

ORIGINAL ARTICLE

Bile duct injury following cholecystectomy: delayed referral to a tertiary care center is strongly associated with malpractice litigation

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Abstract

Background: Bile duct injury (BDI) following cholecystectomy is associated with malpractice litigation. Aim of this study was to evaluate risk factors for litigation in patients with BDI referred in a tertiary care center.

Methods: Patients treated for BDI between 1994 and 2016. Stabilized inverse probability therapy weighting was used and multivariable logistic regression analysis identified risk factors for malpractice litigation.

Results: Of the 211 treated patients, 98 met the inclusion criteria: early-referral group (<20 days; 51.0%), late-referral (≥20 days; 49.0%). 36 patients (36.7%) initiated malpractice litigation with verdict in favor of plaintiff in 86.7% of cases (median payment = €90 500, up to €600 000). Attempts at surgical and endoscopic repair before referral were significantly higher in late-referral group. Failed postoperative management (delayed referral, attempts at repair before referral) was one of the strongest predictors for litigation. Risk of litigation progressively increased from 23.8%, when referral time was within 19 days, to 54.5% (61–120 days), to 60.0% (121–210 days) and to 65.1% (211–365 days).

Discussion: Litigation rate after BDI was 37%. Delayed referral to tertiary care center was one of the strongest predictors for litigation. Prompt referral to tertiary experienced centers without any attempt at repair may reduce the risk of litigation.

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Introduction

Laparoscopic cholecystectomy is considered as the gold standard treatment of gallbladder stones and it is one of the most common routine interventions performed worldwide.¹ It has been estimated that about 750,000 cholecystectomies are performed annually in the United States and the vast majority of which are laparoscopic.^{2,3}

Bile duct injuries (BDIs) are dangerous complications of cholecystectomies. The reported incidence of BDI ranges between 0.4% and 0.5%.^{4–6} BDIs may be complex, in about 14% of

cases associated with vascular injuries⁷ and they require prompt diagnosis and multidisciplinary management in expert referral centers.⁸

BDIs are associated with significant postoperative sequelae in terms of morbidity, mortality and long-term quality of life (work-related limitations, loss of productivity, disability).^{9–11} This impaired quality of life has been reported even years after BDI treatment, mainly due to recurrent cholangitis, biliary strictures requiring repeated treatments and in some cases to the occurrence of biliary cirrhosis.¹² These complications convert a seemingly easy surgical procedure for a benign condition often in young patients, to a severe long-term problem that may become life-threatening and it is associated with poor quality of life. For these reasons, litigation claims are increasingly common in the

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field of BDI following cholecystectomy. In Europe, it has been estimated that about 19–32% of patients with BDI are involved in a malpractice litigation.^{8,12,13} This implicates high costs for the health service.¹⁴ However, in the literature, few papers published information on the probability of litigation in case of BDI.^{13,15–18}

Aim of this study was to evaluate the incidence and risk factors associated with malpractice litigation in patients with BDI following cholecystectomy, referred in a tertiary care center.

Methods

Study design

This is a retrospective monocentric observational study investigating data of all patients referred and treated at our center with BDI occurring during cholecystectomy between January 1994 and December 2016.

Patients were referred to our center from community hospitals. Community hospitals were defined as public hospitals that serve local populations. In community hospitals there are digestive endoscopy units where endoscopic retrograde cholangiopancreatography (ERCP) may be performed, radiology departments with interventional radiology services, and general surgery units. In community hospitals there are no specialized hepatobiliary surgery units.

Population

Inclusion criteria: patients with at least 5 years of follow-up and patients who agreed to participate in a telephone questionnaire focusing on malpractice litigation. Patients were given the choice of declaring the amount of compensation, if any.

Exclusion criteria: patients with a referral time >1 year from cholecystectomy. Such patients were excluded from the analysis because they were not managed at our center during an acute phase of BDI but because of a stricture of a previous hepaticojejunostomy.

BDIs were classified according to Strasberg classification.¹⁹ The severity of BDI was classified as: severity Grade 1 (Type A and D injuries, that are cystic duct leak or lateral injuries which do not result in discontinuity of the biliary tract) and severity Grade 2 (Type B, C, E 1–5, that are axial injuries which result in discontinuity of the biliary tree).

As previously described,²⁰ our database used for all patients, included the type of BDI and its severity, timing of injury diagnosis, therapeutic procedures performed before referral, time of referral, subsequent management. Follow-up consisted of periodic evaluation on an out-patient basis or by telephone interview, together with laboratory tests, liver ultrasound, and magnetic resonance cholangiography if necessary. The evaluation took place every 4 months for 2 years, every 6 months for 3 years, and yearly thereafter.

The outcome of treatment of BDI at our center was assessed according to the grading of patency both for surgical treatment

and for endoscopic/interventional radiologic treatment, as described in the paper by Cho et al.²¹ As stated in that study,²¹ patency is defined as an open functional biliary tree, free of stents, and free of the need for invasive interventions, in a patient who, following completion of treatment, has no episodes of cholangitis, liver abscess, jaundice or external biliary fistula. There are 4 grades of patency: Grade A is primary patency achieved; Grades B–D are for patients who failed to achieve primary patency in the index treatment period or who subsequently lost patency.²¹

Outcomes

The main outcome of the study was to evaluate predictive factors of malpractice litigation related to BDI occurring during cholecystectomy. The last follow-up date was January 31st, 2021.

Statistical analysis

Continuous variables were reported as medians and inter-quartile ranges (IQR). Categorical variables were described as numbers and percentages. Comparisons between groups were made using Fisher's exact test or chi-square test for categorical variables, as appropriate. Mann–Whitney was used for continuous variables.

The entire population was preliminarily divided into two groups according to the referral time after cholecystectomy. The cut-off used for stratifying the population into two groups was arbitrarily set at the median value of 19 days.

With the intent to compensate for the non-randomized design of this retrospective study, the two groups were “balanced” using a stabilized inverse probability therapy weighting (IPTW). We generated a propensity score for each patient on the original population. The score was created using a multivariate logistic regression model considering the variable “malpractice litigation” (no vs. yes) as the dependent variable. We selected 13 possible clinically relevant confounders as covariates: gender, age, severity grade of BDI, vascular injury, intraoperative diagnosis, intraoperative surgical attempts at repair, overall surgical attempts at repair before referral, endoscopic attempts at repair before referral by ERCP, number of ERCP procedures before referral, percutaneous attempts at repair before referral by percutaneous transhepatic cholangiography (PTC), number of PTC procedures before referral, BDI surgical repair at our center, patency grade after treatment at our center.

The IPTW generated a pseudo-population dataset in which the original treated and control cases were reweighted with the intent to create “pseudo-data” in which there is no longer an association between the confounders and treatment.

With the intent to reduce the artificial increase of the sample size, and, therefore, of the type I error rate (i.e., the increased number of false positives) caused by the inflated sample size in the pseudo data, we used stabilized weights (SW) according to the formula: $SW = p/PS$ for the study group, and $SW = (1-p)/(1-$

PS) for the control group, where p is the probability of etiology without considering covariates and PS is the propensity score.

Because p -values can be biased from population size, results from the comparisons between covariates subgroups were reported as effect size (Cohen's D value): values lower than $|0.1|$ indicated very small differences between means, values between $|0.1|$ and $|0.3|$ indicated small differences, values between $|0.3|$ and $|0.5|$ indicated moderate differences, and values greater than $|0.5|$ indicated considerable differences.

A multivariable logistic regression analysis was done in the post-IPTW population to identify the risk factors for malpractice litigation. The same 13 covariates used for constructing the IPTW were investigated. The best model was constructed selecting the most statistically significant covariates with a backward conditional approach. Odds ratios (OR) and 95.0% confidence intervals (95.0%CI) were reported for significant variables.

Variables with a $p < 0.05$ were considered statistically significant. Statistical analyses and plots were run using the SPSS statistical package version 27.0 (SPSS Inc., Chicago, IL, USA).

Results

Between 1994 and 2016, 210 patients with BDI occurring during cholecystectomy were referred at our center.

Four patients (1.9%) died for septic complications before starting any type of treatment at our center and they were excluded from this analysis: one patient presented with Strasberg E3 BDI and three with Strasberg E4 BDI, associated in one patient with vascular injury. The median interval time in such patients between cholecystectomy and referral was 48.5 days. A 66-year-old woman (Strasberg E3 BDI) was referred with bile peritonitis 3 months after open cholecystectomy and subsequent hepatico-jejunostomy, and she died from septic shock shortly after referral despite surgical drainage of the abdomen. Two patients (Strasberg E4 BDI) were referred after cholecystectomy with percutaneous biliary drainages and bile peritonitis; they presented with *Candida albicans* septicemia and they developed irreversible multiple organ failure despite surgical drainage of the bile peritonitis. Finally, a 64-year-old man (Strasberg E4 BDI) was referred at our center after liver packing for postoperative hemorrhage following cholecystectomy. At admission the CT scan documented an associated vascular injury of the proper hepatic artery and the patient died for septic complications and irreversible multiple organ failure.

Out of the 206 remaining patients who were treated at our center, 125 (60.7%) agreed to participate in the questionnaire. Of these, 27 patients were excluded from the analysis because the referral time was >1 year. The remaining 98 patients were referred at our center after a median length of 18.5 days (IQR = 10–83) following cholecystectomy, and they are the object of our study. Characteristics of patients are summarized in Table 1. The mean age was 54.6 ± 15 years (median 56 years; IQR

Table 1 Characteristics of the 98 patients with BDI treated at our center

Variable	
Age, years, median (IQR)	56 (43–66)
Male sex, No. (%)	44 (44.9)
Type of BDI (Strasberg classification), No. (%)	
A	10 (10.2)
B	2 (2.04)
C	2 (2.04)
D	15 (15.31)
E (all types)	69 (70.41)
E1	1 (1.0)
E2	9 (9.2)
E3	33 (33.7)
E4	21 (21.4)
E5	5 (5.1)
Severity of BDI, No. (%)	
Strasberg grade 1 (Type A, D)	25 (25.5)
Strasberg grade 2 (Type B, C, E)	73 (74.5)
Associated vascular injury, No. (%)	9 (9.2)
Timing of BDI diagnosis, No. (%)	
Intraoperative	38 (38.8)
Postoperative	60 (61.2)
Attempts at repair before referral, No. (%)	71 (72.4)
Only surgical intraoperative	16
Only surgical postoperative	6
Only ERCP	23
Only PTC	1
ERCP + PTC	3
Surgical intraoperative + surgical postoperative	4
Surgical intraoperative + postoperative ERCP	10
Surgical intraoperative + postoperative PTC	1
Surgical postoperative + postoperative ERCP	7
Surgical attempts at repair, No. (%) ^a	44 (44.9)
Intraoperative repair	27 (27.5)
Postoperative repair	13 (13.3)
Both intraoperative + postoperative repair	4 (4.1)
Type of surgical attempts at repair before referral	
Intraoperative repair	
Reconstruction with T-tube	13
Reconstruction without T-tube	12
Hepaticojejunostomy	6
Postoperative repair	
Reconstruction with T-tube	7
Reconstruction without T-tube	5
Hepaticojejunostomy	5
Endoscopic/percutaneous attempts at repair before referral, No. (%) ^b	45 (45.9)

(continued on next page)

Table 1 (continued)

Variable	
Number of ERCP procedures before referral, median (range)	1 (1–8)
Number of PTC procedures before referral, median (range)	1 (1–4)
Interval time between cholecystectomy and referral, days, 18.5 median (IQR)	(10–83)

^a Four patients underwent both intraoperative and postoperative attempts at surgical repair before referral.

^b Eighteen patients underwent both surgical and endoscopic/percutaneous attempts at repair before referral.

43–66). The severity grade of BDI was 1 in 25 patients (25.5%) and it was 2 in 73 patients (74.5%) (Table 1).

BDI attempts at repair before referral

Overall, surgical, endoscopic or percutaneous attempts at repair before referral were performed in 71 patients (72.4%) at community hospitals (Table 1). Surgical attempts at repair before referral were performed in 44 patients (44.9%): only intraoperative attempts at repair in 27 patients (27.5%), both intraoperative and postoperative attempts in 4 patients (4.1%) and only postoperative attempts in 13 patients (13.3%). Attempts at repair by endoscopic or percutaneous procedures before referral were performed in 45 patients (45.9%).

BDI repair after referral

The 98 patients of the study were referred at our center from community hospitals after a median time of 18.5 days (IQR = 10–83) following cholecystectomy. After referral, 57 patients (58.2%) underwent surgical repair (hepaticojejunostomy at the hilar plate in most cases: 89.5%; 51/57) and 32 patients (32.6%) underwent endoscopic treatment (Table 2). Surgical repair was significantly more frequently performed in severity grade 2 BDI than in severity grade 1 BDI (76.7% vs. 4.0%; $p < 0.001$). On the other hand, endoscopic treatment was significantly more frequently performed in severity grade 1 BDI than in severity grade 2 BDI (88.0% vs. 13.7%; $p < 0.001$) (Table 2).

Surgical repair after referral

Out of the 57 patients who underwent surgical repair at our center, 21 (36.8%) presented with external biliary fistula, 21 (36.8%) with obstructive jaundice and 15 (26.3%) with biliary peritonitis requiring surgical drainage of bile peritonitis.

Surgical repair was performed at our center after a median time of 46.5 days from referral (IQR = 10–118). The median time between referral and surgical repair in patients with external biliary fistula was 51 days (IQR = 18–99); in patients with biliary peritonitis the median time was 142 days (IQR = 91–203); in patients with obstructive jaundice the median time was 18 days (IQR = 5–47). The median time between referral and surgical repair was significantly different between the three groups ($p = 0.047$).

Long-term outcome after BDI repair at our center

After a median follow-up of 110 months [IQR 73–157], 83 patients (84.7%) achieved primary Grade A patency at 90 days post surgical repair or 12 months post endoscopic/percutaneous treatment as defined by Cho et al. (2) (Table 2). Rate of patency grade A was not significantly different between that obtained after surgical treatment and that obtained after endoscopic/percutaneous treatment (80.7% vs. 87.5%; $p = 0.411$, respectively) (Table 2).

Thirteen patients (13.3%) did not achieve their primary patency in the index treatment period or subsequently lost patency. In such patients a secondary patency was obtained by maintaining endoscopic stents or percutaneous drains within 24 months after initiation of treatment. Overall, primary or secondary patencies were finally achieved in 96 of the 98 treated patients (97.9%).

Table 2 Type of treatment at our center in the 98 patients with BDI

Variable	
Type of treatment at our center, No. (%)	
<i>Surgical repair</i>	57 (58.2)
Hepaticojejunostomy at the hilar plate	51 (52.0)
Hepaticojejunostomy	1 (1.0)
Right hepatectomy	2 (2.0)
Reconstruction with T-tube	2 (2.0)
Liver transplantation	1 (1.0)
<i>ERCP</i>	32 (32.6)
<i>PTC</i>	6 (6.1)
<i>Observation</i>	3 (3.1)
Type of treatment at our center in 25 patients with severity grade 1 BDI, No. (%)	
Surgery	1 (4.0)
ERCP	22 (88.0)
PTC	0
Observation	2 (8.0)
Type of treatment at our center in 73 patients with severity grade 2 BDI, No. (%)	
Surgery	56 (76.7)
ERCP	10 (13.7)
PTC	6 (8.2)
Observation	1 (1.4)
Patency grade after treatment at our center, No. (%)	
A	83 (84.7)
B	5 (5.1)
C	8 (8.2)
D	2 (2.0)
Patency grade A after surgical treatment at our center, No. (%)	46/57 (80.7)
Patency grade A after endoscopic treatment at our center, No. (%)	28/32 (87.5)

Table 3 Characteristics of malpractice litigation in the 98 patients with BDI

Variable	
Malpractice litigation, No. (%)	36 (36.7)
Trial state at the time of last follow-up	
Closed cases	30 (83.3)
Cases pending a verdict	6 (16.7)
Trial outcome, No. (%)	
Plaintiff verdict	26/30 (86.7)
Physician verdict	4/30 (13.3)
Compensation in favor of the plaintiff, €, mean \pm SD (range)	90,500 \pm 131,895 (10,000–600,000)

Two patients (one with Strasberg D BDI and one with Strasberg E5 BDI) underwent endoscopic treatment but they did not achieve their primary patency at the time of last follow-up and biliary stents were retained for more than 24 months after initiation of treatment. They were classified as patency grade D (Table 2).

Malpractice litigation

Out of the 98 patients treated at our center, 36 (36.7%) initiated a medical malpractice litigation against the community hospital where cholecystectomy was performed (Table 3). Thirty cases (83.3%) have been closed at the time of last follow-up. The other 6 cases were still pending a verdict. Out of the 30 closed cases, 26 (86.7%) were settled in favor of the plaintiff with payment, while 4 cases (13.3%) were settled in favor of the physician and resulted in no payment. Out of the 26 victorious plaintiffs, 22 (84.6%) disclosed the compensation they received, which ranged from €10 000 to €600 000, with an average payment of €90 500 \pm 131 895 (Table 3).

They were divided into two groups according to the referral time at our center: early-referral (<20 days; n = 50, 51.0%) and late-referral (\geq 20 days; n = 48, 49.0%).

Timing of referral following BDI

As previously reported, the median interval time between cholecystectomy and referral at our center was 18.5 days (IQR = 10–83). The entire population was dichotomized in two groups, namely the Early-Referral Group (<20 days; n = 50, 51.0%) and the Late-Referral Group (\geq 20 days; n = 48, 49.0%) (Table 4). Comparing the two groups, the two groups were similar in terms of sex, age, severity of BDI and occurrence of vascular injury. The rate of surgical attempts at repair before referral was significantly higher in the Late-Referral Group than that in the Early-Referral Group (58.3% vs. 32.0%; p = 0.008). Similarly, the rate of endoscopic attempts at repair before referral was significantly higher in the Late-Referral Group than that in the Early-Referral Group (54.2% vs. 34.0%; p = 0.04), with a

median greater number of ERCP procedures reported in the Late-Referral Group (1 vs. 0; p = 0.04).

After referral at our center, no substantial differences were observed in terms of treatment according to the interval time from cholecystectomy. After treatment at our center, no differences were observed in terms of biliary patency.

Stabilized IPTW effect

With the intent to minimize the effect of selection biases caused by the non-randomized design of this retrospective study, the entire population was “artificially” balanced using a stabilized IPTW method. As reported in Table 5, the population was efficaciously “balanced” for the 13 potential confounders adopted. In detail, before the IPTW, only one variable showed very small differences, four small, seven moderate, and one variable a considerable difference. After the IPTW, eight variables showed very small differences, four small, and one moderate. Despite the stabilized IPTW was adopted with the intent to minimize the potential modification of sample size respect to the initial population, the post-IPTW pseudo population increased to 259 cases.

Risk factors for medical malpractice litigation

A multivariable logistic regression model was performed on the original population and on the post-IPTW population with the intent to identify the risk factors for medical malpractice litigation. As reported in Table 6b, after the IPTW, nine variables were independent factors for the risk of medical malpractice litigation. In detail, seven covariates were risk factors, namely BDI surgical repair at our center (OR = 5.09; p = 0.001), associated vascular injury (OR = 10.40; p = 0.002), male sex (OR = 4.34; p = 0.003), intraoperative surgical attempts at repair before referral (OR = 29.60; p = 0.004), interval time between cholecystectomy and referral (OR = 1.006; p = 0.006), endoscopic attempts at repair before referral (OR = 3.32; p = 0.007), and severity grade 2 BDI (OR = 14.33; p = 0.02).

Two covariates were protective factors, namely age (OR = 0.92; p < 0.0001) and the intraoperative diagnosis of BDI (OR = 0.02; p = 0.001).

Correlation between medical malpractice payment request and time of referral

Observing the cumulative rate of the cases that led to malpractice litigation, the greater the interval time between cholecystectomy and referral, the greater the risk of medical malpractice litigation (Fig. 1). In detail, 23.8% and 16.2% of patients initiated malpractice litigation when they were referred to our unit within 19 days and during the period of 20–60 days, respectively. When the interval time increased, the rate of malpractice litigation also increased. During the interval time of 61–120 days, 54.5% of cases resulted in malpractice litigation. When the interval time was 121–210 or 211–365 days, the percentages of request for payment were 60.0% and 65.1%, respectively.

Table 4 Characteristics of the population stratified according to the interval time between cholecystectomy and referral at our center

Variable	Early-Referral <20 days (n = 50, 51.0%)	Late-Referral ≥20 days (n = 48, 49.0%)	P-value
	Median (IQR) or n (%)		
Age, years	54 (40–65)	59 (47–68)	0.14
Male sex	23 (46.0)	21 (43.8)	0.84
Type of BDI (Strasberg classification)			
A	9 (18.0)	1 (2.1)	0.009
B	1 (2.0)	1 (2.1)	0.98
C	2 (4.0)	0 (–)	0.50
D	6 (12.0)	8 (18.7)	0.35
E (all grades)	32 (64.0)	37 (77.1)	0.16
E1	0 (–)	1 (2.1)	0.49
E2	4 (8.0)	5 (10.4)	0.74
E3	15 (30.0)	18 (37.5)	0.52
E4	11 (22.0)	10 (20.8)	1.00
E5	2 (4.0)	3 (6.3)	0.61
Severity of BDI			0.30
Strasberg grade 1 (Type A, D)	15 (30.0)	10 (20.8)	
Strasberg grade 2 (Type B, C, E)	35 (70.0)	38 (79.2)	
Associated vascular injury	3 (6.0)	6 (12.5)	0.31
Timing of BDI diagnosis			
Intraoperative	17 (34.0)	21 (43.7)	0.32
Overall surgical attempts at repair before referral	16 (32.0)	28 (58.3)	0.008
Intraoperative surgical attempts at repair before referral	12 (24.0)	19 (39.6)	0.13
Endoscopic attempts at repair before referral	17 (34.0)	26 (54.2)	0.04
Number of ERCP procedures before referral	0 (0–1)	1 (0–1)	0.04
Percutaneous attempts at repair before referral	2 (4.0)	3 (6.3)	0.61
Number of PTC procedures before referral	0 (0–0)	0 (0–0)	0.26
Interval time between cholecystectomy and referral, days	10 (6–14)	91 (36–190)	<0.0001
Type of treatment at our center			
Surgery	29 (58.0)	28 (58.3)	0.97
PTC	1 (2.0)	5 (10.4)	0.08
ERCP	17 (34.0)	15 (31.2)	0.77
Observation	3 (6.0)	0 (–)	0.62
Patency grade after treatment			
A	45 (90.0)	38 (79.2)	0.14
B	3 (6.0)	2 (4.2)	0.68
C	2 (4.0)	6 (12.5)	0.16
D	0 (–)	2 (4.2)	0.28

Discussion

Our study showed that about one third of patients treated at our center for BDI (36.7%) had pursued a legal action against the community hospital where cholecystectomy was performed. This incidence was similar to that previously reported in the literature in the United Kingdom¹³ and in the USA.²² In Europe, about 19–32% of patients with BDI are involved in litigation claims.⁸

In Italy, in a recent paper by Gualniera et al. it has been showed that General Surgery is the most exposed branch to malpractice claims and 56% of these claims originated from surgery of digestive and biliary system.²³ However, in the literature, despite the high frequency with which laparoscopic cholecystectomies are performed worldwide, the specific investigation on the incidence of malpractice litigation related to BDI has been minimal.

Table 5 Effect of the IPTW in the population on the variables used for balancing the two populations

Variables	Pre-IPTW (n = 98)	Post-IPTW (n = 259)
	Cohen's D-value	Cohen's D-value
Male sex	0.04	0.04
Age, years	-0.32	-0.15
Severity grade 2 BDI (Type B, C, E)	-0.50	-0.02
Associated vascular injury	-0.22	-0.17
Intraoperative diagnosis	-0.20	-0.17
Intraoperative surgical attempts at repair before referral	-0.34	-0.07
Overall surgical attempts at repair before referral	-0.64	-0.33
Endoscopic attempts at repair before referral	-0.37	-0.04
Number of ERCP procedures before referral	-0.43	-0.09
Percutaneous attempts at repair before referral	-0.21	-0.08
Number of percutaneous procedures before referral	-0.34	-0.01
BDI surgical repair at our center	-0.12	-0.17
Patency grade after treatment at our center	-0.37	-0.08

Table 6 Risk factors for medical malpractice litigation. Analysis on the original population (a) and on the post-IPTW population (b). a. b

Variable	Beta	SE	Wald	OR	95.0%CI		P-value
					Lower	Upper	
Age	-0.055	0.021	6.722	0.947	0.908	0.987	0.010
Vascular injury	1.914	0.890	4.627	6.777	1.185	38.752	0.031
BDI surgical repair at our center	1.040	0.582	3.189	2.829	0.904	8.858	0.074
Percutaneous attempts at repair before referral	-1.378	0.937	2.162	0.252	0.040	1.582	0.141
Male sex	0.782	0.595	1.725	2.185	0.681	7.015	0.189
Intraoperative diagnosis	-1.323	1.251	1.117	0.266	0.023	3.095	0.290
Severity grade 2 BDI	1.244	1.226	1.030	3.470	0.314	38.382	0.310
Endoscopic attempts at repair before referral	0.421	0.516	0.665	1.523	0.554	4.185	0.415
Interval time between cholecystectomy and referral	0.001	0.003	0.048	1.001	0.995	1.006	0.827
Constant	0.150	1.416	0.011	1.162	-	-	0.915

-2 logLikelihood = 102.727; Hosmer–Lemeshow Test = 0.58.

Abbreviations: SE, standard error; OR, odds ratio; 95.0%CI, 95.0% confidence intervals.

Variable	Beta	SE	Wald	OR	95.0%CI		P-value
					Lower	Upper	
Age	-0.09	0.02	24.01	0.92	0.88	0.95	<0.0001
BDI surgical repair at our center	1.63	0.50	10.51	5.09	1.90	13.63	0.001
Intraoperative diagnosis	-3.73	1.11	11.33	0.02	0.003	0.21	0.001
Associated vascular injury	2.34	0.77	9.37	10.40	2.32	46.57	0.002
Male sex	1.47	0.50	8.62	4.34	1.639	11.59	0.003
Intraoperative surgical attempts at repair before referral	3.39	1.18	8.19	29.60	2.91	301.20	0.004
Interval time between cholecystectomy and referral	0.006	0.002	7.66	1.006	1.002	1.01	0.006
Endoscopic attempts at repair before referral	1.20	0.45	7.20	3.32	1.38	7.99	0.007
Severity grade 2 BDI	2.66	1.16	5.24	14.33	1.47	140.14	0.02
Constant	-0.71	1.22	0.34	0.49	-	-	0.56

-2 logLikelihood = 165.30; Hosmer–Lemeshow Test = 0.42.

Abbreviations: SE, standard error; OR, odds ratio; 95.0%CI, 95.0% confidence intervals.

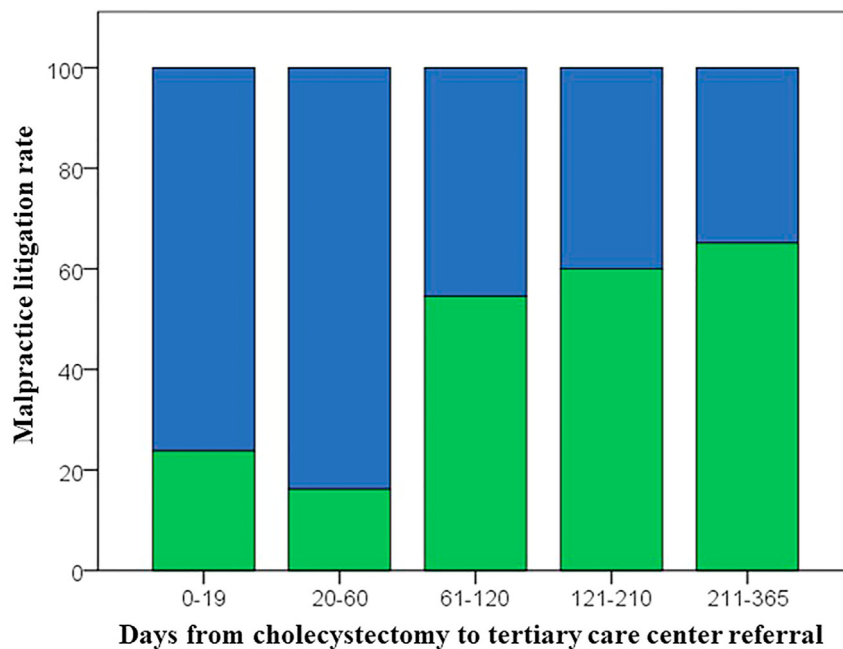


Figure 1 Distribution of malpractice litigation according to the interval time between cholecystectomy and tertiary care center referral. Green = initiated malpractice litigation; blue = not initiated malpractice litigation.

Litigation claims are increasingly common in the field of BDI following cholecystectomy. Indeed, laparoscopic cholecystectomy is considered as a seemingly easy surgical procedure for a benign condition. Patients undergoing laparoscopic cholecystectomy are often young patients who expect a good outcome, which is generally achieved in over 99% of cases. The small minority of patients who face the severe postoperative sequelae related to BDI, in terms of morbidity, mortality and long-term quality of life (work-related limitations, loss of productivity, disability) might be led to pursue legal action against the hospital where cholecystectomy was performed.

Regarding litigation claims for BDI following laparoscopic cholecystectomy, the reported incidence of verdicts in favor of the plaintiff is generally high, ranging from 60% in the USA¹⁷ up to 100% in the United Kingdom.¹³ In our study, out of the 30 closed cases, 26 (86.7%) were settled in favor of the plaintiff with payment. Moreover, it should be highlighted that most of the closed cases with payment often include significant payouts. In the USA, in a study examining malpractice litigation for BDI following laparoscopic cholecystectomy between 1999 and 2004, the mean payment in favor of the plaintiff was \$508 341.¹⁷ Another American study which analyzed trials for BDI from the Verdictsearch database, occurring between 2004 and 2017, reported a mean payment of \$723 844.¹⁵

In the United Kingdom, about 50 000 cholecystectomies are performed annually.¹⁴ Gossage et al.¹⁴ showed that over 300 claims related to laparoscopic cholecystectomy occurred in England between 1995 and 2008. In these cases BDI resulted in the highest proportion of successful claims (86%) and the largest

sums paid to the claimant (average £65 000).¹⁴ Similarly, in another English study, Perera et al.¹³ reported an average payout of £62 500 (range £2500–216 000). However, in that study, only 47.4% of patients disclosed the compensation they received. In our study, the majority of victorious plaintiffs (84.6%) disclosed the compensation they received, which ranged from €10 000 up to €600 000, with an average payment of €90 500.

In other words, BDIs following laparoscopic cholecystectomy result in the highest proportion of successful claims and the largest sums paid to the claimant. For these reasons, BDIs are both morbid and costly for the health service.²⁴

It has been largely demonstrated in the literature that better patient outcomes, with decreased morbidity and long-term complications, are obtained when BDIs are referred and treated at high-volume centers by experienced multidisciplinary teams.^{8,20,25,26} It should be highlighted that the length of follow-up after treatment is crucial to evaluate postoperative results. In our study, after an extensive median long-term follow-up of more than 10 years, about 85% of patients achieved their primary patency within the time interval defined in the paper by Cho et al.,²¹ and 13% of patients achieved a secondary patency. In this way, overall, primary and secondary patencies were finally achieved in 97.9% of patients. The policy in our center is to perform surgical repair by hepatico-jejunostomy at the hilar plate in patients with severity Grade 2 BDI (axial injuries which result in discontinuity of the biliary tree). On the other hand endoscopic treatment was preferred in patients with severity Grade 1 BDI (cystic duct leak or lateral injuries which do not result in discontinuity of the biliary tract). Indeed, surgical repair was

significantly more frequently performed in severity grade 2 BDI than in severity grade 1 BDI (76.7% vs. 4.0%; $p < 0.001$). The endoscopic treatment was significantly more frequently performed in severity grade 1 BDI than in severity grade 2 BDI (88.0% vs. 13.7%; $p < 0.001$). In this way the rate of patency grade A was not significantly different according to the type of repair: 80.7% after surgical repair vs. 87.5% after endoscopic/percutaneous repair; $p = 0.411$.

We consider the biliary repair an elective procedure to be performed several weeks after the resolution of sepsis, when the patient is in good general condition without biliary fistula.²⁰ For these reasons, the median time between referral and surgical repair was significantly different according to the clinical presentation of BDI: 51 days in patients with external biliary fistula, 142 days in patients with biliary peritonitis and 18 days in patients with obstructive jaundice.

We specifically analyzed factors related with malpractice litigation. The median interval time between cholecystectomy and referral at our center was 18.5 days. Patients were divided in two groups: the Early-Referral Group (<20 days) and the Late-Referral Group (≥ 20 days). The rate of surgical and endoscopic attempts at repair at community hospitals before referral was significantly higher in the Late-Referral Group than that in the Early-Referral Group, with a median greater number of ERCP procedures reported in the Late-Referral Group. After balancing the entire population by using the stabilized IPTW method, a multivariable logistic regression model was performed on the post-IPTW pseudo population in order to identify independent factors for the risk of malpractice litigation. Interestingly we found two categories of risk factors: factors related with the severity of BDI and factors related with an improper postoperative management at the community hospital where cholecystectomy was performed. Indeed, severity grade 2 BDI (axial injuries which result in discontinuity of the biliary tree), associated vascular injury and the need to perform a surgical repair at our center were independent risk factors for malpractice litigation. These factors were related with the severity of BDI and of course, no longer modifiable after BDI occurring at the community hospital. On the other hand, other independent risk factors for malpractice litigation were interval time between cholecystectomy and referral at our center, intraoperative surgical attempts at repair before referral and endoscopic attempts at repair before referral. In this study we showed that there was a close relationship between attempts at repair before referral and delay in referral at an experienced center. Indeed, surgical attempts at repair before referral, endoscopic attempts at repair and the number of ERCP before referral were significantly higher in patients referred to our center more than 20 days after cholecystectomy. These factors were related with an improper postoperative management at community hospitals without a specific expertise in BDI treatment. Of course, these factors may be modifiable by implementing and standardizing a correct management of patients with BDI at community hospitals.

In hospitals without the availability of multidisciplinary teams with expertise in hepatobiliary surgery, prompt referral to tertiary expert centers without any attempt at surgical repair, may reduce the risk of litigation. In our study, the interval time between cholecystectomy and referral at our center was a strong predictor for malpractice litigation. Observing the cumulative rate of the cases requiring a medical malpractice litigation, it was interesting to observe that the greater was the interval time between cholecystectomy and referral, the greater the risk of medical malpractice litigation: 23.8% and 16.2% of patients initiated malpractice litigation when they were referred to our unit within 19 days and during the period of 20–60 days, respectively. This rate increased to 54.5% when the interval time was 61–120 days, to 60.0% when the interval time was 121–210 and finally to 65.1% when the interval time was 211–365. Trying to repair the BDI in the community hospital where cholecystectomy was performed and where there is no expertise in hepatobiliary surgery and referring the patient late, only when all attempts at repair have been performed without success, may be represent a strong risk factor for poor long-term results and for malpractice litigation.

This issue has been clearly highlighted in the last published “Multi-society Practice Guideline” on BDI during cholecystectomy.¹ Indeed, in this paper, one of the two strong recommendation made by the experts was the prompt referral of patients with confirmed or suspected BDI to an experienced surgeon/multispecialty hepatobiliary team.¹

The present study has some limitations. Indeed, it was a retrospective study which enrolled only patients who were referred to a tertiary referral center after failure of BDI management at community hospitals. For these reasons the study is unable to evaluate the rate of patients who were not referred to our center because they had successful surgical or endoscopic management at the community hospitals or because they died for severe septic complications following BDI. However, the rate of agreement to participate in the questionnaire was high (60.7%) and the entire population enrolled in the study may well represent the medicolegal consequences related to BDI in Italy.

Conclusions

Our study demonstrated that out of the 98 patients treated for BDI, 36.7% initiated a malpractice litigation and in 86.7% of the closed cases, the verdict was in favor of the plaintiff with a significant payout up to €600 000. Failed postoperative management (delayed referral, attempts at repair before referral) was one of the strongest predictors for litigation. Prompt referral to tertiary experienced centers without any attempt at surgical repair may reduce the risk of litigation.

Declaration of competing interest

None to declare.

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