Bile duct injuries during laparoscopic cholecystectomy

A 1994–2001 audit on 13,718 operations in the area of Rome

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Abstract

Background: Bile duct injuries (BDIs) during laparoscopic cholecystectomy (LC) still are reported with greater frequency than during open cholecystectomy (OC).

Methods: In 1999, a retrospective study evaluating the incidence of BDIs during LC in the area of Rome from 1994 to 1998 (group A) was performed. In addition, a prospective audit was started, ending in December 2001 (group B).

Results: In group A, 6,419 LCs were performed (222 were converted to OC; 3.4%). In group B, 7,299 LCs were performed (225 were converted to OC; 3.1%). Seventeen BDIs (0.26%) occurred in group A and 16 (0.22%) in group B. Overall, mortality and major morbidity rates were 12.1% and 30.3%, respectively, without significant differences between the two groups.

Conclusions: The incidence and clinical relevance of BDIs during LC in the area of Rome appeared to be stable over the past 8 years and were not influenced by the use of a prospective audit, as compared with a retrospective survey.

Key words: Cholecystectomy — Laparoscopic/adverse effects — Bile duct/injuries — Multicenter studies

Laparoscopic cholecystectomy (LC) became the gold standard for gallstone disease in the 1990s [11, 21, 22, 27]. Although a trend in reduction has been reported [20], bile duct injuries (BDIs) during LC are still reported with greater frequency (0.1–1.1%) than during open cholecystectomy (OC) (0–0.7%) [10, 12, 17, 28].

The Lap Group Roma is an association of surgeons founded in 1999 with the aim of investigating the field of laparoscopic surgery in the area of Rome and its province [4]. This study was designed to compare the incidence, mechanism, and clinical relevance of BDIs during LC in the area of Rome using a retrospective survey rather than a prospective audit.

Materials and methods

A retrospective survey evaluating the incidence of BDIs during LC in the area of Rome from 1994 to 1998 was performed (group A). All the surgical centers of the Lap Group Roma received a questionnaire concerning a period of 5 years (January 1994 to December 1998). They were asked to report the total number of LCs performed and the total number of LCs converted to OCs during this 5-year period. No data about OC were requested given the policy of routine laparoscopic management in all the participating centers. Intraoperative cholangiography was performed on a selective basis in all the centers. Specific questions were aimed at disclosing any major injury of the biliary tract. At the same time, a prospective audit was started with the aim of recording all BDIs occurring during LC up to December 2001 (group B).

All the clinical charts for any case of BDI were retrieved and reviewed by a committee of six surgeons (the first six authors). Data concerning the patients' demographics (age, gender, American Society of Anesthesiology [ASA] status), clinicopathologic details of the gallbladder disease (elective/urgent, chronic/acute), experience of the surgeon (years as a specialist, number of previous LCs performed), presumed dynamics of the injury (direct/clip/electrocautery), timing of

Table 1. Results of main outcome measures

	Overall	Group A	Group B	p value
LCs	13,718	6,419	7,299	
No. of centers		13	22	
Mean ± 95% CI for LCs per center per year		98.7 ± 53.6	110.6 ± 27.2	0.23
Conversions n (%)	446 (3.2)	222 (3.4)	224 (3.1)	0.43
Mean ± 95% CI for conversion rates per center		4.3 ± 1.3	3.4 ± 1.4	0.31
BDIs n (%)	33 (0.24)	17 (0.26)	16 (0.22)	0.35
Mean ± 95% CI for BDI rates per center		0.27 ± 0.16	0.22 ± 0.11	0.60
Mean ± 95% CI for follow-up period (years)	3.7 ± 1.1	6.3 ± 1.2	1.8 ± 0.5	0.01
Major morbidity n (%)	10 (30.3)	7 (41.2)	3 (18.7)	0.15
Mortality n (%)	4 (12.1)	3 (17.6)	1 (6.2)	0.31

LC, laparoscopic cholecystectomy; 95% CI, confidence intervals at 95%; BDIs, bile duct injuries
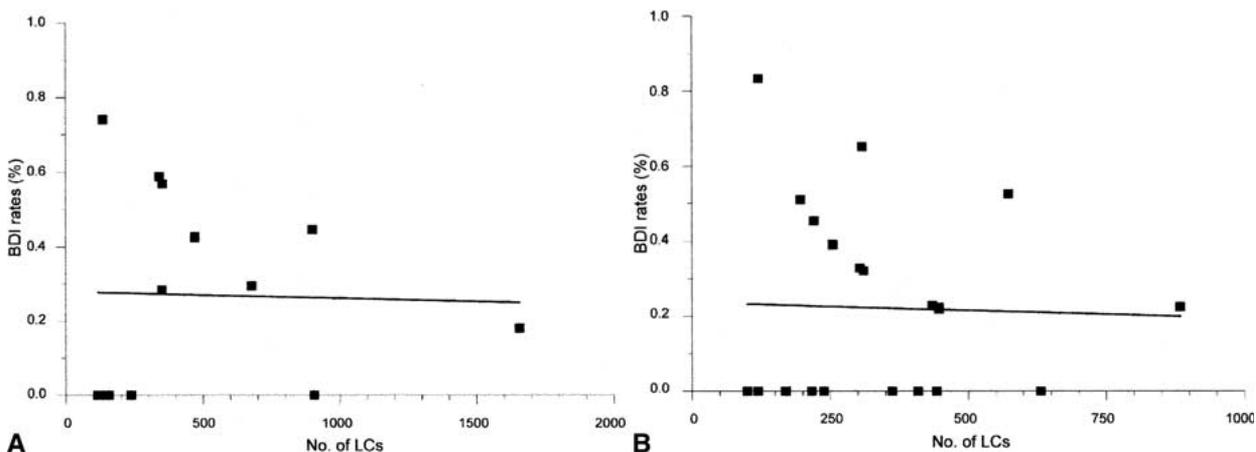

Fig. 1. Linear regression analysis of the effect that the number of laparoscopic cholecystectomies (LCs) performed had on bile duct injury incidence per single center for **A** Group A ($r = -0.00002$; $p = 0.92$) and **B** Group B ($r = -0.00004$; $p = 0.88$).

the diagnosis (intraoperative/postoperative), treatment (immediate/delayed; laparoscopic/open/endoscopic/percutaneous/combined), outcomes, and sequelae during the follow-up period were abstracted. Any controversy was resolved by consensus. All BDIs were classified according to Strasberg et al. [23]. Bilomas occurring as a result of cystic duct stump leaks or self-resolving postoperative drainage of bile were excluded from the study.

The main outcome measures were rates of conversion to OC, incidence of BDI, and overall major morbidity and mortality rates during the follow-up period. Further analysis included age, gender, ASA status, clinicopathologically favorable conditions, experience of the surgeon, presumed dynamics of the lesion, classification, timing of the diagnosis, and type of management.

Confidence intervals (CI) were always calculated at 95%. Statistical analysis between the two groups was performed using the χ^2 test and Fisher's exact test for ordinal variables, and unpaired two-tailed t-test and Mann–Whitney U test for continuous variables. Correlations between the main outcome measures per single center were performed by linear regression analysis. The p value cutoff for statistical significance was set at 0.05.

Results

The questionnaire was returned by 13 centers, giving a total number of 6,419 LCs for group A. During the prospective audit (group B) that involved 22 centers, 7,299 LCs were performed. No significant differences between the two groups were found regarding conver-

sion, BDI, or morbidity and mortality rates (Table 1). No significant correlations were found concerning the effect that the number of LCs performed (Fig. 1) and theconversion rates (Fig. 2) had on theBDI rates per single center. All but three BDI cases (90.9%) were followed up for a median of 3.2 years (Table 1).

The demographic data are presented in Table 2. No clinicopathologic justification for BDI (simple gallbladder lithiasis treated electively without adhesions, inflammation, or anatomic abnormalities) was found in 9 of 33 cases (27.3%). No significant differences ($p = 0.44$) were found between group A (6/17; 35.3%) and group B (3/16; 18.8%). In the remaining cases, chronic cholecystitis with adhesions was present in 12 cases, acute cholecystitis in 7 cases, Mirizzi syndrome in 3 cases, and cholecystoenteric fistula in 2 cases, without significant differences in the distribution between the two groups.

The surgeons' years of experience as a specialist were significantly more in group B than in group A (mean ± 95% confidence interval [CI], 13.9 ± 1.8 versus 11.0 ± 3.2; $p = 0.05$), as also was ($p = 0.005$) the number of LCs previously performed (Fig. 3).

Concerning the causes for BDI, 24 (72.7%) resulted from direct injury, 7 (21.2%) from electrocautery thermal injury, and the remaining 2 (6.1%) from misplace-
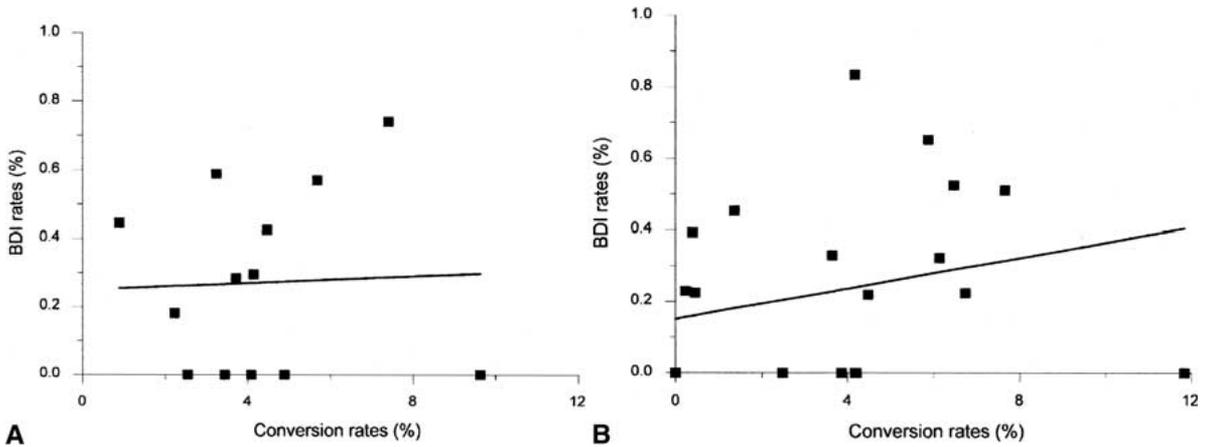
Fig. 2. Linear regression analysis of the effect that the conversion rates had on bile duct injury incidence per single center for **A** Group A ($r = 0.005$; $p = 0.89$) and **B** Group B ($r = 0.02$; $p = 0.22$).

Table 2. Demographic data for 33 cases of bile duct injury

	Overall	Group A	Group B	p value
Gender n (%)				
Males	13 (39.4)	6	7	0.60
Females	20 (60.6)	11	9	
Age (mean ± 95% CI for years)	56.9 ± 5.4	59.0 ± 8.2	54.7 ± 8.0	0.43
ASA status n (%)				
I	18 (54.5)	6	12	0.05
II	13 (39.4)	9	4	
III	2 (6.1)	2	—	

95% CI, confidence intervals at 95%; ASA, American Society of Anesthesiology

ment of clips. The ''French'' technique resulted in 27 BDIs (81.8%), and the remaining 6 BDIs occurred (18.2%) with the ''American'' technique. A 0° optic was used for 26 BDIs (78.8%), and a 30° optic was used for the remaining 7 (21.2%). The dissecting instrument was a scissors for 17 BDIs (51.5%), a hook for 13 BDIs (39.4%), and a Maryland dissector for the remaining 3 BDIs (9.1%). Intraoperative cholangiography before the occurrence of a BDI was performed in only five cases (15.1%). No significant difference in the distribution for any of these patterns was found between the two groups.

There were 18 (54.5%) type D injuries (partial laceration of common bile duct), 7 (21.2%) type E1 injuries (complete laceration > 2 cm), 3 (9.1%) type E2 injuries (complete laceration < 2 cm), and 5 (15.2%) type E3 injuries (complete laceration involving the hilar bifurcation of the hepatic duct), without any difference in the distribution of these injury types between the two groups.

An intraoperative diagnosis of BDI was performed in 23 of 33 cases (69.7%). No significant differences ($p = 0.26$) were found between group A (10/17; 58.8%) and group B (13/16; 81.2%).

The type of management in the case of intraoperatively diagnosed BDI was not significantly different between the two groups, whereas endoscopic and percutaneous treatment was significantly more used in group B than in group A in the case of postoperative diagnosis (Table 3). The details concerning the specific type of repair for BDI are presented in Table 4.
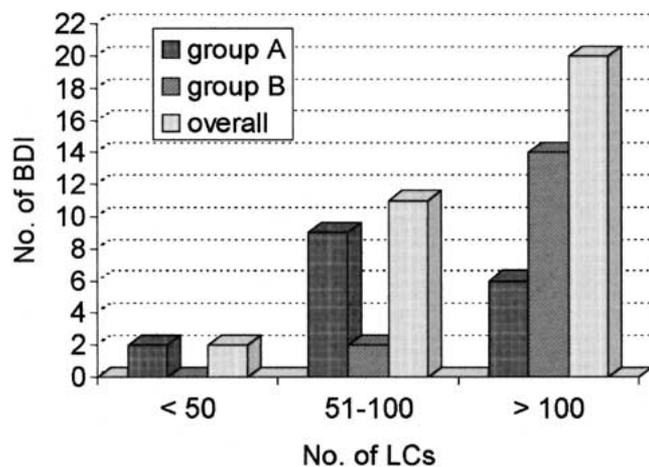
Fig. 3. Distribution of 33 bile duct injury cases according to the number of laparoscopic cholecystectomies (LCs) performed previously by a single surgeon.

Discussion

During the 1990s, LC rapidly became the standard surgical treatment for symptomatic cholelithiasis. Unfortunately, the results of audits, national surveys, and the large number of patients with iatrogenic biliary injuries referred to tertiary centers suggest that LC still is associated with an higher risk of BDI than OC [5, 10, 14, 18]. In addition, findings have shown that LC-associated

Table 3. Type of management in 33 cases of bile duct injury

Treatment type	Overall	Group A	Group B	p value
Intraoperative diagnosis	23	10	13	
Laparoscopic	4	1	3	0.30
Open	19	9	10	
Postoperative diagnosis	10	7	3	
Surgical	8	7	1	0.01
Endoscopic, percutaneous	2	—	2	

Table 4. Detailed types of repair in 33 cases of bile duct injury

Type of repair	Overall	Group A	Group B	p value
Intraoperative diagnosis	23	10	13	
T-tube	9	4	5	0.73
Hepaticojejunostomy	8	3	5	
End-to-end on T-tube	3	2	1	
Laparoscopic direct suture	3	1	2	
Postoperative diagnosis	10	7	3	
T-tube	3	2	1	0.02
Hepaticojejunostomy	5	5	—	
Endoscopic and/or percutaneous drainage	2	—	2	

BDIs are more complex than OC-associated BDIs, more frequently involve the proximal bile duct, and result more extensive stricture formation [2, 6, 15, 19, 23]. Therefore, BDIs represent the main shortcoming of LC, and some patients have required hepatic transplantation for survival [16].

In the current study, we compared the incidence, mechanism, and clinical relevance of BDIs during LC in the area of Rome using a retrospective survey rather than a prospective audit. A total of 13,718 LCs and 33 BDIs (0.24%) were collected.

No significant differences were found regarding conversion, BDI, or morbidity and mortality rates between the two groups (Table 1). No significant correlations were found concerning the effect that the number of LCs performed (Fig. 1) and the conversion rates (Fig. 2) had on the BDI rates per single center. Management in the case of a intraoperative BDI diagnosis was not significantly different between the two groups, whereas endoscopic and/or percutaneous treatment was used significantly more in group B than in group A in the case of a postoperative diagnosis (Table 3). We also observed some nonsignificant trends: a slight increase in the intraoperative diagnosis of BDI in group B, a reduction of BDI cases without pathologically favorable conditions in group B, and reduction of morbidity and mortality rates in group B.

As for the similar incidence of conversion to OC and BDI in the two groups, there may be a trend toward a reduction of these events during LC because prospective audit is more reliable than a retrospective survey [24]. Retrospective surveys are generally biased by the well-known tendency of surgeons to underestimate the frequency of past complications. On the other hand, this memory bias is unlikely to affect the recollection of serious complications with great emotional impact, such as biliary tract injury. Given the sensitive nature of these iatrogenic injuries, we believe indeed in the reliability of the results of this study. Conversion and BDI rates during LC appear therefore to be stable over the past 8 years in the area of Rome and its province.

A potential source of bias in this study could have come from the lower number of centers participating in the retrospective survey (group A) because it may have determined an underreporting of BDIs in this group. Actually, considering only the same 13 centers also in group B, there were 8 BDIs in 3,701 LCs (0.22%), without any significant change in comparison with group A and overall group B results.

There was no correlation between the number of LCs, the conversion rate, and the BDI rate in the two groups. Without any doubt, this means that the "bile duct injury" phenomenon is not influenced by these factors, as shown in other series [25].

Furthermore, surgeon experience was unrelated to the incidence of BDI during LC. Most BDIs occurred in both groups during LCs performed by older surgeons who had experience with more than 100 LCs (Fig. 3). In other words, BDIs seem related to the technique of the operation itself rather than the training of the surgeon [8]. A recent population-based report found that increasing experience was unrelated to the incidence of biliary tract injury during LC [3]. Likewise, other studies have showed, that the learning curve is not important in determining when in a surgeon's experience a bile duct injury would occur during LC [1, 7]. It therefore seems reasonable to conclude that learning curves in LC are no longer relevant, and that an occasional bile duct injury is inherent to the technique of LC [13, 26].

A recent meta-analysis of the available literature on BDIs [9] showed that BDI incidence was 0.21% and intraoperative BDI diagnosis was 87% when intraoperative cholangiography was performed on a routine basis, as compared with 0.43% and 44.5%, respectively, when it was used on a selective basis. In the current study, intraoperative cholangiography was used on a selective basis by all the participating centers. This policy did not change over time or between the two groups. Therefore, we have no data to support the intuitive conclusion that intraoperative cholangiography may lower the incidence and the clinical outcome of BDIs.

The group B patients experienced nonsignificantly lower morbidity and mortality rates and were more frequently treated through an endoscopic and/or percutaneous approach postoperatively ($p = 0.01$, statistically significant). Given the small number of patients, we cannot derive a conclusion from these data. Nevertheless, two possibilities must be suggested. Either we may be improving the postoperative management of patients with BDI after LC, or, most probably, the group B patients had a shorter follow-up periods, so no long-term morbidity and mortality rates are available at this time.

In the current study, we also observed a slight nonsignificant increase in the intraoperative diagnosis of BDI in group B and a nonsignificant reduction of BDI cases without pathologically favorable conditions in

group B. These two findings probably result from the small number of patients and may not correspond to substantial changes.

In conclusion, the conversion rate and incidence of BDIs during LC in the area of Rome showed no substantial changes during the past 8 years, suggesting that BDIs are a stable phenomenon during LC. The use of a prospective audit rather than a retrospective survey and the increasing experience with LC did not affect the overall incidence of BDI in the current multicenter study.

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