ORIGINAL ARTICLE

A comprehensive evaluation of the long-term economic impact of major bile duct injury

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Abstract

Background: Complications and litigation after bile duct injury (BDI) result in clinical and economic burden. The aim of this study was to comprehensively evaluate the long-term clinical and economic impact of major BDI.

Method: Patients with long-term follow-up after Strasberg E BDI were identified. Costs of treatment and litigation were the primary outcome. Relationships between these outcomes and repair factors, like timing of repair and surgeon expertise, were secondary outcomes.

Results: Among 139 patients with a median follow up of 10.7 years, 40% of patients developed biliary complications. Repairs by non-specialist surgeons had significantly higher follow up and treatment costs than those by specialists (£25,814 vs. £14,269, $p < 0.001$). Estimated litigation costs were higher in delayed than immediate repairs (£23,295 vs. £12,864). As such, the lowest average costs per BDI are after immediate specialist repair and the highest after delayed non-specialist repair (£27,133 vs. £49,109, ×1.81 more costly, $p < 0.001$). Repair by a non-specialist surgeon (HR: 4.00, $p < 0.001$) and vascular injury (HR: 2.35, $p = 0.013$) were significant independent predictors of increased complication rates.

Conclusion: Costs of major BDI are considerable. They can be reduced by immediate on-table repair by specialist surgeons. This must therefore be considered the standard of care wherever possible.

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Introduction

Iatrogenic bile duct injury (BDI) is an uncommon but potentially serious complication of cholecystectomy, affecting 0.1%–0.8% of patients.[1–4] The Strasberg Classification system is commonly used to grade the severity of BDI.[5] Type E injuries, or major BDI, are more severe and complex requiring surgical intervention and reconstruction.[6]

Following major BDI, patients are at risk of various complications. In the short-term, these include bile leak and sepsis while, in the longer term, common problems include recurrent cholangitis, anastomotic stricture formation and secondary sclerosing cholangitis.[7–9] Furthermore, BDI is associated with a high risk of litigation; approximately 33% of patients in the United Kingdom pursue litigation after BDI,[9] leading to a cost in excess of £4,500,000 between 1995 and 2008 in claim settlements alone[10] and an average successful claim of £102,827 (US$168,387)[11]. This is not a problem limited just to the UK however, with a range of payout values reported, from an average of €9,826 (US$11,000)[12] in continental Europe to between US$214,000[13] US$508,341[14] in the United States.

Risk factors for biliary complications after BDI are well defined and include the severity of injury,[15,16] presence of a concomitant vascular injury[15–17] surgeon expertise[9,18] and the timing of repair.[8,9,19,20] However, there is a recognition that biliary complications can develop several years after initial repair,

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although most studies fail to address long term follow up. Treating these complications is burdensome on healthcare systems and patients alike, as many require multiple admissions, investigations and procedures over many years. The long term economic burden of BDI is therefore unclear.

The primary aim of this study was to define costs of Strasberg E BDI, taking into account both direct costs of treatment and costs of litigation, among a cohort of patients with sufficient follow up to determine an overall cost to the society/health service. Secondary outcomes were to quantify the clinical burden of major BDI in terms of complications and healthcare resource use along with predictors of complications.

Methods

Patients with Strasberg E BDI between January 1990 and June 2015 were identified from a prospectively collected and maintained database. Institutional approval was obtained. Consultant hepatobiliary and pancreatic surgeons from the University Hospitals Birmingham NHS Trust offer an immediate 'on table' service to local hospitals for bile duct injuries identified at the time of injury as well as a specialist service for the referral of BDI identified after cholecystectomy.

Patients are followed up at the specialist site for a minimum of ten years following injury. Complications are recorded prospectively and categorized into Clavien Dindo severity by a dedicated data manager (Mr Chris Coldham). Interventions, investigations and clinical records are all recorded electronically. Following treatment, patients were also graded according to the standards proposed by Cho *et al.* in 2017.[21]

Surgical technique

Specialist surgeons performed hepaticojejunostomy in the majority of cases. The ends of the bile ducts were resected to healthy tissue and typically into the left hepatic duct for cases of an E1-2 injury to increase the diameter of the hepaticojejunostomy. For cases involving excision of the confluence then separate anastomoses were performed to each duct. Anastomoses were typically reconstructed using 5.0 polydiaxanone (PDS) interrupted sutures. A retrocolic Roux limb was created (50 cm) and brought up to the hepatic duct(s). Arterial injury was typically not repaired though, for immediate on table injuries, this was performed when possible. Surgical repair by non-specialist surgeons was, by definition, not controlled or defined, but the nature of the repair was recorded within the database.

Risk factors for long-term biliary complications

Long-term biliary complications were classified as complications occurring after 90 days from the original repair. Long-term biliary complications were defined as one or more of recurrent cholangitis with or without anastomotic biliary stricture formation; anastomotic biliary stricture formation; need for hepatectomy or liver transplantation due to complications of BDI.

Associations between long-term biliary complications and the following factors were investigated (i) Expertise of surgeon performing the BDI repair – either a specialist surgeon from our tertiary hepatobiliary centre ('specialist') or a surgeon from the local referring centre ('non-specialist') (ii) Timing of repair – the time between cholecystectomy when the BDI was sustained and the repair. This was defined as 'immediate' (during the original operation), 'early' (within 21 days of BDI) or 'late' (greater than 21 days after BDI). This is the same system employed by Perera *et al.* in our study of 2011[9] (iii) Type of injury – patients were classified according to which subtype of Strasberg E injury they sustained ('Strasberg E1-2 or E3-5)[5] and whether or not there was a concomitant vascular injury.

Consequences of long-term biliary complications

Treatment costs

The total cost to the health service for managing follow up and treating biliary complications following BDI repair was calculated for each patient. A cost was assigned to each outpatient and inpatient episode, along with costs of radiological and endoscopic tests, interventional radiologic or endoscopic treatment or surgical treatment, as described above. Costs were obtained from the finance department in our institution. Costs were based upon the 2016–2017 financial year in the UK and as per the standard NHS tariffs for each item costed using OPCS and HRG codes.

Litigation costs and trends in litigation after BDI in the UK

A freedom of information request was sent to the National Health Service Litigation Authority (NHSLA) to obtain the cost of all BDI litigation cases to the health service in the United Kingdom between 2005/6 and 2014/5. Actual costs of successful litigation from subjects within the main study cohort were not sought, as it was not deemed appropriate to ask this information and accurate data would likely not be provided. The rate and costs of litigation among patients undergoing immediate or delayed repair of BDI and following specialist or non-specialist repair was taken from existing UK data.[22] These values were then adjusted, based on the contemporaneous NHSLA data, to estimate costs within the current financial climate. The incidence of litigation amongst patients with BDI was estimated based upon the number of cases of litigation, as provided by the NHSLA, together with the numbers of cholecystectomy for each calendar year, as described within the HES (Hospital episodes statistics) database.

Hospital interventions

For each patient, the number and nature of all relevant hospital investigations and treatments in the years following BDI repair were recorded to the point of last follow up. This included (i) radiological investigations on the biliary tract (CT, MRI, ultrasound, MRCP, plain X-ray, barium follow through, nuclear medicine) (ii) outpatient appointments (OPA) (iii) hospital

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admissions (iv) surgical procedures (v) radiological interventions (PTC+/-balloon dilation of strictures) (vi) endoscopic interventions (ERCP+/- placement of a stent, endoscopic ultrasound, endoscopy). This data was obtained from the informatics department at our institution and cross referenced with our own database.

Statistical methods

Initially, patient factors were compared between the type of surgeon performing the repair (specialist or non-specialist), as well as by the timing of repair (immediate, early or late). Categorical variables were assessed using Fisher's exact test, with independent samples t-tests or one-way ANOVA used for continuous variables, depending on the number of groups being compared.

Time to event outcomes were then compared between these two factors using Kaplan–Meier curves and univariable Cox regression models. Subgroup analyses were also performed, to test whether differences observed between specialist and non-specialist surgeons were independent of the timing of the repair. These were followed by multivariable analyses, with the main factors entered into the model, and a forwards stepwise approach used to select any other independent predictors of the outcomes for inclusion.

In the time to event analyses, patient follow up commenced at the date of BDI repair. When analysing complications, patients that were discharged healthy were assumed not to have developed further complications, and so were censored at the date of data collection or at death. Those patients that had not been discharged were censored at the date of their last known point of contact. There were a small number of patients (N = 5) who were known to have developed complications, but for whom the date that this occurred was not recorded. In these cases, the complication was assumed to have occurred at the midpoint of follow up. A sensitivity analysis was also performed in which these patients were excluded, in order to ensure that this assumption had not impacted on the results.

Treatment costs were then compared between patients where repairs were performed by specialist and non-specialist surgeons using Mann–Whitney tests. In addition to comparing the overall costs, analyses were performed for each type of procedure, to highlight those that were the main contributors to the differences between groups. A large proportion of patients were still receiving treatment at the time of data collection and, hence, still had ongoing costs. As such, a subgroup analysis was also performed on those patients who had been discharged, to ensure that results were comparable. Trends over time in the numbers and costs of litigation claims were assessed using linear regression models.

All analyses were performed using IBM SPSS 22 (IBM Corp. Armonk, NY), with cases with missing data excluded on a per-analysis basis, and $p < 0.05$ deemed to be indicative of statistical significance throughout.

Results

Patient demographics and trends of treatment over time

Amongst 139 patients, 82 (59%) had injuries of type E1-2, with the remainder having type E3-5 injuries. Immediate repairs were performed in 37% of cases, early (1 to <21 days post injury) in 53%, and late (21 + days post injury) in 10%; 74% of repairs were performed by specialist surgeons.

Comparisons of patient factors by the type of surgeon and timing of repair are reported in Table 1. Specialist surgeons were more likely to perform late repairs, carrying out all 14 (100%) of these procedures, compared to 69% of immediate repairs ($p = 0.040$). The use of specialist surgeons increased significantly over time, making up 57% of repairs in 1990–2000, compared to 96% in 2008–2015 ($p < 0.001$).

The timing of the repair (Table 1) was found to be significantly later in those with jaundice ($p < 0.001$) or bile leaks/biloma ($p < 0.001$). It also varied over the years of the study ($p = 0.020$), with immediate repairs performed in 19% of cases from 1990 to 2000, compared to 52% in 2001–2006 and 38% in 2007–2015.

Patient survival

The median follow up from the point of repair was 10.7 years (IQR: 6.4–14.1), during which time 26 patients died, giving Kaplan–Meier estimated survival rates of 98%, 92%, 86% at 1, 5 and 10 years respectively. Some ten of these patients (38% of all deaths or 7% of the whole cohort) died of complications related to BDI (secondary biliary cirrhosis, n = 4, post-operative sepsis, n = 3, sepsis in the setting of biliary strictures, n = 2, death within 90 days of liver transplantation performed for secondary biliary cirrhosis, n = 1).

Univariable Cox regression analysis (Table 2) found no evidence that the expertise of surgeon ($p = 0.366$) or timing of repair ($p = 0.105$) had a significant influence on patient survival. Multivariable analysis was also performed, to account for potentially confounding factors (Supplementary Table 1), in which the type of surgeon ($p = 0.784$) and timing of repair ($p = 0.101$) remained non-significant.

Complications

During follow up, 56 patients developed complications, giving Kaplan–Meier estimated rates of 17%, 24% and 28% at 1, 3 and 5 years respectively.

Univariable Cox regression analysis (Table 2) found no evidence of a significant difference in complication rates by the timing of the repair ($p = 0.339$). However, complication rates for repairs by specialist surgeons were found to be significantly lower than those for non-specialist surgeons (HR = 0.30, $p < 0.001$). A subgroup analysis by the timing of surgery found that this effect was similar for both immediate and early repairs (HR: 0.27 vs. 0.28). This analysis could not be performed for late repairs, since all of these were performed by specialist surgeons, giving no comparator group. By five years post-repair, the estimated

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Table 1 Associations between the type of surgeon and timing of repair and patient and injury related factors

	N	Specialist Surgeon		p-Value	Timing of Repair			p-Value
		No	Yes		Immediate	Early[a]	Late[a]	
Age at LC (Years)	139	52.2 ± 12.2	58.3 ± 14.7	**0.030**	57.6 ± 14.3	56.1 ± 15.1	56.4 ± 10.6	0.843
Sex				1.000				0.902
Male	51	13 (25%)	38 (75%)		19 (37%)	26 (51%)	6 (12%)	
Female	88	23 (26%)	65 (74%)		33 (38%)	47 (53%)	8 (9%)	
Injury Type				0.695				0.515
E1-2	82	20 (24%)	62 (76%)		28 (34%)	44 (54%)	10 (12%)	
E3-5	57	16 (28%)	41 (72%)		24 (42%)	29 (51%)	4 (7%)	
Vascular Injury				0.313				0.267
No	114	32 (28%)	82 (72%)		45 (39%)	56 (49%)	13 (11%)	
Yes	25	4 (16%)	21 (84%)		7 (28%)	17 (68%)	1 (4%)	
Jaundice				0.650				**<0.001**
No	106	29 (27%)	77 (73%)		52 (49%)	47 (44%)	7 (7%)	
Yes	33	7 (21%)	26 (79%)		0 (0%)	26 (79%)	7 (21%)	
Bile Leak/Biloma				0.125				**<0.001**
No	73	23 (32%)	50 (68%)		42 (58%)	27 (37%)	4 (5%)	
Yes	66	13 (20%)	53 (80%)		10 (15%)	46 (70%)	10 (15%)	
Year of LC				**<0.001**				**0.020**
1990–2000	42	18 (43%)	24 (57%)		8 (19%)	29 (69%)	5 (12%)	
2001–2006	52	16 (31%)	36 (69%)		27 (52%)	20 (38%)	5 (10%)	
2007–2015	45	2 (4%)	43 (96%)		17 (38%)	24 (53%)	4 (9%)	
Repair Type				0.157				0.590
Recon	126	31 (25%)	95 (75%)		47 (37%)	67 (53%)	12 (10%)	
CBD Repair	11	5 (45%)	6 (55%)		4 (36%)	5 (45%)	2 (18%)	
Timing of Repair				**0.040**	–	–	–	–
Immediate	52	16 (31%)	36 (69%)		–	–	–	
Early[a]	73	20 (27%)	53 (73%)		–	–	–	
Late[a]	14	0 (0%)	14 (100%)		–	–	–	
Cho Grade[b]				**<0.001**				0.462
A	83	6 (7%)	77 (93%)		31 (38%)	44 (53%)	7 (9%)	
B	34	11 (32%)	23 (68%)		14 (41%)	15 (44%)	5 (15%)	
C	20	17 (85%)	3 (15%)		5 (25%)	14 (70%)	1 (5%)	
D	2	2 (100%)	0 (0%)		2 (100%)	0 (0%)	0 (0%)	

Data reported as mean ± SD, with p-values from t-tests, or N (%), with p-values from Fisher's exact tests, as applicable.
Bold p-values are significant at $p < 0.05$. LC = laparoscopic cholecystectomy; d = days; Recon = hepaticojejunostomy; CBD = common bile duct.
[a] Early repair is classified as being within 21 days of injury, with repairs after more than 21 days classified as late.
[b] Cho grade is a summary of the long-term complication rates where A is least severe and D most severe.

complication rates for specialist vs. non-specialist surgeons were 23% vs. 56% for immediate repairs, and 14% vs. 44% for early repairs (Fig. 1). Analysis of complications using the Cho classification demonstrated consistent results with the above (Table 1).

A multivariable analysis was also performed (Table 3), which found a significant increase in complications for those patients with vascular injury (HR = 2.35, p = 0.013). After accounting for this effect, the previously observed difference between the specialist and non-specialist surgeons remained significant (HR: 0.25, $p < 0.001$).

Complication analyses were repeated after excluding those patients whose complication dates were not known as a sensitivity analysis (N = 5), which returned consistent results (data not shown).

Cost analysis

Follow up procedural data were unavailable for N = 12 patients, hence they were excluded from this analysis, leaving N = 93 patients where the original repair was by a specialist, and N = 34 with repair by non-specialists (Table 4). The average estimated

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Table 2 Patient outcomes by type of surgeon and time of repair

	Mortality		Complications	
	HR (95% CI)	**p-Value**	**HR (95% CI)**	**p-Value**
Specialist		0.366		**<0.001**
No	–	–	–	–
Yes	1.50 (0.62–3.60)	0.366	0.30 (0.18–0.51)	**<0.001**
Timing		0.105		0.339
Immediate	–	–	–	–
Early[a]	0.74 (0.31–1.78)	0.501	0.65 (0.36–1.16)	0.145
Late[a]	2.36 (0.79–7.09)	0.125	0.72 (0.27–1.92)	0.514
Subgroup Analysis				
	Immediate		**Immediate**	
Non-Specialist	–	–	–	–
Specialist	0.34 (0.08–1.37)	0.130	0.27 (0.11–0.65)	**0.004**
	Early[a]		**Early[a]**	
Non-Specialist	–	–	–	–
Specialist	6.18 (0.79–48.21)	0.082	0.28 (0.13–0.60)	**0.001**

Results are from univariable cox regression models. Subgroup analyses were not performed for late repairs, as these were all performed by specialists, leaving no group to use as a comparator.
Bold p-values are significant at $p < 0.05$. HR = hazard ratio.
[a] Early repair is classified as being within 21 days of injury, with repairs after more than 21 days classified as late.

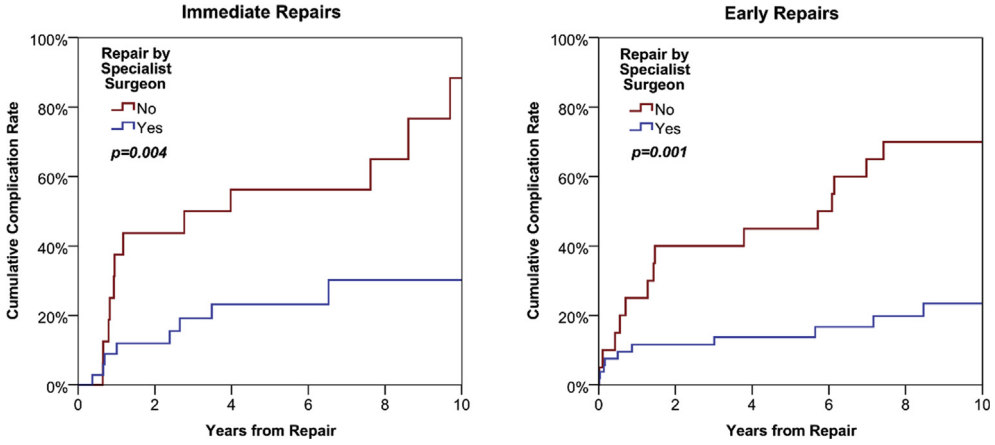

Figure 1 Kaplan–Meier curves of complication rates by type of surgeon for on table immediate or early delayed repair (1–21 days) (every repair after 21 days was performed by a specialist so this data is not shown)

treatment cost per patient was found to be significantly lower in those where a specialist surgeon performed the original repair, at £14,268.52, compared to £25,813.63 for repairs by non-surgical surgeons ($p < 0.001$).

Since some patients were still undergoing treatment at the time of data collection, there was the potential for accrual of additional costs in the future. As a result, the treatment costs reported for these patients would be an underestimate of the true cost of dealing with their BDIs. Since the more recent BDIs had previously been shown to be more likely to repaired by specialist surgeons, there was the potential bias into the analysis, with the effect of artificially reducing the treatment costs in those patients with repairs performed by specialist surgeons. To assess the impact of this potential bias on the findings, a sensitivity analysis was performed, which included only those patients who had been discharged with no further biliary problems at the end of their follow up (Supplementary Table 2). In this subgroup of N = 53 repaired by specialists and N = 16 patients repaired by non-specialists, the total costs (excluding litigation) were consistent with those described previously, with averages of £12,393.67 vs. £24,925.29 per patient ($p < 0.001$).

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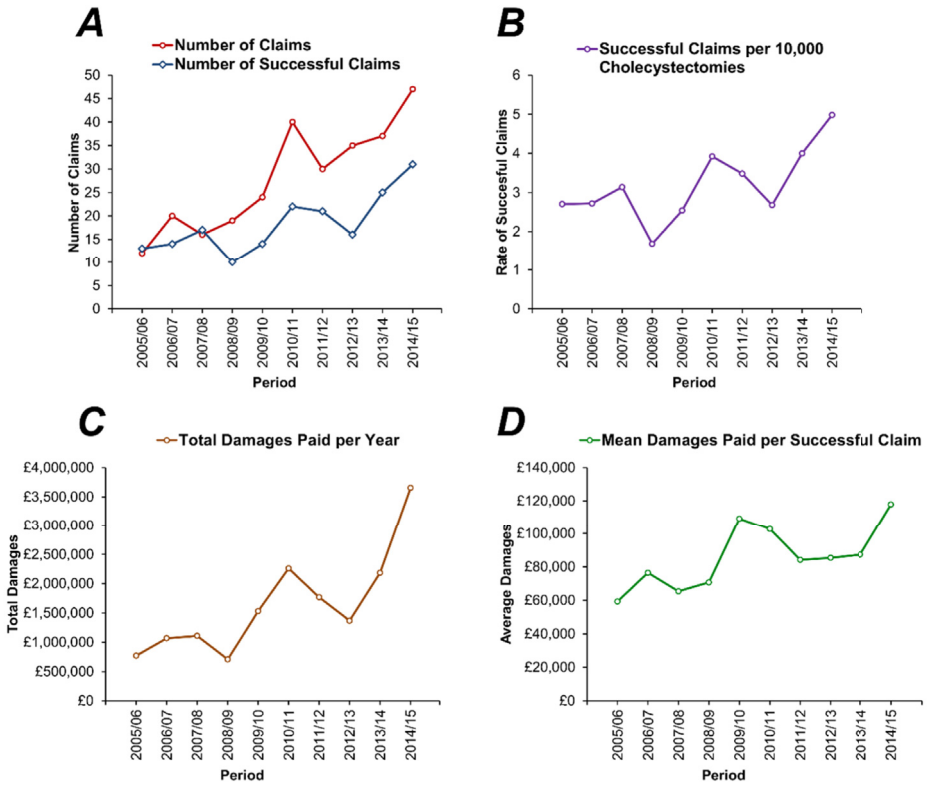

Outcome	Gradient per Year (95% CI)	p-Value
Number of Claims	3.5 (2.3 – 4.7)	**<0.001**
Number of Successful Claims	1.7 (0.7 – 2.7)	**0.007**
Successful Claims per 10,000 Cholecystectomies	0.2 (0.0 – 0.4)	**0.036**
Total Damages per Year (x £100,000)	2.3 (0.9 – 3.8)	**0.005**
Mean Damages per Successful Claim (x £1,000)	4.5 (0.8 – 8.1)	**0.022**

Figure 2 Numerical and graphical display of trends over time in the frequency and cost of litigation claims from national data. Plots and analysis is based on the data in Table 5. Reported values are gradients from linear regression models. Bold p-values are significant at $p < 0.05$

Litigation costs

Roy *et al.*[22] reported costs from 83 cases of litigation arising from BDI, with a mean financial settlement of £53,901. However, only 66/83 of the cases of litigation were successful, hence the mean financial settlement in successful litigation was £67,785. From the FOI request (Table 5), there were 31 successful claims in 2014/15, with a mean financial settlement of £117,845 per claim. This is 1.74 times higher than the average cost calculated above for Roy *et al.*[22]

When broken down by the timing of the repair, Roy *et al.*[22] report average financial settlement costs of £40,000 and £72,435 for successful claims in immediate and late repairs, respectively. Using the adjustment factor above, the estimated costs in 2014/15 would be £69,600 and £126,037 for successful litigation in immediate and late repairs, respectively (Supplementary Table 3).

The United Kingdoms Hospital Episodes Statistics (HES) database reported that there were 62,262 cholecystectomies performed in 2014/15. The UK CholeS prospective study[23] reported a BDI rate of 0.269%, hence there would have been approximately 168 BDIs in 2014/15. There were 31 successful claims in this year, meaning that around 18% of BDIs resulted in financial settlement. Hence, the estimated litigation cost per BDI based on the adjusted Roy *et al.* figures in £12,864 vs. £23,295 in immediate vs. late repair.

Therefore the lowest overall cost of BDI which includes costs of treatment and litigation is associated with immediate on table specialist repair (£27,132.52 average cost per patient with BDI)

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Table 3 Multivariable analysis of complication rates

	HR (95% CI)	p-Value
Specialist Surgeon		**<0.001**
No	–	–
Yes	0.25 (0.14–0.45)	**<0.001**
Timing of Repair		0.158
Immediate	–	–
Early[a]	0.63 (0.35–1.13)	0.123
Late[a]	1.41 (0.50–3.98)	0.519
Vascular Injury		**0.013**
No	–	–
Yes	2.35 (1.20–4.63)	**0.013**

Results are from a multivariable cox regression model. Type of surgeon and timing of repair were entered into the model, and a forwards stepwise approach was used to identify other factors from Table 1 that were significant independent predictors of complications.
Bold p-values are significant at $p < 0.05$. HR = hazard ratio.
[a] Early repair is classified as being within 21 days of injury, with repairs after more than 21 days classified as late.

and the highest with late non-specialist repair being some 181% greater (£49,108.63, average cost per patient with BDI).

In order to calculate these figures some assumptions were made. Firstly, that the cohorts from the NHSLA, Roy *et al.*[22] and CholeS[23] data were similar. Secondly, that the numbers of claims reported by NHSLA relate to injuries occurring in that year. Thirdly, that the relative proportions of early/late repairs and relative rates of litigation from these were similar in the NHSLA and Roy *et al.*[22] data. Finally, that there is no interaction between the timing of a repair and the specialism of the surgeon performing it, with respect to litigation and procedural costs. In other words, the absolute increase in litigation costs for late vs. early repairs is assumed to be similar in specialist and non-specialist surgeons.

Recent litigation trends in BDI

NHSLA data (Table 5) shows that the total number of claims, number of successful claims and financial settlement paid have increased significantly over time. Regression modeling (Fig. 2)

Table 4 Treatment costs by the type of surgeon performing the original repair

Tertiary centre hospital episode	Unit cost (£)	Non-Specialist Surgeon (N = 34)		Specialist Surgeon (N = 93)		p-Value
		Total Number	Mean Cost per Patient	Total Number	Mean Cost per Patient	
Original repair		–	£8,403.59	–	£8,503.18	0.247
Roux-en-Y HJ	£8,587.00	30	–	88	–	
CBD repair + TT	£7,028.00	4	–	5	–	
Subsequent operative procedures		**£5,086.35**		**£494.67**		**<0.001**
Re-do HJ	£8,587.00	16	£4,040.94	3	£277.00	**<0.001**
Incisional hernia repair	£3,517.28	4	£413.80	5	£189.10	0.082
Liver transplant	£17,746.82	1	£521.97	0	£0.00	0.268
Open CBD dilation	£3,728.00	1	£109.65	0	£0.00	0.268
Exploratory laparotomy	£2,656.90	0	£0.00	1	£28.57	1.000
Interventional radiology		**£10,392.20**		**£3,965.12**		**<0.001**
ERCP	£2,960.98	7	£609.61	23	£732.29	0.210
PTC Dilation	£8,074.77	38	£9,024.74	35	£3,038.89	**<0.001**
PTC Drainage/Imaging	£1,288.34	20	£757.85	14	£193.94	**0.008**
Diagnostic radiology		**£409.84**		**£264.26**		**0.016**
CT	£105.59	12	£37.27	20	£22.71	0.650
MRI	£165.44	2	£9.73	4	£7.12	0.610
MRCP	£145.34	10	£42.75	23	£35.94	0.773
US	£52.94	59	£91.87	54	£30.74	0.412
Nuclear Medicine	£542.17	4	£63.78	4	£23.32	0.272
Fluoroscopy	£234.13	11	£75.75	20	£50.35	0.110
Other	–	17	£88.69	16	£94.08	**0.016**
Follow-up		**£1,521.65**		**£1,041.29**		**0.010**
OPA	£188/£120*	413	£1,521.65	756	£1,041.29	**0.010**
Total Procedural Costs	–	–	**£25,813.63**	–	**£14,268.52**	**<0.001**

p-Values are from Mann–Whitney tests for the average costs per patient, and bold p-values are significant at $p < 0.05$. *£188 for the first appointment and £120 for subsequent follow up appointments. HJ = hepaticojejunostomy; CBD = common bile duct; TT = T-Tube; ERCP = endoscopic retrograde cholangiopancreatography; PTC = percutaneous transhepatic cholangiography; CT = computed tomography; MRI = magnetic resonance imaging; MRCP = magnetic resonance cholangiopancreatography; US = ultrasound scan; OPA = outpatient appointment.

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Table 5 Trends over time in the frequency and cost of litigation claims from national data

Year	Number of Cholecystectomies (Previous Year)	Number of Claims[a]	Number of Successful Claims[a]	Successful Claims per 10,000 Cholecystectomies[b]	Total Damages per Year	Mean Damages per Successful Claim
2005/06	48,064	12	13	2.7	£770,500.00	£59,269.23
2006/07	51,457	20	14	2.7	£1,069,604.10	£76,400.29
2007/08	54,202	16	17	3.1	£1,111,105.04	£65,359.12
2008/09	59,354	19	10	1.7	£706,818.22	£70,681.82
2009/10	55,081	24	14	2.5	£1,529,538.57	£109,252.76
2010/11	56,084	40	22	3.9	£2,259,100.00	£102,686.36
2011/12	60,309	30	21	3.5	£1,767,266.00	£84,155.52
2012/13	59,735	35	16	2.7	£1,366,171.74	£85,385.73
2013/14	62,520	37	25	4.0	£2,184,186.40	£87,367.46
2014/15	62,262	47	31	5.0	£3,653,187.00	£117,844.74

Data for the numbers and costs of claims were collected from a FOI request with the NHSLA, whilst the total numbers of cholecystectomies were extracted from HES data.
[a] Litigation claims are recorded in the year that litigation commenced, whilst successful claims and the associated costs are attributed to the year that they were awarded. Hence, there occasions where the total number of claims exceeds the number of successful claims.
[b] The rate of successful claims is a surrogate marker, calculated from the number of successful claims in the stated year, and the number of cholecystectomies in the previous year, on the assumption that litigation will take approximately a year to complete.

found the number of successful claims to be increasing by approximately two per year ($p = 0.007$), and the average financial settlements of these claims by £4,500 per year ($p = 0.022$), resulting in the costs to the health service increasing by £230,000 per year ($p = 0.005$).

Discussion

This is a retrospective study of patients with Strasberg type E BDI with long term follow-up that captures the impact of major BDI upon complications and costs of treatment and litigation. The primary outcome of this study was that overall costs of treatment and litigation are considerable. Importantly, costs are directly related to the timing of repair and specialty of the repairing surgeon – factors which are potentially modifiable. These costs are not trivial – the difference being an average of £21,976 per patient with major BDI. Given that there are currently around 167 major BDI per year in England then the impact of this is clear. Millions of pounds could be saved if all patients were to undergo immediate repair by specialist surgeon. Furthermore, the burden of litigation costs can be expected to increase looking at trends presented in this study. As such, it is imperative that if BDI is suspected or recognised at the time of cholecystectomy immediate specialist repair should be sought. This may require organisational change but given that, within the UK, specialist HPB services provide a regional emergency trauma service, this should be deliverable. There may be issues relating to denial by the injuring surgeon at the time of surgery or of wanting to conceal any possible injury from external review. However, it is clear from the data presented here that it is in the best interest of the patient and health service to involve specialist surgeons as early as possible.

In this study, repair of major BDI by specialist surgeons leads to fewer long-term biliary complications, in accordance with results published previously.[9] Furthermore, specialist repairs in the present study resulted in fewer invasive procedures and hospital admissions and thus healthcare costs. This has been shown previously by Dageforde *et al.*[24] but is quantified here from the perspective of the UK NHS. Like many other recent studies, the timing of repair was not significantly associated with long-term biliary complications in Strasberg type E patients.[8,16,25,26]

There was no significant difference in mortality between patients undergoing repairs performed by specialist surgeons compared to non-specialists. This is in contrast to findings by Flum *et al.*[18]; although that study was based on national datasets with a considerably larger sample size, hence the present study may have been underpowered to detect such differences.

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In this study, there was no significant difference in long-term biliary complications according to the level of the injury (Strasberg E1-2 vs E3-5). There is conflicting data in this regard with both concordant results being reported[16] as well as another study demonstrating a significant relationship between higher level injuries at the confluence and poorer long-term outcomes.[15] It may be that specialist repair can overcome the complication rates of higher level injuries, or that it is not so much the level of injury but the associated vascular (arterial) injury that may accompany BDI that is the determinant; this is supported by our data. Certainly, in the presence of a right hepatic arterial injury and injury to the hilum, there would be no cross flow of arterial blood between left and right biliary ducts. There remains no clear consensus on the effect of an associated vascular injury on long-term biliary complications. Along with other recent studies,[15,17] we have shown that a vascular injury significantly increases the rate of long-term biliary complications. However, other studies have not demonstrated any significant difference.[16,27]

There are weaknesses of this study which include its retrospective nature. However, the method of data capture is strong, since we have a dedicated data manager and comprehensive collection of complications recorded prospectively. The analysis of litigation costs was based on several assumptions, since it was not feasible to collect patient-level data for this, and previously published figures were outdated, especially in light of the significant changes over time in litigation rates and costs that were observed. As such, it may be valuable future work if these findings could be validated in a contemporaneous cohort, if such data could be collected. Nevertheless, we believe that the costs presented here are accurate. National prospective audit would improve data collection and reduce referral bias. Obviously, data can only be presented on patients who were referred to our team. Furthermore, regional practice is likely subject to variation; we understand that some specialist units advocate placing drain in cases of suspected injury and immediate referral to the specialist centre for surgery ideally within 24 hours. Given our data and the perception of the experience of these units it is probable that clinical outcomes are the same as if a patient has an on table outreach specialist repair. However, it is possible that litigation would be higher if patients are referred to a specialist centre and undergo a second operation as opposed to no additional procedures or transfer being necessary as their perception of events would likely be quite different.

In addition, though this study's findings and costs are based on the UK health system they can be applied worldwide since reducing the number of treatments post BDI repair will lower costs in any system. Furthermore, with litigation being prevalent across many different countries[11–14,28] a reduction in litigation costs is an important finding, especially in the United States where litigation costs have been reported to be up to four times higher than the UK.[11,14]

In summary, this study has shown that repair of Strasberg Type E BDI by specialist HPB surgeons is superior to non-specialist repair in terms of long-term biliary complications and costs of both direct health care and litigation. Identification or suspicion of BDI and involvement of specialists at that time is therefore imperative to optimise outcomes among these patients and reduce the financial burden to healthcare systems.

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Conflicts of interest

None declared.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.hpb.2019.01.018.

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