

# Risk Factors for Litigation Following Major Transectional Bile Duct Injury Sustained at Laparoscopic Cholecystectomy

M. T. P. R. Perera · M. A. Silva · A. J. Shah ·  
R. Hardstaff · S. R. Bramhall · J. Issac ·  
J. A. C. Buckels · D. F. Mirza

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## Abstract

**Background** Bile duct injuries after laparoscopic cholecystectomy often cause long-term morbidity, with a number of patients resorting to litigation. The present study aimed to analyze risk factors for litigation and to quantify the subsequent medicolegal burden.

**Methods** A total of 67/106 patients (26 male) with major laparoscopic cholecystectomy bile duct injuries (LCBDI) and a minimum 2-year follow-up, replied to a questionnaire covering patient perception toward the complication, physical/psychological recovery, and subsequent litigation. These data were collated with prospectively collected data related to the LCBDI and subsequent management, and a multivariate regression model was designed to identify potential risk factors associated with litigation.

**Results** Most patients felt they had been inadequately informed prior to surgery [47/67 (70%)] and after the LCBDI [50/67 (75%)], and a majority remained psychologically traumatized at the time of evaluation [50/67 (75%)]. Of these, 22 patients had started litigation by means of a “letter of demand” (LOD;  $n = 10$ ) or prosecution ( $n = 12$ ). Nineteen (19/22%) cases have been closed in favor of the plaintiff. There was no difference between the awards for LOD versus prosecution cases, and average compensation was £40,800 versus £89,875,

respectively ( $p = \text{n.s.}$ ). On multivariate analysis, age  $< 52$  years ( $p = 0.03$ ), associated vascular injury ( $p = 0.014$ ), immediate nonspecialist repair ( $p = 0.009$ ), and perceived incomplete recovery following LCBDI ( $p = 0.017$ ) were identified as independent predictors for possible litigation.

**Conclusions** On the basis of the present study, nearly one third of patients with major transectional LCBDI are likely to resort to litigation. Younger patients and those in whom repair is attempted prior to specialist referral are likely to initiate litigation.

## Introduction

Two decades after its introduction, laparoscopic cholecystectomy (LC) is widely employed as the treatment of choice for symptomatic gallstone disease. However, the incidence of laparoscopic cholecystectomy-induced bile duct injuries (LCBDI) remains unchanged at 0.3–0.6%, a rate higher than that observed in the open era [1–3]. The unfortunate minority of patients who sustain LCBDI have a 10–25% incidence of long-term morbidity mainly due to recurrent cholangitis, biliary strictures requiring repeated interventions, and, occasionally, progressive secondary biliary cirrhosis [4–6].

Medicine is currently being practised in an era where prosecution and claims for damage following medical negligence are increasingly common, especially in fields where the long-term consequences are guarded. From a patient’s perspective, LCBDI converts a seemingly straightforward surgical procedure for a benign and non-life-threatening condition to a serious long-term problem that may even become life-threatening in the course of time and that is associated with poor quality of life [7]. Health

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M. T. P. R. Perera · M. A. Silva · A. J. Shah · R. Hardstaff ·  
S. R. Bramhall · J. Issac · J. A. C. Buckels · D. F. Mirza (✉)  
The Liver Unit, Queen Elizabeth Hospital, Edgbaston,  
Birmingham B15 2TH, UK  
e-mail: darius.mirza@uhb.nhs.uk

care institutions and surgeons dealing with LCBDI should be knowledgeable about the impact of these injuries on health, patient perceptions on outcomes, and the financial burden [8]. An additional victim in LCBDI is the surgeon causing the initial injury, who is faced with evaluating his/her practice, with a view to adopting the best practice in the event of an inadvertent LCBDI. Limited published information is available on the probability of litigation following LCBDI [9–12]. Some of the published studies have attempted to identify risk factors that could lead to a verdict against the defense: namely, delay in diagnosis, male gender, and socioeconomic status [10].

The primary objective of the study was to evaluate the probability and factors leading patients to seek medicolegal redress among a select group of patients referred for tertiary care treatment following LCBDI. This study also analyzed patient opinions on psychological and physical recovery following LCBDI, management prior to and following referral to specialist care, and, finally, the details of medicolegal proceedings in order to quantify the financial burden of this complication.

In brief, the medicolegal process for the United Kingdom National Health Service (NHS) is as follows: patients are permitted to make a formal complaint and can initiate a litigation process in parallel up to 3 years after the index event. The first indication of such action is a letter from the patient's attorney requesting copies of relevant documents from the hospital where the patient received treatment. The next step involves gaining opinions from medical experts who evaluate and comment on the individual patient's management. Following this a writ notice with details on allegation, expert reports, and statement of claim (letter of demand/LOD) is sent to the hospital. Alternatively, the patient's attorney may choose to proceed with litigation in the courts for medical negligence amounting to breach of care. In the UK all cases are reported to the NHS litigation authority (NHSLA). The hospital may settle to "honour" the LOD if the claims made are justified, and it may negotiate a settlement. Alternatively, the hospital may choose to defend the case in a civil court. Once a case reaches court, various methods of "alternative dispute resolution" exist before a final verdict is handed down and include "out of court settlement" and "negotiated settlement approved by court."

## Methods

All patients with LCBDI referred to the Liver Unit at the Queen Elizabeth Hospital, Birmingham, United Kingdom, from 1992 until January 2009 were identified from a continuously updated prospective database. Patient demographics, details pertaining to the index LC, injury

suspicion/diagnosis, subsequent management, and morbidity data were gathered from the database. All injuries were catalogued according to the classification described by Strasberg [13], based on information obtained at the operation and in imaging studies. Survivors with a major transection/excisional main bile duct injury (type E injury) and with at least a 2-year follow-up were selected to receive a mailed questionnaire with an invitation to participate in the survey. Patients with LCBDI referred after January 2007 and those with incomplete follow-up were excluded.

Patients were given the choice to participate in the survey. The initial questions were designed to acquire a broad view of each patient's perception of events after a major bile duct injury. Owing to the sensitivity and complexity of the issue, we created a simple two-page questionnaire, which was approved by consultant colleagues prior to circulation. The questionnaire was then administered to a cohort of selected patients in the follow-up clinic, seeking their opinion on the nature of the questions, and whether they could provide a simple (yes/no) answer to each question. The final questionnaire was modified taking in to account these suggestions.

The first section focused on patient perception and queried whether the patient was satisfied with the information provided prior to the LC, the explanations given once the complication was suspected, and patient satisfaction with subsequent management. In the second section, patient perception on overall physical recovery and the psychological experience following LCBDI was ascertained. No standard validated tools were used to assess physical or psychological recovery.

In the third section of the questionnaire information on any formal complaints related to patient experience, litigation, and outcomes thereof were sought. Patients who had initiated medicolegal proceedings (MLC) were asked to provide more details on triggers, outcomes, and settlements. Patients were given the choice of declaring the amount of compensation, if any, or not. An additional reminder was sent to those who did not respond within two weeks. Telephone conversations were made with consented patients to clarify information where necessary.

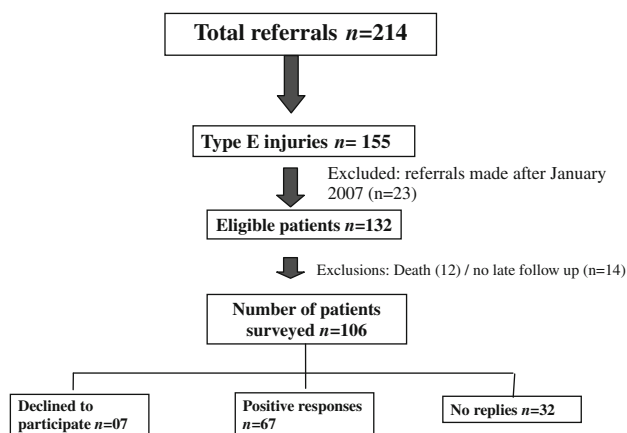
Data analysis was done with SPSS for Windows software (version 13; Chicago, IL). Continuous data are expressed as median (range), whereas categorical data were entered as binary variables and expressed as group percentages. Continuous and ordinal data related to the patient age and year in which index LC was performed were also recategorized in to binary variables based on their median value. Therefore the cut-off points of these two variables were age 52 years and year 2001 for the index LC [14].

Univariate analysis was performed with the general linear model (GLM), a univariate model designed to

identify the risk factors significantly associated with litigation that included age at LC, gender, year of LC, and those factors identified from the questionnaire (unsatisfactory preoperative information, unsatisfactory postoperative information, dissatisfaction with subsequent management of the complication, psychological trauma following BDI, and failure to recover psychologically) and BDI database (referral delay > 10 days [defined as number of days since initial presentation with post-LC symptoms], presence of vascular injury, failure of conversion to open surgery, immediate repair by referring surgeon, immediate repair by outreach specialist HPB surgeon, subsequent morbidity, and subsequent interventions). The predictors identified in the univariate analysis were then entered in to a multivariate (binary logistic) regression analysis model to assess the independent predictors associated with litigation. Significance was assigned to 0.05 at 95% confidence interval. The costs of compensation cited in this article were the amounts received by the patients, given in Pounds Sterling (£). The conversion rate to the U.S. dollar and the Euro at the time of data acquisition in January 2009 was £1 = \$1.44/€1.04 [15].

## Results

A total of 214 [male = 71 (33%), median age 54 years (range: 26–82 years)] patients were referred with LCBDI between 1992 and January 2009, of which 155 (72%) sustained the more severe Strasberg type E excision injury. Of these, 106 patients [72 (68%) female; median (range) age 64 (27–88) years] were eligible to receive the mailed questionnaire, eliminating 49 patients who had incomplete follow up ( $n = 14$ ), those with <2 years follow-up (i.e., patients referred for management after January 2007;  $n = 23$ ), and those deceased at the time of mailing ( $n = 12$ ) (Fig. 1). The initial response to the first letter was 49/106 (46%), which



**Fig. 1** Inclusion and exclusion criteria of patients with LCBDI invited for the survey

increased to 74/106 (70%) after one reminder. Of these, 67/74; (91%) agreed to participate in the survey, and thus they comprised the “study” group. Comparison of the basic demographics of the study group (Table 1) revealed no significant differences in the surveyed population.

## Opinions and perception toward LCBDI

The questions and the responses to seek patient opinion toward the overall experience related to BDI is summarized in Table 2. The majority of the participants of the study believed they were inadequately informed (70% preoperative information, 75% postoperative information) of the possible complications at the LC (Table 2). However, 40/67 (60%) were satisfied with the subsequent management of their complication. The majority [49/67; 73%] believed they were psychologically traumatized following LCBDI. Complete physical recovery was declared by only 20/67 (30%) patients whereas 47/67 (70%) felt they had not yet fully recovered with a similar follow-up of 113 months (range: 25–216) versus 91 months (range: 26–216 months), respectively ( $p = 0.38$  Kruskal–Wallis test). Only 27% patients accepted their experience as an unavoidable surgical complication.

## Bile duct injury profile

Detailed analysis of data related to the diagnosis of BDI, including associated injuries, management, and complications of the study group, is shown in Table 3. In 42/67 patients (63%), the procedure had not been converted to an open surgical procedure. Eight patients (8/67; 12%) sustained concomitant vascular injury. All patients were managed with biliary reconstruction (hepaticojejunostomy). An on-table (immediate) recognition of BDI had been made in 13 cases in total, and all of those were repaired either by the “outreach specialist” HPB surgeon ( $n = 8$ ) or the primary surgeon ( $n = 5$ ) who had performed the index LC. There was a median referral delay of 28 days (range: 0–983 days) from the initial suspicion of LCBDI. Subsequent morbidity involved recurrent biliary strictures with or without cholangitis in 28 patients (42%) during follow-up, whereas in 27(40%) patients some form of intervention, either surgical or radiological, was performed.

## Medicolegal aspects

A total of 22 (32%) patients initiated a medicolegal case (MLC) in the form of a “letter of demand” (LOD;  $n = 10$ ) or a court action ( $n = 12$ ). In three cases, the hospital concerned had not responded favorably to the claims in the “letter of demand” by awarding payout; hence the patients proceeded to litigation, bringing the total number of court

**Table 1** Demographics of the surveyed group and positive responders to the questionnaire

	Surveyed population ( <i>n</i> = 106)	Study population ( <i>n</i> = 67)	Significance, <i>p</i> value
Male:female ratio	34:72	26:41	n.s*
Median age at study, years (range)	64 (27–88)	62 (29–83)	0.76; n.s**
Median follow-up since LC, months (range)	92 (25–217)	91 (25–216)	0.76; n.s**

\* Comparison of two proportions

\*\* Comparison of median—Kruskal–Wallis test

LC laparoscopic cholecystectomy, LCBDI laparoscopic cholecystectomy induced bile duct injury

**Table 2** Patient perceptions of the index LC and related outcome, identified from the postal questionnaire

	Patients responding				Univariate significance <sup>a</sup>
	Yes		No		
	Number of patients	Percent proceeding with MLC	Number of patients	Percent proceeding with MLC	
Do you believe you were adequately informed of the complications of laparoscopic cholecystectomy BEFORE the operation?	47	19 (40%)	20	3 (15%)	0.582
Do you believe you were adequately informed once the complication occurred in the postoperative period?	50	19 (38%)	17	3 (18%)	0.756
Are you satisfied with the subsequent management of your complication?	27	12 (44%)	40	10 (25%)	0.260
Do you believe you were psychologically traumatized from this complication?	50	19 (40%)	17	3 (18%)	0.617
Do you believe you have completely recovered from the complication that occurred at LC?	47	19 (40%)	20	3 (15%)	0.047**

Total number of responders to the questionnaire (*n* = 67); all patients answered these questions<sup>a</sup> General linear model (GLM) univariate analysis\*\* *p* < 0.05 at 95% confidence interval

MLC medicolegal cases

cases to 15. The majority of patients (16/22; 72%) had made a formal complaint to a responsible authority (hospital authority or health care trust) prior to taking any legal action; four patients declared receipt of a letter of regret/apology accepting liability. The remaining patients cited other responses as being either misleading or inaccurate and denied liability. The patients' general dissatisfaction toward this response was not the sole "trigger" in initiating litigation. Some cited additional reasons, including advice/opinion from a health care professional (*n* = 10), advice from friends and relatives (*n* = 2), legal advice (*n* = 1), and their own decision (*n* = 5). In a further four patients, a combination of the above factors led to litigation. In seven court cases (47%) the surgeon involved with the LCBDI was implicated either as the sole respondent or a co-respondent.

Nineteen (19/22; 86%) cases have been closed and all were settled in favor of the plaintiff, and three cases are either being heard or pending a verdict. One case proceeded to a conditional verdict in favor of the plaintiff, and

compensation was ordered by the Court with the "condition" to pay extra compensation should the patient need additional treatment for the same complication in future. All remaining cases were closed as a result of successful negotiations out of court or by honoring the LOD. Only 9/19 patients disclosed the compensation they received, which ranged from £2,500 to £216,000, with an average payout £62,500. Breakdown analysis revealed the average compensation in cases where LOD was honored was lower (*n* = 5; average: £40,800; range: £2,500–£85,000) when compared to those proceeding to prosecution (*n* = 4; average: £89,875; range: £16,000–£216,000). Most of the patients (11/19; 58%) were satisfied with their settlement. The highest payout reported in this series (£216,000) was ordered by the Court after a verdict of medical negligence amounting to damage. Five patients (5/67; 7%) stated that, although they needed to take legal action, financial constraints prevented them from doing so. Other reasons cited for not pursuing legal action included lack of trust in the health care system, legal opinion suggesting lack of strong evidence for a case, complication

**Table 3** Demographics and bile duct injury profile of patients in the study group subsequently proceeding with litigation

	Number of patients in each category	Number of (%) patients proceeding with MLC	Univariate significance
Age <52 versus >52 at LC	31 versus 36	13 (42%) versus 09 (25%)	0.038*
Gender, male/female	26/41	05 (19%) versus 17 (41%)	0.073
Year of LC before 2001/after 2001	26/41	06 (23%)/16 (39%)	0.047*
Failure to convert versus immediate conversion to the open approach	42 versus 25	14 (33%)/22 (32%)	0.969
Presence of associated vascular injury versus no vascular injury	08 versus 59	05 (62%) versus 14 (24%)	0.022*
Referral delay <10 days versus >10 days	21 versus 46	6 (29%) versus 16 (35%)	0.754
Immediate repair performed by HPB outreach team versus referring surgeon	08 versus 05	2 (25%) versus 4 (80%)	0.001*
Presence of subsequent morbidity versus no morbidity <sup>a</sup>	28 versus 39	8 (29%) versus 14 (36%)	0.404
Subsequent interventions versus no interventions <sup>b</sup>	27 versus 40	8 (30%) versus 14 (35%)	0.333

<sup>a</sup> Recurrent cholangitis and/or stricture

<sup>b</sup> Radiological and/or surgical intervention

\* General linear model univariate analysis ( $p < 0.05$ )

attributable to human error, and satisfaction of overall management of the complication.

Only 35 patients (52%) responded to the question based on their opinion of the subsequent management of the LCBDI, and the majority (30/35; 85%) stated they were satisfied with the management. This group included 20 patients who have started litigation and, only 2 of them were unhappy with the subsequent management.

#### Risk factors associated with litigation

The combined risk factor model, including risk factors identified from the BDI profile and the postal questionnaire was tested for significance in predicting litigation following LCBDI. Age, gender, and the year of LC were entered into the model as fixed parameters, whereas all other variables were entered as covariates (Tables 2 and 3). On univariate analysis, several parameters—patient age younger than 52 years ( $p = 0.038$ ), LC performed after the year 2001 ( $p = 0.047$ ), perceived incomplete recovery after complication ( $p = 0.047$ ), associated vascular injury ( $p = 0.022$ ), and immediate repair performed by referring surgeon ( $p = 0.001$ )—were identified as risk factors. When entered in to the multivariate regression model, all these variables except the year in which LC was performed, were identified as independent predictors, resulting in an increased risk of litigation following LCBDI (Table 4).

#### Discussion

In recent years an annual load of over 5000 clinical negligence cases has been reported to the National Health

Service litigation authority (NHSLA) in the United Kingdom, and the majority (39%) of claims have originated from the surgical speciality [14, 16]. The present study highlights several aspects in management of LCBDI that potentially contribute to a significant proportion of the claims of negligence. Using postal based questionnaires, it was possible to achieve a satisfactory response rate of 70%, which is deemed representative of the target cohort of patients [17]. Severe bile duct injury (Strasburg type E) is common, and is more likely to have a complicated outcome than other types of injuries. Therefore it can be expected that this group may resort to litigation more often than patients who have sustained other forms of injuries. For this reason, the former group was targeted for the present study.

In current surgical practice, informed consent is routinely obtained prior to operation. How much information is expected and retained by patients varies according to their level of education, changing clinical scenarios, and the complexity of the surgical procedure. Incomplete information, however, could result in a physician's being held liable in the eyes of the Law [18, 19]. In an era where access to information is a legally protected right of the patient, clinicians need to be accurate in patient communication, and technology may be used to improve the level of understanding [20]. Patients undergoing LC are justified in expecting a good outcome, which is achieved in over 99% of cases. The small minority who eventually face the debilitating complication of a major bile duct injury might be led to believe, in retrospect, that information about such a complication provided prior to surgery was inadequate [21]. Difficulties in retaining information that was, in fact, provided may also be attributable to this belief [22].

**Table 4** Multivariate analysis of risk factors leading to litigation following LCBDI

Factor	Variables identified from univariate analysis	Univariate significance <sup>a</sup>	Multivariate significance <sup>b</sup>	Hazard ratio <sup>c</sup> (95% confidence interval)
Fixed factors	Age under 52 years at LC	0.038*	0.030*	8.27 (6.73–9.81)
	LC performed after the year 2001	0.047*	0.135	2.22 (0.62–3.82)
Factors identified from questionnaire	Incomplete recovery after BDI	0.047*	0.017*	4.09 (2.65–5.53)
Factors identified from BDI database	Associated vascular injury	0.022*	0.014*	5.86 (3.88–7.84)
	Immediate repair performed by referring surgeon	0.001*	0.009*	5.29 (3.57–7.01)

<sup>a</sup> General linear model (GLM) univariate analysis

<sup>b</sup> Binary logistic regression (Nagelkerke R square = 0.442, model statistic significance < 0.001)

<sup>c</sup> Hazard ratio related to multivariate analysis

\* Significant variables at  $p < 0.05$  (df = 2)

BDI bile duct injury

Whereas most of the resources and focus following any surgical complication is centred on correction of physical aspects of the injury, management of psychological trauma could become less of a priority. There is evidence to support the obvious long-term reduction in psychological well-being in patients suffering LCBDI [23]. Overall quality of life (QoL) is derived from both psychological and physical recovery after such an injury, and that could take up to many years [7]. In the present series an equal proportion of patients acknowledged that they were still psychologically traumatized at the time of evaluation.

One third of patients in this study had pursued legal action. A similar incidence of litigation has been reported by a Maryland group [23]. In addition, the present study is one of the first to assess factors that could predict the probability of litigation after LCBDI. Furthermore, on clinic review several patients, who had not responded to the questionnaire stated they had not done so on legal advice, suggesting that the findings of the present study may under-represent the total medicolegal burden. The medicolegal actions were primarily directed against the health care institution, with a 50% likelihood that the surgeon would also be implicated. Patients sought the opinion of other health care professionals before embarking on litigation. The award amounts disclosed by responders may not reflect the actual financial burden of these injuries, although these high figures definitely provide an estimate of that burden. The figures reported represent only what the patient received as compensation; it is likely that the total financial cost to the NHS may be significantly higher, if only because of the expense of defending these cases. In the literature, a similar trend between settled cases and contested cases is reported [10–12]. The present series highlights the high incidence of negotiated settlements, which corresponds with the current incidence of <1% of all reported

medicolegal cases contested in court annually in the United Kingdom [13, 16]. In comparison to the medicolegal cases reported from the Continent, there appears to be a higher likelihood of negotiated settlements within the UK.

Loss of physical and mental health, a longer expected life span living with disability, absence from work, and cosmetic outcomes could prompt younger patients to resort to litigation. Female sex was not predictive as a risk factor for litigation. Patients who had sustained a LCBDI since the turn of the millennium were more likely to claim for damages than those who sustained such injuries prior to 2001. This matches the sharp rise in litigation cases by year since the late 1990s in the UK [14, 16]. Increased awareness, successful lawsuits and access to medical information in the public domain may have contributed to this trend.

The role of specialist intervention in the management of LCBDI is emphasized once again in the present series [24]. From a patient outcome point of view, long-term results are better when intervention by specialist hepatobiliary surgeons occur. Attempts at immediate surgical reconstruction of the biliary tree by the surgeon who caused an LCBDI appears to increase the risk of litigation, and therefore expert assistance sought early may help in reducing this risk. With emerging debate on whether LC should only be performed by surgeons with specialist interest [25], general surgeons may find it more difficult in future to defend themselves in a court of law.

In summary, major bile duct injury is a debilitating complication of laparoscopic cholecystectomy that results in significant long-term physical and psychological morbidity. After LCBDI, approximately one third of UK patients resort to litigation, occurring more frequently in younger patients operated since 2001, and in those where repair was attempted prior to specialist referral. The level of compensation is varied (median £63,000), with



prosecution leading to higher settlements. Early specialist referral may help reduce the medicolegal burden of this devastating complication.

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