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Complications of Cholecystectomy: Risks of the Laparoscopic Approach and Protective Effects of Operative Cholangiography

A Population-Based Study

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Background
Previous studies suggest that laparoscopic cholecystectomy (LC) is associated with an increased risk of intraoperative injury involving the bile ducts, bowel, and vascular structures compared with open cholecystectomy (OC). Population-based studies are required to estimate the magnitude of the increased risk, to determine whether this is changing over time, and to identify ways by which this might be reduced.

Methods
Suspected cases of intraoperative injury associated with cholecystectomy in Western Australia in the period 1988 to 1994 were identified from routinely collected hospital statistical records and lists of persons undergoing postoperative endoscopic retrograde cholangiopancreatography. The case records of suspect cases were reviewed to confirm the nature and site of injury. Ordinal logistic regression was used to estimate the risk of injury associated with LC compared with OC after adjusting for confounding factors.

Results
After the introduction of LC in 1991, the proportion of all cholecystectomy cases with intraoperative injury increased from 0.67% in 1988–90 to 1.33% in 1993–94. Similar relative increases were observed in bile duct injuries, major bile leaks, and other injuries to bowel or vascular structures. Increases in intraoperative injury were observed in both LC and OC. After adjustment for age, gender, hospital type, severity of disease, intraoperative cholangiography, and calendar period, the odds ratio for intraoperative injury in LC compared with OC was 1.79. Operative cholangiography significantly reduced the risk of injury.

Conclusion
Operative cholangiography has a protective effect for complications of cholecystectomy. Compared with OC, LC carries a nearly twofold higher risk of major bile, vascular, and bowel complications. Further study is required to determine the extent to which potentially preventable factors contribute to this risk.

Laparoscopic cholecystectomy (LC) was introduced into Australia in February 1990[1] and within 2 years[2] was being practiced in 74% of Australian hospitals. Voluntary audits[3,4] initially suggested that the procedure was safe, but subsequent studies have found LC to be associated with an increased prevalence of bile duct injury.[5–7] Reports of vascular injury and bowel injury associated with laparoscopic cannulation or insufflation[5,8,9] have added to concerns about the safety of the procedure.

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Much of the early evidence for the safety of the laparoscopic approach was based on results from expert centers,[10] multicenter experience,[11] or a postal voluntary survey.[12] Even though the latter two might be large enough to identify relatively rare complications such as injuries to the bile duct (if accurately reported), such reports cannot be extrapolated to the wider community because the probability of injury is likely to be influenced by many factors, including surgical training and expertise, the size of the institution, the quality of equipment, case volume, and case selection. Only population-based studies can avoid these sources of bias and thus determine the outcome of LC in general use and whether results are improving with surgeon experience, as has been suggested by reports from individual centers.[13,14]

Table 1. PROCEDURES AND DIAGNOSES IN ICD9-CM USED TO IDENTIFY COMPLICATED READMISSIONS

Procedures and Diagnosis	ICD9-CM Code
Endoscopic retrograde cholangiopancreatography in any procedure field	5291, 5197, 5110, 5111, 5184–5188
Thoracentesis	34.91
Other repair of intestine	46.79
Hepatotomy	50.0
Percutaneous aspiration of liver	50.91
Simple suture of common bile duct	51.71
Repair of other bile ducts	51.79
Other percutaneous procedures on biliary tract	51.98
Other operations on biliary tract	51.99
Incision of abdominal wall	54.0
Reopening of recent laparotomy site	54.12
Other laparotomy	54.19
Closed biopsy of intraabdominal mass	54.24
Percutaneous abdominal paracentesis	54.91
Intraoperative cholangiogram	87.53
Computerized axial tomography of the abdomen	88.01
Diagnostic ultrasound of abdomen and retroperitoneum	88.76
Pulmonary scan	92.15
Removal of t-tube, other bile duct tube, or liver tube	97.55
Complications affecting specified body systems, not elsewhere classified	997
Gastrointestinal complications	997.4
Hemorrhage or hematoma complicating a procedure; hemorrhage of any site resulting from a procedure	998.1
Accidental puncture or laceration during a procedure	998.2
Persistent postoperative fistula	998.6
Other specified complications of procedures, not elsewhere classified	998.8
Unspecified complication of procedure, not elsewhere classified	998.9

Western Australia presents many advantages for population-based outcome studies of surgical procedures. First, the Health Department of Western Australia has maintained a statistical collection covering all admissions to all Western Australian hospitals (hospital morbidity data) since 1971. Personal identifiers that can be used for record linkage are included, so that readmissions for complications after surgical procedures can be easily identified. Second, the population is geographically isolated, with low emigration and thus loss to follow-up. From census data, the net migration out of state for long-term residence is estimated to be as low as 1.7% per annum. The capital city, Perth, is the only city large enough to support tertiary referral centers. Patients with major surgical complications are referred to one of three teaching hospitals or a limited number of private hospitals. Finally, the Western Australian State Committee of the Royal Australasian College of Surgeons actively supports outcome studies, thus greatly facilitating the validation of diagnostic coding from examination of the original case records.

Given these advantages, we have undertaken a population-based study to determine first whether the introduction to the community of LC was associated with an increase in major intraoperative injury, and second whether the frequency of major intraoperative injury has decreased with increasing surgical experience.

PATIENTS AND METHOD

A file of all cholecystectomies performed in Western Australia during 1988 to 1994 was created by selecting relevant electronic records from the Health Department of Western Australia's Hospital Morbidity Data System. This covered the 3 years before the introduction of LC, as well as its subsequent rapid uptake and consolidation. Because a separate code for LC as distinct from open cholecystectomy (OC) was not adopted until July 1992, laparoscopic procedures were identified during this time by combining the codes for cholecystectomy and laparoscopy.

A subfile of patients with potential intraoperative injuries was created by searching all diagnostic fields for any of the codes listed in Table 1 in either the record of the operative admission or any readmissions within 30 days with duration of stay of at least 2 days. Single-day admissions for removal of retained stones are frequently seen after cholecystectomy and were therefore excluded from this file. We also excluded any patient who had a code related to malignancy.

In addition to the above, we obtained lists from two major teaching hospitals where endoscopic retrograde cholangiopancreatography was performed on patients who had been diagnosed as having a bile leak on their endoscopic retrograde cholangiopancreatography report. We also obtained from the third teaching hospital a list of patients who had

Table 2. DISTRIBUTION OF CHOLECYSTECTOMIES BY CASE COMPLEXITY AND TYPE OF SURGERY

Type of Surgery		1988–90	1991–92	1993–94
Open	Number	7113	3209	1361
	% Complex*	11.1	17.1	27.3
	% Noncomplex	88.9	82.9	72.7
Laparoscopic	Number	14	2526	4953
	% Complex	0.0	7.0	7.9
	% Noncomplex	N/A	93	92.1

* Complex cases include pancreatitis, cholangitis, obstructive jaundice, and acute cholecystitis.

been reported as having complications associated with a cholecystectomy on an internal morbidity and mortality register. From these sources we identified a total of 456 cases with possible intraoperative injury, of 19,187 cholecystectomies. The relevant hospital case notes were then reviewed.

During the period 1991–92, when there was no specific procedure code for LC, several of the laparoscopic procedures in our population were coded as open. These were corrected on our database. Because the uncomplicated cases could not be validated because of their numbers, the proportion of laparoscopic procedures was underestimated, as were some cases of LC that were converted to open procedures. The proportion of complications after LC may thus be marginally overestimated, whereas the rate of complications in the open procedure for this period may be marginally underestimated. LCs that were converted to open procedures were analyzed as LC, based on the intention to treat.

A biliary injury was defined as an injury to the biliary system as a result of surgery. Information was collected regarding the location and type of injury, time of detection of the injury, and management. Bowel and vascular injuries and hemorrhage were defined as those documented in the operation notes or those requiring reintervention, such as laparotomy.

Bile leaks were defined as being of sufficient severity to require surgical or endoscopic reintervention. Any bile leak, regardless of anatomic source, that adhered to this definition was included. Where available, information was collected on their origin and management. Minor biliary leaks, such as those treated with drainage from drains left *in situ* after surgery, were excluded.

Complex cases of cholecystectomy (Tables 2 and 3) were defined as those having an ICD9 code associated with a diagnosis of pancreatitis, obstructive jaundice, cholangitis, and acute cholecystitis during the operative admission.

Statistical Analysis

The data were analyzed with logistic regression using the SAS[15] statistical analysis software package. Because the number of bile duct injuries was too small for reliable separate multivariate analysis, we combined bile duct injuries, vascular injuries, bowel injuries, and hemorrhage as a single category—intraoperative injuries. The other outcome categories were bile leaks and no complications. Considering these outcome categories as ordered in terms of severity, we fitted a proportional odds ordinal logistic regression model. This model assumes that the effect of a risk factor is the same for injury *versus* major leak or no injury, and for injury or major leak *versus* no complication. The proportional odds assumption was tested via a chi square test[15] ($p = 0.79$), as well as by fitting separate logistic regression models for different combinations of outcome levels. Neither of these checks indicated any departure from the proportional odds assumption.

Because calendar year was an independent variable of particular interest, but very few cases of LC were performed during the first 3 years of the study, we explored alternative models in which calendar time was treated in different ways—for example, considering the first 5 years as a single category or omitting the first 3 years entirely. The results from these models relating to the other independent variables were all consistent with the model presented here.

To confirm that the results applied to bile duct injuries specifically, we also fitted an ordinary logistic regression model with a limited number of risk factors using the presence or absence of bile duct injury as the outcome.

RESULTS

Laparoscopic cholecystectomy was introduced into Perth at the end of 1990 and rapidly became the preferred method of surgery. By 1993–94, LC accounted for 75% of all cholecystectomies, and the annual number of procedures performed had increased by 33%, representing a 12% increase in the age- and sex-standardized cholecystectomy rate. During the same period, the proportion of operations associated with intraoperative injury doubled (Table 4). This applied equally to bile duct injuries, major bile leaks, and other injuries to bowel and blood vessels. From Table 5

Table 3. TYPE OF SURGERY IN COMPLEX CASES

	1988–90	1991–92	1993–94
Number	788	736	768
% Open	100	74.6	48.3
% Laparoscopic	0.0	24.6	51.7

Complex cases include pancreatitis, cholangitis, obstructive jaundice, and acute cholecystitis.

Table 4. ALL CHOLECYSTECTOMIES—PROPORTIONS OF COMPLICATIONS BEFORE, DURING, AND AFTER INTRODUCTION OF LAPAROSCOPIC METHOD

Period*	Bile Duct Injuries	Other Injuries	Bile Leaks	All Complications	Procedures
1988–90					
n	11	9	22	42	7436*
%	0.15	0.12	0.30	0.56	
95% CI	(0.06–0.24)	(0.04–0.20)	(0.17–0.42)	(0.39–0.74)	
1991–92					
n	14	9	15	38	6011
%	0.23	0.15	0.25	0.63	
95% CI	(0.11–0.36)	(0.05–0.25)	(0.12–0.38)	(0.43–0.83)	
1993–94					
n	19	21	32	72	6637
%	0.29	0.32	0.48	1.09	
95% CI	(0.16–0.42)	(0.18–0.45)	(0.31–0.65)	(0.83–1.33)	

* Note that the first period (1988–90) includes 3 years, whereas the second and third periods include 2 years.

it is apparent that this increase occurred mainly in laparoscopic procedures, although the proportion of injury also increased in the declining number of open procedures (Table 6).

Table 2 shows that as the number of cases selected for OC declined, there was a marked relative increase in the complexity of cases selected for this type of surgery. In contrast, there was only a small relative increase in the number of complex (high-risk) cases selected for LC, but because of the rapid growth in such operations, the number of complex cases in which LC was performed doubled between 1991–92 and 1993–94 (see Table 3).

The distribution of outcomes for demographic and other independent variables can be seen in Table 7.

Selection of cases for LC or OC also varied considerably with age, sex, and hospital type; the frequency of intraoperative cholangiography varied with each of these variables and with the type of surgery. Other aspects of care, such as the proportion of patients undergoing intraoperative cholangiography and admitted to different types of hospitals, also changed over time. When assessing the independent effects of type of surgery or intraoperative cholangiography on the risk of intraoperative injury, it was therefore necessary to consider all of these variables as potential confounders. The univariate risks of injury associated with each are shown in Table 8. In addition to LC and later calendar period, the risk of both bile leaks and severe injury increased with age and with severity of disease; it was higher in men than in women and in teaching hospitals *versus* nonteaching hospitals. Intraoperative cholangiography was associated with a reduced risk of injury.

The results of the ordinal logistic regression model are

Table 5. LAPAROSCOPIC CHOLECYSTECTOMY—PROPORTIONS OF COMPLICATIONS BEFORE, DURING, AND AFTER INTRODUCTION OF LAPAROSCOPIC METHOD

Period*	Bile Duct Injuries	Other Injuries	Bile Leaks	All Complications	Procedures
1988–90					
n	1	0	0	1	15
%	6.66			6.66	
95% CI	(0.0–19.3)			(0.0–19.3)	
1991–92					
n	9	7	7	23	2593
%	0.35	0.27	0.27	0.89	
95% CI	(0.12–0.57)	(0.07–0.47)	(0.07–0.47)	(0.53–1.25)	
1993–94					
n	15	19	26	60	5067
%	0.30	0.37	0.51	1.18	
95% CI	(0.15–0.44)	(0.21–0.54)	(0.32–0.71)	(0.89–1.48)	

* Note that the first period (1988–90) includes 3 years, whereas the second and third periods include 2 years.

Table 6. OPEN CHOLECYSTECTOMY—PROPORTIONS OF COMPLICATIONS BEFORE, DURING, AND AFTER INTRODUCTION OF LAPAROSCOPIC METHOD

Period*	Bile Duct Injuries	Other Injuries	Bile Leaks	All Complications	Procedures
1988–90					
n	10	9	22	41	7421
%	0.13	0.12	0.30	0.55	
95% CI	(0.05–0.21)	(0.04–0.20)	(0.17–0.42)	(0.38–0.72)	
1991–92					
n	5	2	8	15	3418
%	0.15	0.06	0.23	0.44	
95% CI	(0.02–0.27)	(0.0–0.14)	(0.07–0.40)	(0.22–0.66)	
1993–94					
n	4	2	6	12	1570
%	0.25	0.13	0.38	0.76	
95% CI	(0.0–0.5)	(0.0–0.30)	(0.08–0.69)	(0.33–1.20)	

* Note that the first period (1988–90) includes 3 years, whereas the second and third periods include 2 years.

shown in Table 9. Two important conclusions emerge from this. First, after adjusting for all known confounders, LC remains a significant risk factor for bile duct injuries, other injuries, and major bile leaks (odds ratio [OR] 2.5, 95% confidence interval [CI] 1.53–4.22). Second, intraoperative cholangiography has a statistically significant protective effect for all injuries and leaks (OR 0.5, 95% CI 0.35–0.70). None of the interactions between the variables in this model were statistically significant, including the interaction between intraoperative cholangiography and LC ($p = 0.84$).

Several alternative models were designed to investigate further the risk associated with LC and the protective effect of intraoperative cholangiography. Because few LCs were performed in the first 3 years, we reanalyzed the data after first combining the first and second periods, and second after omitting the first period altogether. These models yielded ORs for LC of 2.04 and 2.03, respectively. Thus, the estimate of the effect of LC is not sensitive to period factors. Within these models, the protective effect of intraoperative cholangiography also remained constant.

Although these results demonstrate a protective effect of intraoperative cholangiography for all injuries and bile leaks, this finding is of clinical relevance only if it is protective against bile duct injury. The number of cases of bile duct injury was too small for reliable, separate analysis of the relation between intraoperative cholangiography and bile duct injury, adjusting for type of surgery and all the confounding factors included in Table 9. We were, however, able to fit a limited ordinary logistic regression model including type of surgery, case complexity (with two classes only: complicated cases and acute cholecystitis combined *vs.* all other cases), and intraoperative injury. In this model, the OR was 1.9 (95% CI 1.03–3.60) for LC and 0.41 (95% CI 0.21–0.80) for intraoperative cholangiography, demon-

Table 7. DISTRIBUTION OF OUTCOMES FOR ALL OTHER INDEPENDENT VARIABLES

Variable	Categories	Total Number of Procedures	Bile Leaks n (%)	Bile Duct & Other Injuries n (%)
Age	<55	10,941	28 (0.26)	33 (0.30)
	55–64	3569	17 (0.47)	10 (0.28)
	65–74	3112	16 (0.52)	17 (0.55)
	75+	1524	8 (0.48)	11 (0.66)
Sex	M	5219	34 (0.65)	31 (0.59)
	F	13,967	35 (0.25)	41 (0.29)
Hospital type	Teaching	4017	32 (0.80)	26 (0.65)
	Nonteaching	15,170	37 (0.24)	46 (0.30)
Clinical diagnosis	Pancreatitis/cholangitis/obstructive jaundice/acute cholecystitis	2292	18 (0.79)	16 (0.70)
	Other cholecystitis/cholelithiasis	16,587	50 (0.30)	54 (0.33)
Operative cholangiogram	Y	10,977	25 (0.23)	27 (0.24)
	N	8157	44 (0.54)	45 (0.55)

Table 8. UNIVARIATE EFFECTS OF RISK FACTORS ON INJURY/BILE LEAK AFTER CHOLECYSTECTOMY

Variable	Categories	Odds Ratio	95% Confidence Interval	p Value
Sex	M	2.30	1.64–3.22	0.0001
	F	1.00	—	—
Age	Per year	1.02	1.01–1.03	0.0005
Age groups	75+	2.27	1.35–3.80	0.0019
	65–74	1.91	1.25–2.93	0.0027
	55–64	1.30	0.81–2.06	0.27
	<55	1.0	—	—
Hospital type	Teaching	2.64	1.88–3.70	0.0001
	Nonteaching	1.00	—	—
Surgery type	Laparoscopic	1.52	1.09–2.13	0.018
	Open	1.00	—	—
Disease class	Per level	1.86	1.45–2.38	0.0001
Disease class	Pancreatitis/obstructive jaundice/cholangitis	3.47	2.04–5.90	0.0001
	Acute cholecystitis	1.84	1.11–3.04	0.17
	Other cholecystitis/cholelithiasis	1.00	—	—
Year	Per year	1.15	1.05–1.26	0.0014
Period	93–94	1.88	1.26–2.79	0.002
	91–92	1.10	0.70–1.75	0.66
	88–90	1.00	—	—
Operative cholangiogram	Yes	0.74	0.52–1.04	0.08
	No	1.00	—	—

strating the increased risk associated with LC and the protective effect of intraoperative cholangiography.

In Table 10, the proportions of cases with bile duct injury are shown for type of procedure and case complexity, according to whether intraoperative cholangiography was performed. The risk of bile duct injury is more than halved when intraoperative cholangiography is performed in both LC and OC. This confirms that there is a high risk of injury in the absence of intraoperative cholangiography when both disease severity and operative type are held constant. When case complexity is examined, as Table 10 shows, the risk of bile duct injury is dramatically increased. The protective effect of intraoperative cholangiography is most obvious in this group, reducing the risk of duct injury nearly eightfold. The protective effect of intraoperative cholangiography is also seen in the more numerous noncomplex cases: the risk of bile duct injury was less than half when intraoperative cholangiography was performed. Based on the expected number of injuries if intraoperative cholangiography were performed on all cases, about one third of all cases of bile

Table 9. MULTIVARIATE EFFECTS OF RISK FACTORS FOR INJURY/BILE LEAK AFTER CHOLECYSTECTOMY

Variable	Categories	Odds Ratio	95% Confidence Interval	p Value
Sex	M	1.92	1.36–2.70	0.0002
	F	1.00	—	—
Age	Per year	1.01	1.00–1.02	0.06
Hospital type	Teaching	2.16	1.50–3.08	0.0001
	Nonteaching	1.00	—	—
Surgery type	Laparoscopic	2.50	1.53–4.22	0.0004
	Open	1.00	—	—
Disease class	Pancreatitis/obstructive jaundice/cholangitis	2.56	1.40–4.42	0.0013
	Acute cholecystitis	1.32	0.76–2.19	0.30
	Other cholecystitis/cholelithiasis	1.00	—	—
Period	93–94	0.80	0.44–1.45	0.47
	91–92	0.65	0.37–1.12	0.13
	88–90	1.00	—	—
Operative cholangiogram	Yes	0.50	0.35–0.70	0.0001
	No	1.00	—	—

Table 10. PROPORTION OF BILE DUCT INJURIES BY OPERATIVE CHOLANGIOGRAPHY (IOC), TYPE OF SURGERY, AND CASE COMPLEXITY

	IOC No		IOC Yes	
	Total Cases	Injuries per 1000	Total Cases	Injuries per 1000
Laparoscopic	4140	4.3	3397	2.1
Open	4017	2.7	7632	1.0
Complex*	295	16.9	446	2.2
Not complex	7862	3.1	10,583	1.3

* Complex cases include pancreatitis, cholangitis, obstructive jaundice, and acute cholecystitis.

duct injury in the period of the study could be attributed to failure to perform this procedure. From a clinical point of view, this is the major finding to emerge from Table 10.

DISCUSSION

Laparoscopic cholecystectomy offers considerable advantages to patients compared with open surgery. Despite the increases in overall procedure rates stimulated by its use, it has on balance led to more efficient use of hospital services. Concerns remain, however, because of the increased frequency of intraoperative complications associated with its use. Accurate monitoring of these relatively rare complications (*i.e.*, on the order of 1%) requires large population-based studies of all cholecystectomies to avoid the selection biases that inevitably occur in hospital-based audits. This study is one of three such studies[16,17] to have examined changes in operation and surgical complication rates over the period 1988 to 1994, during which time LC was introduced (generally in 1990 or 1991). Despite differences in methods, the results of these agree in most major respects. All have shown that injuries to major bile ducts associated with cholecystectomy increased two- to threefold after the introduction of LC. The increased numbers of injuries occurred particularly in laparoscopic cases, but the prevalence of injuries in OC also increased. While LC rapidly became the most common form of surgery, OC decreased in both absolute and relative terms. The cases selected for LC have tended to be uncomplicated, whereas the residual cases in which OC is used have become more complex.

Important differences between these studies were, however, also observed. These relate to the absolute level of bile duct injury both before and after the introduction of LC and the extent to which initially high proportions of injuries after the introduction of LC have declined over time—the so-called "learning curve" effect. The largest study was that undertaken in Ontario for the period 1989 to 1994, which included 108,000 patients.[16] The prevalence of bile duct injury before the introduction of LC was 0.3% to 0.4%, increasing to 1.2% in 1992–93 and falling to 0.93% in 1993–94. A statewide study of experience in Connecticut included 30,211 patients who underwent surgery in the period 1989 to 1993.[17] The prevalence of bile duct injury before the introduction of LC was 0.06%; it increased to 0.27% in 1992 before declining to 0.11% in 1993. In the present study, the prevalence of bile duct injury before LC was 0.15%, increasing to 0.23% in 1991–92 and 0.29% in 1994. To date, there has thus been no confirmation in Western Australia of a decline in injuries with increasing surgical experience.

The marked differences between the prevalence of bile duct injury in Connecticut and Western Australia on the one hand, and in Ontario on the other, are unlikely to result from differences in surgical practice. They are more likely the result of differences in methods used to identify possible cases of injury, validation procedures, and the type of bile duct injuries included.

All the studies identified possible cases from routinely collected hospital morbidity statistics, using nonspecific diagnostic codes suggestive of injury in the operative admission or readmissions within 1 month such as those illustrated in Table 1 (in our study, additional cases were identified through examination of results of endoscopic retrograde cholangiopancreatography examinations). Confirmatory evidence of injury and its exact nature was sought from case records in Connecticut and Western Australia but not in Ontario. In Connecticut, 47 of 175 cases of suspected injury were confirmed as bile duct injury, whereas in our present study only 43 of 456 cases of suspected injury were confirmed as bile duct injury. These results suggest that the occurrence of bile duct injury was substantially overestimated in Ontario. However, it may be that the prevalence of injuries in OC in Connecticut before the introduction of LC (0.05% *vs.* 0.15% in Western Australia) was underestimated. Accurate identification of bile duct injury in OC is crucial, given that the population impact of LC on the occurrence of bile duct injury can be determined only by comparing the prevalence of bile duct injury in all cases of cholecystectomy in the pre- and post-LC eras.

Our study demonstrated a more than twofold increase in the frequency of all major intraoperative injuries after the introduction of LC. Disease complexity, increasing age, male gender, and admission to a teaching hospital were also associated with a significantly increased risk of injury. The most likely explanation is that either a proportion of cases in teaching hospitals are done by less experienced trainees, or our method of categorizing disease severity based on coded information does not adequately reflect selection of the most difficult cases for surgery in such hospitals.

Intraoperative cholangiography appeared to protect against intraoperative injury. It was noted that after the introduction of LC, the frequency of intraoperative injury also increased in open cases. This may have resulted, at least in part, from the relative increase in complex cases that occurred in the declining number of open procedures. Declining use of intraoperative cholangiography, as discussed below, may also have contributed.

Whereas all the types of complication included in our study are associated with increased short-term morbidity, injuries to the bile ducts, which may be associated with long-term problems, are of particular concern. Although the number of cases was too small to undertake a detailed analysis of the separate factors contributing to the increase in bile duct injury, it is clear that introduction of LC was the most important contributing cause. A second, and potentially correctable, factor may have been the decline in the use of intraoperative cholangiography. In OC, such use fell from more than 70% in 1988 to 50% in 1993–94; it was used in only 45% of LC cases. Although the protective effect of intraoperative cholangiography has been previously suggested in nonpopulation-based studies in both the open[18] and the laparoscopic era,[19] this population-based study has shown it is particularly so in high-risk cases, with an additional substantial reduction in injuries. Nevertheless, even in low-risk cases, the risk of bile duct injury associated with intraoperative cholangiography was less than half that in cases in which intraoperative cholangiography was not performed, irrespective of type of surgery. Because we could not identify situations in which intraoperative cholangiography may have been performed to display the anatomy of the biliary system after injury had occurred, it is possible that the protective effect of intraoperative cholangiography was underestimated.

Although this study is based on small numbers (only 44 cases of bile duct injury), the findings suggest that about one third of all cases of bile duct injury might have been prevented by universal use of intraoperative cholangiography. The findings of this study are consistent with other studies in the laparoscopic era suggesting that intraoperative cholangiography protects against bile duct injury by preventing misidentification of anatomy.[20–22] Olsen[22] has shown that the majority of major bile duct injuries result from mistaking the common bile duct for the cystic duct; this is immediately recognized during intraoperative cholangiography because contrast either leaks or goes down the common bile duct only.[23,24] Our findings are contrary to two recent studies, however, that concluded there was no protective effect from intraoperative cholangiography.[25,26] In both these studies, however, the rate of intraoperative cholangiography was so low that there would be insufficient numbers of patients who had a cholangiogram to show any significant effect. This present study, with its larger numbers showing a protective effect of intraoperative cholangiography, should now resolve this major issue in clinical practice.

Other potentially correctable factors contributing to intraoperative complications during LC are technique, case selection, and surgeon training and experience. With regard to the first, we have not been able to determine the specific method of cannulation (open or closed),[8,9] whether diathermy was used, or the type of endoscope (0° versus 30°), all of which have been suggested to affect the risk of injury.[20,23,24,27]

A decline in the frequency of bile duct injury after an initial rise after the introduction of LC noted in other studies has been attributed to acquisition of surgical experience (the learning curve).[13,28,29] So far, this has not been apparent in Western Australia. One possible reason is that the annual number of cases may be too low to demonstrate such a trend. A second is that the number of new surgeons performing LC is continuing to increase. Finally, our study has shown that the complexity of cases selected for LC has increased over time, which may to some extent offset the effect of increasing surgical experience. Because patients with complicated biliary disease, who often have significant comorbidity, have the most to gain from the minimal-access surgery, this trend is likely to continue. Clearly, however, such operations should be performed by surgeons with the greatest experience.[27] The persistence of an increased risk of bile duct injury is therefore a complex issue, and further research into the roles of both surgical practices and surgeon experience is required. In the meantime, ongoing monitoring of the frequency of bile duct injury and factors that may be contributing to this is mandatory. It is also essential that patients should be adequately informed of the risks associated with LC. To achieve these aims, the Quality of Surgical Care project[30] (sponsored by the Royal Australian College of Surgeons, the Health Department of Western Australia, and the University of Western Australia) was established to monitor outcomes and provide feedback to individual surgeons and health care providers.

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