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Mortality and Complications Associated with Laparoscopic Cholecystectomy

A Meta-Analysis

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Objective

The purpose of this study was to perform a meta-analysis of large laparoscopic cholecystectomy case-series and compare results concerning complications, particularly bile duct injury, to those reported in open cholecystectomy case-series.

Summary Background Data

Since the introduction of laparoscopic cholecystectomy in the United States, hundreds of reports about the technique have been published, many including statements about the advantages of laparoscopic cholecystectomy compared with those of open cholecystectomy. There is an unevenness in scope and quality of the studies. Nevertheless, enough data have accumulated from large series to permit analyses of data regarding some of the most important issues.

Methods

Articles identified *via* a MEDLINE (the National Library of Medicine's computerized database) search were evaluated according to standard criteria. Data regarding the patient sample, study methods, and outcomes of cholecystectomy were abstracted and summarized across studies.

Results

Outcomes of laparoscopic cholecystectomy are examined for 78,747 patients reported on in 98 studies and compared with outcomes of open cholecystectomy for 12,973 patients reported on in 28 studies. Laparoscopic cholecystectomy appears to have a higher common bile duct injury rate and a lower mortality rate. Estimated rates of other types of complications after laparoscopic cholecystectomy generally were low. Most conversions followed operative discoveries (*e.g.*, dense adhesions) and were not the result of injury.

Conclusions

There is wide variability in the amount and type of data reported within any single study, and patient populations may not be comparable across studies. Except for a higher common bile duct injury rate, laparoscopic cholecystectomy appears to be at least as safe a procedure as that of open cholecystectomy.

Laparoscopic cholecystectomy, developed in France in 1987, was introduced in the United States in 1988.[1] Diffusion and adoption of the new technology were rapid. By early 1992, more than 80% of the general surgeons in the United States had adopted the procedure.[2] Laparoscopic cholecystectomy now is clearly the treatment of choice for symptomatic cholelithiasis. Since the early 1990s, the volume of cholecystectomies has increased dramatically.[3–6]

Acceptance of laparoscopic cholecystectomy was preceded only by case-series and not by randomized clinical trials showing convincingly that its benefits surpassed, or at least equaled, those of open cholecystectomy. The obvious and purported advantages of laparoscopic cholecystectomy made it attractive to patients, surgeons, and hospitals (*e.g.*, less scarring, shortened hospital stays, earlier returns to usual activities). In fact, reports of several laparoscopic cholecystectomy series support the claims of shortened hospital stay and early return to activities.[7–14] Conversely, many authors have cautioned about higher rates of common bile duct injury, especially during the learning curve, problems of dealing with possible common bile duct stones, and the increased incidence of retained stones.[15–21]

Three randomized trials comparing laparoscopic and open cholecystectomy have been reported.[14,22,23] Although the total number of patients enrolled among the three studies is quite small (approximately 400), together they suggest that rates of morbidity for laparoscopic cholecystectomy are equal to or less than those for open cholecystectomy, and the recovery time and patient satisfaction are much higher. At this point, it is doubtful that a large trial with long-term follow-up will be done, given the widespread adoption of the procedure by surgeons, interest in it by patients who are unwilling to consent to a randomization procedure, and the large sample size that would be needed to detect small differences in event rates that would be expected between laparoscopic and open cholecystectomy. Thus, to assess outcomes of laparoscopic cholecystectomy compared with those of open cholecystectomy, it is necessary to examine evidence gathered by other methods. The purpose of this study was to summarize what could be learned from the published literature regarding outcomes of laparoscopic cholecystectomy. Specifically, the goal was to perform a meta-analysis of the large laparoscopic cholecystectomy case-series and compare results to a similar meta-analysis of open cholecystectomy case-series.

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Since the introduction of laparoscopic cholecystectomy in the United States, hundreds of reports about the technique have been published, as have a small number of reviews.[15,24] There is an unevenness in scope and quality of the studies. Moreover, there are not enough studies with long-term follow-up to address issues adequately such as retained stones and late-developing complications, such as biliary strictures. Nevertheless, enough data have accumulated from large series to permit analyses of data regarding some of the most important issues, including the relative rates for mortality and common bile duct injuries when laparoscopic cholecystectomy is compared with that of open cholecystectomy and the rate of conversion from laparoscopic to open cholecystectomy.

METHODS

We conducted a MEDLINE search of all English language articles published through March 1995 using the Medical Subject Heading (MeSH) "cholecystectomy." We also reviewed the bibliographies of articles retrieved from the MEDLINE search to identify additional titles. For each MEDLINE citation, we downloaded the title, abstract, authors, institution, journal, and major and minor descriptors.

Two nonphysician research staff members independently read the abstracts and selected articles for full review based on prespecified inclusion and exclusion criteria (Table 1A). The goal was to select case-series or randomized controlled trials with more than 100 patients that appeared to be representative of the general population of patients undergoing cholecystectomy in the United States. The exclusion criteria were developed by a study team composed of physicians (most of whom were trained in epidemiology and health services research) and a biostatistician. Copies were obtained of all articles that could not be excluded at this stage of the investigation. If there was any doubt regarding the suitability of an article, it was obtained.

Each article was reviewed by three trained research staff members who separately extracted data on the following:

1. The patient population, including the total number of patients and their gender, age, other patient characteristics, indications for cholecystectomy, and details of patient exclusions and contraindications.
2. Surgical details, including the type of surgery, the duration of the procedure, and, for laparoscopic cholecystectomy, the method of dissection, the number of conversions to open cholecystectomy, and whether these patients were the surgeon's initial patients.
3. Study characteristics, including the dates for pa-

Table 1. CRITERIA FOR EXCLUDING PUBLISHED STUDIES FROM CONSIDERATION

Titles and abstracts
Not original data, for example, news stories or clinical reviews
Animal studies
Non-Western populations
Atypical patients, for example, only elderly or children
Data limited to special topics, for example, acalculous cholecystitis
Fewer than 100 patients
Journals without a national audience
Full articles
No data on any of the outcomes of length of stay; the length of time for return to work or normal activities; the frequency of readmissions, reoperations, relief of symptoms, complications, or mortality
Special/unusual patient population, for example, all patients had indications of common bile duct stones
Nonstandard/unusual application of the procedure, for example, cholecystectomy following extracorporeal shock wave lithotripsy (ESWL)
Biased patient sample, for example, nonconsecutive patients
Final selection
No data on mortality and/or complications
Limited study focus, for example, comparison of prophylactic antibiotics or the use of drains *vs.* no drains
Patient enrollment began before 1980
Redundant patients

tient enrollment, the type of research design (*e.g.*, consecutive series, randomized trial), whether data were collected prospectively or retrospectively, the length of patient follow-up, the number of surgeons, and the number and names of hospitals in the study.

4. Outcomes, including the length of stay; the length of time for return to work or normal activities; the frequency of readmissions, reoperations, relief of symptoms, complications, mortality, other outcomes; and a description of how common bile duct stones were diagnosed and managed.

After abstraction, the three readers met as a group to compare notes and resolve differences. For each article, a decision was made about excluding the article from further consideration using the criteria listed in Table 1B.

Finally, four additional criteria were applied (Table 1C). The fourth criterion, eliminating redundant patient populations, requires elaboration. For some centers, the initial series of patients was incorporated into later series, often focusing on a different research question. We selected the article that had the broadest range of outcomes and, when possible, reported on the largest number of patients. Decisions were made by the most experienced of the article abstractors. When the decision was not obvious, the study team was consulted.

We divided the articles into three groups for analysis: 1) laparoscopic cholecystectomy series from a single hospital, institution, system, health care provider, or community; 2) laparoscopic cholecystectomy series reporting the experiences of multiple institutions; and 3) open cholecystectomy series from a single institution. The laparoscopic cholecystectomy series was divided into two groups because the data often were collected on a patient-by-patient basis in single-institution studies and by other means in multi-institution studies. The focus of this article is on single-institution laparoscopic cholecystectomy series, because as a group, those studies had the most data reported within them.

We performed descriptive analyses to provide 1) an overview of the types of data that were presented in the articles and of the patient population, 2) the rates of mortality, common bile duct injuries, and conversions (when applicable) reported in laparoscopic cholecystectomy and open cholecystectomy series, 3) a description of other complications reported in laparoscopic cholecystectomy series, and 4) a summary of the reasons for conversions reported in a subset of laparoscopic cholecystectomy studies.

Rates of mortality, complications, and conversions are reported as ranges. The low end of the range assumes that in the articles in which the outcome was not mentioned, it did not occur. The high end of the range makes no such assumptions, thereby excluding studies that did not report on a particular outcome. We do not report confidence intervals for the rates because, in almost all cases, the range of values generated by the different denominators was far wider than the corresponding confidence intervals.

We used group-level logistic regression to assess which patient and clinical characteristics were associated with rates of mortality, common bile duct injury, and conversion from laparoscopic to open cholecystectomy. The study was the unit of analysis, but the logistic regression, in effect, weights each study by the number of patients in the study.[25] The predictor variables we examined are if the patients were the surgeon's initial laparoscopic cholecystectomy patients, the total number of surgeons, if there were any patients operated on as outpatients and not admitted, the year the study started, and if there were any patients with acute cholecystitis.

We also created three additional variables to describe reporting thoroughness. Nine variables that reflected the presence or absence of information in the article were recorded during abstraction: 1) age and gender of patients, 2) additional descriptive information about patients (*e.g.*, weight, comorbidities, American Society of Anesthesiologists [ASA] Physical Status classifications), 3) dates of patient enrollment, 4) time frame of the study (*e.g.*, prospective, retrospective), 5) study design (*e.g.*, consecutive series of patients), 6) patient follow-up, 7)

patient exclusions, 8) methods of establishing diagnosis, and 9) clinical or pathologic diagnoses of the patient sample. These variables were entered into a principal components analysis to observe how they clustered together into distinct domains. After orthogonal rotation, three components emerged. The first three variables loaded on component 1, the second two variables loaded on component 2, and the remaining four variables loaded on component 3. Three subscale scores were created by summing the number of elements present for each component. The three components were treated as covariates, and the subscale scores were treated as ordinal variables in the regression models.

RESULTS

The MEDLINE search identified 4420 abstracts for review. After application of the initial exclusion criteria, 598 articles were obtained and abstracted. Application of additional exclusion criteria led to elimination of additional articles. Notably, 28 of 111 single-institution laparoscopic cholecystectomy articles were excluded because of redundant patients. The final numbers of articles for analyses were 83 single-institution laparoscopic cholecystectomy studies (30,052 patients), 15 multi-institution laparoscopic cholecystectomy studies (48,795 patients), and 28 single-institution open cholecystectomy studies (12,973 patients). The references for the accepted articles are included in Appendixes 1, 2, and 3, respectively. Although the studies were selected using the same criteria (Table 1), comparisons do not account for any differing patient selection criteria that may exist.

Table 2. SUMMARY OF DATA REPORTED IN 83 SINGLE-INSTITUTION ARTICLES ABOUT LAPAROSCOPIC CHOLECYSTECTOMY

Data Element	N	%
Patient population		
Gender	63	76
Age	71	86
Method of confirming diagnosis	45	55
Indication for surgery	68	80
Study methods		
Date of series	73	88
Type of research design	62	75
Retrospective or prospective data collection	49	59
How/if follow-up was done	25	30
No. of surgeons	74	89
Surgical details		
If patients were the surgeon's initial patients	55	66
Duration of procedure	61	73
If conversions occurred	78	94
Outcomes		
Length of stay	68	82
Return to work/normal activities	34	41
Readmissions	31	37
Reoperations	59	71
Relief of symptoms	8	10
Complications	81	98
Mortality	70	84
How CBDS were diagnosed and treated	37	45

CBDS = common bile duct stones.

Types of Data Reported and Patient Population

There was variability in the amount and type of data reported in the series. Except for the total number of patients and the type of surgery, there was no variable that was reported consistently in every article (Table 2). Descriptive statistics used (*e.g.*, means, medians, ranges) also varied among studies. Nevertheless, it was possible to obtain general descriptions of the aggregate patient population. Aggregating data across 61 studies showed that on average, the percentage of women in the studies was 76% (standard deviation [SD] = 5%). For the subset of 56 studies that reported the mean age of the patients, the mean of the means, weighted by sample size, was 49.0 years (SD = 3.2 years). For nearly all (93%) of the studies that reported the indications for surgery, the leading indication was chronic cholecystitis/symptomatic cholelithiasis, although most studies did not indicate how the diagnosis was established.

The duration of surgery was reported in 47 studies and was variable with a weighted average of 89 minutes with an SD of 24.5 minutes. For the 13 studies that provided information on the length of total hospital stay, the overall weighted mean was 2.0 days (SD = 0.80 day); in the 14 studies that provided information on the length of postoperative stay, the average was 1.6 days (SD = 0.58 day).

Estimated Rates of Mortality, Common Bile Duct Injury, and Conversions

In Table 3, we present aggregated data about the rates of mortality, common bile duct injury, and conversion from laparoscopic to open cholecystectomy according to the type of study. Three findings stand out:

1. The data were nearly identical for single-institution and multi-institution laparoscopic cholecystectomy studies.
2. Reported mortality rates were lower for laparo-

Table 3. ESTIMATED RATES OF MORTALITY, COMMON BILE DUCT (CBD) INJURY, AND CONVERSION FROM LAPAROSCOPIC CHOLECYSTECTOMY (LC) TO OPEN CHOLECYSTECTOMY (OC)*

Type of Study	No. of Studies	No. of Patients	Mortality	CBD Injury	Conversions
LC, single institution	83	30,052	0.0014-0.0016	0.0036-0.0047	0.049-0.052
LC, multiple institutions	15	48,795	0.00086-0.00091	0.0046-0.0047	0.055
OC, single institution	28	12,973	0.0066-0.0074	0.0019-0.0029	NA

NA = not applicable.

* The low end of each range was computed by assuming that the actual number was 0 for those studies that did not report a number for the outcomes of interest. The high end of the range was based only on the data reported in the subset of studies that reported a specific number for a particular outcome.

scopic cholecystectomy than for open cholecystectomy.

3. Rates of common bile duct injury were higher for laparoscopic cholecystectomy than for open cholecystectomy.

Because there was considerable variation in these rates, we performed group-level logistic regressions in an attempt to identify the sources of systematic variation for the single-institution laparoscopic cholecystectomy studies (refer to Table 4). The available variables were not helpful in identifying factors associated with mortality rates. However, several variables were associated with the rates for common bile duct injury and for the conversion from laparoscopic to open cholecystectomy.

Initially, three predictors were significant in predicting common bile duct injuries, but after adjustment for the covariates based on reporting thoroughness, only presence of patients operated on as outpatients ($p = 0.071$) and the year the study started ($p = 0.004$) were significant. Specifically, studies without outpatients reported fewer common bile duct injuries than did studies with outpatients or studies not mentioning if they included outpatients. Common bile duct injuries were infrequent in early studies, increased for studies initiated in early 1990, and subsequently decreased.

Adjusted p values identified four significant predictors of conversions. Higher conversion rates were associated with multisurgeon studies, performing all procedures as inpatients (or not reporting if there were outpatients), including patients with acute cholecystitis, and studies initiated in 1990, as opposed to earlier or later. Also, when the covariates based on components 1 and 2 (defined in the Methods section) were significant, higher scores (*i.e.*, more reporting thoroughness) were associated with higher rates of common bile duct injuries or conversions. The opposite was true for the subscale based on component 3.

Laparoscopic Cholecystectomy Complications

In Table 5, we present data for some of the more commonly reported complications for the single-institution laparoscopic cholecystectomy studies. Complications are listed in the first column. The second column of the table lists the number of articles that specifically mentioned the complication (either its presence or absence). The third column lists the number of the complications and the total number of patients in the articles that mention the particular complication. The fourth and final column provides an estimated range of complication rates.

Reasons for Conversions to Open Cholecystectomy

A subset of the laparoscopic cholecystectomy articles ($n = 75$) provided rather specific data about the reasons for conversion to open cholecystectomy for 1400 of 25,763 patients (Table 6). We have grouped the conversions into four categories: 1) operative complications, 2) technical problems, 3) operative findings, and 4) miscellaneous/unspecified. The majority (55%) of the conversions were because of technical problems. The most common reported reasons for conversion were dense adhesions ($n = 290$) and inflammation ($n = 146$). Notably, there were 41 duct injuries and 12 bowel injuries.

DISCUSSION

Our goal was to perform a meta-analysis of the large laparoscopic cholecystectomy case-series and to compare the results to those observed for open cholecystectomy case-series. With this goal in mind, we began with a MEDLINE search that included more than 4000 titles. After the review process, 98 articles about laparoscopic cholecystectomy and 28 articles about open cholecystec-

Table 4. SUMMARY OF WEIGHTED MEANS FOR MORTALITY, COMMON BILE DUCT (CBD) INJURY, AND CONVERSIONS FOR SUBGROUPS OF SINGLE INSTITUTION LAPAROSCOPIC CHOLECYSTECTOMY (LC) STUDIES

Characteristic of Study	No. of Studies	No. of Patients	Mortality	CBD Injury	Conversions
Predictors					
Initial patients					
No	4	1599	0.0006	0.0019*	0.069†
Yes	51	16,538	0.0011	0.0029	0.047
Not mentioned	28	11,915	0.0019	0.0048	0.049
No. of surgeons					
1	11	32,845	0.0014	0.0032	0.036†
>1	63	25,031	0.0015	0.0037	0.053
Not mentioned	9	2176	—	0.0028	0.026
Any outpatients					
No	14	4888	0.0014	0.0037*	0.055†
Yes	13	5437	0.0006	0.0020	0.034
Not mentioned	56	19,727	0.0016	0.0040	0.052
Year study started					
≤1989	18	9382	0.0011	0.0025*	0.038†
Jan–Jun 1990	32	11,413	0.0016	0.0058	0.053
Jul–Dec 1990	12	3532	0.0020	0.0023	0.079
≥1991	8	2536	0.0012	0.0020	0.046
Not mentioned	13	3189	0.0013	0.0019	0.039
Any patients with acute cholecystitis					
Yes	56	19,408	0.0012	0.0038	0.053†
Not mentioned	27	10,644	0.0017	0.0032	0.043
Covariates					
Component 1					
0	4		—	—*	0.010†
1	8		0.0016	0.0006	0.044
2	20		0.0019	0.0034	0.060
3	51		0.0010	0.0048	0.052
Component 2					
0	14		0.0007	0.0031*	0.027†
1	27		0.0008	0.0040	0.055
2	42		0.0017	0.0044	0.059
Component 3					
0	5		0.0015	0.0062	0.093†
1	15		0.0018	0.0033	0.063
2	24		0.0005	0.0044	0.055
3	27		0.0019	0.0034	0.052
4	12		0.0005	0.0050	0.053

* Three of the predictor variables were initially significant ($p < 0.10$). However, adjusted p values after controlling for the two thoroughness components significantly associated with CBD injury (component 1 and component 2) are $p = 0.144$ for initial patients, $p = 0.071$ for outpatients, and $p = 0.004$ for year study started.

† All five variables were initially significant ($p < 0.10$). Adjusted p values after controlling for all three thoroughness components that were significantly associated with conversion rates were $p = 0.12$ for initial patients, $p < 0.001$ for number of surgeons, outpatients, and year started, and $p = 0.007$ for acute cholecystitis.

tomy were included in the analyses. From the data analyzed, we draw several conclusions.

First, there is extensive variability in the range and type of information reported in any single article. This is particularly true for aspects of the study method, where it was often not mentioned if follow-up was done, how many surgeons participated in the study, or if the data were collected retrospectively or prospectively. In a few articles, what we considered to be basic information (*e.g.*, date of the series, age and gender of the patients, patients' diagnoses) was not provided.

Because of the variable manner in which study methods are described and results are presented, combining data across studies is not a straightforward process that involves simply adding the frequencies of, for example, complications that are given in each article. Even if a particular complication was discussed when the authors were presenting data on their conversions from laparo-

Table 5. SUMMARY OF COMPLICATIONS REPORTED IN 83 SINGLE-INSTITUTION LAPAROSCOPIC CHOLECYSTECTOMY SERIES*

Complication	No. of Articles	No. of Complications/ Total N	Low Rate–High Rate
Postoperative bile leak	49	115/18,168	0.0038–0.0063
Urinary tract infection	14	35/5085	0.0012–0.0069
Retained stone	24	56/6950	0.0019–0.0081
Ileus	28	95/10,900	0.0032–0.0087
Myocardial infarction	11	16/3367	0.0005–0.0048
Bowel injury	12	19/5373	0.0006–0.0035
Wound infection	38	153/13,724	0.0051–0.0111
Bleeding	39	163/15,596	0.0054–0.0105
Subhepatic fluid	10	13/5111	0.0004–0.0025
Wound hematoma	17	41/6461	0.0014–0.0063
Pulmonary edema	4	3/1480	0.0001–0.0020
Postoperative fever	17	63/6748	0.0021–0.0093
Atelectasis	13	56/5609	0.0019–0.0100
Urinary retention	18	116/8143	0.0039–0.0142
Pulmonary embolism	6	7/2947	0.0002–0.0024

* N = 30,052 patients.

scopic to open cholecystectomy, it may not have been included in the discussion of complications. Careful reading was required to detect redundancies and to clarify discrepancies within an article.

Second, despite the variability in the amount and types of information presented in the various articles, our results concerning rates of mortality and common bile duct injury confirm what has been suggested by others.[15,26] Namely, rates of mortality are low for laparoscopic cholecystectomy, and rates of common bile duct injury appear to be higher for laparoscopic cholecystectomy than for open cholecystectomy. Caution is needed, however, in evaluating our estimates of the mortality associated with open cholecystectomy. In particular, the range we report (0.0066–0.0074) is somewhat higher than the 0.0017 reported by Roslyn et al.[27] for more than 40,000 patients and the 0.002 reported by McSherry[28] for patients operated on between 1978 and 1984 (although these latter data are limited to patients whose only procedure was cholecystectomy). Moreover, it should be emphasized that comparisons between the two procedures do not take into account any differing patient selection criteria that may exist. A recent article showing that the proportion of patients with an elective admission and the proportion with uncomplicated gallstone disease increased after the introduction of laparoscopic cholecystectomy supports the conclusion that clinical thresholds have been lowered.[6] Such changing patient characteristics offer one possible explanation of the lower mortality rate for laparoscopic cholecystectomy.

Third, to a limited extent, the variability in rates of common bile duct injury and conversion could be explained by characteristics of the patients or study settings. For example, rates of common bile duct injury were higher in studies that did not include outpatients and in the studies commencing in 1988 through the first half of 1990. These findings are clinically plausible, given that only the most straightforward cases are selected for outpatient surgery and that there was some increased frequency of injury associated with the learning curve. Similarly, conversion rates were higher when there were many surgeons (some perhaps with less experience than others), no outpatients (the more difficult cases remaining), and some patients with acute cholecystitis. Conversion rates also peaked in the midyears of the study, a time when surgeons were beginning to attempt laparoscopic cholecystectomy with more complex patients. What makes these findings difficult to interpret, however, is that for many of the predictors we studied, a large number of articles did not include relevant information on the predictor. Moreover, our assessments of reporting

Table 6. SUMMARY OF REASONS FOR CONVERSION TO OPEN CHOLECYSTECTOMY

Reason	No. of Conversions (% out of 1400)
Complications	206 (14.7)
Cystic artery injury	25 (1.8)
Bleeding	112 (8.0)
Duct injuries	41 (2.9)
Bowel injury	12 (0.9)
Other (e.g., gallbladder perforation, intraoperative bile leak, trocar injury, cautery injury)	16 (1.1)
Technical problems	776 (55.4)
Dense adhesions	290 (20.7)
Inflammation	146 (10.4)
Unclear or aberrant anatomy	117 (8.4)
Difficult dissection	71 (5.1)
Equipment failure	30 (2.1)
Poor visualization	18 (1.3)
Other (*e.g.*, gallbladder difficult to grasp, pneumoperitoneum lost/not achieved, obesity, unable to clip cystic duct, failed intraoperative cholangiogram)	104 (7.4)
Operative findings	290 (20.7)
Common bile duct stones	95 (6.8)
Acute cholecystitis	96 (6.9)
Abnormal cholangiography	21 (1.5)
Gangrenous gallbladder	15 (1.1)
Empyema	10 (0.7)
Other (*e.g.*, gallbladder cancer, liver tumor, hydrops, cholechoduodenal fistula, intrahepatic gallbladder, acute pancreatitis)	53 (3.8)
Miscellaneous; unspecified	128 (9.1)

thoroughness suggest that, to some extent, higher common bile duct injury and conversion rates are associated with more thorough reporting.

Fourth, the types and ranges of complications, other than death and common bile duct injury, indicate tremendous variability in the types of complications reported among laparoscopic case-series with more than 100 patients. Some authors provide rather exhaustive lists,[8,9,11] whereas others focus on a more limited set.[29–32] As discussed earlier, it is not clear when it is valid to assume that a complication did not occur if not mentioned. Consequently, it is hard to draw conclusions about the true risks associated with laparoscopic cholecystectomy. Nevertheless, even the highest estimated rates suggest the probability of the most serious of the complications (*e.g.*, pulmonary embolism, pulmonary edema, bowel injury, and myocardial infarction) is less than 5 in 1000. True rates from the published studies are almost certainly lower.

Fifth and finally, the reasons for conversion mirror what has been reported in other investigations.[33,34] Namely, only 15% occur because of a complication involving injuries. In the majority of cases, conversion to open cholecystectomy occurred after a surgeon encountered a technical problem.

In summary, these data aggregating thousands of patients over many institutions and surgeons confirm what many other authors have suggested: laparoscopic cholecystectomy is a reasonably safe procedure. Admittedly, the results may reflect some publication bias (*i.e.*, the tendency for surgeons experiencing the most favorable results to publish their data). This issue cannot be studied with the current data, but if publication bias is occurring, it is likely affecting reported results for both open cholecystectomy and laparoscopic cholecystectomy. Potentially more problematic is the under-reporting of certain complications for laparoscopic cholecystectomy given the generally early discharge of these patients. Although this probably did not affect reports of certain types of common bile duct injury, such as transections or leaks, it certainly could have led to under-reporting of many of the other complications, such as wound infection or late biliary strictures. It also may be that the lower mortality rate for laparoscopic cholecystectomy reflects the fact that even after the learning process has been completed, it still is restricted to the healthiest patients. Unfortunately, from the studies in this meta-analysis, it was rare that data on patients undergoing open cholecystectomy were presented. Thus, the comparability of recent series of patients undergoing cholecystectomy to past series of patients undergoing cholecystectomy is limited, and the data do not address adequately changing patient selection criteria. Although an extremely large body of data has been reported concerning laparoscopic cholecystectomy, and some reasonably secure conclusions can be drawn, there still are some considerable uncertainties that need to be addressed by better-designed studies and more complete reporting.

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