Prevalence and outcome of litigation claims in England after laparoscopic cholecystectomy

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SUMMARY

Background: Approximately, 50,000 cholecystectomies are performed annually in the United Kingdom resulting in a number of negligence claims referred to the NHS Litigation Authority (NHSLA). The aim of this study was to assess the prevalence and outcomes of claims reported to the NHSLA after laparoscopic cholecystectomy performed in England between 1995 and 2008. Methods: Data were requested from the NHSLA on all claims related to laparoscopic cholecystectomy which occurred in England between 1995 and 2008. Results: A review of the data provided by the NHSLA data identified over 300 claims in this time period. Of the claims identified, 244 have been completed. Common bile duct injury (41%), bile leak (12%), bowel injury (9%), haemorrhage (9%) and fatality (9%) were the most frequent types of claim. Common bile duct injury resulted in the highest proportion of successful claims (86%) and the largest sums paid to the claimant (average £65,000). Discussion: Common bile duct injury is the most common claim to the NHSLA after laparoscopic cholecystectomy and results in the highest proportion of successful claims and the largest sums paid to the claimant.

What’s known
Cholecystectomy is one of the most common operations performed in the UK. The prevalence of litigation after injury during cholecystectomy has not been assessed before in the United Kingdom.

What’s new
Surgeons should be aware of potential litigation and the costs involved when performing any surgical procedures. Common bile duct injury is the most common cause for litigation after cholecystectomy and leads to the highest payments to the claimant.

Background
Cholecystectomy is one of the most common general surgical procedures performed in the United Kingdom, with over 50,000 cases performed annually. The introduction of laparoscopic cholecystectomy has resulted in a substantial increase in the number of litigation claims, leading to high costs for the health service (1–3).

The NHS Litigation Authority (NHSLA) was established in 1995 to manage claims for clinical negligence in the NHS. The NHSLA ensures claims are dealt with consistently and helps to raise standards of care. It is designed to provide mechanisms for the proper, prompt and cost-effective resolution of disputes, to manage the financial consequences of claims and to advise the Department of Health of the likely future costs. In addition to dealing with claims, there is an active risk management programme to help raise standards of care in the NHS and hence reduce the number of incidents leading to claims. All claims against NHS bodies should be reported to the NHSLA, providing a method of analysing claims made for specific procedures.

This study was undertaken to assess claims reported to the NHSLA after laparoscopic cholecystectomy.

Methods
In this study, all claims reported to the NHSLA based on the key terms ‘laparoscopic’ and ‘cholecystectomy’ were requested. The data received included information on the type of injury and the result and cost of the claim. Data were collected from all reported operations which occurred in England between 1995 and 2008. Patient details did not include name, date of birth or occupation to protect patient confidentiality.

Results
In 2007/08, the NHSLA received 5470 claims (including potential claims) under its clinical negligence schemes. In the same year, the Authority made payments totalling approximately £456 Million. Surgery represented the highest number of claims reported to the NHSLA (17,817 claims since 1995), although Obstetrics and Gynaecology resulted in...
higher payments (£3,332,916 compared with £1,283,208 for surgery in the same time period) (4).

There were over 300 claims identified from the NHSLA database relating to laparoscopic cholecystectomy between 1995 and October 2008. Of those identified, 244 (81%) have been completed. The highest proportion of claims was related to common bile duct injury (41%) (Figure 1). Of these, the majority were successful (86%) and led to the highest amount of compensation (average £65,000 – range £1000–£350,000) (Figure 2). Bile leak accounted for 12% of claims which were successful in 69% resulting in an average claim of £44,000 (range £5000–£252,000). Bowel injuries represented 9% of the total claims. Of these, eight of 12 (71%) led to a successful claim (£64,000 – range £2000–£390,000), of which three had resulted in a mortality. There were two injuries caused by misplacement of the trocar, all of which resulted in a successful claim. Haemorrhage accounted for 9% of claims with 44% being successful and an average payout of £31,000 (range £3000–£252,000). Three patients had retained stones resulting in two successful claims (£2500 and £15,000). Fatality was recorded in 9% and led to a successful claim in 80% of cases with an average cost of £42,000 (range £5000–£210,000).

Other injury claims included port site hernia, postoperative pain, infection and deep vein thrombosis (19%). These cases resulted in successful claims in 53% of patients with an average claim of £19,000 (range £3000–£750,000).

**Discussion**

For negligence to be proven, the patient must show that the doctor owed a duty of care to the patient, that the doctor was negligent, that the care provided deviates from accepted standards of practice and that the patient has suffered harm as a result. The patient’s loss is then assessed in terms of loss of current and future earnings, reduced quality of life and psychological distress. These factors make this a costly and time consuming procedure, justifying any investment in trying to reduce the number of litigation claims in any institution.

Observational studies have shown that bile duct injury occurs in between 0.5% and 0.8% of patients undergoing laparoscopic cholecystectomy (5,6). With over 50,000 laparoscopic cholecystectomies performed annually, it would be expected that there would be a higher number of injuries reported to the NHSLA during the study period. However, the small numbers of bile duct injuries found in this study would imply that only a small proportion of the injuries, which have occurred, have led to a claim reported to the NHSLA.

Common bile duct injury was found to be the most common claim to the NHSLA after laparoscopic cholecystectomy. It resulted in the highest proportion of successful claims and the largest sums paid to the claimant. Other studies also report bile duct injury as the most common cause of litigation, but report a much lower proportion of successful
claims. A Dutch study (1) showed only an 18% success rate after bile duct injury and a study in the United States an 8% success rate (7). The higher claim success rate in this study may be because of failure of trusts to report all injuries which have led to litigation. The injuries which have been reported to the NHSLA may be more severe and more likely to lead to a successful claim.

It is well recognised that the majority of bile duct injuries (approximately 75%) which occur during laparoscopic cholecystectomy are not detected before the patient leaves the operating room. However, unrecognised injuries are not always associated with a higher probability of indemnity payment (8). The major factor resulting in a successful claim is usually failure to adequately treat the biliary tract injury, even if it is recognised (9,10). This is further proved by approximately 95% of patients, with a recognised injury, requiring at least one additional operative procedure after their initial repair (8,11).

Litigation after open cholecystectomy is uncommon and is reportedly associated with a 50% lower incidence of bile duct injury. The apparent lower incidence of bile duct injuries is supported by the rising incidence of remedial biliary operations in many tertiary care centres after laparoscopic cholecystectomy (12,13). Kern compared the claim outcomes after an open vs. a laparoscopic cholecystectomy in cases that proceeded to trial (7). Acceptance of a claim or settlement in this series was associated with death of patient or a patient’s loss of income. Rejection of a claim was generally based on the fact that the bile duct injury did not result from negligence. This study also showed that if a relaparotomy was performed in the initial centre financial compensation was doubled. This supports the poorer outcomes after reconstructive surgery in centres without hepatobiliary expertise (9,14).

Other studies report similar types of injuries to those observed in this study (7). Bowel injuries also result in high compensation and are almost as expensive to settle as bile duct injuries (7).

The findings of this study ought to provide guidance in the practice of adequate consent. Reviews of consenting practice have shown bleeding is mentioned 56% of the time, postoperative wound infection 63% of the time, and retained stones in the biliary tree 44% of the time. However, other complications such as bile duct injury, bile leak and injury to other organs are mentioned less frequently (15). These other injuries are more frequently associated with a successful claim and should be discussed and documented more openly prior to the surgical procedure. The discussion of these risks does not, however, protect the surgeon against litigation.

The data available from the NHSLA does not include information on patient age, sex and employment status to protect their confidentiality. This limits further analysis to assess patient factors which may influence whether a claim is successful or not and the size of the claim. It is also not known if all cases have been reported by hospital trusts and how this has changed over time. The data from this study may, therefore, not accurately reflect the incidence of all injuries and claims related to laparoscopic cholecystectomy, but should act as a guide on litigation practice in the NHS.

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References

1 de Reuver PR, Wind J, Cremers JE, Bosch OR, van Galik TM, Gouma DJ. Litigation after laparoscopic cholecystectomy: an evaluation of the Dutch arbitration system for medical malpractice. J Am Coll Surg 2008; 206: 328–34.
2 US Department of Health and Human Services. Confronting the New Health Care Crisis: Improving Health Care Quality and Lowering Costs by Fixing our Medical Liability System. Washington, DC: US Department of Health and Human Services, 2002.
3 Morris JA Jr, Carrillo Y, Jenkins JM et al. Surgical adverse events, risk management, and malpractice outcome: morbidity and mortality review is not enough. Ann Surg 2003; 237: 844–51.
4 NHS Litigation Authority Factsheets 2 & 3 – http://www.nhsla.com
5 The National Health Service Litigation Authority Report and Accounts (2008); Printed by the UK Stationary office, on behalf of the controller of HMSO, ID 5797845 07/08
6 de Reuver PR, Grossmann I, Busch OR, Obertop H, van Galik TM, Gouma DJ. Referral pattern and timing of repair are risk factors for complications after reconstructive surgery for bile duct injury. Ann Surg 2007; 245: 763–70.
7 Go FM, Schol F, Gouma DJ. Laparoscopic cholecystectomy in The Netherlands. Br J Surg 1993; 80: 1180–3.
8 Kern KA. Malpractice litigation involving laparoscopic cholecystectomy. Cost, cause, and consequences. Arch Surg 1997; 132: 392–7 discussion 397–8.
9 Chandler JG, Randle Voles C, Floore TL, Bartholomew LA. Litigious consequences of open and laparoscopic biliary surgical mishaps. J Gastrointest Surg 1997; 1: 138–45.
10 Stewart L, Way LW. Bile duct injuries during laparoscopic cholecystectomy: factors that influence the results of treatment. Arch Surg 1995; 130: 1123–9.
11 Schol FPG, Go PMNYH, Gouma DJ. Outcome of 49 repairs of bile duct injuries after laparoscopic cholecystectomy. World J Surg 1995; 19: 753–7.
12 McLean TR. Risk management observations from litigation involving laparoscopic cholecystectomy. Arch Surg 2006; 141: 643–8.
13 Huang ZQ, Huang XQ. Changing patterns of traumatic bile duct injuries: a review of forty years experience. World J Gastroenterol 2002; 8: 5–12.
14 Walsh RM, Vogt DP, Ponsky JL, Brown N, Mascha E, Henderson JM. Management of failed biliary repairs for major bile duct inju-
14 Flum DR, Cheadle A, Prela C, Dellinger EP, Chan L. Bile duct injury during cholecystectomy and survival in medicare beneficia-
ries. JAMA 2003; 290: 2168–73.

15 Chen AM, Leff DR, Simpson J, Chadwick SID, McDonald PJ. Variations in consenting practice for laparoscopic cholecystectomy. Ann R Coll Surg Engl 2006; 88: 482–5.

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