

Quality of Life and Medico-Legal Implications Following Iatrogenic Bile Duct Injuries

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Abstract In this review we aimed to evaluate quality of life after bile duct injury and the consequent medico-legal implications. A comprehensive English language literature search was performed on MEDLINE, Embase, Science Citation Index and Google™ Scholar databases for articles published between January 2000 and April 2016. The last date of search was 11 April 2016. Key search words included bile duct injury, iatrogenic, cholecystectomy, prevention, risks, outcomes, quality of life, litigation and were used in combination with the Boolean operators AND, OR and NOT. Long-term survival after bile duct injury is significantly impaired (all-cause long-term mortality approximately 21 %) along with the quality of life (especially psychological/mental state remains affected). Bile duct injury is associated with high rates of litigation. Monetary compensation varied from £2500 to £216,000 in the UK, €9826–€55,301 in the Netherlands and \$628,138–\$2,891,421 in the USA. Bile duct injuries have profound implications for patients, medical personnel and healthcare providers as they cause significant morbidity and mortality, high rates of litigation and raised healthcare expenditure.

Introduction

Laparoscopic cholecystectomy is the accepted standard for the treatment of symptomatic gallstones, as its benefits are undisputed when compared with open cholecystectomy (less perioperative pain, improved cosmesis, decreased length of hospital stay and earlier return to normal activities) [1]. However, the rates of iatrogenic bile duct injury are higher following laparoscopic cholecystectomy [2].

Bile duct injuries have profound implications for patients, medical personnel and healthcare providers as they cause significant morbidity and mortality, high rates of

litigation and raised healthcare expenditure [3–5]. Prompt recognition and appropriate management of bile duct injuries have been shown to improve patient outcomes [2]. In this review we aimed to evaluate quality of life after bile duct injury and the consequent medico-legal implications.

Methods

A comprehensive English language literature search was performed on MEDLINE, Embase, Science Citation Index and Google™ Scholar databases for articles published between January 2000 and April 2016. The last date of search was 11 April 2016. Key search words included bile duct injury, iatrogenic, cholecystectomy, prevention, risks, outcomes, quality of life, litigation and were used in combination with the Boolean operators AND, OR and NOT. The search was supplemented using the ‘related article’ function. Bibliographies of selected articles were further searched manually for studies that were missed in the initial electronic search.

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A total of 398 published articles were identified of which a large majority were case reports, along with foreign language and irrelevant articles, and these were excluded ($n = 272$). Abstracts were screened electronically for potentially relevant papers, leading to further exclusion of 88 articles. Studies outlining preventative management strategies, quality of life (QoL) and medico-legal implications following bile duct injury were retrieved and analysed further ($n = 38$).

Results

Strategies for prevention and treatment of bile duct injury

The reported incidence of bile duct injury varies from 0.4 to 1.5 % [3, 6, 7] probably due to differences in patient selection, definition of injury and the methodology used. The causes of bile duct injury are multifactorial, as shown in Table 1 [8–10]. Overconfidence on the part of the surgeon, chronic underestimation of the risk of bile duct injury

and spatial disorientation leading to ‘functional fixity’ as a cause for human error are contributing factors [11, 12].

A heightened awareness of the risk of bile duct injury is needed when performing cholecystectomy [11, 13, 14]. The implementation of ‘stopping rules’ along with early intraoperative consultation with another experienced surgical colleague when operative difficulties are encountered during cholecystectomy should become mandatory, and demonstration of the ‘critical view of safety’ should be standardised and made part of routine surgical practice [13, 14]. Some of the recommended strategies to prevent BDI are summarised in Table 2 [14–20].

The role of intraoperative cholangiography and conversion to open surgery in the prevention of bile duct injury remains controversial [12]. Bile duct injury is an uncommon event, and in order to identify 50 % reduction in such a rare event following intraoperative cholangiography, a sample size in excess of 30,000 patients would be needed for the study to be sufficiently powered [20].

Management is tailored according to the time of detection, extent of injury and availability of hepatopancreatobiliary specialist service. Principles of treatment are

Table 1 Causes of bile duct injury

Cause of bile duct injury	%	Mechanism
Misidentification of biliary anatomy and cystic duct [8, 9]	73.3	Presence of severe inflammation or fibrosis, and/or anatomic variations
Inappropriate use of electrocautery [8–10]	12.3	Direct coupling, capacitative coupling or pedicle effect [10]
Difficulty controlling bleeding [8, 9]	4.9	Use of excessive clips or inappropriate suturing
Unspecified technical issues [8]	9.8	–

Table 2 Strategies to prevent bile duct injury

Strategy	Comment
Conversion to open procedure [14]	Conversion recommended if uncontrolled haemorrhage or inadequate exposure However, it is controversial to suggest that conversion reduces bile duct injury as there is no objective evidence [12]
Avoid retrograde or infundibular technique of cholecystectomy [13]	Increases risk of bile duct injury [13]
Activate ‘stopping rule’ [14]	Stop and reassess situation if failing to progress during dissection, anatomic disorientation, failure of laparoscopic equipment to perform usual tasks, difficulties in the visualisation of the field
Seek early intraoperative consultation from experienced colleague [14]	Underutilised strategy
Demonstrate critical view of safety [14]	Commonly used technique with wide acceptance amongst surgical colleagues [19]
Use of intraoperative cholangiogram [15–20]	Some studies suggest regular intraoperative cholangiography reduces the risk of bile duct injury [5, 16, 17]. However, this estimated benefit is subject to unmeasured confounding and its use amongst surgeons is not widespread [18, 19]

Table 3 Essential principles outlining the management of bile duct injury

Sepsis control
Detailed contrast-enhanced computed tomography scan to
(a) Enable drainage and exclude undrained collections
(b) Exclude concomitant right hepatic arterial injury
Complete cholangiogram to define site, type and extent on biliary injury

outlined in Table 3, and initial management algorithms are suggested in Figs. 1 and 2. Treatment options vary depending on the degree and severity of injury as shown in Table 4.

The aim of definitive repair undertaken in a specialist centre by an experienced hepatopancreaticobiliary surgeon is to restore bile flow to the proximal gastrointestinal tract [2]. A multivariate analysis of factors influencing surgical outcomes following bile duct injury concluded that the timing of the repair was unimportant ($P = 0.572$). Instead, success correlated definitively with eradication of intra-abdominal infection ($P = 0.0001$), complete preoperative cholangiography ($P = 0.002$), use of correct surgical technique ($P = 0.0001$) and repair performed by a biliary surgeon ($P = 0.0001$) [21].

Survival after bile duct injury

A Swedish population-based study that included major and minor bile duct injuries showed mortality at 1 year following injury was 3.9 % compared with 1.1 % in the non-injured [3]. The risk of death was doubled in patients with a bile duct injury during the first year after surgery, compared with those without [hazard ratio (HR) 1.92, 95 % confidence interval (CI) 1.24–2.97]. Furthermore, reduced survival was reported in patients with late detection of bile duct injury when compared with injury detected at the time of laparoscopic cholecystectomy [HR 1.95, CI 1.12–3.37].

On the other hand, an American study that included bile duct injuries mandating surgical repair reported a mortality rate of 26.1 % in patients with injury within the first year after cholecystectomy compared with 6.6 % in the non-injured patients, adjusted for age, sex and comorbidity [6]. Furthermore, when the surgeon performing the reconstruction was the same as the one causing the injury (this was the case in 75 % of the repairs in the study), the hazard ratio of death was 11 % greater. The reason for this may be the relative inexperience of surgeon causing the injury, moral responsibility of surgeon towards the patient who in an attempt to make what's gone wrong right causes greater harm, along with fear of losing credibility with peers and eventually litigation. Interestingly, in the same paper, the likelihood of survival increased with surgical experience

[6]. The adjusted hazard ratio for death was decreased by 11 % for every successful case of repair undertaken by an experienced surgeon (HR 0.89, 95 % CI 0.82–0.98). Additionally, the hazard ratio for death was increased significantly with advancing age of patient, complexity of the case and comorbidity index.

In a study analysing long-term mortality (follow-up: from 4 to 9 years), the all-cause mortality was 20.8 % [4]. While assessing mortality based on type of definitive surgery performed, the long-term mortality was 8.3–10 % following hepaticojejunostomy (follow-up 7–246 months) performed for postcholecystectomy bile duct injury [22, 23]. The mortality rates after hepatectomy and transplantation were higher at 13 and 22 %, respectively [24].

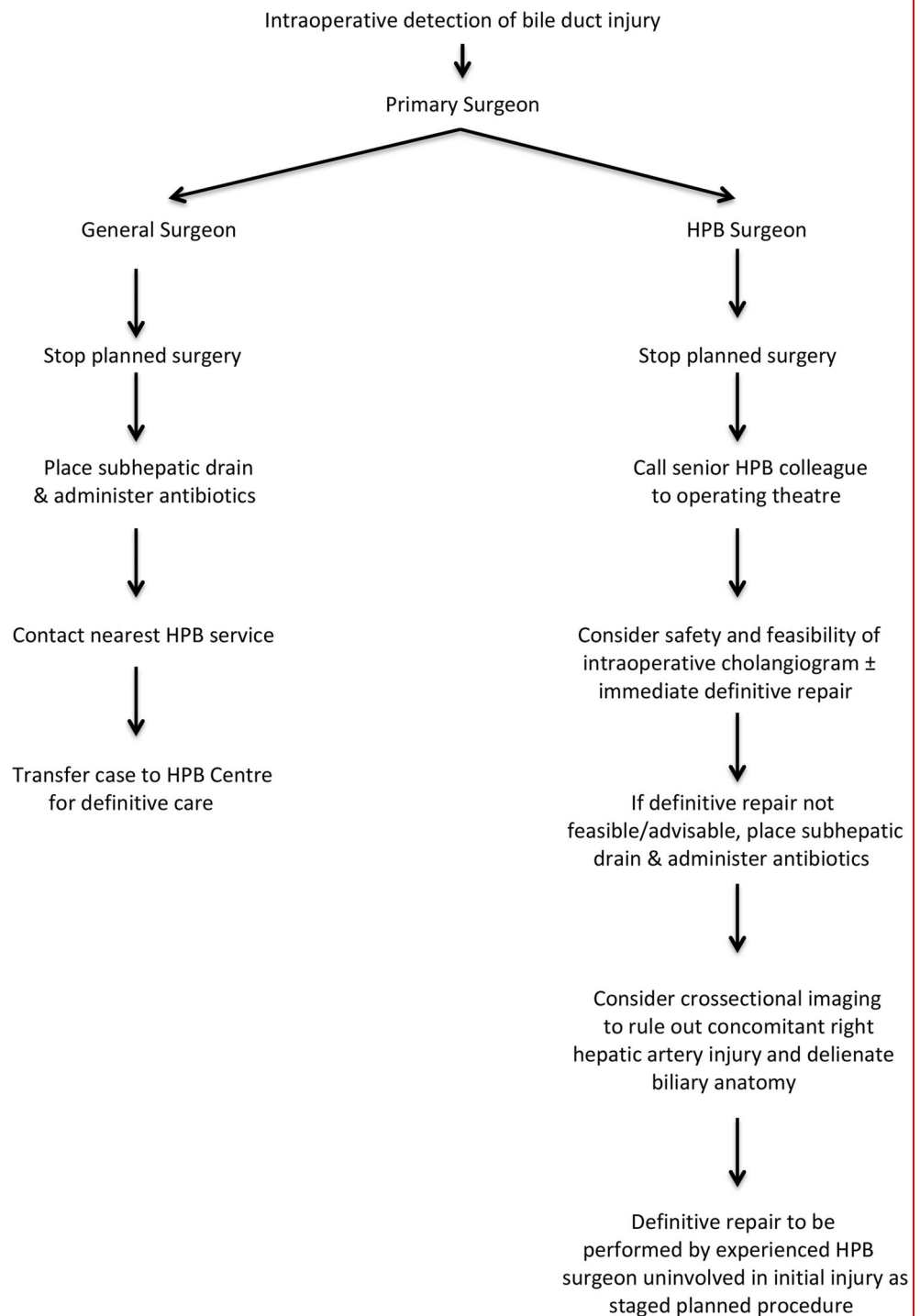
Quality of life after bile duct injury

Multiple studies have attempted to analyse health-related quality of life (HRQoL) (Table 5 [25–32]). A Dutch study was the first to publish the impact of bile duct injury on HRQoL and found HRQoL indices significantly worse after bile duct injury compared with healthy age- and sex-matched controls and patients 2 years after uncomplicated laparoscopic cholecystectomy ($P < 0.05$) [25]. Interestingly, patients with minor bile duct injuries reported poorer physical and mental QOL when compared with patients who sustained major injuries. Probable reasons for this included the small number of patients studied and use of endoscopic treatment strategies, which consist of several procedures that tend to extend the final resolution of the problem, hence impacting negatively on quality of life.

In a study performed in Baltimore, USA, where minor duct injuries were excluded, lower HRQoL trends were seen in the physical and social domains in the surgically treated bile duct injury group (76 and 75 %, respectively) compared with the uncomplicated laparoscopic cholecystectomy group (81 and 80 %, respectively) and healthy controls (80 and 80 %, respectively) [26]. However, the scores were significantly lower ($P < 0.05$) in the psychological domain when cases were treated surgically (77 %) when compared with 85 % in the laparoscopic cholecystectomy group and 84 % in healthy control group.

A study from Tennessee, USA, reported worse physical and mental HRQoL in patients who sustained bile duct injury compared with those who underwent uncomplicated laparoscopic cholecystectomy [27]. Three different questionnaires were used in order to minimise bias. Patients with minor cystic duct leaks were excluded from the study. The scores and outcomes were lower and poorer in the bile duct injury group across all three HRQoL tools used. The Karnofsky Performance Scale score for patients with bile duct injury was 77 ± 9 versus 93 ± 8 in the laparoscopic cholecystectomy group ($P < 0.001$), while on all 8

Fig. 1 Management algorithm of bile duct injury detected intraoperatively. *HPB* hepatopancreaticobiliary



subscales of the SF-36 patients with bile duct injury had significantly lower scores ($P < 0.01$) and psychological assessment to illness scale scores showed trends towards a poorer outcome after bile duct injury than uncomplicated laparoscopic cholecystectomy (mean \pm SD, 45 ± 25 vs. 33 ± 23 ; $P = 0.06$).

A separate study from Rochester, USA, showed no difference in HRQoL between patients who had surgical reconstruction following bile duct injury and those who had uncomplicated laparoscopic cholecystectomy [28]. Comparing this with the Baltimore study [26] (as the inclusion criteria were similar), the quality of life scores

Fig. 2 Management algorithm of bile duct injury detected postoperatively. *CT* computed tomography, *ERCP* endoscopic retrograde cholangiopancreatography, *HPB* hepatopancreaticobiliary, *MRCP* magnetic resonance cholangiopancreatography, *PTC* percutaneous transhepatic cholangiography, *USS* ultrasound scan

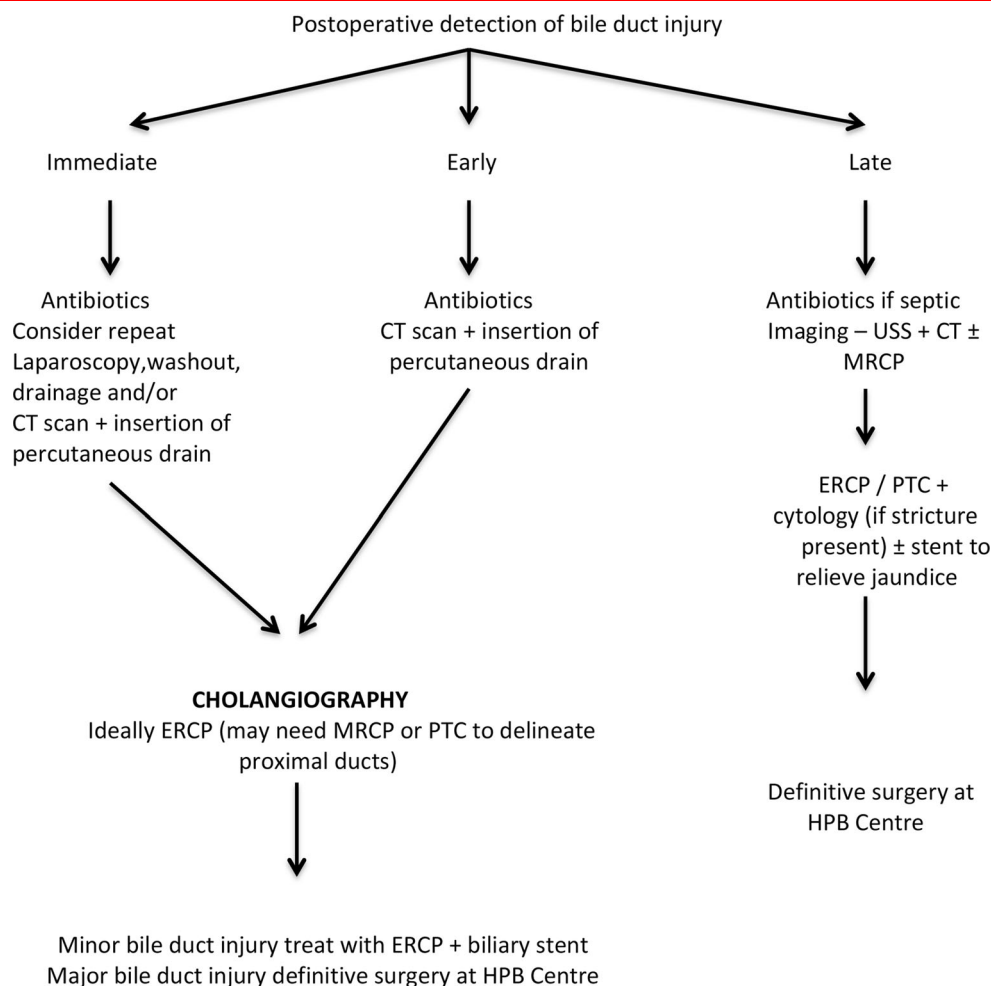


Table 4 Definitive treatment options for bile duct injury

Minor injuries

Endoscopic retrograde cholangiography or percutaneous transhepatic cholangiography and temporary placement of plastic stent for 6 weeks minimum

Major injuries

Often, surgical Roux-en-Y hepaticojejunostomy,
And rarely liver resection ± biliary reconstruction or
Liver transplantation

were no different in the physical and social domains but significantly lower in the psychological domain. The reasons for this were the prolonged periods of hospitalisation and recovery contributing to and influencing the HRQoL scores in the Baltimore study [28].

A study done in Ireland that excluded patients with cystic duct leaks reported HRQoL (physical and mental states) to be marginally lower in patients with bile duct injury but not statistically different when compared with

uncomplicated laparoscopic cholecystectomy [29]. The notable difference in this study as compared with other studies was that the questionnaire was administered directly over the telephone in the evening or on weekends to minimise selection bias.

Given the above differences in results of HRQoL, a meta-analysis was conducted to determine whether bile duct injury and laparoscopic cholecystectomy patients differ in the likelihood of having substantially diminished HRQoL [33]. It included all the above-mentioned six studies representing 521 patients (6 unique groups) with bile duct injury and 310 patients (5 unique groups) who underwent laparoscopic cholecystectomy. Due to the substantial differences in the follow-up time between the six studies, the authors determined three follow-up time categories: ≤ 5 , 6–8 and ≥ 8 years after bile duct injury or laparoscopic cholecystectomy. In patients who were followed up for more than 8 years, 72 % were less likely to have reduced physical HRQoL (OR 0.28, CI 0.14–0.56, $P < 0.001$). After controlling for follow-up time the

Table 5 Summary of studies assessing quality of life after bile duct injury

Studies	Number of cases	Cases included	Response rate	HRQoL tool	Duration of follow-up (months)
Boerma et al. [25], Amsterdam, Netherlands	82	Minor and major BDI—endoscopically, surgically and radiologically treated	92 %	SF-36	70 (37–110)
Melton et al. [26], Baltimore, USA	54	Major BDI—treated surgically	61 %	Minor modification of the City of Hope Medical Center Quality of Life Survey	59 ± 33
Moore et al. [27], Tennessee, USA	50	Minor and major BDI—treated endoscopically, surgically and radiologically	58 %	Karnofsky Performance Scale, SF-36, psychological assessment to illness scale, medical outcomes study	62 ± 6
Sarmiento et al. [28], Rochester, USA	45	Major BDI—treated surgically	81 %	SF-36	100 (62–136)
Hogan et al. [29], Dublin, Ireland	62	Major BDI—treated endoscopically, surgically and radiologically	78 %	SF-36	152 (2–240)
de Reuver et al. [30], Amsterdam, Netherlands	279	BDI—treated endoscopically, surgically and radiologically	69 %	SF-36	71
Dominguez-Rosado et al. [31], Mexico	Group 1 (Long-term follow-up) = 41 Group 2 (short-term follow-up) = 44	Major BDI—treated surgically	33 % 90 % at 1 year 68 % at 5 years	SF-36	120 12–60
Ejaz et al. [32], Baltimore, USA	62	Major BDI—treated surgically	37.1 %	Combination of SF-36 GIQLI CLDQ	169 (125–222)

BDI bile duct injury, CLDQ chronic liver disease questionnaire, GIQLI gastrointestinal quality of life index, SF-36 short form 36

physical HRQoL in bile duct injury patients was no different from laparoscopic cholecystectomy patients. Mental HRQoL was significantly reduced ($P < 0.001$) in patients followed up for more than 5 years. After controlling for follow-up time bile duct injury patients were about 38 times more likely to have a reduced mental HRQoL than laparoscopic cholecystectomy patients (OR 38.42, CI 19.14–77.10, $P < 0.001$).

A Dutch study assessed the HRQoL after 5.5 and 11 years in patients referred to their centre for surgical, endoscopic or radiological treatment [30]. The HRQoL in patients with bile duct injury was significantly lower in three of the eight domains when compared with patients who underwent cholecystectomy ($P < 0.05$), while it was lower in seven of the eight domains when compared with healthy population norms ($P < 0.05$). The HRQoL did not improve between the two time points of 5.5 and 11 years, and the type of injury or the type of treatment did not affect HRQoL outcomes.

In a study from Mexico, a homogenous group of patients with major bile duct injury (Strasberg type E) that mandated a Roux-en-Y hepaticojejunostomy performed by a single surgeon was studied [31]. HRQoL was assessed across two groups: Group 1 comprised patients operated upon from January 1990 to December 2003, and these had long-term follow-up assessed at 10 years. The patients in Group 1 were compared with Mexican norms pre-established in randomly selected non-institutionalised Mexican adults. Group 2 comprised patients operated upon between January and December 2008 and had short-term follow-up assessment at 1 and 5 years. Those in Group 2 had pre-operative scores determined. Thus, patients acted as their own control after repair. This was different from the studies done earlier as they considered patients who underwent laparoscopic cholecystectomy as normal or control group. The reason for assessment in these two time periods is because the centre moved from being a low to a high volume centre for repair of bile duct injuries. The results in Group 1 showed significantly poorer HRQoL scores compared with SF-36 Mexican norms across physical and mental domains, while in Group 2 they found significant improvement across physical and mental domains at 1 and 5 years after surgery compared with preoperatively obtained scores. However, on comparison of quality of life data between the two groups, there was no significant difference seen across physical and mental quality of life scores at 1, 5 and 10 years. The key limitation of this study is the selection bias due to non-compliance (>60 %) to long-term follow-up. This, however, remains the reality of healthcare provision in developing countries.

In a follow-up of their study published previously [26], the group from Baltimore used a comprehensive questionnaire drawing elements from three previously existing

tools [32]. The HRQoL was assessed before and many years after definitive repair (median 14 years, range 10–18 years) of bile duct injury. In their assessment, mental health was most affected at the time of bile duct injury, which significantly improved postoperatively (depressed mood 49.2 vs. 18.3 %, low energy levels most or all of the time 40 vs. 18 %, $P < 0.05$). Surprisingly physical and general health parameters were unchanged before and after surgical intervention. Additionally, 70.5 % ($n = 43$) sought legal aid following bile duct injury and 70.7 % ($n = 29$) reported a successful legal outcome. No difference was noted in HRQoL in patients who won their medico-legal lawsuits. The same group previously found HRQoL to be worse in those who pursued a lawsuit after injury, while the Dutch showed HRQoL to be higher in those who had lawsuits ruled in their favour [30].

Litigation

Laparoscopic cholecystectomy is one of the most common surgical procedures leading to civil litigation [34]. In order for civil litigation to be successful, the Claimant has to prove all three components, ‘liability’, ‘breach of duty’ and ‘causation’. ‘Liability’ is not usually in dispute for the surgeon responsible for the injury. A ‘breach of duty’ is proven as bile duct injury is a technical error which is avoidable, while ‘causation’ is shown easily if there is a delay in recognition of injury or if the patient is faced with harm due to sepsis and/or need for definitive repair, prolonged hospital stay, recovery and finally complications following revisional surgery.

In a retrospective analysis of laparoscopic cholecystectomy-related claims reported to the National Health Service Litigation Authority (NHSLA), UK, in a 5-year period (2000–2005), only 116 of the 133 claims were analysed, as 17 were still open at the time of the study [5]. Bile duct injury accounted for majority of the claims 72 % (83/116) followed by bowel injury (9 %), bleeding (4 %), vascular damage (3 %) and other issues (12 %). Only 20 % (17/83) of bile duct injuries were identified at the time of surgery. There were a total of 12 laparoscopic cholecystectomy-related deaths of which 7 were due to bile duct injury. Of the total £6.3 million paid to settle laparoscopic cholecystectomy-related claims £4.4 million was used to settle claims for bile duct injury. The figures include damages and legal expenses incurred by the NHS, and 80 % (63/83) were settled in favour of the Claimant. The vast majority (90 %) of claims were successful in the group of cases where bile duct injury was detected late, while only half of those claims were successful when the injury was identified at the time of surgery.

In a separate study, risk factors leading to litigation following laparoscopic cholecystectomy in England were

assessed [35]. In the 15-year period (April 1995 to April 2009), a total of 418 claims of alleged clinical negligence were registered following laparoscopic cholecystectomy, of which 303 had been settled by April 2009. In 65 % (198/303), the claims were successful and the NHS paid a total of £13,551,275 in damages and £6,808,471 in other associated costs. The average payout was approximately £102,827 per case. The predictors of successful claims were intraoperative error present in 84.9 % of cases ($P = 0.0230$) along with complications of bile duct injury occurring in 37 % of cases ($P < 0.001$).

In a separate study the probability and factors leading patients to seek medico-legal redress were evaluated [36]. Survivors, following major transection/excision bile duct injury (Strasberg type E) with at least 2-year follow-up, referred to a large tertiary referral centre over a 17-year period were included. Surveys regarding patient perception on information provided prior to laparoscopic cholecystectomy, explanations provided following complication, patient satisfaction with subsequent management, perception of physical recovery and psychological experience and complaints related to patient experience, litigation proceedings and final outcomes were assessed. Only 67 of a total 106 eligible patients consented to participate in the study. The majority of the patients believed they were informed inadequately (70 % preoperatively and 75 % postoperatively). Most (73 %) felt psychologically traumatised, physical recovery was possible in 30 % of cases, and only 27 % believed their experience to be an unavoidable surgical complication. A total of 22 (32 %) patients sought medico-legal redress, of which 86 % ($n = 19$) were closed and all were settled in favour of the Claimant. Only 9 of the 19 patients disclosed the compensation they received which ranged from £2500 to £216,000 with an average settlement fee of £62,500, and the final compensation received by the Claimant is the settlement figure deducting the Claimant's legal costs incurred.

In terms of factors leading to litigation, univariate analysis revealed: (1) age < 52 years ($P = 0.038$), (2) laparoscopic cholecystectomy performed after the year 2001 ($P = 0.047$), (3) perceived incomplete recovery after complication ($P = 0.047$), (4) associated vascular injury ($P = 0.022$) and (5) immediate repair performed by the surgeon causing the initial injury ($P = 0.001$) as independent significant risk predictors resulting in an increased risk of litigation. While applying a multivariate regression model, all the above risk factors except the year in which laparoscopic cholecystectomy was performed were identified as significant.

The Dutch evaluated their experience with bile duct injury litigation following laparoscopic cholecystectomy [37]. Their study analysed 133 claims filed following

laparoscopic cholecystectomy specifically due to bile duct injury, in the period 1994–2005. A review of the medical and operation notes revealed that informed consent was found in 23 % of the patients and the content of the informed consent was documented in 11.5 % of the patients. The complication of bile duct injury was documented in 9.7 % of the case notes. Documentation that the laparoscopic cholecystectomy was complicated was found in 49 patients (43.4 %) with bile leakage to account for 42.5 %, adhesions 39.8 %, haemorrhage 21.2 % and anatomic variations for 15.0 %. Dissection of Calot's triangle was documented in 11.5 % of the operation notes with the critical view of safety mentioned in 1.8 %. Cholangiography was performed in 8 patients (7.1 %), and the bile duct injury was recognised in 66 (58.4 %). Following identification of bile duct injury, intraoperative advice from colleagues was sought in 12.4 % and from a tertiary centre in 4.4 % of instances. In terms of the claim outcomes, 88 claims were filed after a mean of 2.4 years (range 5 months to 6.5 years). Of the 88 claims, 69 % ($n = 61$) were rejected, 18 % ($n = 16$) claims were accepted, and 15 % ($n = 11$) were settled. The characteristics of the accepted claims were: patients in active employment (62.5 % vs. 27.9 % in rejected claims, $P = 0.02$), documentation of complications occurred during laparoscopic cholecystectomy (62.5 % vs. 31.1 % in rejected claims, $P = 0.03$), bile duct injury-related death (18.5 % vs. 1.6 % in rejected cases, $P = 0.004$). The median financial compensation in the accepted and settled claims was €9826 with maximum amount of €55,301 and minimum €1588. Factors that influenced the financial compensation were delay in diagnostic imaging (median €13,780, $P = 0.003$), delay in diagnosis (median €13,885, $P = 0.009$), relaparotomy with repair in the initial centre (median €11,652, $P = 0.028$ %) and involvement of the Claimant's attorney (median €13,885, $P < 0.001$).

In the USA, a database of published jury verdicts and settlements from 48 state and regional reporters was searched and a retrospective analysis of non-consecutive sample of medical malpractice claims performed [38]. A total of 104 cases of laparoscopic cholecystectomy litigation were seen. They found that bile duct injury was the dominant adverse event that triggered legal action. Litigation was terminated by negotiated settlement in 17 % of cases, while verdict-favouring the Claimant (VC) noted in 46 %, and the remaining 37 % of cases the verdict favoured the involved surgeon (SV). Furthermore when the litigation was terminated by negotiated settlement, the Claimant received on average \$628,138, and when terminated by VC, the Claimant received on average \$2,891,421. Additionally, delayed recognition of the adverse event remained a recurrent theme in the litigation that followed laparoscopic cholecystectomy.

Conclusion

Bile duct injury following laparoscopic cholecystectomy affects the patient adversely and impacts negatively on the surgeon as well. Reviewing lessons learnt globally from litigation involving laparoscopic cholecystectomy, bile duct injury accounted for majority of claims with significant monetary settlement in favour of the Claimant, especially when the injury was detected late. As trained surgical professionals there is a need to enhance and refine how we communicate with our patients. This would help balance expectations from the surgical outcomes we constantly seek to improve. In England it is a statutory requirement by law for all healthcare professionals to adhere to the duty of candour [39]. Surgical care providers are duty bound to be transparent when patients are harmed after intended treatments. A formal apology with an explanation must be provided, in addition to immediate and appropriate treatment to rectify the harm caused [39]. Furthermore, incident reporting and appropriate clinical governance proceedings as per locally agreed norms must be initiated to prevent such incidents from occurring in future [39]. This will enable care providers and organisations develop a culture of learning, openness and help promote patient safety.

Compliance with ethical standards

Conflict of interest None of the authors has a conflict of interest to declare.

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