Open Cholecystectomy A Contemporary Analysis of 42,474 Patients

Joel J. Roslyn, M.D.,* Gregory S. Binns, Ph.D.,† Edward F. X. Hughes, M.D., M.P.H.,‡ Kimberly Saunders-Kirkwood, M.D.,§ Michael J. Zinner, M.D.,§ and Joe A. Cates, M.D.§

From the Departments of Surgery, The Medical College of Pennsylvania, * Philadelphia, Pennsylvania, and the UCLA School of Medicine,§ Los Angeles, California; and the Center for Health Services and Policy Research and J. L. Kellogg Graduate School of Management,‡ Northwestern University, Evanston, and the Lexecon Health Service, Inc.,† Chicago, Illinois

Objective

This study evaluated, in a large, heterogeneous population, the outcome of open cholecystectomy as it is currently practiced.

Summary Background and Data

Although cholecystectomy has been the gold standard of treatment for cholelithiasis for more than 100 years, it has recently been challenged by the introduction of several new modalities including laparoscopic cholecystectomy. Efforts to define the role of these alternative treatments have been hampered by the lack of contemporary data regarding open cholecystectomy.

Methods

A population-based study was performed examining all open cholecystectomies performed by surgeons in an eastern and western state during a recent 12-month period. Data compiled consisted of a computerized analysis of Uniformed Billing (UB-82) discharge analysis information from all non-Veterans Administration (VA), acute care hospitals in California (Office of Statewide Planning and Development [OSHPD]) and in Maryland (Health Services Cost Review Commission [HSCRC]) between January 1, 1989, and December 31, 1989. This data base was supplemented with a 5% random sample of Medicare UB-82 data from patients who were discharged between October 1, 1988, and September 30, 1989. Patients undergoing cholecystectomy were identified based on diagnosis-related groups (DRG-197 and DRG-198), and then classified by Principal Diagnosis and divided into three clinically homogeneous subgroups: acute cholecystitis, chronic cholecystitis, and complicated cholecystitis.

Results

A total of 42,474 patients were analyzed, which represents approximately 8% of all patients undergoing cholecystectomy in the United States in any recent 12-month period. The overall mortality rate was 0.17% and the incidence rate of bile duct injuries was approximately 0.2%. The mortality rate was 0.03% in patients younger than 65 years of age and 0.5% in those older than 65 years of age. Mortality rate, length of hospital stay, and charges were all significantly correlated (p < 0.001) with age, admission status (elective, urgent, or emergent), and disease status.

Conclusions

These data indicate that open cholecystectomy currently is a very safe, effective treatment for cholelithiasis and is being performed with near zero mortality. The ultimate role of laparoscopic

cholecystectomy needs to be defined in the context of current and contemporary data regarding open cholecystectomy.

Calculous disease of the biliary tract continues to be a major national and international health problem. In 1882, Carl Langenbuch, a German surgeon, performed the first successful cholecystectomy.¹ Although surgical removal of the gallbladder has been the gold standard of treatment for cholelithiasis for more than 100 years, its dominant position has been challenged by the development of several new nonoperative modalities, including oral dissolution agents,^{2,3} contact dissolution with methyl-tert-butyl ether (MTBE),⁴ and electroshock wave lithotripsy (ESWL).⁵⁻⁹ Recently, the introduction of new technology for minimally invasive surgery and, specifically, laparoscopic cholecystectomy, has revolutionized our approach to a number of problems and caused a re-evaluation of clinical strategies.¹⁰ Although laparoscopic cholecystectomy has become the preferred treatment for symptomatic cholelithiasis in many parts of this country,¹¹⁻¹⁴ some questions remain regarding issues of cost and safety. Efforts to define the role of laparoscopic cholecystectomy in the management of patients with symptomatic gallstone disease have been hampered by the lack of contemporary data regarding open cholecystectomy.

Cholecystectomy has been a commonly performed operation, with estimates suggesting that between 500,000 and 700,000 patients undergo surgical removal of the gallbladder each year in the United States. Despite the frequency with which this procedure is performed, our understanding of current practice patterns and outcome is limited. Existing studies that focus on large numbers of patients are either longitudinal, covering periods of 27 to 43 years,¹⁵ or are from a single institution.¹⁶ In these studies, the mortality rate for patients undergoing open cholecystectomy was between 0.5%¹⁶ and 1.8%.¹⁵ The relevance of a longitudinal study over a long period of time to current practice is unclear. Furthermore, the appropriateness of extrapolating data from a single institution to nationwide practice is questionable.

The aim of the current study, therefore, was to evaluate, in a large, heterogeneous population, the outcome of open cholecystectomy as it is currently practiced in the United States. This information could then serve as the basis for comparison with laparoscopic cholecystectomy in terms of outcome, cost-effectiveness, and utilization of resources. Data from this analysis of 42,474 patients

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undergoing open cholecystectomy indicate that this procedure is indeed a safe and effective operation.

METHODS

Study Design

A population-based study was undertaken examining all cholecystectomies, as defined by diagnosis-related groups (DRG-197 and DRG-198), performed by surgeons in an eastern and western state during a recent 12-month period. This approach was designed to define, in an unselected population, the morbidity and mortality rate, utilization of resources, including length of stay and cost, and factors affecting outcome.

A cholecystectomy data base was developed by Lexecon Health Service, Inc. (Chicago, IL). The data compiled consisted of a computerized analysis of Uniformed Billing (UB-82) discharge analysis information. The sources for this study included discharges from all non-Veterans Administration (VA), acute care hospitals in California (Office of Statewide Planning and Development [OSHPD]) and in Maryland (Health Services Cost Review Commission [HSCRC]) between January 1, 1989, and December 31, 1989. This data base was supplemented with a 5% random sample of Medicare UB-82 data from patients who were discharged between October 1, 1988, and September 30, 1989 in states other than California and Maryland. The Medicare data (Expanded Modified Medpar data base) were obtained from the Health Care Financing Administration. All patients undergoing cholecystectomy as the primary procedure were included in this study.

Study Population

Patients undergoing cholecystectomy were identified based on two diagnosis-related groups: DRG-197 (total cholecystectomy without complications) and DRG-198 (total cholecystectomy with complications). Patients were then classified by Principal Diagnosis and divided into three clinically homogeneous subgroups: (1) acute cholecystitis, (2) chronic cholecystitis, and (3) complicated cholecystitis (gangrenous cholecystitis, empyema, perforation, etc.). Patients were excluded from further analysis because of gallstone pancreatitis, choledocholithiasis as the primary diagnosis, or inability to define disease status.

Of the 42,474 patients who formed the basis for the study, 31,643 (74.5%) were female and 10,831 (25.5%) were male. Approximately 71% of patients (30,059) were

Address reprint requests to Joel J. Roslyn, M.D., Department of Surgery, The Medical College of Pennsylvania, 3300 Henry Avenue, Philadelphia, PA 19129.

younger than 65 years of age, while the remaining 29% (12,415) were 65 years of age or older. Less than 8% of the group were younger than 25 years of age, and most patients undergoing cholecystectomy were in the fifth and sixth decades of life.

Recent studies have demonstrated a relationship between insurance status and condition on admission, utilization of resources, and ultimate outcome.¹⁷ Table 1 lists the insurance status of the 42,474 patients studied. Most patients were privately insured (nongovernment sponsored) and the overall profile is consistent with patient profiles in the many community and private hospitals throughout the country.

Data Analysis

Specific factors were analyzed as they influence outcome. These outcome modifiers selected for analysis included age, admission status (elective vs. urgent vs. emergent), disease status (acute vs. chronic cholecystitis), and associated procedures. Morbidity rates were determined for each outcome modifier and were stratified according to organ of complication. Bile duct injury is a complication of great importance in terms of analyzing treatment modalities for gallstone disease. This specific complication was not recorded as a separate modifier. Therefore, a decision was made to consider all complications identified as "accidental operative laceration" or "postoperative fistula" to be bile duct injuries. While this decision may not be optimal, it, if anything, overestimates the true incidence of this complication in the current series. We believe that the categories used to capture this complication were sufficiently inclusive. Mortality was limited to in-hospital deaths because 30-day mortality data were not available for the entire series. Length of stay was defined as the total number of in-hospital days during which the cholecystectomy was performed. Charges refers to hospital-based charges for hospitalization and specifically excludes physician fees.

Table 1. PATIENT PROFILE: INSURANCE STATUS			
Insurance Status	No. of Patients	%	
Medicare	12,460	29.3	
Medicaid	4286	10.1	
Private	14,263	33.6	
HMO/PPO	9247	21.8	
Worker's comp	23	0.1	
Self pay	1271	3.0	
Other	915	2.2	
Total	42,465	100.0	

Frequency missing = 7.

Table 2	. OUTC	OME F	OR
CHOL	ECYSTE	стом	Y

	Current Series	Biliary Registry* (1932–1979)
No.	42,474	10,008
Morbidity rate (%)	14.7	_
No. of deaths	71	177
Mortality rate (%)	0.17	1.77
Length of stay (days)	5.4	_
Charges (\$)	7076	—

* Glenn F. Trends in surgical treatment of calculous disease of the biliary tract. Surg Gynecol Obstet 1975; 140:877–884.

Statistical Analysis

All results are expressed as mean \pm standard deviation. The effects of outcome modifiers on morbidity and mortality rates were determined using analysis of variance and logistic regression models. Differences were considered to be significant at the 1% probability level.

RESULTS

Overall Series

Table 2 summarizes the outcome for the entire series of 42,474 patients. Data from a large, longitudinal, single institution study¹⁵ are provided for the purpose of comparison. In the current series, the overall morbidity rate was 14.7%. This figure includes all complications, regardless of their severity or effect on length of stay or outcome. In addition, it also includes 91 patients (0.21%)who had an accidental intraoperative laceration (82) of the gastrointestinal tract or postoperative biliary fistula.9 Although the incidence of bile duct injury is probably not significantly different between the two groups, the mortality rate in the current, contemporary series (0.17%) is markedly less than that in earlier reports.¹⁵ The mean length of stay in the current series of 42,474 patients was less than 6 days and in-hospital based charges were \$7,076.

Outcome Modifiers

Age

For the purpose of assessing the risk of age on outcome, patients were classified as either younger than 65 years of age or 65 years of age or older (elderly group). Data summarizing the effects of age on outcome are displayed in Table 3. The complication rate was significantly greater (p < 0.001) in elderly patients (25.7%) as compared to patients younger than 65 years of age (10.1%). In addition, there was a 17-fold increase (p < 0.001)

Table 3. EFFEC	CT OF AGE ON OUTCOME		
	Age (yr)		
	< 65	> 65	
No.	30,059	12,415	
% of group	70.8	29.2	
Morbidity rate (%)	10.2		
No. of deaths	9		
Mortality rate (%)	0.03	0.50*	
Length of stay (days)	4.7	7.3*	
Charges (\$)	5980	9728*	

* p < 0.0001 vs. age < 65 years.

0.001) in the death rate for elderly patients (0.50%) as compared to patients younger than 65 years of age (0.03%). Length of hospital stay was significantly increased (p < 0.001) in elderly patients, as were in-hospital charges (p < 0.001), compared to the younger cohort.

Admission Status

The effect of admission status on outcome is detailed in Table 4. Non-Medicare patients were classified in terms of admission status as either emergent (11.8%), urgent (27.8%), or elective (60.4%). Morbidity and mortality rates were significantly increased in patients requiring emergent admission to the hospital *versus* the group of patients who were admitted for elective cholecystectomy. In addition, length of stay and charges were almost double in patients requiring emergent admission compared to elective cases.

Disease Status

The impact of chronic cholecystitis *versus* acute cholecystitis on outcome is displayed in Table 5. Although patients with acute or complicated cholecystitis ac-

Table 4.EFFECT OF ADMISSION STATUSON OUTCOME AFTER CHOLECYSTECTOMY*

	Admission Status		
	Emerg	Urgent	Elective
No.	4512	10,586	23,038
% of group	11.8	27.8	60.4
Morbidity rate (%)	20.0	18.3	10.1†
No. of deaths	14	5	4
Mortality rate (%)	0.31	0.05†	0.02†
Length of stay (days)	7.6	6.2	4.2†
Charges (\$)	9270	9144	5135†

* Non-Medicare patients.

† p < 0.0001 vs. emerg.

Table 5. II	ON OUTC		DIATUS
	Disease Status		
	Chronic	Acute	Complicated
No.	27,892	13,246	1336
% of group	65.7	31.2	3.1
Morbidity rate (%)	11.9	19.4*	25.2*
No. of deaths	29	34	8
Mortality rate (%)	0.10	0.26*	0.60*
Length of stay (days)	4.8	6.6*	8.6*
Charges (\$)	5881	9043*	12,510*

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* p < 0.0001 vs. chronic cholecystitis.

counted for only 34% of the total group, 59% of all deaths occurred in this patient population. The death rates in patients with acute cholecystitis (0.26%) and with complicated cholecystitis (0.60%) were 2.5 and 6 times, respectively, as great as for patients with chronic disease (0.10%, p < 0.0001). Utilization of resources, as defined by length of stay and hospital-based charges, was significantly increased in patients with acute or complicated cholecystitis.

Acute and complicated cholecystitis, emergency admission, and age older than 65 years were associated with increased mortality rates. In an effort to identify which of these factors accounted for the outcome noted, multivariate analysis with logistic regression was performed. Chi square analysis indicates that the presence of complicated cholecystitis and age older than 65 years were the critical factors. Further analysis reveals that age older than 65 years was the single most important determinant of a fatal outcome.

Associated Procedures

The decision to perform secondary procedures was based on physician preference, operative findings, or patient condition. Data summarizing the effect of secondary procedures on outcome are detailed in Table 6. Intra-

Table 6. EFFECT OF SECONDARY PROCEDURES ON OUTCOME			
Procedure	% of Cases	Mortality Rate (%)	
Intraop. cholang.	53.6	0.19	
Appendectomy	4.8	0.18	
Adhesiolysis	2.7	0.80	
Open liver biopsy	1.9	1.10	
Percutaneous liver biopsy	0.8	2.01	
Arterial blood gas	0.8	2.09	
Umbilical hernia repair	0.7	0.59	

operative cholangiography was performed in approximately 61% of all patients, and did not appear to adversely affect outcome as defined by mortality rate. In fact, the mortality rate was significantly greater in patients who did not have intraoperative cholangiography. This may reflect patient selection and the surgeon's decision not to proceed because of patient-related factors that could not be discerned from this analysis. Similarly, incidental appendectomy was performed in approximately 4.7% of patients with virtually no effect on outcome. Once again, the increased mortality rate noted in patients in whom this secondary procedure was not performed is probably related to patient selection.

Co-Morbid Factors

The presence of co-morbid factors was recorded. A total of 26 groups of risk factors (composed of 1085 ICD-M codes) were analyzed. Linear regression analysis demonstrated that specific diagnoses, whether they were present preoperatively or developed postoperatively, were associated with a significant effect on both length of stay and charges (Table 7). Of these factors, only three—hypertension, congestive heart failure, and diabetes—were shown to independently impact on mortality. Factors that were notable for being associated with no mortality included obesity, asthma, previous coronary artery bypass, and hypothyroidism.

Complications

The effects of intraoperative and postoperative complications on mortality, length of stay, and in-hospital based charges are summarized in Table 8. Although the development of postoperative wound infection or biliary fistula significantly prolonged length of stay and increased cost, neither was associated with a significant increase in mortality during that admission. While the absolute number of patients with central nervous system complications, intraoperative hemorrhage, postoperative cardiac complications, intraoperative hemorrhage, postoperative cardiac complications, or shock was relatively small, each of these problems was associated with a significant risk of death.

DISCUSSION

Over the last two decades, the management for patients with symptomatic gallstone disease has undergone significant change. Although open cholecystectomy has been performed quite successfully for more than 100 years, its preeminent position in the treatment strategy for patients with cholelithiasis has been challenged by the recent introduction and widespread application of

Table 7. CO-MORBID FACTORS: RISK FACTOR TABULATION

	No.	Length of Stay (Days)	Charges (\$)
Anemia			
Absent	41,301	5.3	6858
Present	1173	9.4	14,777
Angina			
Absent	42,132	5.4	7046
Present	342	8.0	10,815
Atrial fibrillation			
Absent	41,738	5.4	6924
Present	736	10.0	15,734
Hypertension			
Absent	37,754	5.4	6945
Present	4720	6.0	8128
Cancer			
Absent	41,726	5.4	7010
Present	748	8.4	10,799
Cerebral infarct		••••	
Absent	42,427	5.4	7068
Present	47	10.3	14,596
Congestive heart failure			,
Absent	41,723	5.3	6848
Present	751	12.0	19,746
Coagulpathy	701	12.0	10,110
Absent	42,366	5.4	7041
Present	108	10.9	20,767
COPD	100	10.5	20,707
Absent	41,218	5.4	6920
Present	1256	8.0	12,200
Diabetes with complications	1200	0.0	12,200
Absent	41,850	5.4	6982
Present	624	9.4	13,407
Diabetes without complication		5.4	13,407
Absent	40,498	5.4	6954
Present	40,498	6.8	9578
	1970	0.0	9576
Aortic valve replacement	40.000	E 4	7041
Absent	42,080	5.4	
Present	394	7.2	10,898
Nephrotic syndrome	40.004		7004
Absent	42,261	5.4	7034
Present	213	9.7	15,419
Neurologic disease	40.40.4		7000
Absent	42,134	5.4	7026
Present	340	9.1	13,308
Renal disease		. .	
Absent	42,163	5.4	7052
Present	311	11.1	17,329

All of these are significantly different, absent vs. present p < 0.001.

laparoscopic cholecystectomy and the development of several nonoperative modalities, including medical dissolution with oral agents,^{2,3} contact dissolution with methyl-tert-butyl ether (MTBE),⁴ and electroshock wave lithotripsy (ESWL).⁵⁻⁷ Few procedures in the annals of medicine have been accepted in such a universal manner and with such speed as laparoscopic cholecystectomy.

Table 8. EFFECTS OF COMPLICATIONS ON OUTCOME				
	No.	Length of Stay (Days)	Charges (\$)	
CNS				
Absent	42,447	5.4	705 9	
Present	27	19.4	34,619	
Cardiac				
Absent	42,177	5.4	7010	
Present	297	9.5	16,522	
Respiratory				
Absent	41,492	5.4	6909	
Present	982	9.2	14,157	
GI tract				
Absent	41,696	5.4	6967	
Present	778	9.3	12,961	
Urinary tract				
Absent	42,026	5.4	7065	
Present	448	7.4	8101	
Postop shock				
Absent	42,460	5.4	7064	
Present	14	14.7	44,908	
Hemorrhagic comps				
Absent	42,297	5.4	7043	
Present	177	9.0	15,031	
Accident. lac				
Absent	42,392	5.4	7063	
Present	82	8.5	14,178	
Wound disruption				
Absent	42,415	5.4	7053	
Present	59	8.5	24,235	
Postop. fistula				
Absent	42,465	5.4	7065	
Present	9	28.2	63,071	

Although laparoscopic removal of the gallbladder was only first reported in 1988, it has rapidly become the preferred procedure in many parts of this country and throughout the world for patients with symptomatic gallstone disease.¹⁰⁻¹⁴ Recent studies have advocated its selective use for patients with more complicated clinical situations, including acute cholecystitis.^{18,19} Despite the obvious advantages of this procedure over open cholecystectomy in terms of length of stay, patient discomfort, and cosmesis, concern has lingered about the incidence of complications arising during laparoscopic cholecystectomy. In particular, attention has been focused on the incidence of bile duct injuries associated with this procedure.^{20,21} It has been difficult to compare outcome data for laparoscopic cholecystectomy to the gold standard because of the lack of contemporary data available for the latter procedure, open cholecystectomy. While it might be ideal to have a prospective, randomized, controlled study comparing these two procedures, it is unreasonable to propose this given the universal appeal and widespread acceptance of laparoscopic cholecystectomy.

The current population-based study has defined, in a large, heterogeneous population, the status of open cholecystectomy as it is currently being practiced throughout the United States, in terms of utilization of resources and outcome. Analysis of 42,474 patients who underwent open cholecystectomy during a recent 12-month period indicates that this operation is currently being performed in a very safe manner with minimal morbidity and mortality (0.17%), particularly in the younger than 65 years of age group (0.03%). Length of hospitalization, cost, and outcome are all directly linked to the severity of disease.

The 42,474 patients reported in the current study represent between 5.6% and 8.5% of all patients undergoing cholecystectomy in the United States in any recent 12-month period. Moreover, the population-based approach used in the current study provides an opportunity to analyze a large population, which is consistent with gallstone patients throughout the country based on stratification by sex, age, and insurance status. This type of analysis has proved quite useful in the assessment of cost-effectiveness and quality of health care provided, and is beginning to be employed to assess outcome after surgical procedures.²² Such studies, however, can be flawed and caution should be exercised in extrapolation of data.

In the current population-based study, which consisted of 42,474 patients undergoing cholecystectomy in two separate states, the overall complication rate was 14.7%. Most of these complications were of minimal clinical significance. However, the development of intraoperative hemorrhage or postoperative cardiac complications was associated with a significantly higher risk of mortality. In fact, most deaths that occurred in this study were the result of a postoperative cardiac complication. This phenomenon has been well documented in earlier reports.²³⁻²⁴ In terms of analysis of safety of laparoscopic and open cholecystectomy, perhaps the most critical complication is a bile duct injury. Numerous reports in the literature have suggested that the risk of bile duct injury during open cholecystectomy is approximately 0.1% to 0.2%.²⁵⁻²⁷ Early experience with laparoscopic cholecystectomy suggests that the incidence with which this complication occurs is ten times as great (1%).¹¹ Although it has been difficult to determine the exact frequency with which this complication occurs during laparoscopic cholecystectomy, the number of recent series that have focused on this problem^{20,21} suggest that perhaps bile duct injury does occur more frequently than is being reported. These injuries may well represent part of the learning curve and ultimately the incidence with which this complication occurs during laparoscopic procedures will be appreciably less. However, bile duct injury during open cholecystectomy is usually recognized

before discharge, but this is not the case in laparoscopic cholecystectomy. The way the current study was structured, it was impossible to precisely identify those patients who had bile duct injuries. However, we grouped all patients listed as having an "accidental operative laceration" or "postoperative fistula" as representing a group of patients who may have had bile duct injuries. While this approach is not ideal, it probably overestimates the incidence of intraoperative bile duct injuries during open cholecystectomy in the current series. Due to the nature of this study, it is conceivable that patients who required readmission at a later date as a result of bile duct injury that was not recognized during the index admission may not have been identified. The 0.21% incidence with which these findings were identified in the current series correlates well with previous reports from the literature.

In the current series, there were 71 deaths for a mortality rate of 0.17%. This would appear to be significantly less than the mortality rate for open cholecystectomy that has been previously reported in the literature. In 1975, a longitudinal study examining outcome in more than 12,000 patients undergoing biliary tract surgery at a single institution between 1932 and 1979 indicated that the overall mortality rate was approximately 1%.15 In this same report, the authors summarized the experience in more than 19,000 patients undergoing cholecystectomy at ten different institutions worldwide during the years 1946 to 1973. Outcome in this large group of patients was comparable, with the rate being approximately 1.6%. It has primarily been these data that have provided the basis for the 1% mortality rate that has been widely quoted in both the medical and lay literature during the last 15 years. Extrapolation of this data has suggested that approximately 5000 deaths occur each year in the United States as a direct result of cholecystectomy. More recently, Ganey et al.¹⁶ reported their experience with cholecystectomy in 1035 patients undergoing operation at a single institution during the 5-year period between 1978 and 1983. The mortality rate in this series of patients was 0.5% (five deaths). However, all five deaths occurred in elderly patients who required either urgent or emergent operation for complications associated with acute cholecystitis. Although the large longitudinal studies cited above and this more recent experience from a single institution have provided important information regarding outcome from cholecystectomy, it has been difficult to define the relevance of these data to current practice.

The technical aspects of open cholecystectomy have not changed appreciably during the last 25 years. Nonetheless, our ability to provide optimal perioperative care has significantly improved during this time period. This fact is underscored by the realization that cardiovascular disease is the most frequent cause of mortality in patients undergoing cholecystectomy.^{23,24} Analysis of specific outcome modifiers indicates that age, admission status, and disease status all influence patient outcome as defined by morbidity, mortality, length of stay, and hospital-based charges. Each of these factors influences utilization of resources and patient outcome. The most critical determinant of outcome would appear to be the age of the individual patient, with patients older than 65 years of age having a 17-fold increase in mortality rate as compared to those patients younger than 65 years of age. While this cutoff is somewhat arbitrary, it has been used previously in the literature and allows comparison between earlier studies. In more than 12,000 patients undergoing biliary tract surgery at a single institution between 1932 and 1979, the mortality rate in patients vounger than 50 years of age was 0.3%; it was 5% in patients older than 65 years of age.¹⁵ The presence of specific co-morbid factors also determines outcome. Severe co-morbid factors identified in the current study include congestive heart failure, a prior myocardial infarction, atrial fibrillation, and cirrhosis. These data are consistent with previous reports that indicate that outcome after cholecystectomy is determined more by the overall medical status of the patient than by the extent of the gallbladder disease.23,24

In recent years, considerable attention has been focused on utilization of resources and cost-effectiveness of therapy. These types of analyses are assuming new importance as trends in health care delivery continue to evolve. Munoz et al.²⁸ suggested that the cost of caring for patients with acute cholecystitis was significantly increased as compared to that for patients with more chronic disease. These findings are consistent with our own data. Length of stay data are one index of resource utilization. Data from the current study indicate that length of stay is significantly increased for patients with acute and/or complicated cholecystitis. These findings, in conjunction with hospital-based charge data, provide an economic rationale for identifying patients early on with symptomatic gallstone disease who would benefit from elective as opposed to emergent care. One of the advantages of laparoscopic cholecystectomy over the open procedure is the reduction in length of stay and, presumably, hospital charges. In the current series, the average length of stay for patients admitted electively was just more than 4 days. In a recent report of 355 patients undergoing laparoscopic cholecystectomy, the mean length of stay was 1.6 days.²⁹ This difference in length of stay presumably should be associated with a decrease in hospital-based charges. Recent data, however, failed to identify any significant savings from the decrease in length of stay.³⁰ The authors suggest that the failure to document any significant savings despite a marked reduction in the length of hospitalization may be due to the high cost of equipment and technology required for laparoscopic cholecystectomy. Furthermore, when viewed from a population-based perspective, the overall cost of laparoscopic cholecystectomy should include the additional direct and indirect expenses that result from bile duct injury. Similar analysis for ESWL, which included estimates for the cost of evaluating and treating gallstone recurrence, provided important insight into the economics of alternative treatments for cholelithiasis.^{8,9}

The design of this study allows for a comprehensive analysis of a large, unselected population receiving similar care by a large number of health care providers in widely disparate areas of the country during a recent 12month period. Since the large number of patients entered into this study from two different states avoids extraneous influences by regional practices and is not influenced by physician bias or compliance (as can occur with survey type studies), we believe that the status of open cholecystectomy as it is currently being performed in the United States is accurately represented. There are, of course, potential flaws inherent with this type of study. The data are, by definition, retrospective and are based on the accuracy of hospital-derived discharge analysis. Although the assessment of hospital-associated deaths from hospital discharge analysis may be inaccurate,³¹ the nature of cholecystectomy and its associated complications suggests that this is probably not a major flaw in the current study.

The introduction of laparoscopic cholecystectomy has completely revolutionized the management of patients with symptomatic cholelithiasis and it has largely replaced open cholecystectomy in many parts of the country. The advantages of this procedure over the conventional approach relate primarily to patient satisfaction, reduction in hospitalization, ease of recovery, earlier return to work, and cosmetic considerations.

This study does not promote open cholecystectomy over the laparoscopic removal of the gallbladder or any of the nonoperative modalities. Although data are rapidly being compiled for laparoscopic cholecystectomy, efforts to understand this procedure's role in the overall treatment strategy have been hampered by our inability to compare it in a meaningful way to the standard of care, open cholecystectomy. Data from the current analysis of 42,474 patients undergoing open cholecystectomy during a 12-period indicate that this procedure is a safe and effective operation with minimal morbidity and mortality. Moreover, important information is provided regarding utilization of resources and outcome that will provide the opportunity to assess new and innovative approaches to the management of patients with gallstone disease. Ultimately, the role of laparoscopic cholecystectomy needs to be defined in the context of current and contemporary data regarding open cholecystectomy.

References

- 1. Glenn F, Grafe WR Jr. Historical events in biliary tract surgery. Arch Surg 1966; 93:848-852.
- Schoenfield LJ, Lachin JM, the Steering Committee, The National Cooperative Gallstone Study Group. Chenodiol (chenodeoxycholic acid) for dissolution of gallstones: The National Cooperative Gallstone Study: a controlled trial of efficacy and safety. Ann Intern Med 1981; 95:257–281.
- Salen G, Colalillo A, Verga D, et al. Effect of high and low doses of ursodeoxycholic acid on gallstone dissolution in humans. Gastroenterology 1980; 78:1412–1418.
- 4. Thistle JF, May GR, Bender CE, et al. Dissolution of cholesterol gallbladder stones by methyl tert-butyl ether administered by percutaneous transhepatic catheter. N Engl J Med 1989; 320:633-639.
- Sackmann M, Delius M, Sauerbruch T, et al. Shock-wave lithotripsy of gallbladder stones. N Engl J Med 1988; 318:393–397.
- Heberer G, Paumgartner G, Sauerbruch T. A retrospective analysis of 3 year's experience of an interdisciplinary approach to gallstone disease including shock-waves. Ann Surg 1988; 208:274– 278.
- Sackmann M, Ipposch E, Sauerbruch T, et al. Early gallstone recurrence rate after successful shock-wave therapy. Gastroenterology 1990; 98:392–396.
- Bass EB, Steinberg EP, Pitt HA, et al. Cost-effectiveness of extracorporeal shock-wave lithotripsy versus cholecystectomy for symptomatic gallstones. Gastroenterology 1991; 101:189–199.
- Nealon WH, Urrutia F, Fleming D, Thompson JC. The economic burden of gallstone lithotripsy: will cost determine its fate? Ann Surg 1991; 213:645-650.
- Dubois F, Icard P, Berthelot G, et al. Coeliscopic cholecystectomy: preliminary report of 36 cases. Ann Surg 1990; 211:609–612.
- Peters JH, Ellison CE, Innes JT, et al. Safety and efficacy of laparoscopic cholecystectomy: a prospective analysis of 100 initial patients. Ann Surg 1991; 213:3–12.
- The Southern Surgeon's Club. A prospective analysis of 1518 laproscopic cholecystectomies. N Engl J Med 1991; 324:1073–1078.
- Graves HA Jr, Ballinger JF, Anderson WJ. Appraisal of laparoscopic cholecystectomy. Ann Surg 1991; 213:655–664.
- Schirmer BD, Edge SB, Dix J, et al. Laparoscopic cholecystectomy: treatment of choice for symptomatic choleslithiasis. Ann Surg 1991; 213:665–677.
- 15. Glenn F. Trends in surgical treatment of calculous disease of the biliary tract. Surg Gynecol Obstet 1975; 140:877-884.
- Ganey JB, Johnson PA Jr, Prillaman PE, McSwain GR. Cholecystectomy: clinical experience with a large series. Am J Surg 1986; 151:352–357.
- Hadley J, Steinberg EP, Feder J. Comparison of uninsured and privately insured hospital patients: condition on admission, resource use, and outcome. JAMA 1991; 265:374–379.
- Flowers JL, Bailey RW, Scovill WA, Zucker KA. The Baltimore experience with laparoscopic management of acute choleystitis. Am J Surg 1991; 161:388-392.
- Reddick EJ, Olsen D, Spaw A, et al. Safe performance of difficult laparoscopic cholecystectomies. Am J Surg 1991; 161:377–381.
- Davidoff AM, Pappas TN, Murray EA, et al. Mechanisms of major biliary injury during laparoscopic cholecystectomy. Ann Surg 1992; 215:196-202.
- Moosa AR, Easter DW, van Sonnenberg E, et al. Laparoscopic injuries to the bile duct: a cause for concern. Ann Surg 1992; 215:203-208.

- Edwards WH, Morris JA Jr, Jenkins JM, et al. Evaluating quality, cost-effective health care: vascular database predicated on hospital discharge abstracts. Ann Surg 1991; 213:431–439.
- McSherry CK, Glenn F. The incidence and causes of death following surgery for nonmalignant biliary tract disease. Ann Surg 1980; 191:271-275.
- McSherry CK, Ferstenberg H, Calhoun WF, et al. The natural history of diagnosed gallstone disease in symptomatic and asymptomatic patients. Ann Surg 1985; 202:59–63.
- 25. Andren-Sanberg A, Alinder G, Bengmark S. Accidental lesions of the common bile duct at cholecystectomy: pre- and postoperative factors of importance. Ann Surg 1985:201:328
- 26. Viikari SJ. Operative injuries to the bile ducts. Acta Chir Scand 1960; 119:83–92.

- Henry ML, Carey LC. Complications of cholecystectomy. Surg Clin North Am 1983; 63:1191–1204.
- 28. Munoz E, Tinker MA, Margolis I, Wise L. Surgonomics: the cost of cholecystectomy. Surgery 1984; 96:642–646.
- Bailey RW, Zucker KA, Flowers JL, et al. Laparoscopic cholecystectomy: experience with 375 consecutive patients. Ann Surg 1991; 214:531-541.
- Graves HA, Ballinger JF, Anderson WJ. Appraisal of laparoscopic cholecystectomy. Ann Surg 1991; 213:655–664.
- Jencks SF, Williams DK, Kay TL. Assessing hospital-associated deaths from hospital discharge data: the role of length of stay and co-morbidities. JAMA 1988; 260:2240-2246.