focused on the safety of this new procedure and established baseline data for morbidity and mortality during the learning or introductory phase.[3,4]

Recommendations for laparoscopic cholecystectomy during the introductory phase favored selection of patients with straightforward, nonacute gallbladder disease. Despite increasing surgeon experience and expanded indications for laparoscopic cholecystectomy, several questions remained about the long-term safety and efficacy of the procedure.[5–8]

In 1994, during its introductory phase, the authors reported the first complete review of 99.4% of laparoscopic cholecystectomies performed in the Military Health Services System (MHSS).[9] The military experience found that laparoscopic cholecystectomy was being performed at a rate of 65.9%. The study was conducted by an external auditing group to allow an objective review of the frequency of complications, especially bile duct, bowel, and vascular injuries in a complete population of patients undergoing the procedure. Bile duct injuries remain a major focus in laparoscopic cholecystectomy. Our first study presented a Bile Duct Injury Classification System to standardize the reporting of laparoscopic bile duct injuries.

This study is the first complete review of laparoscopic cholecystectomy in the steady state. With expanded indications for the procedure,[10] and increased surgeon experience, the penetrance of laparoscopic cholecystectomy now approaches 90%. The authors wanted to assess the results of this standard surgical approach for nonmalignant gallbladder disease and compare them to those from the introductory phase.

This study represents the results of an evaluation, by the Civilian External Peer Review Program of the Department of Defense health care system, of 9054 laparoscopic cholecystectomies performed at 94 military medical treatment facilities from January 1993 through May 1994. The evaluation was performed by FMAS Corporation (Rockville, MD) under the direction of the Uniformed Services University for the Health Sciences and was authorized by the Office of the Assistant Secretary of Defense for Health Affairs.

MATERIALS AND METHODS

Data Collection

Medical records for review were identified by inspecting operative logs and by querying the Defense Medical Information System, which includes data from the Defense Enrollment Eligibility Reporting System, the Standard Inpatient Data Records, and the Civilian Health and Medical Program of the Uniformed Services. The study sample, compiled from medical records at 94 military medical treatment facilities, included all patients who underwent both open and laparoscopic cholecystectomies performed in the United States MHSS during the study period from January 1993 through May 1994. The medical abstracters visited the 94 military medical treatment facilities for several months to review and abstract clinical data from the medical records of the patients in the study sample. The database consisted of two components: 1) the abstracters' uniform questionnaire data sets and 2) the materials for individual case review and data set verification, which included the facesheet, operative report, pathology report, anesthesia record, and progress notes. Because the MHSS is a closed system, all inpatient medical records can be reviewed. The medical records included in the study were abstracted between October 1994 and January 1995.

The records indicated that 10,458 cholecystectomies were performed during the study period, of which 9130 (87.3%) were laparoscopic cholecystectomies and 1328 (12.7%) were performed as traditional open procedures. The complete medical records of 9054 (99.2%) of the patients who underwent laparoscopic cholecystectomies were obtained. The medical records for 76 (0.8%) of the 9130 patients undergoing laparoscopic cholecystectomy were incomplete, although there was sufficient information to determine mortality and bile duct injury rates. The authors conducted individual case reviews of 3018 medical records (33%) that supported the morbidity and mortality analysis, validation of the abstracting, and statistical data analysis.

Table 1. LAPAROSCOPIC CHOLECYSTECTOMY DEMOGRAPHICS

	No.	%
Records reviewed	9130	100.00
Sex		
Female	7151	78.32
Male	1979	21.68
Age (yr)		
Median	41	—
Range	2 to 92	—
Median, female	38	—
Median, male	50	—
Race		
White	7495	82.09
Black	901	9.87
Asian/Pacific Islander	290	3.18
American Indian/Eskimo/Aleut	19	0.21
Spanish origin/Hispanic	402	4.40
Not documented	23	0.25

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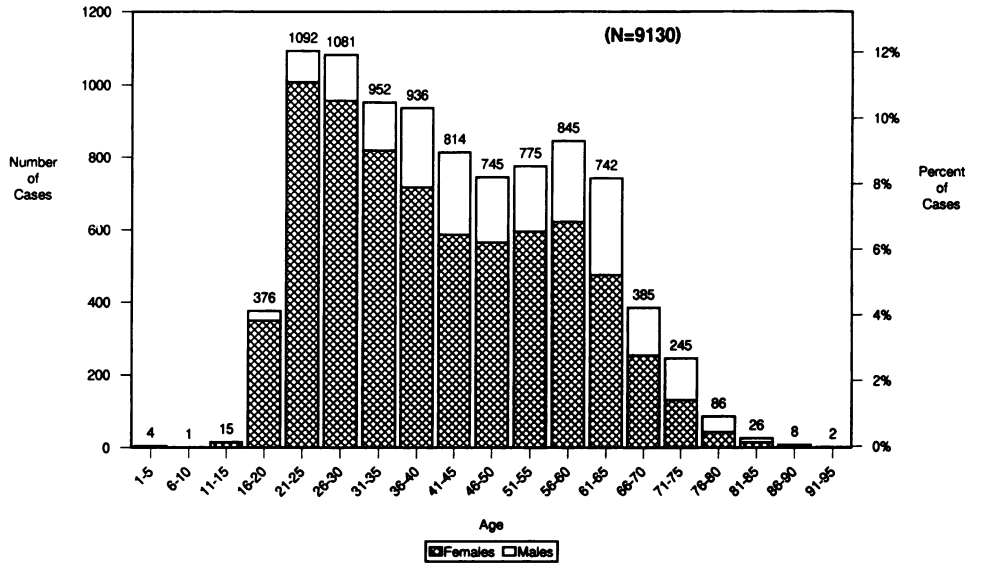

Figure 1. Laparoscopic cholecystectomy distribution of cases by age and gender.

Statistical Analysis

The data were subjected to stringent editing, validation, and verification processes. The authors identified risk factors potentially related to conversion to open cholecystectomies and to adverse outcomes. Backward stepwise logistic and Poisson regression analysis were used to determine those factors with significant effects on the risk of conversion and bile duct injury.

RESULTS

Table 1 identifies the demographics of the 9130 laparoscopic cholecystectomy patient records reviewed. Figure 1 provides the distribution of the patient population by age and gender. The study data indicated 78.3% of the patients were women, and the patients older than age 60 (61.6%) were women.

Because 76 medical records were incomplete, all subsequent analyses, tables, and figures are based on 9054 complete case records of the patients who underwent laparoscopic cholecystectomies. The preoperative diagnoses are displayed in Figure 2. The authors observed a 73.7% increase in the proportion of patients treated for acute cholecystitis in the current study; 13.2% compared with 7.6% in the previous study. Review of the diagnostic tests performed before the procedure found ultrasound was the most frequent test and was performed on 94.6% of the patients. Oral cholecystograms were performed on 3.3% of the patients. Technetium HIDA or cholecystokinin-HIDA scans or both were performed on 11% of the patients. A preoperative endoscopic retrograde cholangi-

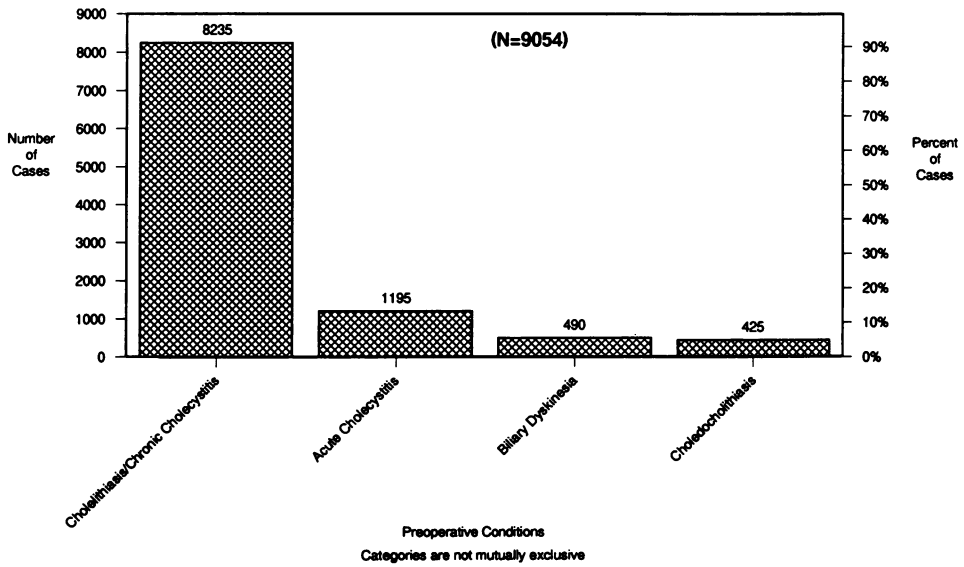

Figure 2. Laparoscopic cholecystectomy selected preoperative conditions.

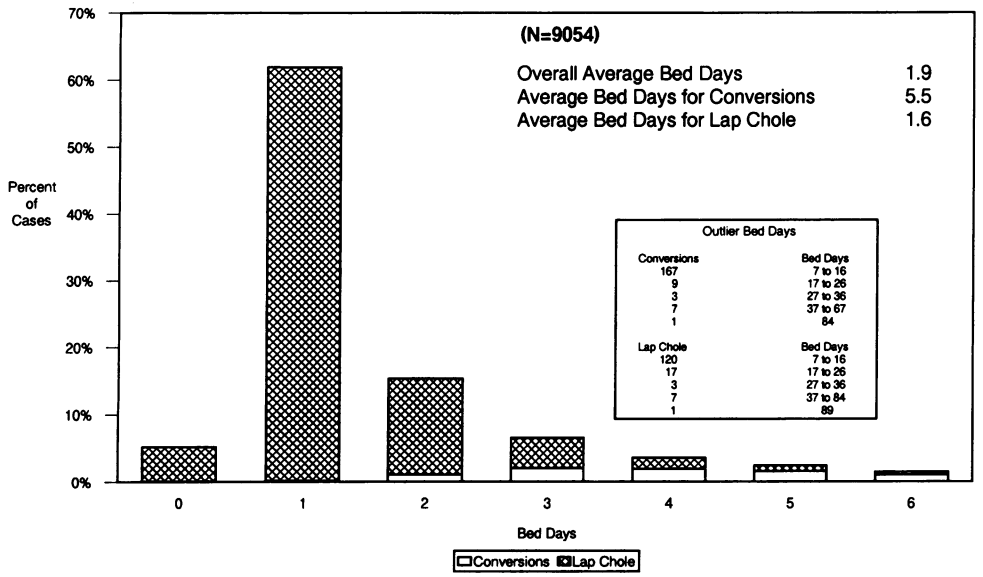

Figure 3. Laparoscopic cholecystectomy distribution of postoperative bed days.

opancreatography was performed on 5.9% of the patients, reflecting an increase from 3.9% in the previous study. Figure 3 identifies the average postoperative length of stay for patients undergoing laparoscopic cholecystectomy as 1.6 bed days compared with an average length of stay of 5.5 bed days for those patients whose procedures were converted to open cholecystectomy.

Surgical Access

In 57.6% of the patients, a closed (Veress) technique was used to access the peritoneum. An open (Hasson) technique was used in 42.4% of the patients. In the previous study, a closed (Veress) technique was used to access the peritoneum in 82.9% of the patients. The open (Hasson) technique was used in 17.1% of the patients.

Intraoperative Cholangiogram

Intraoperative cholangiograms were attempted in 42.7% of all patients. Cholangiograms when attempted

Table 2. FACTORS PRESENT FOR CONVERSION TO OPEN CHOLECYSTECTOMY* (N = 892)

	No.	%
Adhesions/inflammation	489	54.8
Dissection difficulty	365	40.9
Acute cholecystitis	339	38.0
Visualization difficulty	279	31.3
Suspected bile duct stone	132	14.8
Unspecified technical difficulty	100	11.2
Bleeding	79	8.9
Aberrant anatomy	66	7.4
Obesity	50	5.6
Suspected bile duct injury	37	4.1
Stone spillage	31	3.5
Suspected organ injury	31	3.5
Trocar placement limitations	31	3.5
Equipment failure	21	2.4

* Categories are not mutually exclusive.

Table 3. FACTORS AFFECTING THE RISK OF CONVERSION*

Factor	Odds Ratio	Z	p
Choledocholithiasis	7.596	16.221	<0.001
Acute cholecystitis	4.101	13.945	<0.001
Aberrant anatomy	2.849	6.576	<0.001
Adhesions	2.511	11.538	<0.001
Obesity (BMI > 40)	2.369	5.949	<0.001
Cirrhosis and benign disease of liver	2.047	4.639	<0.001
Emergency admission	1.888	6.321	<0.001
Male	1.824	6.716	<0.001
Acute pancreatitis	1.624	2.499	0.012
Age >60 yr	1.486	4.088	<0.001
Cholethiasis	1.330	2.380	0.017
Prior abdominal surgery	1.326	3.491	<0.001
Cholesterolosis	0.719	2.773	0.006
Biliary dyskinesia	0.404	2.525	0.012

* The odds ratio is the ratio by which the presence of (or 1 unit increase in) a factor increases the odds of conversion. An odds ratio of <1 means that the odds are decreased. The Z statistic reflects how large the measured effect of the factor is relative to variation expected by chance and p is the probability that an effect that large could be due to chance. If Z is high, then p is low and there can be more confidence that the odds ratio differs from 1 in the observed direction. Only those factors with p < 5% are reported.

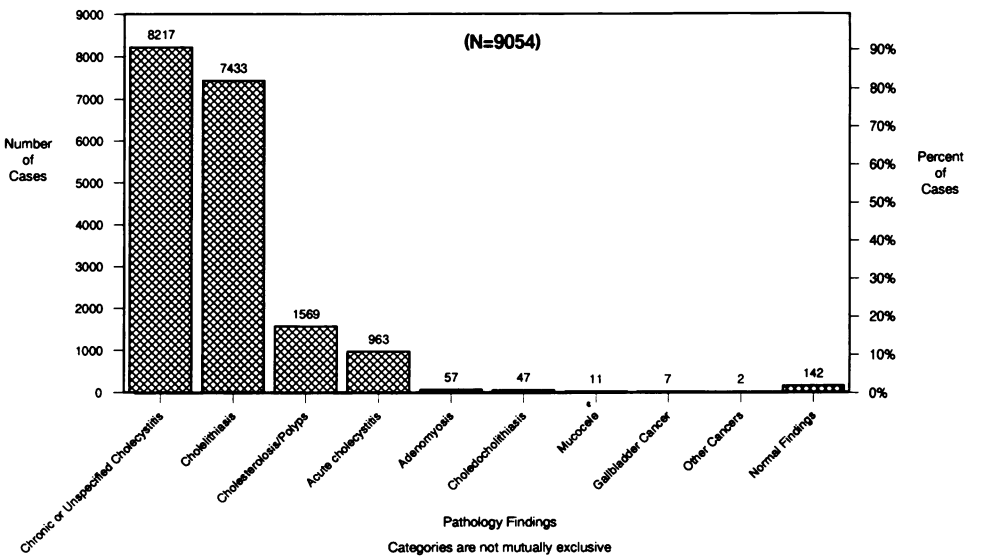

Figure 4. Laparoscopic cholecystectomy findings of pathology report.

were completed successfully in 86.2% of the cases. In the previous study, intraoperative cholangiograms were attempted in 46.5% of all patients and successfully completed in 80.6%.

Conversion to Open Procedure

Laparoscopic cholecystectomies were converted to open cholecystectomies in 9.8% of the patients. Table 2 lists the factors for conversion to an open cholecystectomy. Acute inflammation, aberrant anatomy, and factors limiting biliary duct visualization continue to be predictors of conversion. Table 3 indicates the factors affecting the risk of conversion identified by backward stepwise logistic regression.

Operative Findings

Pathology reports were available for the 9054 cases studied. Figure 4 displays the pathology report findings. The surgeons' operative findings correlated with the pathology findings in 87.8% of the cases.

Morbidity

Within 30 days after surgery, 6.09% of the patients experienced one or more of the complications identified in Table 4. The overall incidence of complications remained essentially unchanged from the previous study (6.87%), despite the expanded indications for laparoscopic cholecystectomy.

Bile Duct Injuries

Bile duct injuries were sustained by 37 (0.41%) of the 9130 patients. Thirty-one (0.34%) of these injuries occurred during laparoscopic dissection. Of the 37 bile duct injuries, 11 (29.7%) occurred among the cases completed laparoscopically. Six (16.2%) of 37 occurred after conversion during open dissection. Of the 37 injuries, 20 (54.1%) occurred before conversion in subsequently converted cases.

The previous study presented the military Bile Duct Injury Classification System (BDICS), which divides bile duct injuries into three classes: 1) BDICS class I, which includes lateral or partial injury to a duct; 2) BDICS class II, which includes the transection of a bile duct; and 3) BDICS class III, which includes the transection and resection of a portion of the bile duct system.[9]

Of the 37 bile duct injuries in this study, 23 (62.2%) were lateral injuries (BDICS class I injuries), 7 (18.9%) were transections (BDICS class II), and 7 (18.9%) were transections with resections (BDICS class III). Detailed information on injuries by BDICS class and patient demographics is presented in Table 5. Information on bile duct injury management is presented in Table 6. Of these 37 injuries, 27 (73.0%) were identified during the initial surgery, and 10 (27.0%) were identified after operation.

Factors associated with the risk of bile duct injury were identified by backward stepwise and Poisson regression. The risk factors, associated incidence rate ratios, and p values include the following:

1. Female, ratio 6.663 (p value 0.01)
2. Aberrant anatomy, ratio 7.849 (p value < 0.001)
3. Acute cholecystitis, ratio 2.665 (p value 0.01)

Bowel Injuries

Twenty-nine patients (0.32%) sustained bowel injuries. Four were duodenal injuries, of which one of the patients died. Bowel injuries are identified by dissection

Table 4. LAPAROSCOPIC CHOLECYSTECTOMY COMPLICATIONS* (N = 9054)

	No.	%
Intraoperative blood loss (>500 mL)	139	1.54
Urinary retention	106	1.17
Wound infection	79	0.87
Bile leak	48	0.53
Pneumonia	41	0.45
Bile duct injury	37	0.41
Prolonged ileus	37	0.41
Bowel injury	29	0.32
Postoperative pancreatitis	26	0.29
Respiratory insufficiency/failure	16	0.18
Acute respiratory distress syndrome	13	0.14
Intraabdominal abscess	13	0.14
Unsuspected bile duct stones	12	0.13
Bleeding requiring return to OR	11	0.12
Deep vein thrombosis	11	0.12
Vascular injury	10	0.11
Acute myocardial infarction/ischemic heart disease	9	0.10
Pulmonary edema	9	0.10
Pulmonary embolus	8	0.09
Cardiac arrest	4	0.04
Cerebrovascular incident	3	0.03
Fever of unknown origin	3	0.03
Sepsis	2	0.02
Air embolism	1	0.01
Peritonitis	1	0.01
Total complications	551	6.09
No complications	8503	93.91
Death†	12	0.13

* Categories are not mutually exclusive.
† Death during the same hospitalization or within 30 days.

versus access-related bowel injury and are depicted based on the site of the injury. Of these 29 injuries, 20 (69.0%) were injuries to the small bowel, 5 (17.2%) were injuries to the large bowel, and 4 (13.8%) were injuries to the duodenum. Table 7 displays bowel injury characteristics and management.

Of the 15 patients who sustained injury during initial access, 4 of the injuries occurred during the closed (Veress) technique and 11 occurred during the open (Hasson) technique.

Major Vascular Injuries

Major arterial or venous injuries were sustained by 10 (0.11%) of the patients. Although major vascular injuries were limited and did not include injury to the inferior vena cava or to the infrarenal abdominal aorta, there were two injuries to the common iliac artery and other major vascular structures that always represented an emergent life-threatening situation. One of the common iliac artery injuries occurred during access by the open (Hasson) technique. Characteristics of vascular injury are displayed in Table 8.

Mortality

Twelve patients died during the same hospitalization or within 30 days after operation for a mortality rate of 0.13%. Five (41.7%) of these patients were men. Five (41.7%) of the deaths were directly related to the laparoscopic cholecystectomy: one air embolus, two duodenal perforations, and two hemorrhage-related deaths. The remaining seven patients (58.3%) died of a combination of pre-existing disease and associated complications (refer to Table 9).

DISCUSSION

This is the second study within a large multihospital system patient population using a methodology that achieved a record review rate of 99.38% in the previous study and 99.2% in the current study. Because studies based on incomplete data may not reflect the true complication rates associated with laparoscopic cholecystectomy, it is widely accepted that "only an outside anonymous audit of an institution's experience can give a relatively clear picture of the data, including complication rates and bile duct injuries at that particular institution."[11] The methodology used in these two studies offers the unique opportunity for complete, system-wide analysis of the performance and outcomes of a procedure. Both studies have included all surgeons and institutions system wide, providing benchmarks defining laparoscopic cholecystectomy during both the introductory phase and the steady state.

Since the initial study, laparoscopic cholecystectomy continues to be the procedure of choice for nonmalignant gallbladder disease in the MHSS. This is the first review of a large, complete cohort of patients undergoing laparoscopic cholecystectomy in a multihospital system in the steady state.

Comparing the previous study to the current study, laparoscopic cholecystectomy as the choice for the initial approach to gallbladder disease increased by 32.5%, from 65.9% to 87.3%. The increased penetrance of this procedure raised concerns that complications may increase as indications for laparoscopic cholecystectomy expand to include more acute and difficult cases. This study shows an increase of 72.5%, from 7.65% to 13.2%, in the proportion of patients treated laparoscopically for acute cholecystitis in the introductory phase as compared with the steady state. Despite this increase, the overall complication rate was unchanged, 6.87% (introductory phase) compared with 6.09% (steady state).

If comparing the results of the introductory phase to

Table 5. BILE DUCT INJURY CHARACTERISTICS

	All Cases		BDICS Class* I		BDICS Class* II		BDICS Class* III	
	No.	%	No.	%	No.	%	No.	%
Total	37	100.0	23	63.2	7	18.9	7	18.9
Age (yr)								
Median	36		42		27		41	
Sex								
Male	2	5.4	1	2.7	1	2.7	0	0.0
Female	35	94.6	22	59.5	6	16.2	7	18.9
Time of occurrence								
Laparoscopic dissection	31	83.8	19	51.4	5	13.5	7	18.9
Open dissection	6	16.2	4	10.8	2	5.4	0	0.0
Intraoperative cholangiogram performed								
Yes	25	67.6	18	48.7	6	16.2	1	2.7
No	12	32.4	5	13.5	1	2.7	6	16.2
Time identified								
Intraoperative	27	73.0	19	51.4	7	18.9	1	2.7
Postoperative	10	27.0	4	10.8	0	0.0	6	16.2

* Bile duct injury classification system.

the steady state, conversion from laparoscopic cholecystectomy to open cholecystectomy is shown to have increased slightly from 8.08% to 9.85%. Several factors have been delineated by other authors as being associated with conversion to open cholecystectomy.[1,12–14] As in this study, the literature indicates that the overriding parameter correlated with conversion to open cholecystectomy is the severity of the disease, such as inflammation in the area of the gallbladder, which makes dissection difficult.[1,12] The literature is divided regarding the role of obesity and prior abdominal surgery as risk factors for conversion from laparoscopic cholecystectomy to open cholecystectomy.[1,12–14] Based on the large sample size with complete data, this study found prior abdominal surgery and obesity to be increased risk factors. In addition, as previously reported, the male gender appears to be a factor related to conversion.[9,12] In this study, the male population is older (median age, 50 for men *versus* 38 for women) and age correlates with conversion.

The detection and management of choledocholithiasis remains controversial. Comparing the previous study

Table 6. BILE DUCT INJURY MANAGEMENT

	All Cases		BDICS Class* I		BDICS Class* II		BDICS Class* III	
	No.	%	No.	%	No.	%	No.	%
Total	37	100.0	23	63.2	7	18.9	7	18.9
Management of injury								
Lateral repair with t-tube	15	40.5	15	40.5	0	0.0	0	0.0
Lateral repair without t-tube	5	13.5	5	13.5	0	0.0	0	0.0
Hepaticojejunostomy	5	13.5	0	0.0	0	0.0	5	13.5
Biliary anastomosis	5	13.5	0	0.0	5	13.5	0	0.0
Choledochojejunostomy	4	10.8	0	0.0	2	5.4	2	5.4
External drainage only	1	2.7	1	2.7	0	0.0	0	0.0
Choledochoduodenostomy	1	2.7	1	2.7	0	0.0	0	0.0
None	1	2.7	1	2.7	0	0.0	0	0.0

* Bile duct injury classification system.

Table 7. BOWEL INJURY CHARACTERISTICS

	All Cases		Type			
			Serosal		Full Thickness	
	No.	%	No.	%	No.	%
Total	29	100.0	17	58.6	12	41.4
Age (yr)						
Median	55		56		52.5	
Sex						
Male	9	31.0	5	17.2	4	13.8
Female	20	69.0	12	41.4	8	27.6
Time of occurrence						
Access	15	51.7	8	27.6	7	24.1
Laparoscopic dissection	12	41.4	8	27.6	4	13.8
Open dissection	2	6.9	1	3.4	1	3.4
Site						
Small bowel	20	69.0	10	34.5	10	34.5
Duodenum	4	13.8	2	6.9	2	6.9
Large bowel	5	17.2	5	17.2	0	0.0
Time identified						
Intraoperative	22	75.9	15	51.7	7	24.1
Postoperative	7	24.1	2	6.9	5	17.2
Management of injury						
Suture repair	22	75.9	17	58.6	5	17.2
Resection	6	20.7	0	0.0	6	20.7
None (expired)	1	3.4	0	0.0	1	3.4

with the current study, intraoperative cholangiography has decreased slightly from 46.5% to 42.7% and continues to be practiced selectively. There was a small increase

Table 8. VASCULAR INJURY CHARACTERISTICS

	No.	%
Total	10	100
Age (yr)		
Median	45.5	
Sec		
Male	5	50
Female	5	50
Time of occurrence		
Access	3	30
Laparoscopic dissection	5	50
Open dissection	2	20
Site		
Hepatic artery	4	40
Portal vein	3	30
Common iliac artery	2	20
Mesenteric artery	1	10
Time identified		
Intraoperative	9	90
Postoperative	1	10

Table 9. LAPAROSCOPIC CHOLECYSTECTOMY: DEATHS

	No.	%
Total	12	100.0
Age (yr)		
Median	65	
Sex		
Male	5	41.7
Female	7	58.3
Converted		
Yes	4	33.3
No	8	66.7
Days postoperative		
Median	16.5	
Range	0-89	
Causes of death		
MOSF	Postoperative hemorrhage, perioperative MI	
	Hemorrhagic pancreatitis	
	Underlying alcoholic cirrhosis, hemorrhage	
ARDS	Preexisting pneumonia and pulmonary embolism	
	Underlying pancreatic cancer	
	Postoperative aspiration pneumonia, sepsis	
	Aspiration pneumonia, open duodenal injury	
Sepsis	Pancreatitis with abscess	
	Missed laparoscopic injury of duodenum	
	Gangrenous cholecystitis with cholangitis	
Postoperative MI	Cardiac arrhythmia	
Air embolus	Portal vein injury*	

ARDS = acute respiratory distress syndrome; MOSF = multiple-organ system failure; MI = myocardial infarction.
* Intraoperative death.

in the number of preoperative endoscopic retrograde cholangiopancreatography (ERCPs) from 3.9% to 5.9%. In the MHSS, ERCP availability is variable. Some surgeons remain inexperienced with laparoscopic common bile duct exploration and select preoperative ERCP in patients with suspected choledocholithiasis. As experience and the ability with performing laparoscopic common bile duct exploration increase, the necessity for surgeons to perform preoperative ERCP should decrease.

Surgical access by the Hasson technique increased to 42.4% of the patients in the current study *versus* 17.1% in the previous study. Of the 15 patients who sustained bowel injuries during access in the steady state, 4 occurred during the closed (Veress) technique and 11 occurred during the open (Hasson) technique. Compared with 11 access-related injuries in the introductory phase, 5 were related to the Veress technique and 6 were related to the Hasson technique. The data on bowel injuries suggest that the Hasson technique offers no absolute protection from bowel injury during access to the peritoneal cavity for laparoscopy.

The risk of bile duct injury during laparoscopic cholecystectomy remains a special concern. The bile duct in-

Table 10. LAPAROSCOPIC CHOLECYSTECTOMY IN THE MILITARY HEALTH SERVICES SYSTEM

	Introductory (July 90–May 92)	Steady State (January 93–April 94)	p*
No. of laparoscopic cholecystectomies performed	5642	9130	
% of all cholecystectomies	65.91	87.30	<0.001
% of laparoscopic cholecystectomies with:			
Acute cholecystitis noted preoperatively	7.65	13.20	<0.001
Choledocholithiasis noted preoperatively	2.94	4.69	<0.001
Conversion rate (%)	8.08	9.85	<0.001
Morbidity rate (%)	6.87	6.09	0.070
Bile duct injury rate (%)	0.57	0.41	0.167
Mortality rate (%)	0.04	0.13	0.064

* From a two-sided exact test of a difference in the two rates.

jury rate was 0.41% during the steady state compared with 0.57% in the introductory phase, this difference not being statistically significant. The majority of the injuries (62.2%) were lateral injuries (BDICS class I) amenable to simple management (refer to Table 6). The remaining injuries (37.8%) were ductal injuries (BDICS class II and class III) and required more complex repairs (refer to Table 6). Of note, 83.8% of the bile duct injuries occurred during laparoscopic dissection, whereas 16.2% occurred during open dissection after conversion. Of the BDICS class III injuries, 85.9% were not discovered until the postoperative period. Only one intraoperative cholangiogram was performed among this group, representing the only case discovered intraoperatively. An intraoperative cholangiogram before cholecystectomy may preclude a class II injury from becoming a class III injury by defining the biliary anatomy before transection and resection of the biliary duct. The BDICS facilitates the classification of bile duct injuries and remains a useful tool.

During the introductory phase, inexperience of the surgeon was the most important factor for bile duct injury. In the previous study, of the 27 bile duct injuries that occurred during laparoscopic surgery, 25 of the injuries took place on or before the 10th procedure in the surgeon's experience.[9] In the steady state, the incidence of bile duct injuries did change significantly. Increased surgical experience has been offset by the increased risk associated with expanded indications and more difficult cases. Acute cholecystitis, aberrant anatomy, and female gender were identified as leading independent risk factors for bile duct injuries.

The mortality rate in the previous study was 0.04% compared with 0.13% in the current study. The mortality rate increase between the two study periods was not statistically significant. Comorbidities were major factors in 58.3% of the deaths. As expected, the median age in those who died was older than that of the entire cohort (65 years *versus* 41 years).

This is the second complete study within a large multihospital system patient population. The first study examined laparoscopic cholecystectomy in the MHSS during the introductory phase when 65% of gallbladders were removed laparoscopically. This second study examines laparoscopic cholecystectomy in the steady state, when the penetrance approached 90%. Despite this increased penetrance, laparoscopic cholecystectomy does not show an increase in morbidity and mortality rates as compared with the introductory phase (Table 10).

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