ANNALS OF SURGERY
Vol. 227, No. 3, 343–350

Indications for and Outcomes of Cholecystectomy

A Comparison of the Pre and Postlaparoscopic Eras

Judy A. Shea, PhD,*†‡ Jesse A. Berlin, ScD,‡@ Dale R. Bachwich, MD,†|| Rudolf N. Staroscik, MD,¶# Peter F. Malet, MD,||¶ Maryanne McGuckin, Dr ScEd,*† J. Sanford Schwartz, MD, *†‡** and José J. Escarce, MD, PhD, *†‡

From the Division of General Internal Medicine, Department of Medicine, University of Pennsylvania, Leonard Davis Institute of Health Economics, University of Pennsylvania,† Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania School of Medicine,‡ Department of Biostatistics and Epidemiology,@ Division of Gastroenterology, Department of Medicine, University of Pennsylvania,||, Veteran's Affairs Medical Center, Philadelphia, PA¶, Department of Surgery, University of Pennsylvania#, and The Wharton School, University of Pennsylvania***

Purpose

Examine changing patient characteristics and surgical outcomes for patients undergoing cholecystectomy at five community hospitals in 1989 and 1993.

Procedures

In a retrospective chart review, data were gathered regarding gallstone disease severity, type of admission, patient age, number of comorbidities, American Society of Anesthesiologists (ASA) Physical Status Classification, length of stay, and multiple outcomes of surgery.

Main Findings

The volume of nonincidental cholecystectomies increased 26%, from 1611 in 1989 to 2031 in 1993. Nearly all of the increase occurred among patients with uncomplicated cholelithiasis and with elective admissions. In 1993, lengths of stay were significantly shorter and percentages of complications were significantly lower for infectious, cardiac, pulmonary, and gastrointestinal complications when controlling for patient case-mix characteristics. There were more major intraoperative complications (unintended wounds or injuries to the common bile duct, bowel, blood vessel(s), or other organs) in 1993.

Conclusions

Different types of patients underwent cholecystectomy in 1993 compared with patients in 1989, which supports the hypothesis of changing thresholds. Statements supporting the safety of cholecystectomy in the laparoscopic era were borne out when controlling for differences in patient characteristics.

Laparoscopic cholecystectomy was introduced in the United States in 1988. By early 1992, more than 80% of the general surgeons in the U.S. had adopted the procedure.[1] The introduction of laparoscopic cholecystectomy has affected both the selection of patients for and the outcomes of cholecystectomy. Several studies have suggested that the number of patients undergoing cholecystectomy has risen 20% to 30% since the introduction of the laparoscopic procedure,[2–5] and an analysis of Medicare discharge data has suggested that this was because the threshold, or likelihood of performing surgery on patients with certain clinical characteristics, had fallen.[5] Moreover, the results of several studies suggest that patients undergoing laparoscopic cholecystectomy have shorter hospital stays, an earlier return to activities,[6–13] and generally lower mortality and morbidity rates[2,14–16] than those undergoing open cholecystectomy. A recent meta-analysis concurred that the mortality rate and the rates of most surgical complications are quite low for laparoscopic cholecystectomy, although the rate of common bile duct injury is somewhat greater than injury for open cholecystectomy.[17]

This work was supported by a grant from the Agency for Health Care Policy and Research (HS06481).

Correspondence and reprint request to: Judy A. Shea, PhD, Division of General Internal Medicine, University of Pennsylvania, Ralston House 318, 3615 Chestnut Street, Philadelphia, PA 19104-2676.

Accepted for publication December 11, 1997.

Some questions remain about the findings. For example, the study that showed lower thresholds used Medicare discharge data.[5] Thus, the assessment of disease severity could be challenged and its generalizability to younger patients is unknown. Moreover, with the exception of three small randomized trials[13,18,19] that corroborated the positive outcomes of laparoscopic cholecystectomy, most comparisons of laparoscopic cholecystectomy to open cholecystectomy have not adequately controlled for potential differences in patient populations. It is not sufficient to compare patients undergoing laparoscopic cholecystectomy with those undergoing open cholecystectomy in the same time-frames because surgeons choose open cholecystectomy based on patients' clinical characteristics.[20] There also is inconsistency in prior studies about how patients whose cholecystectomies were initiated laparoscopically but converted to open procedures are analyzed (e.g., laparoscopic, open, or omitted), which could potentially cause biased results.[17] An alternative strategy is to compare patient populations undergoing cholecystectomies in the pre and postlaparoscopic eras, making appropriate adjustments for case-mix.

This article has two objectives. We first reconsider the issue of increasing cholecystectomy volumes and changing patient characteristics (e.g., lower surgical thresholds as evidenced by greater likelihoods of surgery on patients with less serious disease) utilizing a younger sample of cholecystectomy patients and assessing disease severity with data abstracted from patients' charts. Secondly, we compare outcomes of cholecystectomy in 1989 with outcomes in 1993, utilizing appropriate adjustments for case-mix. Our study is based on a chart review of all nonincidental cholecystectomies performed at five community hospitals during the two study years. We chose 1993 because of a desire to examine morbidity and mortality rates of cholecystectomy in the laparoscopic surgery era without confounding adverse outcomes with the learning curve. A survey of Pennsylvania hospitals indicated that laparoscopic cholecystectomy was adopted in each of the five study communities by the last quarter of 1991.[21] This study refines the usual question regarding comparison of outcomes by making clear that the patient populations undergoing laparoscopic cholecystectomy and open cholecystectomy are not comparable, and thus adjustments are needed before comparisons are made. This study also adds to prior work by examining data from multiple sites and multiple surgeons.

METHODS

Data Collection

Charts were abstracted for all patients undergoing nonincidental cholecystectomies at five hospitals in 1989 and 1993. The five study hospitals were participating in a larger study of gallbladder disease (the Biliary Tract Disease PORT funded by the Agency for Health Care Policy and Research [HS06481]). The hospitals are located in eastern and central Pennsylvania: Geisinger Hospital (Danville); Lancaster General Hospital; Lehigh Valley Hospital (Allentown); York Hospital; Williamsport Hospital and Medical Center.

The chart abstraction form was developed in three steps. First, forms used in other studies were obtained and combined into a single form, omitting redundancies, etc. Second, a committee composed of 10 surgeons, gastroenterologists, and internists selected the elements of interest to the current study. Third, an experienced chart abstracter pilot-tested the form with a sample of 10 charts to ensure that the requested data were available.

The final form contained several sections: patient identification and demographics, including dates of admission, surgery, and discharge; principal and secondary diagnoses and procedures; clinical history (e.g., location and frequency of pain, signs and symptoms, preoperative diagnoses and findings); physical examination (e.g., temperature, abdominal tenderness); preoperative diagnostic tests (dates and findings); admission tests; peri and postoperative antibiotic use; details of the operative procedure (e.g., American Society of Anesthesiologists (ASA) Physical Status Classification, incision start time, surgical assistant); tests and procedures involving the common bile duct; intraoperative complications; operative findings; postoperative complications; and related reoperations and readmissions.

Study Sample

Rosters of all cholecystectomies (ICD-9-CM codes 51.22 and 51.23) performed in 1989 and 1993 were generated by the information management departments at each hospital. Trained abstracters (most of whom were nurses) requested charts from the medical records departments and did the abstraction on site. All completed forms were sent to a central site for review and processing. Abstraction forms of all cholecystectomies *without* a primary diagnosis directly related to gallbladder disease (e.g., cholecystitis, gallbladder perforation, choledocholithiasis, cholangitis, pancreatitis, or septicemia) were reviewed by three physicians. Forms were excluded for the 149 surgeries judged to be incidental (e.g., the primary diagnosis was related to a malignancy, or cholecystectomy accompanied surgery for trauma). In the end, forms were analyzed for 1611 patients in 1989 and 2031 patients in 1993.

A roster of patients who were readmitted within a year of the original admission was developed, which showed the date of the cholecystectomy, the date of readmission, and a reason for the readmission. This list was circulated to a committee of six physicians, and they were asked to indicate which readmissions were "possibly" related (e.g., abdominal pain) and which were "definitely" related to the cholecystectomy or gallbladder disease (e.g., incisional hernia and retained common bile duct stone). If any of the physicians indicated a readmission was "definitely" related, or three or more thought that it was "possibly" related, or if the readmission occurred with 30 days of the original admission, it was labeled as related.

Assessment of Case-Mix

We used five clinical characteristics of cholecystectomy patients to assess case-mix. Similar to earlier work,[5] we used stage of gallstone disease and type of admission as measures of the acuity and severity of the gallstone-related illness. Patient age and comorbidities were used as indicators of patients' general health status. In addition, the American Society of Anesthesiologists (ASA) Physical Status Classification[22] provided an overall assessment of health status.

We developed a system for staging gallstone disease using operative and pathology reports, results of certain imaging tests (e.g., ultrasound and radionuclide hepatobiliary scans) and laboratory tests (e.g., alkaline phosphatase, aspartate aminotransferase [AST], alanine aminotransferase [ALT], total bilirubin, and white blood cell count); physical examination findings (e.g., fever and rebound tenderness); and reasons for conversions from laparoscopic to open cholecystectomy. In an iterative process, four physicians outlined the clinical definitions of five stages of gallstone disease: normal gallbladder (e.g., no cholelithiasis or other pathology), uncomplicated cholelithiasis, acute cholecystitis without gangrene or empyema, gallbladder gangrene or empyema, and gallstone complications extending beyond the gallbladder (e.g., pancreatitis, cholangitis, or peritonitis). Final definitions are summarized in Table 1. Of the total 3642 patients, 31 were omitted because insufficient data were recorded to enable a classification.

Patient comorbidities were assessed using the Charlson index[23,24] applied to the secondary diagnoses listed in the hospital chart. Age, ASA status, and type of admission were obtained directly from the chart. Definitions for ASA classifications are as follows: I - normal healthy patient; II = patient with mild systemic disease; III - patient with severe systemic disease that limits activity but is not incapacitating; IV - patient with an incapacitating systemic disease that is a constant threat to life; V - moribund patient not expected to survive 24 hours.

Table 1. SUMMARY OF DISEASE SEVERITY STAGES

Normal gallbladder
- Ultrasound is normal or not done **and** 50% or more of the liver enzyme tests for which there are data are normal* **and** the pathology report says "normal" *or* "no stones."

Uncomplicated cholelithiasis
- ≥50% of the liver enzyme tests for which there are data are normal **and** a pathology report supporting uncomplicated disease†
- ≥50% of the liver enzyme test for which there are data are normal **and** the pathology report is missing
- The liver enzyme tests are missing **and** the pathology report supports uncomplicated disease
- One or more elevated liver enzymes tests **but** the pathology report supports uncomplicated disease **and** there are no signs of acute cholecystitis‡
- The ultrasound report documents gallstones or sludge
- Normal or missing liver enzyme tests **and** the pathology report supports uncomplicated disease **even though** the hepatobiliary scan is nonfilling

Acute cholecystitis without gangrene or empyema
- Fever (documented presence of a fever or a recorded temperature >101 F) or a white blood cell count >12,000/mm^3 **plus** one of the following: rebound tenderness, ultrasound finding of fluid or wall thickening, conversion from laparoscopic cholecystectomy due to inflammation, pathology report indicates acute cholecystitis, nonfilling hepatobilary scan
- Some elevated liver enzyme tests **and** a nonfilling hepatobiliary scan **even though** the pathology report indicates uncomplicated disease
- Some elevated liver enzyme tests **and** a fever **even though** the pathology report indicates uncomplicated disease
- Conversion to open cholecystectomy due to inflammation
- Pathology report indicates acute cholecystitis

Gallbladder gangrene or empyema
- An operative **or** pathology report of gangrene or empyema

Gallstone complications extending beyond the gallbladder
- [Fever or white blood count >15,000/mm[cf1 1]3] **and** amylase >1500 IU/L **or** an operative report indicating pancreatitis or cholangitis

* Normal liver enzyme tests are defined as alkaline phosphatase <200 IU/L, SGOT or SGPT <80 IU/L, serum total bilirubin <2.0 mg/dL.

† A pathology report supporting uncomplicated disease is defined as a report that indicates cholelithiasis or chronic cholecystitis but acute cholecystitis, gangrene, and empyema are *not* noted in the pathology report and gangrene, empyema, pancreatitis, and cholangitis are *not* noted in the operative report **or** the pathology report indicates cholesterolosis in the absence of any other diagnosis.

‡ Signs of acute cholecystitis are a fever (documented presence of a fever or recorded temperature >101 F), a white blood cell count >12,000/mm^3, rebound tenderness, conversion from laparoscopic to open cholecystectomy due to inflammation, an ultrasound showing thickened wall or fluid, a nonfilling hepatobiliary scan, and a pathology report indicating acute cholecystitis.

Outcome Measures

Outcome measures included length of stay, postoperative length of stay, several specific surgical complications, reoperations, readmissions, and mortality rates. Because the prevalence of most events (e.g., complications) was small, complications were grouped into five categories: infectious complications, cardiac complications, pulmonary complications, gastrointestinal complications, and major intraoperative complications. Infectious complications included wound infection, sepsis, urinary tract infection, bacteremia, and pneumonia. Cardiac complications included myocardial infarction, pulmonary edema, and cardiac arrest. Pulmonary complications included pneumonia, atelectasis, pulmonary embolism, and respiratory failure. Gastrointestinal complications included pancreatitis, jaundice, and ileus. Major intraoperative complications were defined as unintended wounds or injuries to the common bile duct, bowel, blood vessel(s), or other organs. They included the more serious (e.g., common bile duct) to the less serious (e.g., gallbladder wall).

Statistical Analyses

Analyses of case-mix consisted of comparing patient characteristics between 1989 and 1993 using chi-square tests. A p value of 0.05 or less was chosen as the criterion for statistical significance. Analyses assessing outcomes were done in two phases. First, outcomes for all patients undergoing cholecystectomy in 1989 were compared to those for all patients undergoing cholecystectomy in 1993. Length of stay and postoperative length of stay (and log-transformations of length of stay) were compared with analysis of variances (ANOVAs). The numbers (and percentages) of patients experiencing specific complications, reoperations, readmissions, and death were tallied and compared between groups with the chi-square statistic. Results of those comparisons were confirmed using Fisher's exact test. For the five categories of complications, logistic regressions were fit separately for each outcome category, adjusting for patient age, comorbidities, severity of gallbladder disease, admission status (elective *vs.* emergent/urgent), and ASA status.

RESULTS

The number of nonincidental cholecystectomies was 1611 in 1989 and 2031 in 1993, an increase of 26%. Sizable increases, ranging from 23% to 35%, were observed in four of the five study hospitals. In the remaining hospital the increase in volume was 9%. A total of 1831 (90%) of the cholecystectomies performed in 1993 were initiated as laparoscopic procedures; 1702 (83%) were completed laparoscopically. The number of patients with common bile duct stones detected at the time of surgery was 190 (11.8%) in 1989 and 166 (8.2%) in 1993.

Table 2. CHARACTERISTICS OF PATIENTS UNDERGOING CHOLECYSTECTOMY IN 1989 AND 1993 AT FIVE COMMUNITY HOSPITALS

	1989 (N = 1611) [N (%)]	1993 (N = 2031) [N (%)]	p
Disease stage*			<0.0001
Normal	21 (1.3)	79 (3.9)	
Uncomplicated	960 (59.6)	1338 (65.9)	
Acute cholecystitis	386 (24.0)	361 (17.8)	
Gangrene or empyema	116 (7.2)	122 (6.0)	
Extensive complications	117 (7.3)	111 (5.5)	
Type of admission*			<0.0001
Elective	754 (47.1)	1167 (58.6)	
Urgent/emergent	848 (52.9)	825 (41.4)	
ASA status*			<0.0001
I	335 (21.1)	376 (18.9)	
II	789 (49.7)	1100 (54.9)	
III	388 (24.4)	479 (23.9)	
IV, V	77 (4.8)	50 (2.5)	
Age (yr)			0.159
<40	501 (31.1)	590 (29.1)	
40–65	664 (41.2)	823 (40.5)	
>65	446 (27.7)	618 (30.4)	
Charlson Index			0.214
0	1344 (83.4)	1672 (82.3)	
1	179 (11.1)	253 (12.5)	
2	49 (3.0)	76 (3.7)	
3	39 (2.4)	30 (1.5)	

* The numbers of patients within the various categories sum to less than the total because of a small amount of missing data.

Case-Mix

Patient characteristics related to changing thresholds for surgery are shown in Table 2. There were significant differences in disease stage, type of admission, and ASA classification (p < 0.0001). Notably, nearly all of the increases in patient volume occurred among patients with uncomplicated gallstone disease. There also was a fourfold increase in the number of patients assigned to the normal gallbladder category. Similarly, the increase in volume was observed among patients who underwent elective operations, and among those without incapacitating disease (ASA II and III). Conversely, the number of patients with acute cholecystitis or more severe gallstone complications, and the number of urgent/emergent admissions were unchanged. There were no significant differences in age or comorbidities between 1989 and 1993.

Analyses of patients less than 65 years of age found the same pattern of results. The increase in volume was 21% from 1165 in 1989 to 1413 in 1993. Further, the number (percentage) of patients with normal gallbladders increased from 20 (2%) to 71 (5%) (p < 0.001). The number with uncomplicated gallstones grew from 750 (65%) to 985 (71%) (p < 0.004), with corresponding decreases in other categories: acute cholecystitis changed from 263 (23%) to 233 (17%), (p < 0.001); gangrene or empyema changed from 53 (5%) to 50 (4%), (p = 0.192); and extensive complications changed from 72 (6%) to 58 (4%), (p < 0.017). Similarly, the elective admissions increased from 608 (52%) to 888 (64%) (p < 0.001), while urgent/emergent admissions did not change.

Outcomes

The mean lengths of stay for the 2 years and for the subgroups within 1993 are shown in Table 3. Hospital stays were significantly shorter in 1993 than in 1989 (p < 0.001) and in 1993, stays were shorter among patients whose surgery was completed laparoscopically.

Complications are summarized in Table 4 for the total patient groups. There are some significant differences be-

Table 3. ANALYSES OF LENGTH OF STAY (LOS) FOR 1989 AND 1993 COHORTS UNDERGOING CHOLECYSTECTOMY*

	n	LOS (days) [mean (SD)]	Postoperative LOS (days) [mean (SD)]
1989			
Total	1611	7.4 (8.9)	6.3 (11.1)
1993			
Total	2031	4.1 (11.3)	3.0 (7.6)
Laparoscopic	1702	3.2 (11.7)	2.0 (4.7)
Open	200	9.8 (9.0)	8.9 (18.3)
Conversion	129	7.5 (5.5)	6.4 (5.9)

* Comparisons of differences based on the log transformation of the values were statistically significant between 1989 and 1993, and among the three 1993 subgroups ($p < 0.001$). Differences remained significant when controlling for differences in patient case-mix characteristics.

tween the years but caution must be used in interpreting the results because of the small number of events such as those for the more serious complications such as sepsis, pulmonary embolism, stroke, and myocardial infarction. Moreover, numerous comparisons were made, thus capitalizing on chance.

From Table 4, three findings stand out. First, the relative frequency of all complications was low in both years, especially among the serious complications. The prevalence of most of the complications was less than 2%. Second, when rates greater that 5% were observed they were for the generally less serious complications, for example, urinary retention or ileus. Third, among the statistically significant differences, results tended to favor 1993. The exceptions were other major intraoperative complications, wound hematoma, bile leak and collections, and persistent right upper quadrant pain.

Table 4. COMPLICATIONS FOR COHORTS OF PATIENTS UNDERGOING CHOLECYSTECTOMY

	1989		1993		
Complication	n	%	n	%	p
Major intraoperative complication/injury					
Common bile duct	2	0.1	4	0.2	0.590
Bowel	5	0.3	6	0.3	0.935
Blood vessel	9	0.6	16	0.8	0.405
Other (*e.g.*, liver, pancreas, lymph node, cystic duct, gallbladder)	20	1.2	42	2.1	0.005
Transfusion required	21	1.3	14	0.7	0.059
Wound hematoma	4	0.3	17	0.8	0.020
Shock	9	0.6	7	0.4	0.333
Urinary retention	288	17.9	132	6.5	<0.001
Bile leak/collection	12	0.8	113	5.6	<0.001
Acute renal failure/tubular necrosis	10	0.6	9	0.4	0.458
CVA/stroke	4	0.3	1	0.1	0.107
Thrombophlebitis/DVT	3	0.2	0	—	0.052
Persistent RUQ pain	30	1.9	62	3.1	0.023
Infections					
Wound infection	42	2.6	16	0.8	<0.001
Sepsis	12	0.8	20	1.0	0.443
Urinary tract infection	94	5.9	50	2.5	<0.001
Bacteremia	19	1.2	18	0.9	0.385
Pneumonia	37	2.3	10	0.5	<0.001
Cardiac					
Myocardial infarction	2	0.1	1	0.1	0.433
Pulmonary edema	27	1.7	7	0.4	<0.001
Cardiac arrest	12	0.8	8	0.4	0.154
Pulmonary					
Pneumonia	37	2.3	10	0.5	<0.001
Atelectasis	161	10.0	109	5.4	<0.001
Pulmonary embolism	5	0.3	2	0.1	0.147
Respiratory failure	23	1.4	24	1.2	0.516
Gastrointestinal					
Pancreatitis	16	1.0	22	1.1	0.794
Jaundice	20	1.2	21	1.0	0.554
Ileus	192	12.0	108	5.3	<0.001

CVA = cardiovascular accident; DVT = deep vein thrombosis; RUQ = right upper quadrant.

Table 5. REOPERATIONS, READMISSIONS, AND MORTALITY FOR PATIENTS UNDERGOING CHOLECYSTECTOMY

	1989		1993		
	n	%	n	%	p
Reoperations this admission	26	1.6	25	1.2	0.325
12-month readmission					
All readmissions	251	15.6	335	16.5	0.456
Related readmissions	92	5.7	153	7.5	0.029
Deaths this admission	8	0.5	10	0.5	0.986
Laparoscopic			7	0.4	
Open			3	1.5	
Conversion to open	—	—	—	—	

The differences that were significant in bivariate comparisons were maintained when logistic regressions were run for the five complication areas adjusting for admission, type, age, comorbidities, disease severity, and ASA status. With one exception the prevalence of complications was lower in 1993 than in 1989. Overall complication rates for infections were 9.8% (n = 158) in 1989 compared to 4.3% (n = 88) in 1993, $p < 0.0001$. For cardiac complications they were 2.0% (n = 32) compared to 0.8% (n = 16), p = 0.002. For pulmonary complications they were 11.7% (n = 189) in 1989 and 6.2% (n = 126) in 1993, $p < 0.0001$ and for gastrointestinal complications they were 13.6% (n = 219) and 6.9% (n = 141), $p < 0.0001$. The exception is that there were more major intraoperative complications in 1993 (3.7%, n = 76) than in 1989 (2.2%, n = 36), $p < 0.0001$. This category includes both the serious (e.g., bile duct) and the less serious (e.g., gallbladder perforations) intraoperative complications.

DISCUSSION

We found that cholecystectomy rates rose at all hospitals between 1989 and 1993. The increase of 26% was in line with prior work.[2,3,5] In 1989, all procedures were open, whereas in 1993, 90% were initiated as laparoscopic procedures.

Confirming earlier findings in a Medicare population,[5] we found that the increases in volume were restricted to patients with uncomplicated cholelithiasis and to those undergoing elective surgery. The numbers of patients with complicated gallstone disease and with emergent admissions remained constant. On the other hand, there were no differences in the distributions of the two characteristics that describe patients' general condition, age, and number of comorbidities, although we did find differences in ASA classification, which also reflects overall patient health.

The replication of earlier findings in different populations and using different methods is noteworthy. In particular, we found evidence of falling cholecystectomy thresholds in nonelderly patients. Although this study increases our confidence in the suggestion that cholecystectomy thresholds have fallen since laparoscopic cholecystectomy was introduced, the ''why?'' remains unanswered. One possibility is that patients with long-standing biliary symptoms who refused open cholecystectomy were willing to undergo laparoscopic cholecystectomy. However, the backlog of any such patients must be nearing exhausting. Alternatively, it may be that more newly diagnosed patients with mild symptoms opted for surgery given the relative ease of laparoscopic cholecystectomy.

One noteworthy feature in the data was a significant 4-fold increase in the number of normal (e.g., no gallstones) gallbladders removed in the 1993 cohort. Since the principal indication for elective cholecystectomy is symptomatic gallstones, the data suggest an erosion of those criteria may have occurred. However, we must caution that a limitation of this study is the lack of information on patients' symptoms, which could not be meaningfully assessed from hospital charts. Additionally, these patients comprised a minority of all cholecystectomy patients in 1993.

Overall, these data suggest that cholecystectomy is a quite safe procedure, in both the pre and postlaparoscopic eras. Serious complications and morbidity rates were low for both periods. There appears to be a somewhat greater incidence of surgical injuries and potentially related readmissions associated with the laparoscopic cholecystectomy era. On the other hand, major morbidity was less frequent in the laparoscopic cholecystectomy era compared to the time when all cholecystectomies were performed using the open technique.

The results as summarized above are reassuring: cholecystectomy has been and continues to be a safe procedure. The vast majority of the published reports summarizing the results of laparoscopic cholecystectomy concur with these results.[2,6–19] Indeed, a meta-analysis of the largest case-series found low mortality and complication rates for patients undergoing laparoscopic cholecystectomy.[17] Because the large majority of cholecystectomies are now performed laparoscopically, it is logical that similar findings would extend to the entire cohort of cholecystectomy patients (unless large numbers of complicated patients now were being referred for open cholecystectomy – an unlikely hypothesis). It is noteworthy that whereas the meta-analysis reported greater bile duct injury rates for laparoscopic than for open cholecystectomy, no such differences were found here. Indeed there were few bile duct injuries in either cohort, though the overall major intraoperative complication rate was greater in the 1993 cohort.

The contribution of this study is that it has two features that strengthen its credibility. First, we compared two clinical cohorts undergoing a surgical procedure in two different eras: all cholecystectomy patients in 1989 and 1993. Other studies have created comparison groups based on the procedure alone, such as open cholecystectomy patients in

1989 compared with laparoscopic cholecystectomy patients in 1993, (perhaps omitting patients whose procedures were converted to open) or laparoscopic patients in 1993 compared with open patients in 1993. We believe it is more appropriate to take a broader view and ask the question that is asked by patients and physicians, "What are the likely outcomes of cholecystectomy?" Second, because of much evidence that clearly shows the volume of cholecystectomy has changed since the introduction of laparoscopic cholecystectomy,[2–5] we and others suspect patient characteristics also have changed. Thus, we adjusted for a number of patient characteristics that could have influenced the outcomes of cholecystectomy.

Despite our rigorous methods, this study has several limitations. Most notably, our design was a retrospective chart review. Although retrospective studies are rarely viewed as favorably as prospective studies, and chart reviews always raise questions regarding the training and skills of the abstracters and the completeness of data in the charts, in lieu of large randomized controlled trial, it is hard to imagine how this question could have been answered in another way. Second, there is always the possibility that we did not adjust for other patient characteristics that might explain the differences we observed, and we did not perform other adjustments that are arguably important (e.g., for the surgeon or assistant). Third, we did not consistently record extensive data regarding hospitalizations in the year subsequent to the initial hospitalization. Thus, we cannot be sure that the patients in the current era are not returning to correct the problems that arose (e.g., lacerations and serious leaks), or should have been attended to (e.g., common bile duct stones, misdiagnosis), during the initial hospitalization. Fourth, hospital stays are shorter so some complications may now not be reported. Those that occur after discharge may be tended to on an outpatient basis. Moreover, from reports in the literature, we know there are injuries that are undetected at the time of surgery and that in many cases, these patients do not return to the same site for care.[25] That could have occurred in our study and we had no means for detecting it. Finally, this study was conducted at five nonuniversity hospitals that serve largely white, rural, and suburban populations. This probably limits the generalizability of the results.

Though the results are conclusive and favorable when considering the likely outcomes of cholecystectomy in the laparoscopic era, there are many issues surrounding laparoscopic cholecystectomy that warrant further study. The most prominent are those that relate to detection and treatment of common bile duct stones. Intraoperative cholangiograms are no longer routine, and common indicators for common bile duct stones have relatively low positive predictive values.[26] Although new technologies are constantly evolving, at this time there does not appear to be consensus on how and when to investigate for common bile duct stones. Other important research questions have to do with patient selection decisions. Given the increase in patient volume since the introduction of laparoscopic cholecystectomy, we need to learn more about how and why different types of patients are having this procedure. There is also much to learn about how the threshold for seeking surgical therapy, and the outcomes of treatment, are related to the patient's initial symptoms and overall functional status. On a broader scale, we need to seek an understanding of why the serious complications are less frequent in the laparoscopic cholecystectomy era. Is it because patients are ambulatory sooner? Do these findings extend to other laparoscopic procedures? Although more data are being published, more investigation is needed to clarify these and other issues.

Acknowledgments

The authors acknowledge the contributions of Kimm Ebersole of Medisys Inc., Inge Myers, Jane Musser, Sherrylee Pfirman, Pamela Robson, and Cynthia Sheaffer, the Biliary Tract Disease PORT project team and the medical records departments at each of the participating hospitals.

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