ANNALS OF SURGERY
Vol. 220, No. 5, 626–634
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An External Audit of Laparoscopic Cholecystectomy Performed in Medical Treatment Facilities of the Department of Defense

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Objective
This study provided an objective survey by an outside auditing group of a large, complete patient population undergoing laparoscopic cholecystectomies, determined the frequency of complications, especially bile duct injuries, and presented a system for classifying and comparing the severity of bile duct injuries.

Summary Background Data
This is the first study of laparoscopic cholecystectomy to encompass a large and complete patient population and to be based on objectively collected data rather than self-reported data. The Civilian External Peer Review Program (CEPRP) of the Department of Defense health care system conducted a retrospective study of 5642 patients who underwent laparoscopic cholecystectomies at 89 military medical treatment facilities from July 1990 through May 1992.

Methods
The study sample consisted of the complete records of 5607 (99.38%) of the 5642 laparoscopic cholecystectomy patients.

Results
Of the sample, 6.87% of patients experienced complications within 30 days of surgery, 0.57% sustained bile duct injuries, and 0.5% sustained bowel injuries. Among 5154 patients whose procedures were completed laparoscopically, 5.47% experienced complications. Laparoscopic procedures were converted to open cholecystectomies in 8.08% of cases. Intraoperative cholangiograms were attempted in 46.5% of cases and completed in 80.59% of those attempts. There were no intraoperative deaths; 0.04% of the patients died within 30 days of surgery.

Conclusions
The frequency of complications found in this study is comparable to the frequency of complications reported in recent large civilian studies and earlier, smaller studies. The authors present a system for classifying bile duct injuries, which is designed to standardize references to such injuries and allow for accurate comparison of bile duct injuries in the future.

Laparoscopic cholecystectomy is one of the most important new techniques in modern general surgery. The procedure ushered in the widespread use of video endoscopic surgery. This review represents the first analysis of more than 99% of a large patient population treated with laparoscopic cholecystectomy throughout a large multihospital system by a large group of surgeons. This review includes all surgeons at all hospital facilities in the Department of Defense military health services system (MHSS) who performed laparoscopic cholecystectomies during the study period, and therefore, includes virtually all cases treated in the system during that period.

Laparoscopic cholecystectomy has been controversial since its introduction approximately 5 years ago, for several reasons. First, the procedure proliferated faster than any technological advance in surgery in recent memory and achieved widespread acceptance in less than 18 months.[1] This was largely because of a tremendous demand from patients, which drove many surgeons to adopt the technique.[2] More than 500,000 cholecystectomies are performed annually,[3] and the laparoscopic approach has become the procedure of choice.[4,5]

Second, there has been widespread concern about the training, proctoring, and experience of many of the surgeons performing laparoscopic cholecystectomies.[6,7] Until its introduction, most general surgeons were unfamiliar with laparoscopic surgical techniques because the techniques were not taught in most general surgery training programs. Another concern was that the procedure had been introduced through short courses, often with little oversight, in which surgeons learned the technique during a weekend through lectures, videotapes, and hands-on laboratory surgery. Some of these courses were excellent, but others were "hurriedly and incompletely organized."[6,7]

The highest rates of injuries occur early in a surgeon's experience with laparoscopic cholecystectomy,[8] so it is generally agreed that before being credentialed or granted hospital privileges to do the procedure, surgeons should be required first to observe a certain number of these procedures while assisting another surgeon, and then to perform another series while being proctored by a surgeon experienced in the technique.[6,9]

Third, although such guidelines currently are being put into place throughout the health care system, there have been instances of unacceptably high rates of serious complications,[9] including injury to bile ducts (including the common bile duct, the common hepatic duct, and the right and left hepatic ducts), the bowel, the bladder, the liver, and the major arteries—many of which are less common in open cholecystectomy.[10] Such occurrences led to seven deaths in New York when the technique initially was introduced. As a result, New York issued guidelines suggesting training, assisting, and proctoring requirements for surgeons to fulfill before a hospital issues them credentials to perform the procedure independently.[9]

In light of these concerns, the need has been cited for large scale studies that accurately ascertain complication rates. Large studies of this sort were published in 1992 and 1993.[4,8,11-13] Although these studies yielded important information about complications, especially the frequency of bile duct injuries, they still did not cover complete populations. As a result, there has been some doubt about whether they delivered a full view of the actual rates of complications. For example, the coordinators of one of these studies note that the cases submitted to them "may represent only between 85% and 90% of the cases performed during the study period."[11]

This 10% to 15% of cases may be missing for a number of reasons, including the inherent difficulty in marshalling records or the possibility that various participating hospitals did not report all cases with complications. In addition, the largest of these reviews is based on data from only a portion of the targeted hospitals from which information was requested; in that study, 60% of hospitals queried for sample cases failed to respond.[12]

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."[8]

This study was conceived and performed to answer the need for such an objective look, by an outside auditing group, at the frequency of complications, especially bile duct injury, in a complete population of patients undergoing laparoscopic cholecystectomies. In addition, based on the data from this study, this article presents a system for classifying and comparing the severity of bile duct injuries so that the true frequency of each type of injury can be known.

Although it is critically important to maintain an acceptable frequency of bile duct injuries during laparoscopic cholecystectomy,[2,10,14-16] it also is important to be able to ascertain the severity of bile duct injuries, and to be able to compare injuries of varying severity. It always has been difficult to compare the severity of the range of bile duct injuries that occur during this procedure. Bile duct injuries range from simple lacerations, which can be repaired at the time of surgery, and which may cause no lasting ill effects, to resections, which can significantly diminish the length and quality of the patient's life. Bismuth has described the mechanisms through which bile

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Accepted for publication February 18, 1994.

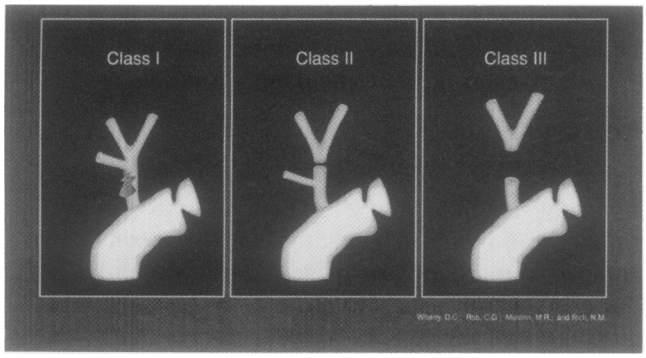

Figure 1. Laparoscopic cholecystectomy classes of bile duct injuries.

duct injuries occur during open cholecystectomy and has proposed a system for classifying postoperative bile duct strictures.[17] However, to date, there is no reporting system that allows surgeons to classify the severity of an injury that has occurred during a laparoscopic procedure. We have developed a Bile Duct Injury Classification Scale (BDICS) to make such classifications and comparisons possible.

The Bile Duct Injury Classification Scale divides bile duct injuries into the following three classes: Class I, which includes lateral or partial injury to a duct; Class II, which includes the transection of a bile duct; and Class III, which includes the transection and resection of a portion of the bile duct system. These three classes of bile duct injury are illustrated in Figure 1.

This study represents the results of an evaluation by the Civilian External Peer Review Program (CEPRP) of the Department of Defense MHSS of 5642 laparoscopic cholecystectomies performed at the 89 military medical treatment facilities at which the procedure was performed from July 1990 through May 1992. The evaluation was performed under the direction of the Uniformed Services University for the Health Sciences (USUHS) and was authorized by the Office of the Assistant Secretary of Defense for Health Affairs. The study was performed by Forensic Medical Advisory Service, Inc. (FMAS), the prime contractor for the CEPRP, which collected, analyzed, and validated all the data.

MATERIALS AND METHODS

Collection of Data

Cases to be reviewed were identified by inspecting operative logs and by querying hospital systems, such as the Automated Quality of Care Evaluation Support System (AQCESS) or the Composite Health Care System (CHCS). The sample at 87 medical treatment facilities included patients who underwent both open cholecystectomies and laparoscopic cholecystectomies between July 1990 and May 1992. In the other two medical treatment facilities, archiving policies for patient records limited the study sample and study period to open and laparoscopic cholecystectomies performed between January 1991 and May 1992. The study sample included all the laparoscopic cholecystectomies performed in the MHSS worldwide during the study period. The medical abstractors visited all 89 medical treatment facilities to review the records of patients in the study sample. All case records included in the study were abstracted between July and September 1992.

The available records showed that 8560 cholecystectomies were performed during the period under review, of which 34.09% (2918) were traditional open procedures and 65.91% (5642) were laparoscopic cholecystectomies. The study group obtained the complete records of 99.38% (5607) of the patients who underwent laparoscopic procedures. The records for 35 patients who underwent laparoscopic cholecystectomies were incomplete and could not be included in the study. However, we do have enough information about these 35 patients to know that all of them are alive and did not have major problems, such as bile duct injury. Table 1 shows the demographic profiles and discharge disposition of the 5607 patients with complete records. Figure 2 gives the distribution of this patient population by age and sex.

Statistical Analysis

The data were subjected to stringent editing, validation, and verification processes, and to other quality control procedures, including logic assessment, that are required for pattern analysis. Statistical analyses were performed on the data, including the application of the z score (or t ratio) statistic to identify areas of statistical significance. In addition, logistic regression analysis, in conjunction with univariate analysis using the chi square statistic, was used to identify risk factors related to the decision to convert laparoscopic procedures to open cholecystectomies.

Surgeon Training and Experience

In studies done to date on laparoscopic cholecystectomy, there has been no reliable way to link complication rates with the training, proctoring, and experience of the surgeons performing the procedure. A key reason for this has been that the training available to civilian surgeons varies widely in quality, and that although most surgeons agree on the need for hands-on laboratory training courses and proctoring, there are no universally accepted or enforced standards for granting credentials in laparoscopic cholecystectomy.[6,15]

This study was similarly unable to definitively link complication rates with surgeon experience and training.

Table 1. LAPAROSCOPIC CHOLECYSTECTOMY SUMMARY STATISTICS

	No.	Percent
Records reviewed	5607	100
Disposition		
Alive	5605	99.96
Expired	2	0.04
Sex		
Male	1275	22.74
Female	4332	77.26
Race		
White	4495	80.17
Black	582	10.38
Asian/Pacific Islander	207	3.69
American Indian/Eskimo/Aleut	16	0.29
Hispanic	304	5.42
Not documented	3	0.05

However, it was possible to verify the level of training and, in some cases, the experience of a significant fraction of the participating surgeons, because the Department of Defense medical system insists that military surgeons take a training course that includes hands-on laboratory experience, either within the military medical system or in the civilian medical system. Each service has guidelines on the training, proctoring, and credentialing of physicians to perform the procedure. Credentialing is done locally by individual medical treatment facilities, based on their assessment of a surgeon's competence to perform the procedure.

The Uniformed Services University for the Health Sciences (USUHS) offers such a standardized training course and recommends that after training, all surgeons assist in several procedures and then be proctored during several more. This study included 162 Department of Defense surgeons who took the USUHS course. Because of confidentiality requirements in the CEPRP contract, the identities of all surgeons who participate in CEPRP studies are encrypted, which made it impossible to determine the total number of Department of Defense surgeons who participated in this study. Also, as a result of this encryption policy, it was not possible to establish the rate of complications for each surgeon.

RESULTS

The indications that most frequently led to cholecystectomy were cholelithiasis, chronic or unspecified cholecystitis, acute cholecystitis, and choledocholithiasis. Figure 3 displays the distribution of these conditions and the proportions of patients with each condition or a combination of conditions. Ultrasound was the most frequent preoperative test and was performed on 95.42% of the patients. Oral cholangiograms were performed on 7.9% of patients. A preoperative endoscopic retrograde cholangiopancreatography was performed on 3.94% of patients. As shown in Figure 4, the average number of postoperative bed days for patients whose procedures were completed laparoscopically was 1.7, in contrast with an average of 5.16 bed days for those whose procedures were converted to open cholecystectomies.

Surgical Approach

Table 2 displays the basic procedures performed during surgery. In 82.9% of patients, a closed technique us-

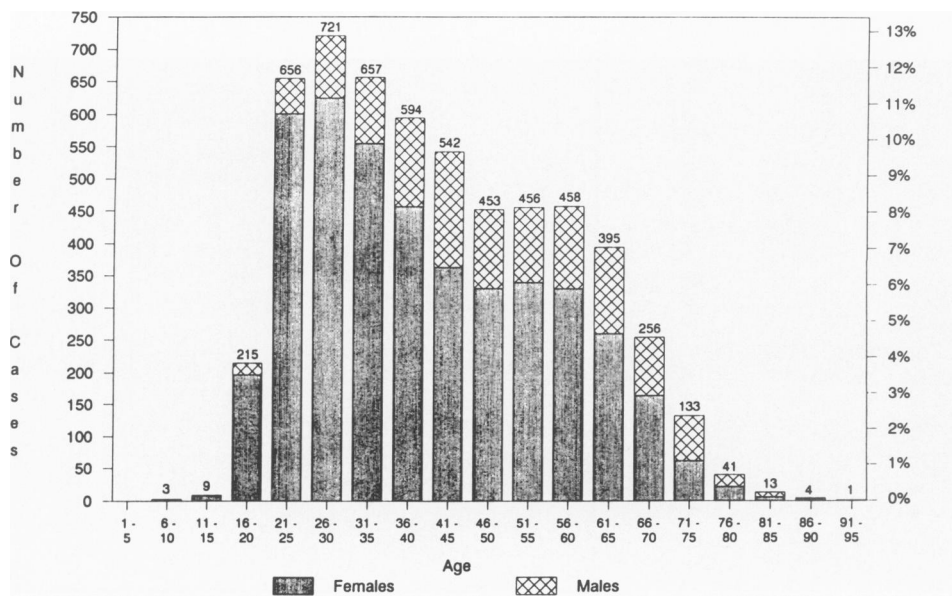

Figure 2. Laparoscopic cholecystectomy distribution of cases by age and sex.

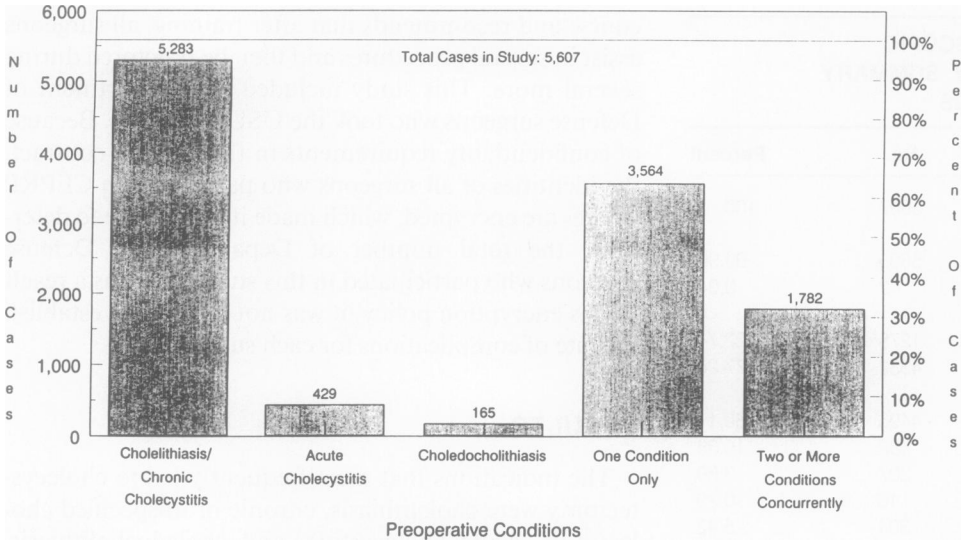

Figure 3. Laparoscopic cholecystectomy selected preoperative conditions.

* Categories are not mutually exclusive.

ing a Veress or similar needle was used to insufflate the peritoneum, and in 17% of patients, open techniques using a Hasson or similar cannula was used.

Intraoperative Cholangiogram

An intraoperative cholangiogram was attempted in 46.5% of patients, and completed successfully in 80.59% of those attempts. Among the cases that were completed laparoscopically, 81.21% of intraoperative cholangiograms were completed successfully. Among the 137 intraoperative cholangiograms performed on the patients who were eventually converted to open cholecystectomies, 69.34% were successful.

Conversion to Open Operation

Laparoscopic cholecystectomies were converted to open cholecystectomies in 8.08% of the patients. Figure 5 lists the reasons for conversion in these cases. A logistic regression model, in conjunction with univariate analysis using the chi square statistic, identified the variables in Table 3 as risk factors related to the decision to convert to an open cholecystectomy. The table also contains associated coefficients, the standard errors, and the p values.

As in the civilian sector, it is stressed within the military medical system that it is sound policy to convert to open cholecystectomy if there is a problem that cannot be solved readily and easily using the laparoscopic technique. Surgeons also are apprised that a low conversion

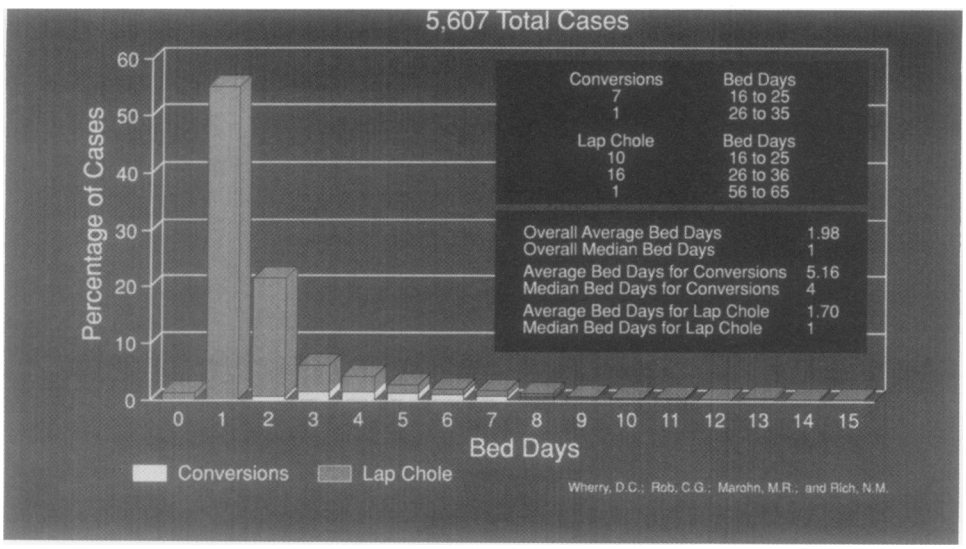

Figure 4. Laparoscopic cholecystectomy distribution of postoperative bed days.

Table 2. LAPAROSCOPIC CHOLECYSTECTOMY OPERATIVE INFORMATION

	No.	Percent
Bladder drainage during procedure	5480	97.73
Gastric decompression during procedure	5186	94.49
Prophylactic antibiotics	5155	91.94
Anesthesia		
General	5606	99.98
Epidural	1	0.02
Operative technique		
Veress or other needle	4648	82.90
Hasson technique or cannula	957	17.07
Not documented	2	0.04
Operative energy source:		
Electrocautery	5421	96.66
Argon beam coagulation	28	0.50
Laser	23	0.41
Other	1	0.02
Not documented/cannot determine	134	2.39

rate may be associated with an increased incidence of complications, such as bile duct injury, and that a high conversion rate does not reflect inadequate surgical skill and will not be used to judge the competence of a surgeon.

Findings

There were no intraoperative deaths. However, two patients died during the 30-day period after the operation, for a mortality rate of 0.04%. One patient, a 71-year-old man, developed postsurgical septic shock, his abdomen became distended, and a laparotomy showed an intact alimentary tract and murky intraperitoneal fluid that grew gram-negative rods. The patient developed polymicrobial sepsis, followed by multiple organ failure, and died 28 days after the cholecystectomy. The other patient was a 62-year-old woman with acute cholecystitis and pre-existing biliary cirrhosis. The laparoscopic procedure was converted to an open cholecystectomy because her bile duct anatomy was unclear, and the gall bladder was removed. The patient developed liver failure postoperatively, and died as a result of that condition 23 days after surgery. Postmortem examinations were not performed on either patient.

Pathology reports were available for 99.28% of the cases in the study. Figure 6 displays the findings of those reports.

Intraoperative blood transfusions were received by 0.1% of patients, 0.54% of patients received postoperative blood transfusions within 7 days after surgery, and 0.11% of these patients received both intraoperative and postoperative transfusions.

Complications

Within 30 days after surgery, 6.87% of the patients in the sample experienced one or more of the complications illustrated in Table 4; 5.56% of patients in the study had one complication, and 1.3% of the patients in the study had two or more complications. The four most common complications were wound infection (66 cases), bile leaks (56 cases), prolonged ileus (55 cases), and unexplained fever (54 cases). Eight of the patients who experienced bile leaks were found to have bile duct injuries. Among the patients in whom the procedure was completed laparoscopically, 5.47% experienced complications.

Bile Duct Injuries

Bile duct injuries were sustained by 0.57% of the patients in the study; 0.48% of the cases in the study sus-

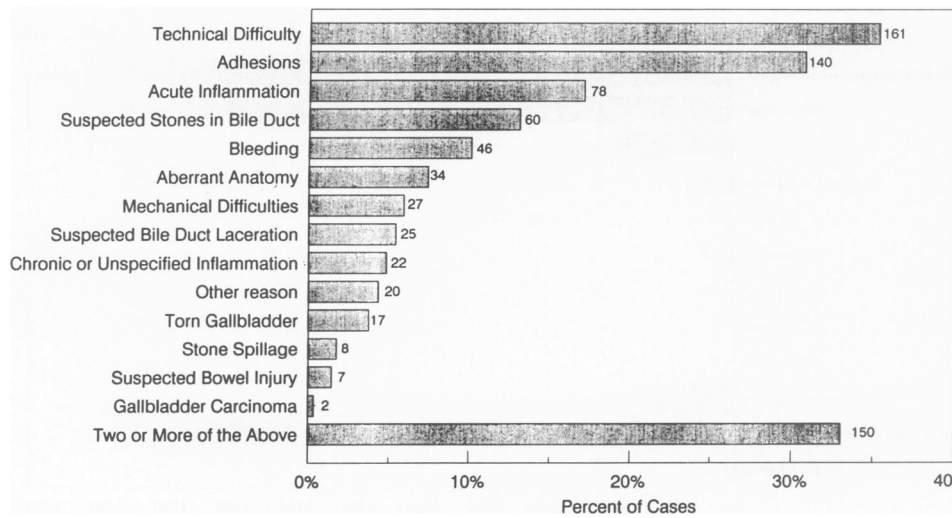

Figure 5. Laparoscopic cholecystectomy reasons for conversion to open cholecystectomy.

* Categories are not mutually exclusive.

Table 3. CONVERSIONS TO OPEN CHOLECYSTECTOMY (453)

Factor	Coefficient	Standard Error	p*
Jaundice	1.0506	0.2897	0.0003
Cirrhosis	1.5814	0.5624	0.0049
Pancreatitis	0.8549	0.2458	0.0005
Intraoperative cholangiogram†	−1.2646	0.1306	0.0001
Bile duct stones	2.6517	0.2240	0.0001
Acute cholecystitis (operative report)	1.4663	0.1451	0.0001
Gallbladder path report‡	−0.1983	0.5566	0.7216
Normal findings on path report‡	−1.7556	1.0341	0.0896
Acute cholecystitis (path report)	0.8015	0.1609	0.0001
Abnormal anatomy§	0.9453	0.1374	0.0001
Male	0.3984	0.1170	0.0007
Age	0.0171	0.0035	0.0001
Intercept	−3.3075	0.5743	0.0001

* A p value of 0.05 or less represents a significant variable.

† Because the variable for intraoperative cholangiogram and its associated subquestion on bile duct stones have significant relationships with conversions, the two variables must be viewed in tandem. Because bile duct stones are not identified unless a cholangiogram is performed, the combined effect on the likelihood of a conversion is (2.6517–1.246) = 1.4057. If bile duct stones are not identified when a cholangiogram is performed, the combined effect is −1.2646.

‡ These factors are associated with the factor acute cholecystitis but are not significant, rendering the calculations as performed for cholangiograms unnecessary.

§ The abnormal anatomy variable represents a combination of the variables aberrant anatomy and abnormal biliary tract.

tained bile duct injuries during the laparoscopic procedure, and 0.09% of patients had their bile ducts injured after their procedures were converted to open cholecystectomies. This last group of patients represents 1.1% of the cases that were converted to open cholecystectomies. Of the 32 bile duct injuries, 31.25% occurred among the cases that were completed laparoscopically, 53.13% occurred before conversion, and 15.63% were sustained after conversion.

Of the 32 bile duct injuries, 62.5% were simple lateral injuries (Class I in the BDICS), 21.87% were transections (Class II), and 15.63% were transections with resections (Class III).

The median age for those sustaining bile duct injuries was 35 years, and the average age was 41 years, compared with the average age for all laparoscopic cholecystectomies, which was 42 years. The average ages of patients who sustained bile duct injuries were 43 years for Class I, 42 years for Class II, and 36 years for Class III.

Twenty-five percent of the patients who sustained bile duct injuries suffered from acute cholecystitis, and 75% suffered from chronic cholecystitis with or without

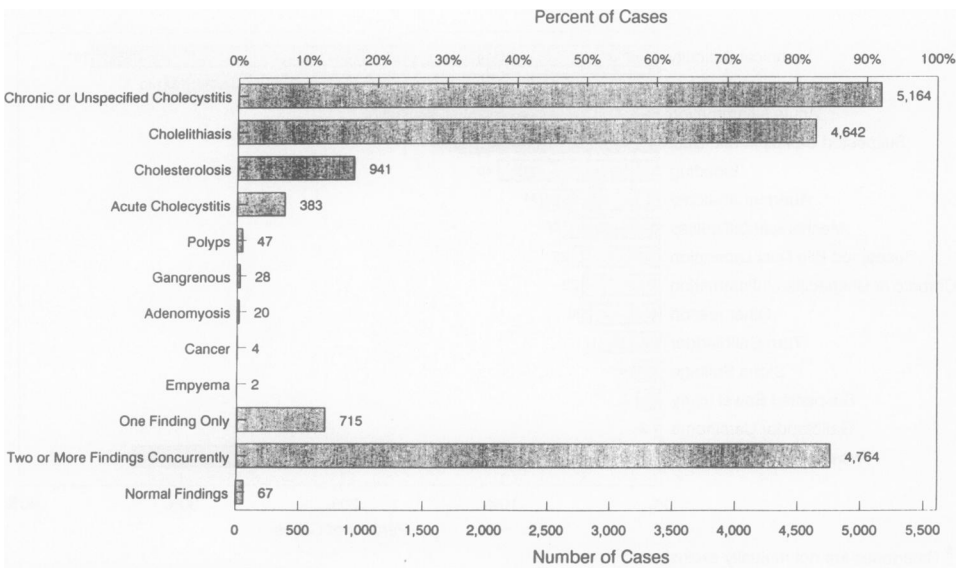

Figure 6. Laparoscopic cholecystectomy findings of pathology report.*

Categories are not mutually exclusive.

Table 4. LAPAROSCOPIC CHOLECYSTECTOMY COMPLICATIONS WITHIN 30 DAYS AFTER SURGERY

Complication*	Total Cases		Laparoscopic Cases		Converted Cases	
	No.	Percent	No.	Percent	No.	Percent
Wound infection	66	1.18%	53	1.03%	13	2.87%
Bile leak	56	1.00%	40	0.78%	16	3.53%
Prolonged ileus	55	0.98%	31	0.60%	24	5.30%
Unexplained fever	54	0.96%	44	0.85%	10	2.21%
Retained stone in bile duct	44	0.78%	34	0.66%	10	2.21%
Bile duct injury	32	0.57%	10	0.19%	22	4.86%
Abdominal wall hematoma	29	0.52%	26	0.50%	3	0.66%
Bowel injury	28	0.50%	14	0.27%	14	3.09%
Postoperative jaundice	23	0.41%	22	0.43%	1	0.22%
Postoperative pancreatitis	23	0.41%	18	0.35%	5	1.10%
Subcutaneous emphysema	21	0.37%	21	0.41%	0	0.00%
Hemorrhage requiring transfusion	17	0.30%	9	0.17%	8	1.77%
Intra-abdominal hematoma	12	0.21%	10	0.19%	2	0.44%
Incisional hernia	7	0.12%	6	0.12%	1	0.22%
Deep venous thrombosis or thrombophlebitis	4	0.07%	2	0.04%	2	0.44%
Myocardial infarction	4	0.07%	4	0.08%	0	0.00%
Pulmonary embolus	2	0.04%	2	0.04%	0	0.00%
Pulmonary edema	2	0.04%	1	0.02%	1	0.22%
Death	2	0.04%	1	0.02%	1	0.22%
Major vascular aortic injury	1	0.02%	1	0.02%	0	0.00%
No complications	5222	93.13%	4,872	94.53%	350	77.26%
One complication	312	5.56%	232	4.50%	80	17.66%
Two or more complications	73	1.30%	50	0.97%	23	5.08%

* Categories are not mutually exclusive.

cholelithiasis.

Of these injuries, 68.75% were identified during the initial surgery, and 31.25% were identified postoperatively. Fifteen of these patients, 46.87%, underwent intraoperative cholangiograms, and all had abnormal results. Bile duct injuries were recognized during the initial surgery in 13 of these 15 patients, but in two cases, the surgeon failed to recognize the bile duct injury and continued with the laparoscopic procedure despite the abnormal test results. Consequently, these two injuries were not identified until after the surgery.

Of the Class I injuries, 80% were managed with primary lateral repair over a T tube, and 15% were managed with primary lateral repair without a T tube; a single case (5%) was managed with a choledochojejunostomy. Of the Class II injuries, 28.57% were managed with choledochojejunostomies and 57.14% were managed with primary end-to-end biliary anastomoses over a T tube; one case (14.28%) was managed with a hepaticojejunostomy. Forty percent of the Class III injuries (two cases) were managed with choledochojejunostomies, and 60% were managed with hepaticojejunostomies.

The pattern of these injuries supported the generally accepted conclusion that the frequency of complications associated with laparoscopic cholecystectomy, especially bile duct injuries, is related inversely to the experience of the surgeon doing the procedure and that the highest rates of such injuries occur early in a surgeon's experience with the technique, usually during the surgeon's first 10 to 15 cases.[5,8,14,18]

Of the 27 bile duct injuries that occurred during laparoscopic surgery, 92.59% took place on or before the tenth procedure in which the surgeon was the primary surgeon, despite the fact that the surgeons in this study fulfilled the stringent Department of Defense requirements for training, proctoring, and experience.

Bowel Injuries

Twenty-eight of the patients in the study, 0.5%, sustained 29 bowel injuries (one patient sustained two injuries). Of these injuries, 65.52% were injuries to the small bowel and 34.48% were injuries to the colon, 37.93% of these injuries were limited to the serosa only, 65.52% of the injuries occurred during initial access to the peritoneal cavity, 27.58% occurred during dissection, and 6.89% were caused by electrocautery.

Among the patients who sustained their injuries during initial access, 26.32% of injuries were caused during closed technique by the Veress needle, 31.58% were

caused during open technique using the Hasson cannula, and 42.11% were caused by the introduction of the trocar.

Among the bowel injuries which occurred during dissection, 50% occurred during procedures completed laparoscopically, and 50% occurred after the procedure had been converted to the open technique.

DISCUSSION

This study, an outside evaluation of laparoscopic cholecystectomy, is the first to assess the outcome of this procedure among a virtually complete (more than 99%), large study population. As a result, the study answers the longstanding need for a review of a large, complete patient population undergoing laparoscopic cholecystectomies performed by a large number of surgeons in a large number of hospitals.

The frequency of complications found in this study, including bile duct injuries, was 6.87%. The frequency of bile duct injury alone was 0.57%. These findings parallel the incidences of complications and bile duct injuries reported in earlier, less complete studies, even though those studies may have been missing 10% to 15%, and often more, of their target patient populations.[11-13]

The Bile Duct Injury Classification Scale facilitates the classification and analysis of bile duct injuries and may be useful in formulating management strategies and estimating prognoses for these injuries.

Overall, this review confirms the safety of laparoscopic cholecystectomy during its introduction into a large multihospital system and supports the widespread acceptance of the procedure as the standard of care for gallbladder surgery.

Acknowledgments

The authors thank Col. Alfred S. Buck, M.C., U.S.A., for initiating this study; the Surgeons General of the U.S. Army, Navy, and Air Force; all the military surgeons who participated in the care of the patients; the medical service consultants who contributed to this study; the commanding officers, chiefs of surgery, directors of quality assurance, and directors of medical records at the participating hospitals. They also thank Maria M. Caschetta, R.R.A.; Judith E. Samuels, R.R.A.; Linda S. Battin, M.E.A.; Daniel L. Kagan; Kimberly Webster, A.R.T.; Brigitte Didier, A.R.T.; Patricia Gordon, R.R.A.; Ernani Morgan, R.R.A.; H. Shelton Brown III, M.A.; Arthur Furnia, M.S.; Tom Wallis; Tran Phuong; the regional coordinators and field staff of FMAS, Inc.; and Vector Research, Inc., for their valuable assistance designing the study, collecting and analyzing the data, and helping prepare this article.

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