Surgeons Opinions of Legal Practice in Bile Duct Injury Following Cholecystectomy

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Abstract

Introduction
Litigation for bile duct injury (BDI) following laparoscopic cholecystectomy (LC) places financial strain on the health service, causes significant patient morbidity and adversely affects both the patient and the surgeon. Claimants argue that the injury itself is evidence of negligence.

Methods
A questionnaire addressing the views on BDI causation was sent to 273 members of the AUGIS working in the National Health Service, UK. A grounded theory was used. Response themes and responses were compared between groups of surgeons.

Results
Of 117 respondents, 45 % experienced BDI and 22% had medicolegal experience. 47% of respondents identified factors outside the surgeons control as being relevant to BDI. Those that had experienced BDI from their own surgery were less likely to identify surgeon/systems errors as the primary cause for BDI than those that had not (34% vs 74% $p<0.001$). Medicolegal expert surgeons were more likely to report that substandard technique should be presumed (50% vs 19%, $p=0.002$), however, 25% of medicolegal experts indicated that not all BDIs caused by their own surgery could have been avoided.

Conclusion
A significant number of experienced surgeons indicated that BDI following LC should not be assumed to result from surgeon negligence or institutional failure. This suggests that negligence should not be inferred from the act of BDI alone.

Introduction

Bile duct injury (BDI) is a rare but recognised complication of laparoscopic cholecystectomy (LC). It is associated with significant morbidity related predominantly to recurrent cholangitis and biliary stricture(1) and a significantly increased risk of mortality over long-term follow-

up(2). Bile duct injury accounts for the largest proportion of negligence claims following LC in the UK(3), and reports indicate that the number of negligence claims is increasing. It has been suggested that increased awareness, access to medical information and a history of successful lawsuits are responsible for this trend(4). In the UK, claims arising out of BDI frequently succeed, either at trial or, more commonly, settlement out of court,(5),(6) This has led some to speculate that BDI resulting from LC is indefensible(6).

An understanding of the aetiology of bile duct injury has evolved with laparoscopic experience. Early in the development of the technique, BDI was often attributed to surgical learning curve and operator inexperience(7),(8) and so at this time litigation was more likely to be successful for injuries resulting from laparoscopic than open cholecystectomy(9). Now that LC is one of the most commonly performed general surgical operations, it is not considered acceptable to cite lack of familiarity with the technique as a contributory factor to BDI.

Alternative factors that may contribute to bile duct injury include anatomic variation, severe inflammation, errors related to skill, knowledge or judgement or demographic factors such as patient age or sex(10),(11). Lack of binocular vision and distorted visuospatial perception may also contribute to misidentification of biliary anatomy during laparoscopic cholecystectomy(12). The risk of BDI was attributed to this lack of 3-dimensional vision and visual disorientation that is inherent with laparoscopic surgery. In the 1990's, the risk of BDI was greater with LC than with the open technique, however, this is no longer the case(10)..

Over a 15-year period to 2009, in the UK, 65% of 303 settled litigation claims following bile duct injury were found in favor of the plaintiff at a total cost of 20.4 million GBP(3). More recent analyses have demonstrated that the mean cost of damages to the NHS per successful claimant suffering a BDI is in excess of £50,000(12),(13). This finding is mirrored in the USA, where on average the payout awarded to successful claimants is significantly higher. In contrast, studies in other European countries demonstrate a low proportion of successful litigation. In a Dutch study, 69% of claims were rejected, despite 55% of claimants experiencing Amsterdam criteria Grade D BDI(14).

The financial burden resulting from BDI litigation within the NHS is significant, however the impact of litigation extends beyond the financial implications alone. Lengthy legal proceedings create immense psychological burden for practicing surgeons, who face difficult reflection on their practice and may be less likely to attempted complex cholecystectomy in the future. Litigation may also negatively impact the doctor-patient relationship and generate an attitude wherein a medical complication must be compensated irrespective of the risk taken by the medical professional. To date there has been little consideration of the medical professions' opinion of the role of litigation in relation to bile duct injury. Furthermore, differences exist between the opinions of the judiciary and the medical profession with regards to the liability and causation of BDI(15), with medical literature being less concerned with the concepts of negligence and civil liability than the technicalities of surgical practice.

Here, the views of upper gastrointestinal surgeons working in the National Health Service were investigated to determine whether operating surgeons believe that bile duct injury implies operative error, and whether BDI automatically implies negligence.

Methods

The Consolidated Criteria for Reporting Qualitative Research (COREQ)(16) were consulted during the design and reporting of this study.

An anonymised online questionnaire addressing the background, experience and familiarity with BDI and views on BDI causation was designed by consultant hepatobiliary (HPB) surgeons (MS, ZS) working in a tertiary referral center (Churchill Hospital, Oxford, UK). Both surgeons have extensive experience with the surgical management of bile duct injury following laparoscopic cholecystectomy and have each performed over 1000 LCs. As well as collecting demographic information, the questionnaire (Supplementary Table 1) sought to enable participants to express their reasoning and opinions relating to the cause of bile duct injury and potential negligence on the part of the operating surgeon. The authors initial assumptions were that BDI results from various factors, is not always the result of negligence and so it is wrong to assume negligence following BDI.

The questionnaire was distributed to all practicing general surgeons who were members of the Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland (AUGIS) as of June 2016 via email. This association was chosen because its members are a broad surgeon demographic including HPB surgeons, surgeons with medicolegal experience and surgeons who perform LC but who are not members of the HPB surgical subspecialty. It was made clear that the questionnaire was designed by hepatobiliary surgeons and a letter of invitation (Supplementary Figure 1), with relevant information accompanied the questionnaire. The questionnaire remained active on an online platform for 2 months. No respondent-identifiable details were recorded and once submitted, responses could not be altered. Respondents were given single access to the questionnaire so that it could not be completed on multiple occasions by the same respondent. AUGIS members were sent 2 further reminders at 4 week intervals to complete the questionnaire, following which data was exported and the questionnaire closed. Ethical approval for the study was granted by the host institution.

Two authors (AGW and HS) reviewed and coded responses to the open questions (7, 8, 11 and 12) in order to identify themed responses for each. The key themes were generated following, rather than prior to data collection and were based upon an initial review of the responses obtained. For specific themes, representative responses are presented in quotations. The resulting binomial data was compared between groups of surgeons using Fishers exact test.

Results

Respondent Demographics

Of the 273 potential participants sent the questionnaire, 117 responses (43%) were received. Respondents comprised 91 upper gastrointestinal (78%), 23 hepatobiliary (20%), 1 colorectal, 1 transplant and 1 bariatric surgeon (1% each). 9 (8%), 18 (15%), 22 (19%) and 68 (58%) surgeons reported performing <250, 250-500, 500-1000 or >1000 cholecystectomies during

their consultant career respectively, confirming that the responders were experienced laparoscopic surgeons with over 90% having carried out more than 250 procedures. 3 respondents (3%) denied consenting patient of the risk of BDI prior to LC.

53 respondents (45%) reported experiencing BDI because of surgery that they had performed, of which 48 (90%) were upper gastrointestinal surgeons and 5 (9 %) were hepatobiliary surgeons. 36 surgeons (31%) were involved in the specialist surgical management of patients with BDI, of which 23 were hepatobiliary, 11 were upper gastrointestinal, 1 was colorectal and 1 a transplant surgeon. 26 respondents (22%) reported having expert medicolegal experience of relevance to BDI of whom 7 were hepatobiliary surgeons.

Notably, although 54 respondents (46%) estimated that a proportion of BDIs in their experience would not have been avoidable even with reasonable care, the responses were highly variable and several respondents indicated that it was difficult to estimate such a figure. These data were therefore not analysed further.

Identification of Key Response Themes

Response themes for question 7 broadly fell into 6 categories (Table 1). Responses were categorised as being due to difficult anatomy if any reference was made to anatomical variation, but categorised as poor decision making or misinterpretation if the response indicated a failure to recognise aberrant anatomy as a cause of injury. Systems failures were classified as factors considered outside the surgeons control. 52 respondents (44 %) felt that poor decision making was the most important cause of BDI, whilst 27 (23%) and 24 (21%) felt that abnormal pathology or aberrant anatomy respectively were the most important causes (Figure 1).

Respondents 1st answers to question 7 were subdivided into those that indicate the operating surgeon or healthcare system is primarily at fault in patients with BDI and those that indicate factors outside of the control of the surgeon or healthcare system are responsible (Table 1). Surgeons who had experienced a bile duct injury as part of their own practice were significantly more likely to cite factors outside of the surgeons control as the most important reason for BDI, than surgeons who had not experienced BDI ($p=0.0001$), (Table 2).

For question 8, responses fell into similar categories as for question 7 (Table 3) and 82 respondents (70%) indicated that not all BDIs they had managed were avoidable with a reasonable standard of care. Those respondents that felt all of the BDIs they had managed were avoidable cited technical failure, poor decision-making and inadequate experience as causative factors (Table 3). In response to question 11, only 22 (19%) of 113 respondents indicated that there were no circumstances in which BDI can occur despite a reasonable standard of care. Of the 91 respondents who indicated that they could conceive a situation in which BDI can occur despite a reasonable standard of care, 98% cited difficult anatomy or pathology as a cause. 8 of 26 medicolegal experts (31%) felt that there were no circumstances in which BDI should occur if a reasonable standard of care was taken, compared with 14 of 91 non-experts (16%). Finally, 48 of 53 respondents (91%) who had experienced BDI as a result of their own surgery felt that there were circumstances in which

BDI could occur despite a reasonable standard of care, compared with 30 of 64 respondents (47%) who had not experienced BDI as a result of their own surgery (p=0.004).

Determination of Response Trends

The answers to questions 8 and 10 where then compared for different groups of respondents. Notably, respondents with medicolegal experience were significantly more likely to report that the BDIs they had managed were avoidable with a reasonable standard of care. Similarly, this cohort were also more likely than non-experts to conclude that in patients with BDI, sub-standard technique should be presumed (Table 4). However, over 50% of medicolegal experts felt that some of the bile duct injuries that they have managed were not avoidable, even with a reasonable level of care, and a similar proportion felt that following the occurrence of a bile duct injury, substandard technique should not be presumed. For surgeons who had never experienced a bile duct injury in their own practice, the proportion reduced to 47% and 36% respectively. Respondents who had experienced BDI secondary to surgery they had performed were less likely to indicate that BDIs were avoidable even with a reasonable standard of care, or that substandard technique should be assumed in such situations (Table 4).

Discussion

Litigation for BDI sustained during LC is putting increasing financial strain on healthcare systems worldwide. In England or Scotland a claimant must prove that the surgeon failed to take reasonable care – the 'Bolam'(17) or 'Hunter v Hanley'(18) tests respectively – in order to be provided with compensation. Courts rely on expert evidence from independent experts with experience of LC. In BDI litigation some experts contend that the fact of the injury itself indicates a failure to take reasonable care. A presumption of negligence following BDI risks increasing the practice of defensive medicine, may promote an unwillingness to perform complex surgery and increase stress for the surgeon. Litigation for injury caused by negligence is justified to maintain standards and to provide the claimant with the financial support required for recovery, ongoing care, loss of earnings or the psychological morbidity experienced. However, damages are not appropriate where the complication is considered to be inherent to the surgery and at times unavoidable even with a reasonable level of practice and technical expertise.

The type of surgery is also of relevance here. Patients may be willing to accept a greater rate or severity of complication for life-saving, emergency or major surgery than for a day-case, elective operation. Also, the significance of BDI in terms of morbidity is very high when compared with the typical recovery following LC. In comparison, the recovery from a pancreatectomy is expected to be lengthy and so a pancreatic fistula, although significant, may be considered less of a deviation from the norm. Such emotional issues may play a significant part in determining whether patients initially seek compensation, however this might be at odds with the reality of clinical practice. In some other European countries liability for BDI on the part of the surgeon is more frequently rejected than accepted(14), indicating that in these healthcare systems an inherent risk to LC is presumed.

Although a response rate of only 43% was achieved, the respondents comprise a group of upper gastrointestinal surgeons with a broad range of experience levels, a significant

proportion of whom have performed >1000 cholecystectomies throughout their career, perform specialist surgical intervention for bile duct injuries and/or have experience as medicolegal experts in the management of BDI.

The current data demonstrate that there is significant variation in opinion with regards to whether the surgeon/healthcare system is primarily at fault for BDI. Thus, although poor decision making was the most commonly identified reason for BDI, almost half of respondents identified factors outside the surgeon's control as being the most important cause of BDI. Furthermore, a quarter of medicolegal experts agreed that not all bile duct injuries could have been avoided in their clinical experience, and half of them felt that substandard technique cannot be presumed. However, whilst this is the case, it was notable that (although in the minority), many experienced surgeons responding to the questionnaire still feel that bile duct injuries should never occur with good surgical technique, and that their occurrence would imply negligence. Interestingly, despite this, there were only three respondents who did not consent patients of the risk of BDI prior to performing LC, therefore indicating that the overwhelming majority of participants believe the risk of BDI cannot be eliminated in their own hands.

A potential limitation of the study however, is the relatively small sample size. Indeed, the low response rate makes comparison of groups of surgeons with regard to a particular opinion difficult. In particular, the sample size was not sufficiently large enough to perform a multivariate analysis. Nonetheless, from the analysis of the demographic details of respondents and the ranges of opinions expressed in questions 7, 8 and 10, it is evident that the data generated represent the views of a broad spectrum of upper gastrointestinal surgeons throughout the UK and that data saturation has been reached. The questionnaire could have been disseminated to surgeons from other countries in order to increase the sample size. However, given the differences in legal practice with regards medical negligence between countries, it is likely that this approach would have added an additional layer of complexity and subgroup analysis would have been required.

Nonetheless, a clear dichotomy of opinion between surgeons who have experienced BDI as part of their own practice and those with medicolegal experience in patients with BDI has been identified. Indeed, most of the 53 respondents who reported experiencing BDI in their own practice felt that factors outside of the surgeon/health care systems control were responsible for BDI and that BDI was infrequently the result of poor technique or lack of care. This is in contrast to those with medicolegal expertise, who felt that BDI was more frequently the result of surgical error, lack of adequate care or poor surgical technique. Despite this, 53% of medicolegal experts stated that not all the bile duct injuries they had managed were related to poor or negligent technique. Whether this level of uncertainty is sufficient to alter current medicolegal opinion in the UK remains unclear.

From the data presented here, the reasons for this difference of opinion are not clear. However, it is notable that this result is not related to the surgeon's experience level with regards to the number of LCs performed, as those who have performed more or less than 1000 LCs demonstrated no difference of opinion with regards to their answers to question 7, 8 and 10. Equally, it was notable that there was no significant difference of opinion for these

questions between hepatobiliary surgeons and those of other upper gastrointestinal specialties.

This study has shown that there are a number of experienced surgeons in the UK (50% of medicolegal experts, 56% of HPB surgeons and 72% of surgeons who have carried out over 1000 LC) who have expressed the view that it should not always be assumed that BDI is due to surgeon negligence or institutional failure. It is unlikely that the risk of BDI during LC (or indeed open cholecystectomy) can ever be eliminated, even in the hands of an expert and with due care. The results of this survey therefore suggest that it is inappropriate to assume negligence from the fact of BDI alone. It would be sensible, as with other injuries following surgery, to examine each injury on its own merits before deciding whether the injury was the result of negligent technique.

Question	Example responses	Theme	Category
7. What are the most important causes of bile duct injury?	"Not performing a cholangiogram" "Unwilling to seek help" "Poor training" "Surgeons misconception about biliary anatomy"	Poor decision making or misinterpretation	Surgeon/systems error
	"Delay in operative scheduling" "Equipment failure"	Systems failure	
	"Poor dissection – no critical view obtained" "Ill-judged attempts to control bleeding" "Excessive use of diathermy"	Technical failure	
	"Aberrant anatomy" "Short, wide cystic duct"	Aberrant/difficult anatomy	Uncontrollable factors
	"Inflammation around Calots triangle" "Difficult case (e.g. Mirrizzi)"	Abnormal/dangerous pathology	

	“Increasing obesity” “Elderly men with shrunken gallbladders”	Demographic issues	

Table 1. Identification of response themes from question 7.

Demographic		Surgeon or systems error [numerator/denominator](%)	p*
Experience of >1000 cholecystectomies	yes	[37/68](54)	0.85
	no	[27/47](57)	
Medicolegal expertise in BDI	yes	[18/26](69)	0.12
	no	[46/89](52)	
Hepatobiliary surgeon	yes	[17/23](74)	0.06
	no	[47/92](51)	
Experienced BDI in own practice	yes	[18/53](34)	***<0.001***
	No	[46/62](74)	
Provide specialist BDI management	yes	[23/36](64)	0.41
	no	[41/79](52)	

Table 2. Comparison of the 1st responses themes from question 7 by demographics of responder (*Fishers exact test).

Question	Qualifier	Example responses	Theme
8. In your experience, were all the bile duct injuries that you have managed avoidable with a reasonable standard of care?	For participants answering '**no**'	"Even with a full critical view dissection anatomy can be miss-leading…" "Abnormal anatomy and fistulae… mean bile duct 'injury' is not unavoidable"	Aberrant/difficult anatomy
		"…the severity of inflammation means that removing the gallbladder exposes injury to the bile duct…" "My single bile duct injury occurred [in a] patient with intense fibrosis... this was unavoidable."	Abnormal/dangerous pathology
		"… An understanding of human factors teaches us that all humans are fallible..." "I have encountered several near misses... That even in experienced hands would have fooled the operator"	Surgeon fallibility
	For participants answering '**yes**'	"All CBD injuries are avoidable with adequate care" "Failure to recognise anatomy…" "bile-duct injury [is a] never event… dissecting on & around gall bladder with care is the most important fundamental surgical technique required to avoid complications."	Technical failure
		"… the option of subtotal cholecystectomy should be considered" "Major bile duct injury can… be avoided by appropriate patient selection, pre-operative work up and intra-operative decision making"	Poor decision making or misinterpretation
		"It is an operation performed by too many occasional laparoscopic cholecystectomy surgeons."	Inexperience
		"Bile duct injury and bile leaks are never events and can be avoided with careful operation…" "A reasonable standard of care avoids bile duct injury, otherwise it is not reasonable"	Never event

Table 3. Identification of response themes from question 8.

Demographic		Responding 'yes' to question 8 (%)	p*	Responding 'yes' to question 10 (%)	p*
Experience of >1000	yes	31	0.84	28	0.53
	no	29		23	

cholecystectomies					
Medicolegal expertise in BDI	yes	46	***0.05***	50.	***0.002***
	no	25		19	
Hepatobiliary surgeon	yes	44	0.13	44	0.11
	no	27		27	
Experienced BDI in own practice	yes	9	***<0.001***	13	***0.006***
	no	47		36	
Provide specialist BDI management	yes	36	0.38	36	0.38
	no	27		27	

Table 4. Comparison of responses to question 8 and 10 by demographics of responder (*Fishers exact test).

Figure legends

Figure 1. Response distribution for question 7, demonstrating the order in which respondents ranked the various causes of bile duct injury.

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