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Medicolegal claims following laparoscopic cholecystectomy in the UK and Ireland

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ABSTRACT

INTRODUCTION The causes and outcomes of medicolegal claims following laparoscopic cholecystectomy were evaluated.

SUBJECTS AND METHODS A retrospective analysis of the experience of a consultant surgeon acting as an expert witness within the UK and Ireland (1990–2007).

RESULTS A total of 151 claims were referred for an opinion. Sixty-three related to bile duct injuries and four followed major vascular injury. Bowel injury resulted in 17 claims. A postoperative biliary leak not associated with a bile duct injury was responsible for 25 claims. Other reasons for claims included spilled gallstones, port-site herniae, haemorrhage and other recognised complications associated with laparoscopic cholecystectomy. Twelve of the claims are on-going, two went to trial, 79 (52%) were settled out of court and 58 (38%) were discontinued after the claimants were advised that they were unlikely to win their case. Disclosed settlement amounts are reported.

CONCLUSIONS Bile duct and major vascular injuries are almost indefensible. The delay in diagnosis and (mis)management of other recognised complications following laparoscopic cholecystectomy have also led to a significant number of successful medicolegal claims.

KEYWORDS

Laparoscopic cholecystectomy – Bile duct injury – Bile leak – Medicolegal

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Cholecystectomy remains one of the commonest abdominal surgical procedures performed, with over 90% being carried out laparoscopically. In England in 2005/2006 there were approximately 50,000 laparoscopic cholecystectomies performed within the National Health Service.[1]

Table 1 shows the common complications of laparoscopic cholecystectomy. Most of these could potentially result in the affected patient initiating a medicolegal claim. If a complication has been managed in a substandard or delayed manner, a claim is more likely to result. The situation is often made worse by poor communication, with the patient and their family feeling that they had not been made aware of these risks or that an inadequate explanation has been given as to why the complication occurred.

The commonest reported reason for medical negligence claims has been injury to the bile ducts.[2] With a view to seeing what causes claims and which claims are worth pursuing, we report the individual experience of a single consultant surgeon (senior author, JHS) instructed as an expert witness in medical negligence claims following laparoscopic cholecystectomy.

Subjects and Methods

A retrospective analysis of cases was carried out by reviewing the records of 151 consecutive claims following laparoscopic cholecystectomy from the period 1990–2007. A database of instructed cases relating to general surgical claims has been kept since 1990. The database is organised by type of case (*e.g.* cholecystectomy, varicose veins, hernia, *etc.*) and case details (*e.g.* common bile duct injury, nerve damage, vascular damage, *etc.*). JHS's personal medicolegal experience of both clinical negligence and personal injury now includes over 5800 cases.

Details of the claim, grade of operating surgeon, relevant sector (NHS/private) and outcome (discontinued, settled or on-going) were recorded. Where settlement amounts were disclosed, they have been included to give some idea of the scale of settlement. There is, of course, enormous variation in the settlement amounts due to special damages, which are related to an individual's circumstances.

Results

There were 151 claimants of whom 113 were female. One

Table 1 Complications following laparoscopic cholecystectomy

General laparoscopic
Establishing pneumoperitoneum/insertion of ports
Bowel perforation
Vascular injury – aorta, vena cava, iliac vessels
Diathermy injury
Port-site hernia
Specific to laparoscopic cholecystectomy
Bile duct injury
Clip
Cut/transection
Resection
Diathermy*
Hepatic artery injury
Biliary leak
Biliary peritonitis
Lost stones
General surgical complications
Bleeding
Infection
Venous thrombo-embolism

*Diathermy injury may cause perforation of a bile duct or result in the development of a stricture.

hundred of the operations had been performed within the National Health Service, 19 in the UK private sector and 32 in the Republic of Ireland. Consultant surgeons had performed 125 of the procedures, registrars 24 and staff grade/associate specialists two. The vast majority of operations were performed by general surgeons. Table 2 demonstrates the reasons for the claims and the combined outcomes. Twelve of the claims are on-going, two went to trial, 79 (52%) were settled out of court and 58 (38%) were discontinued after the claimants were advised that they were unlikely to win their case.

Bile duct injury

The majority of claims related to bile duct injuries. A consultant surgeon had performed 46 of the 63 cholecystectomies that resulted in a bile duct injury in this series. The other bile duct injuries had occurred during procedures performed by a registrar (n = 15), a staff grade surgeon (n = 1) and an associate specialist (n = 1). A concomitant hepatic artery injury had occurred in 12 out of 63 (19%) of the bile duct injury claims.

An injury to the biliary system was recognised at the time of surgery in 17 (27%) of the 63 bile duct injury claims. However, most of the bile duct injuries went unnoticed during

Table 2 Claims and outcome

Claim	*n*	On-going	Abandoned	Settled	Trial
Vascular injury	4	0	0	3	1
Bowel injury	10	4	2	4	0
Duodenal injury	7	0	2	5	0
Resectional BDI	33	1	0	31	1
Cut/transected BDI	16	0	0	16	0
Clip BDI	5	1	0	4	0
Diathermy BDI	9	1	2	6	0
Hepatic artery injury with no BDI	1	0	0	1	0
Bile leak	25	3	18	4	0
Retained CBD stones	1	0	1	0	0
Wound closure	3	0	2	1	0
Spilled gallstones	5	0	5	0	0
Unnecessary operation	1	0	0	1	0
Postoperative bleeding	14	0	13	1	0
VTE	2	0	0	2	0
Port-site hernia	3	0	3	0	0
Incisional hernia following conversion to open	1	0	1	0	0
Instrument failure	1	1	0	0	0
Foreign body	1	1	0	0	0
Wound infection	2	0	2	0	0
Chronic pain	7	0	7	0	0
Total	**151**	**12**	**58**	**79**	**2**

BDI, bile duct injury; CBD, common bile duct; VTE, venous thrombo-embolism.

the initial procedure and were detected postoperatively either before discharge or due to early re-admission with abdominal pain and/or jaundice.

Following a bile duct injury, the initial repair was attempted by the original operating surgeon in 22 (35%) of the claims. Twenty-nine (46%) of those who had suffered a bile duct injury were transferred to a specialist unit for a bile duct repair. Resection of a segment of bile duct, cutting the bile duct or clipping across the bile duct all resulted in successful medicolegal claims (Tables 2 and 3). Only two of the nine injuries to the bile duct caused by diathermy injury were not pursued.

Of these 63 claims, an intra-operative cholangiogram had only been performed in six cases, including the case below that went to trial. Three of the cholangiograms were performed because a bile duct injury was already suspected to have occurred. One cholangiogram was misinterpreted by a consultant general surgeon during a laparoscopic cholecystectomy for biliary colic where the intra-operative cholangiogram actually showed the cystic duct was very short and drained into the right hepatic duct. The operating surgeon proceeded with a 'difficult' dissection laparoscopically. The patient was re-admitted on the 7th postoperative day with severe abdominal pain. An ultrasound scan showed dilated intrahepatic ducts and endoscopic retrograde cholangiopancreatography (ERCP) identified occlusion of the right hepatic duct. After transfer to a specialist unit, the right hepatic duct was found to have been doubly clipped and transected, but the common bile duct and left hepatic duct were intact; therefore, a hepaticojejunostomy to the right hepatic duct was performed. Despite the cholangiogram, the surgeon had still mistaken the right hepatic duct for the cystic duct. This claim was settled out of court in Ireland for €80,000.

A claim in 2001 followed a procedure performed by a consultant surgeon who had used 13 clips. The operative note recorded 'cystic artery caused a lot of difficulty' and 'long cystic duct'. A specialist unit later identified and repaired the common bile duct that had been clipped and divided (four clips) just above the duodenum. In addition, the common hepatic duct had been clipped four times (but not divided) and the right hepatic artery had also been clipped four times and divided. This case was settled out of court for £50,000.

Only one bile duct injury claim went to court to be resolved. This involved a 40-year-old woman who underwent an elective laparoscopic cholecystectomy performed by a consultant general surgeon in 1992. The surgeon recorded 'difficult anatomy' and performed an intra-operative cholangiogram 'with difficulty', yet did not convert to an open procedure. Postoperatively, the patient became jaundiced with complete biliary obstruction. Investigations identified that, instead of the cystic duct, the common hepatic duct had been clipped (twice) and divided just below the confluence of left and right hepatic ducts. Although transferred to a specialist unit for a hepaticojejunostomy, she suffered severe long-term abdominal pain (relating to the wound) and depression preventing her from returning to work. The judge at trial said she was unlikely to secure any paid employment and awarded £470,000 (including £60,000 in general damages).

Table 3 Examples of settlement amounts

Claim	UK Damages £ (range)	Republic of Ireland Damages € (range)
Vascular injury	15,000–75,000	–
Bowel injury	7500–22,000	65,000
Duodenal injury	40,000–100,000	–
Resectional BDI	5000–470,000	–
Cut/transected BDI	10,000–160,000	50,000-225,000
Clip BDI	42,500–118,000	40,000
Diathermy BDI	12,000–32,000	–
Bile leak	6000– 30,000	–
Wound closure	55,000	–
Unnecessary operation	45,000	–
VTE	35,000–37,500	–

BDI, bile duct injury; VTE, venous thrombo-embolism.

Two of the claims involved patients that died in the 1990s as a result of biliary peritonitis secondary to a bile duct injury. In the first, the cause was a diathermy injury to the common bile duct causing a bile leak in a 19-year-old woman with two dependants. This procedure had been performed by a registrar without supervision who had a total operative experience of less than 20 laparoscopic cholecystectomies. There was a significant delay in diagnosing and managing the developing peritonitis, which resulted in death from multi-organ failure. The other death occurred in a 67-year-old man with ischaemic heart disease, who had a cardiac arrest secondary to untreated biliary peritonitis that had resulted from a transection injury to the common bile duct. Both of these cases settled out of court for undisclosed sums.

Vascular injury

There were four claims following major vascular injury during procedures performed by consultant surgeons. A thin, 28-year-old woman had an internal iliac artery damaged by the Veress needle used to create the pneumoperitoneum. Arterial bleeding was identified and the procedure converted to an open operation with arterial repair. The case settled for £15,000 in 1995. A different claim involved a

trocar that had been inserted through the anterior and posterior wall of the right common iliac artery. This patient had an intra-operative cardiac arrest and required an aorta-femoral bypass to restore perfusion to the right lower limb. The case proceeded to trial in 1998 and a large undisclosed sum was awarded. The abdominal aorta was injured by a consultant surgeon in a third case in 2000 that settled out of court for an undisclosed sum. Three years later, in a different claim, the same consultant surgeon noted profuse bleeding after insertion of laparoscopic ports and called two colleagues to theatre to help. Together, they repaired four holes in the inferior vena cava, two holes in the aorta and a hole in the small bowel mesentery. This case was settled out of court for £75,000.

Bowel injury

Bowel injury resulted in 17 claims. This included seven claims that involved injury to the duodenum. The other 10 claims involved injury to the small bowel or transverse colon. All the injuries to the transverse colon were settled in favour of the claimant. Small bowel injury caused during creation of the pneumoperitoneum or insertion of ports did not result in a successful claim as long as this had been recognised and managed correctly.

Bile leak

A postoperative biliary leak not associated with a bile duct injury was responsible for 25 claims. The majority of these (n = 18) were discontinued as it was clear that this complication (*e.g.* cystic stump leak, accessory bile duct leak) had been managed correctly by the surgical team involved. Four claims following a postoperative biliary leak were settled out of court in favour of the claimant. The management of these four patients had been delayed or was inappropriate, resulting in major morbidity.

Postoperative haemorrhage

Postoperative bleeding, often resulting in the need to return to theatre for control, resulted in 14 claims. All but one were discontinued, as this recognised complication had been managed correctly. In the case that settled out of court in 2000, the patient had required three laparotomies to control the bleeding. This was a 22-year-old, obese patient that had undergone a conversion to an open procedure due to bleeding that occurred during the laparoscopic dissection of the gallbladder. That evening, she became hypotensive and was transfused with blood. The next day, a laparotomy was performed but no bleeding point identified. She was sent to intensive care and went on to have a cardiac arrest. A massive blood transfusion was performed and a third laparotomy identified bleeding from the cystic artery, which was controlled. She was on intensive care for 20 days, requiring respiratory, inotropic and renal support. It was agreed that it was unacceptable to fail to control bleeding at the second laparotomy and to return a patient to intensive care when still bleeding. The case settled out of court for £14,000.

Other complications

Five claims were initiated due to spilled/lost gallstones at the time of cholecystectomy. Three patients who developed a postoperative port-site hernia and a patient that developed an incisional hernia following a conversion to open procedure also made claims. All of these were eventually discontinued. A claim in which the small bowel was stitched into a port-site wound, resulting in small bowel obstruction, had a delayed diagnosis and management. This resulted in the need for a small bowel resection and the claim was settled for £55,000. In another case in 2001, the defendants admitted that surgery should not have been undertaken. The gallbladder had not been visualised on a pre-operative ultrasound scan or at a previous endoscopic retrograde cholangiopancreatography (ERCP) and could not be found during an aborted laparoscopic procedure. The operation resulted in significant morbidity and the case settled for £45,000.

A claim involved a patient who died of a pulmonary embolus following a laparoscopic cholecystectomy in 1998. This 71-year-old man was returned to theatre the day after his cholecystectomy for a washout of a subhepatic (haematoma) collection. He had been provided with venous thromboprophylaxis but when he developed respiratory symptoms on day 5 postoperatively, a diagnosis of a pulmonary embolus was considered but no investigations requested and the patient was not anticoagulated. On the 11th postoperative day, a diagnosis of deep vein thrombosis was again considered but no treatment or investigations instigated. The patient went on to have a fatal pulmonary embolus on day 15. This claim was settled out of court for £35,000. A different claim, previously reported, relating to the failure to provide venous thromboprophylaxis settled for £37,500.[3]

Discussion

In the early 1990s when surgeons were first learning to perform laparoscopic cholecystectomies, the incidence of bile duct injuries was reported to be much higher than in open cholecystectomy.[2] Bile duct injuries can have serious consequences for the patient, especially if there is a delay in recognition or a repair attempted by an inexperienced surgeon.[4] Even with a successful repair there remains significant long-term morbidity for these patients (including symptomatic adhesions, strictures, recurrent cholangitis and secondary biliary cirrhosis). Injuries can result from division of the common or hepatic bile ducts, the inaccurate or excessive placement of clips or from a diathermy injury.

The routine use of intra-operative cholangiography has been reported to reduce the incidence of bile duct injuries by clarifying the anatomy,[5] but it does not prevent them.[6] An intra-operative cholangiogram should be used to confirm the anatomy if any doubt exists. If safe dissection can no longer be performed laparoscopically, the surgeon should convert to an open procedure. An intra-operative cholangiogram also allows ductal stones to be detected but, more importantly, any injury to the biliary tree can be identified intra-operatively, allowing for early repair with improved outcomes.[6]

If a biliary tract injury is suspected, the surgeon must decide if he or she is experienced enough to be able to manage the situation or call for expert help from an experienced hepatobiliary surgeon. If a biliary injury/leak is confirmed and the surgeon is not experienced in bile duct repair, then drains should be placed and a referral made to a specialist hepatobiliary unit. In at least one part of the UK, specialist hepatobiliary surgeons are currently providing a call-out service allowing bile duct injuries recognised during the procedure to be assessed and primarily repaired without delay within the same procedure.[7]

The best long-term results for bile duct repair are achieved in specialist hepatobiliary centres where a Roux-en-Y hepaticojejunostomy is performed.[6,8,9] Flum *et al.*[4] reported that 75% of repairs were attempted by the same surgeon that caused the bile duct injury. In 1998, the reported success rate of the surgeon causing the injury and then performing a primary repair was only 27% compared to 79% at a specialist referral centre.[10] By 2005, Schmidt *et al.*[8] reported only a 17% success rate by the primary surgeon but 94% by an experienced hepatobiliary surgeon.

A possible biliary tract injury must be suspected in patients following a laparoscopic cholecystectomy if they are not making the expected recovery, experience abdominal pain, or develop a fever. These patients should undergo urgent investigations, including an ultrasound scan and liver function tests. Magnetic resonance cholangiopancreatography (MRCP) and endoscopic retrograde cholangiopancreatography (ERCP) are used to define biliary anatomy. ERCP also allows intervention to treat a cystic stump leak or remove residual common bile duct stones. Concomitant vascular (hepatic artery) injuries have been reported to be present in approximately 20% of patients with bile duct injuries and have an adverse influence on the outcome of biliary injury.[8,11]

Although small bowel injury caused during creation of the pneumoperitoneum or insertion of ports is a recognised complication of laparoscopic surgery,[12,13] it is considered unacceptable to damage retroperitoneal structures such as the aorta, inferior vena cava and the iliac arteries and veins.[14,15] These claims cannot be defended even in thin patients, where retroperitoneal structures can be quite close to the anterior abdominal wall.

Indications for conversion from a laparoscopic to an open procedure include difficult or uncertain anatomy, obscured vision due to bleeding or any other indication where the surgeon feels that they cannot complete a laparoscopic procedure safely. Conversion is not a complication. Nobody can be criticised for converting to an open procedure; the criticism relates to the surgeon who converts too late or following damage to major intra-abdominal structures. All patients must be consented for the possible need to convert to an open procedure.

All the claims involving spilled gallstones were discontinued in this series. The UK Healthcare Commission has advised one group of surgeons[16] that the risk and possible complications of spilled gallstones should be part of informed consent and that if this does occur and the stones are not retrieved, the patient and their general practitioner should be informed.

A venous thrombo-embolism risk assessment should be carried out on all patients prior to cholecystectomy. Although a laparoscopic cholecystectomy can now be carried out as a day-case and be of short duration, many patients will still have risk factors for venous thrombo-embolism. Patients at risk must receive appropriate prophylaxis.[3]

The number of claims in this series, since a peak in 1992, has fallen to 3–6 per year. The number of claims handled by the National Health Service Litigation Authority (NHSLA) has also been reported to have fallen significantly since 2003.[17] This decline is hopefully due to increasing surgical experience and better training in laparoscopic cholecystectomy. The NHSLA have settled 66% of the 397 claims made between 1995 and 2007, with a total cost of more than £20.3 million.[17]

Conclusions

Bile duct and major vascular injuries are almost indefensible. The delay in diagnosis and (mis)management of other recognised complications (*e.g.* bile leak) following laparoscopic cholecystectomy have also led to a significant number of successful medicolegal claims.

Conflict of interest

JHS has acted as a paid Expert Witness for all the cases reported in this article.

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