Hypothesis: Bile duct injury (BDI) remains the most serious complication of cholecystectomy. With laparoscopic cholecystectomy (LC), the incidence has become more frequent. This study verifies the current incidence, mechanism, presentation, and treatment of BDI occurring during LC in general surgical practice.

Design: Anonymous retrospective multicenter survey.

Setting: Department of surgery at a university referral center, collecting data from general surgical units.

Patients: Data from 56,591 patients who underwent LC between January 1, 1998, and December 31, 2000, in 184 hospitals in Italy were analyzed.

Main Outcome Measures: Current incidence, mechanism, presentation, and treatment of BDI occurring during LC in general surgical practice.

Results: Two hundred thirty-five BDIs were reported, with an overall incidence of 0.42%. There were no risk factors in 80.0% of the patients. Poor identification of the anatomical features of the hepatic pedicle was the most frequently reported cause (36.8%), and technical problems accounted for 27.0% of causes. The incidence of BDI was higher during cholecystitis (P<.001) and decreased with increasing number of LCs performed by the surgical teams (P<.01). There was no difference in incidence according to technique (French or US) or to routine or selective intraoperative cholangiography. One hundred eight BDIs (46.0%) were recognized intraoperatively and immediately repaired in 89.8% of patients. One hundred twenty-seven BDIs (54.0%) were diagnosed postoperatively, the dominant manifestation being biliary fistula (44.1%).

Conclusions: This study confirms a higher incidence of BDI during LC. It highlights the relevance of the number of previously performed LCs and of the correct surgical technique to avoid BDI. The need for correct procedures, adequate expertise of the repairing surgeon in BDI repairs, and a multidisciplinary approach in the management of BDI is emphasized.

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Methods

The national survey was based on anonymous questionnaires sent to 316 heads of surgical units, all members of the Italian Society of Surgery.

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Questions were divided into 4 main sections. The first section included general information on the number of LCs performed in the 3-year period (1998-2000) in each unit, use of the French technique (ie, surgeon between the
legs of the patient, umbilical telescope, operating port in left upper quadrant, liver retractor in epigastrum, and grasper in right upper quadrant) or the US technique (ie, surgeon to the left of the patient, umbilical telescope, operating port in epigastrum, and liver retractor and grasper in the right upper quadrant), use of intraoperative cholangiography and abdominal drainage, and number of BDIs that occurred during the 3-year period. The second section included preoperative data on BDI: indications for cholecystectomy, patient risk factors (obesity, previous abdominal surgery, and liver cirrhosis), and number of LCs performed by the surgical team (teams in Italy are usually composed of permanent members of hospital staff with prolonged collective shared experience). The third section included intraoperative data on BDI: technical complexity of LC, identification of the cause of injury, recognition of the injury (by the presence of bile in the operative field, at cholangiography, or by other modalities), immediate treatment, and immediate results. The fourth section included postoperative data on BDI: clinical presentation of the injury and decisions on treatment. The sources of data were in-depth medical record reviews, operative dictations, and detailed written records of the units. Statistical analysis was performed using Stata 7.0 software (Stata Corp, College Station, Tex), with data expressed as means, medians, and ranges and with the use of χ² and Fisher exact tests.

RESULTS

The survey collected 56,591 LCs from 184 Italian surgical units (response rate, 58.2%) between January 1, 1998, and December 31, 2000. The geographical distribution throughout the country was homogeneous.

INCIDENCE OF BDI

A total of 235 BDIs were reported (overall incidence, 0.42%). These were major injuries (involving the common bile duct [CBD], main biliary confluence, or main bile ducts) in 178 patients (75.7%) and minor injuries (involving the cystic duct or small peripheral or Luschka ducts) in 57 patients (24.3%).

The incidence of major injuries was 0.31%, ranging from 0% to 3.75% in individual units. At least 1 injury was reported by 68.5% (126/184) of the units.

CAUSES AND MECHANISMS OF BDI

These were identified in 163 patients (69.4% of cases). The most frequently reported cause was poor identification of the anatomical features of the hepatic pedicle (36.8% of cases), followed by inflammatory changes in the gallbladder (23.3%), anatomical anomalies (12.9%), improper use of monopolar coagulation (12.3%), an unspecified technical mistake (9.8%), and a problem during the control of intraoperative hemorrhage (4.9%). Thus, technical mistakes, reflected by the latter 3 factors, accounted cumulatively for 27.0% of the recognized causes of injury.

With regard to the technical complexity of the operation during which the injury had occurred, the procedure was described as easy in 46.8% and difficult in 53.2% of cases, a rate that did not change significantly with the number of LCs performed.

RISK FACTORS FOR BDI

In 188 cases (80.0%), no risk factors related to the patient were reported. These were reported in only 47 cases (20.0%): obesity in 33, previous abdominal surgery in 9, and cirrhosis in 5. In 33 of these 47 cases, cholecystitis was an associated risk factor.

In 112 (47.7%) of the 235 BDIs, LC was performed for simple cholelithiasis; and in 123 (52.3%), for cholecystitis.

Laparoscopic cholecystectomies were performed for simple cholelithiasis in 61.1% of patients, and for cholecystitis in 38.9% of patients; the incidence of injuries was 0.32% in the former and 0.56% in the latter group of patients (P<.001).

The incidence of BDI significantly decreased with increasing number of LCs performed by the teams, ranging from 0.9% for teams who had performed fewer than 150 LCs in the 3-year period to 0.3% for those who had performed more than 450 LCs (P<.01). A similar result was observed for major injuries (Figure 1).

Interestingly, BDIs reported by teams performing more LCs were more frequently associated with cholecystitis (Figure 2), while those reported by teams performing
fewer LCs were more frequently associated with simple cholelithiiasis.

**SURGICAL TECHNIQUE**

The French technique was used in 123 units (66.8%) and the US technique in 58 units (31.5%). Three units (1.6%) did not answer this question. (Percentages do not total 100 because of rounding.)

One hundred sixty-six BDIs occurred in 85 units using the French technique (85/123 = 69.1%). For a total of 41,256 LCs, the incidence of BDI was 0.40% (and 0.29% of major injuries).

Sixty-eight BDIs occurred in 40 units using the US technique (40/58 = 69.0%). For a total of 15,239 LCs, the incidence of BDI was 0.43% (and 0.36% of major injuries).

The incidence of injuries was, thus, similar for units using different techniques.

**INTRAOPERATIVE CHOLANGIOGRAPHY**

Routine cholangiography was performed in 10.3% of the units, and a total of 25 BDIs occurred. Fourteen injuries (56.0%) were recognized during LC: 7 before performing cholangiography, by the presence of bile in the operative field, and 7 during cholangiography (in one case, the injury was caused by cannulation of the cystic duct). The incidence of BDI in these units was 0.32%.

Selective cholangiography was used in 89.7% of the units, and a total of 210 BDIs occurred. Ninety-four injuries (44.8%) were diagnosed during LC: 72 by the presence of bile, 14 at cholangiography, and 8 by the presence of a double biliary stump. The incidence of BDI in these units was 0.43%. Of the 94 patients who had a BDI diagnosed intraoperatively, only 43 (45.7%) underwent cholangiography after diagnosis.

The overall incidences of BDI (0.32% vs 0.43%) and of intraoperative diagnosis of BDI (56.0% vs 44.8%) were not significantly different in units using routine vs selective cholangiography (P = .25 and .38, respectively).

**DIAGNOSIS OF BDI AND TREATMENT**

A total of 108 BDIs (46.0%) were diagnosed during LC; these were 100 major and 8 minor injuries. The remain-

**Intraoperative Diagnosis of BDI**

Intraoperative diagnosis occurred in 79 cases (73.1%) by the presence of bile in the operative field, in 21 (19.4%) by cholangiography, and in 8 (7.4%) by the presence of a double biliary stump. (Percentages do not total 100 because of rounding.)

Major BDI occurred in 100 patients. Immediate repair of BDI was performed in 93 patients (93.0%), in 90 after laparotomy and in 3 during laparoscopy. The most frequent repair was suture or reconstruction of the CBD with positioning of a T tube (63.0%) (Table 1).

Immediate failure of repair was reported in 15 patients (15/93 = 16.1%): 7 required a subsequent operation within a week, 5 were treated endoscopically, I was treated percutaneously, and 2 were treated with a combination endoscopic/percutaneous method.

In 7 patients (7.0%), simple abdominal drainage was performed, in 6 during laparoscopy and in 1 after laparotomy (Table 1). Three of these patients needed a subsequent operation early, and 4 underwent endoscopic or percutaneous treatment.

Minor BDI occurred in 8 patients. Immediate repair of BDI was performed in 3 patients during laparoscopy and in 1 after laparotomy (followed in this patient by endoscopic treatment). In the other 4 patients, simple abdominal drainage was performed, in 3 during laparotomy and in 1 during laparoscopy.

**Postoperative Diagnosis of BDI**

The clinical manifestation was biliary fistula (bilious drainage from an operatively placed drain) in 44.1% of cases, bile peritonitis in 37.8%, and jaundice in 18.1%. When 2 or more manifestations coexisted, the dominant one determining management priorities was considered.

Biliary fistula tended to be more frequently associated with a minor than a major injury (58.9% vs 41.1%; P = .30). Bile peritonitis was associated more frequently with a major injury (66.7% vs 33.3%; P < .005), and jaundice was always associated with a major injury (100.0% vs 0%; P < .005).

The clinical manifestation of a BDI was only partly conditioned by the presence of an abdominal drainage. Abdominal drainage was used routinely in 45.7% (84/184) of units. In these units, 55 BDIs were diagnosed postoperatively, and the most frequent clinical presentation (60.0% of cases) was an external biliary fistula; this was associated with bile peritonitis in an additional 27.3% of cases. In the 54.3% (100/184) of units in which drainage was not used routinely, 72 BDIs were diagnosed postoperatively, and the most frequent clinical presentation was bile peritonitis (45.8% of cases). The manifestation through a biliary fistula was more frequent in units using routine abdominal drainage (P = .002), whereas bile peritonitis was more frequent in units not using routine drainage (P = .03).
Treatment of Postoperatively Diagnosed BDI

Surgical treatment was performed in 60.6% of patients, and endoscopic or radiologic treatment in 19.7% of patients (Table 2).

There were 56 patients with a biliary fistula: 23 (41.1%) had a major injury and 33 (58.9%) had a minor injury.

For the 23 major injuries, the most common treatment was surgical repair (Table 3). For the 33 minor injuries, the most common treatment was endoscopy (13 patients, or 39.4% of cases). In 11 patients (33.3%), the fistula closed spontaneously. Of the remaining 9 patients (27.3%), 7 underwent a new laparoscopy with closure of the cystic stump or of a minor bile duct and 2 underwent laparotomy (in one case, combined with endoscopy).

There were 48 patients with bile peritonitis: 32 (66.7%) had a major injury and 16 (33.3%) had a minor injury.

For the 32 major injuries, the most common decision was to reoperate immediately on the patient to drain the bile peritonitis and at the same time repair the injury (Table 4). For the 16 minor injuries, the most frequent treatment was also surgical drainage and simultaneous repair of the injury (9 patients [56.2%]). In the other 7 patients (43.8%), treatment was by endoscopy, in 5 after surgical or percutaneous drainage of the abdomen.

There were 23 patients with jaundice, all with a major injury. Surgical treatment was most common, and in 12 patients (52.2%), was performed within 15 days of LC (Table 5).

These data provide the most recent and comprehensive information on BDI associated with LC in Italy.

The relevance of this survey is supported by the high rate of response to the questionnaire (58.2%), higher than the mean rate for similar national surveys pub-
lished during the past 10 years (43.7%) (Table 6). Furthermore, the geographical distribution of participating surgical units throughout the country was homogeneous, as was the distribution of surgical teams with different expertise.

The survey was limited to a brief period (3 years) to facilitate verification of data, and was performed long enough (10 years) after the introduction of LC in Italy to grant stabilization of the learning curve in the interviewed units.

The reported incidence of major BDI during LC ranges from 0.25% to 0.74%, and that of minor BDI from 0.28% to 1.7%. In our survey, the overall incidences of injuries and major injuries were 0.42% and 0.31%, respectively, and were, thus, similar to those reported in other Western national surveys. Contrary to the results of another recent report, this confirms that the incidence of BDI during LC remains higher than during traditional cholecystectomy.

Since the early days of LC, a higher incidence of injuries has been related to the learning curve of the surgeon, also in our survey, the incidence has increased significantly with decreasing volume of LCs performed. However, this explanation alone is insufficient, and analysis of BDI occurring after stabilization of the learning curve has shown that one third of injuries may still be related to technical mistakes. Therefore, a critical component is also the correct operative technique.

Misidentification of the CBD for the cystic duct (the classical injury) is reported most commonly as the cause of BDI. The cause may also remain unrecognized, and this occurred in 30.6% of cases in our survey. In about a quarter of the patients in whom the cause was recognized, this was related to the surgical technique, and misidentification of the CBD for the cystic duct accounted for most injuries (36.8%).

Our results confirm that no cholecystectomy can be considered as a simple routine procedure, immune to the risk of BDI. Indeed, about half of BDIs occurred during LCs described as “technically easy”: furthermore, in 80.0% of injuries, no risk factors related to the patient were present. Among risk factors, the survey confirms the importance of cholecystitis, by showing a higher incidence of BDI in the presence of cholecystitis compared with simple cholelithiasis (0.56% vs 0.32%, P<.001). Interestingly, BDIs were more often associated with cholecystitis in teams performing more LCs, and with simple cholelithiasis in teams performing fewer LCs. This probably reflects a more cautious attitude of the latter in the presence of cholecystitis, with less frequent use of laparoscopy or more frequent conversion. This may highlight the importance of conversion to laparotomy in difficult cases.

With regard to the choice of the French or US technique, neither one, if correctly used, seems to be associated with an increased risk of injury, and indeed, the risk was not significantly different in our survey. With either technique, the critical points are good exposure of the cystic duct and hepatic pedicle and adhesion to the same principles that apply to laparotomic cholecystectomy. This was emphasized recently by Strasberg et al, who reported that in more than 80% of cases of a series of BDIs, the cystic duct had been interrupted prematurely before completing identification and preparation of anatomical structures.

Opinions on the advantages of routine vs selective use of intraoperative cholangiography are still diverging. Routine cholangiography should reduce the risk of BDI by providing a clear map of the biliary tree and of its variants and a more prompt diagnosis of unsuspected injuries, thus avoiding an increase in their complexity. However, this has not yet been proved. Furthermore, in some instances, cholangiography may not prevent the injury or may carry its own risk of causing an injury. In our survey, 10.3% of units were using routine cholangiography, and these did not report a significantly different incidence of BDI or of intraoperatively recognized injuries. Whatever the explanation of these results (incorrect execution or interpretation of cholangiography or occurrence of the injury after cholangiography), routine cholangiography does not seem to entirely protect from BDI.

In units not using routine cholangiography, it was surprising that 54.3% of the patients with intraoperatively recognized BDIs (presence of bile in the operative field) did not undergo subsequent intraoperative cholangiography. Indeed, independently of the preference for routine or selective cholangiography, the cholangiographic assessment of an already recognized lesion is essential to the choice of appropriate treatment. This is also a reason for including intraoperative cholangiography in the training for LC.

The issue is also relevant for the appropriate timing of BDI repair, because a factor increasing the chances of a successful immediate repair is adequate intraoperative

### Table 6. Rate of Reply to National Surveys on BDI During LC

<table>
<thead>
<tr>
<th>Source</th>
<th>Country</th>
<th>No. of Mailed Questionnaires</th>
<th>No. of Answered Questionnaires</th>
<th>Rate of Reply, %*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deziel et al, 1993</td>
<td>United States</td>
<td>4292</td>
<td>1750</td>
<td>40.8</td>
</tr>
<tr>
<td>Gouma and Go, 1994</td>
<td>The Netherlands</td>
<td>138</td>
<td>122</td>
<td>88.4</td>
</tr>
<tr>
<td>Gigot et al, 1997</td>
<td>Belgium</td>
<td>98</td>
<td>75</td>
<td>76.5</td>
</tr>
<tr>
<td>Windsor and Pong, 1998</td>
<td>New Zealand</td>
<td>164</td>
<td>111</td>
<td>60.3</td>
</tr>
<tr>
<td>Torkington et al, 1998</td>
<td>United Kingdom–Ireland</td>
<td>1100</td>
<td>362</td>
<td>32.9</td>
</tr>
<tr>
<td>Regoly-Merei et al, 1998</td>
<td>Hungary</td>
<td>119</td>
<td>105</td>
<td>88.2</td>
</tr>
<tr>
<td>Archer et al, 2001</td>
<td>United States</td>
<td>3657</td>
<td>1661</td>
<td>45.4</td>
</tr>
<tr>
<td>Present study, 2002</td>
<td>Italy</td>
<td>316</td>
<td>184</td>
<td>58.2</td>
</tr>
</tbody>
</table>

Abbreviations: BDI, bile duct injury; LC, laparoscopic cholecystectomy.

*The average rate of reply for all evaluable surveys, excluding the last one (the Italian survey), was 43.7% (calculated as 100 × [total number of replies/total number of questionnaires]).
Another major component is the adequate expertise of the surgeon in BDI repair. These are important points because failure of immediate repair worsens the injury, increases the complexity of subsequent repairs, and impairs short- and long-term results.\(^{1,17,24,20,30}\) Also, the decision to convert to laparotomy depends on the balance between expertise of the surgeon and complexity of the injury. If the conditions for an optimal treatment are not available, even after laparotomy, an adequate choice is simple drainage of the abdomen and referral to a tertiary care center.

In our survey, immediate recognition of the injury took place in 46.0% of cases, which falls within the range (27%-73%) observed in previous multicenter surveys.\(^{2,8,13,31}\) There was a high rate of conversions (91.0%) and of immediate repair of major BDIs (93.0%), mostly with T-tube reconstructions, which are known to have the risks of dehiscence and long-term stricture.\(^ {17}\) Although treatment of strictures may be performed successfully by endoscopic stenting,\(^ {22}\) repairs over a T tube should be reserved only for small side wall injuries, while major BDIs and total transactions should be treated with hepaticojjunostomy.

With regard to postoperatively recognized BDI, after the introduction of LC, rates of occurrence of biliary fistula and bile peritonitis have increased, although biliary fistula is caused more frequently by a minor BDI.\(^ {20,23}\) This was also the case in our survey, in which biliary fistula accounted for 44.1% of postoperative manifestations. There was a significantly more frequent association of bile peritonitis with major BDI, and jaundice was always due to a major BDI. A corollary of these findings is also the tendency of major injuries associated with LC to be more complex than those that were previously associated with open cholecystectomy.

The fact that 27.3% of patients undergoing drainage developed bile peritonitis despite the drainage may emphasize the importance of the correct positioning of drainages of adequate size (small sizes are usually used in LC) following the decision to drain the abdomen. However, the presence of drainage may not totally protect from the occurrence of bile peritonitis.

The treatment of postoperatively recognized injuries was surgical in 60.6% of patients, with a definite tendency to subsequently operate early on those with biliary fistula or jaundice. In patients with bile peritonitis, the most common decision was to reoperate quickly, with simultaneous repair of the lesion, and only 6.3% of patients were referred to a tertiary care center. Although our survey did not address long-term success (and results are, thus, unknown), these high percentages of early repair, and those of immediate repair in intraoperatively recognized BDIs, do not correspond with the diffusion of expertise in complex hepatobiliary surgery and repairs, and are partly in contrast with the indications reported in the literature. For instance, the indication for simultaneous repair of a major injury during surgery for drainage of bile peritonitis is not largely accepted.\(^ {34,37}\) Furthermore, in the case of a major injury with a biliary fistula, which is well drained and not associated with other complications (in particular with sepsis), urgent repair is not needed. Also, an accurate cholangiographic assessment may show that surgical treatment is not needed or, conversely, that it requires a more expert surgeon. A recent large survey\(^ {30}\) has shown that outcome in patients with BDI after cholecystectomy is worse for those repaired by the same surgeon who caused the injury, and improves with the experience of the repairing surgeon.

The choice of type and timing of repair of a postoperatively recognized injury should take into account 2 important aspects. First, the recent advances in endoscopy and interventional radiology should be considered, which may quite often permit an appropriate nonsurgical treatment, especially in the case of minor BDI or partial injuries of the CBD.\(^ {20,32,30,40}\) In our survey, this occurred in 19.7% of postoperatively recognized BDIs, a rate that probably underestimates the actual impact of nonsurgical treatment of BDIs. This greatly emphasizes the need for multidisciplinary care of these patients. Second, experience with surgical repairs has shown that the best results are generally obtained by repairs on a dilated biliary tree, performed by a surgeon expert in biliary repair, at a distance from cholecystectomy.\(^ {1,17,30,37}\) This may be about 2 weeks after cholecystectomy in the case of jaundice without secondary complications or about 2 months after cholecystectomy in the case of bile peritonitis or biliary fistula, after complete control of sepsis and other secondary complications and total recovery of good health and nutritional state.

In conclusion, BDI during LC represents a risk for every general surgeon. This may be a severe complication, and, quite often, a young patient is involved. The frequency of BDI remains higher than that reported for open cholecystectomy. Our survey provides an overview of risk factors, mechanisms, type, severity, and patterns of detection and repair of BDI. It highlights the importance of surgical experience and correct technique to avoid BDI. In turn, the optimal management of BDI requires the use of correct procedures with regard to choice, timing of repair, or referral to a tertiary care center. A multidisciplinary approach in dedicated centers may also be needed, as more patients benefit from nonsurgical treatments.

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