Litigation in thyroid surgery in England

Thyroid surgery has the potential for significant life-changing postoperative complications. Since 1995, the NHS Litigation Authority has handled litigation claims in England. This article reviews all thyroid surgery litigation claims between 1995 and 2012 and looks at potential strategies to minimize future claims.

In England, approximately 12 000 thyroid operations are performed each year (NHS Digital, 2014). These operations carry the potential risks of bleeding, airway compromise, nerve injury, vocal cord paralysis and death (Doran et al, 2012). Based on the administrative dataset for England, the Hospital Episode Statistics, the 30-day all-cause mortality following thyroid excision is 0.1–0.3% (NHS Digital, 2014). Patients who incur complications or believe they have received suboptimal care may seek financial compensation through legal challenge. The NHS pays out an estimated £500 million in legal costs, settlements and successful negligence claims per annum (NHS Litigation Authority, 2016a,b).

The NHS Litigation Authority was established in 1995 to manage claims and maintain a database for alleged clinical negligence. Since 2002, all NHS trusts in England must report all claims to the NHS Litigation Authority. The NHS Litigation Authority aims 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 (NHS Litigation Authority, 2016a,b).

This review analysed negligence claims reported to the NHS Litigation Authority with respect to the types of incidents and financial payouts specifically relating to thyroid surgery and the perioperative period. The literature was then reviewed to identify how these claims may be mitigated.

Methods

The NHS Litigation Authority was asked to supply data on all claims between January 1995 and July 2012 within their database using the key term 'thyroid'. For each claim data were provided on the year of the claim, year of the alleged incident, a brief description of the type of incident, cause, type of injury incurred and costs including damages, claimant and defence costs. Patient identifiers including name, date of birth, occupation and reporting hospital were not supplied to protect patient confidentiality. Costs are stated in GB pounds.

Claims pertaining to alleged errors in medical endocrinology management (e.g. failure to diagnose hypothyroidism, failure to identify thyroid storm during child birth, failure to diagnose thyroid eye disease) were separated from those related to thyroidectomy and/or the decision to proceed with surgery.

The surgical-related claims were further categorized into subtypes: problems with 'diagnosis', 'consent', 'anaesthesia' 'surgery', 'postoperative care' and 'other'. The authors identified the total number of claims, the average cost and the range for each sub-group.

Results

Between 1995 and 2012 there were a total of 223 claims pertaining to thyroid cases, of which 161 were related to surgery and the perioperative period. *Figure 1* illustrates

Figure 1. Number of litigation claims registered with the NHS Litigation Authority for thyroid diagnoses between 1995 and 2012. Claims are split into those relating to the surgical episode or subsequent thyroid surgery, and all other claims.

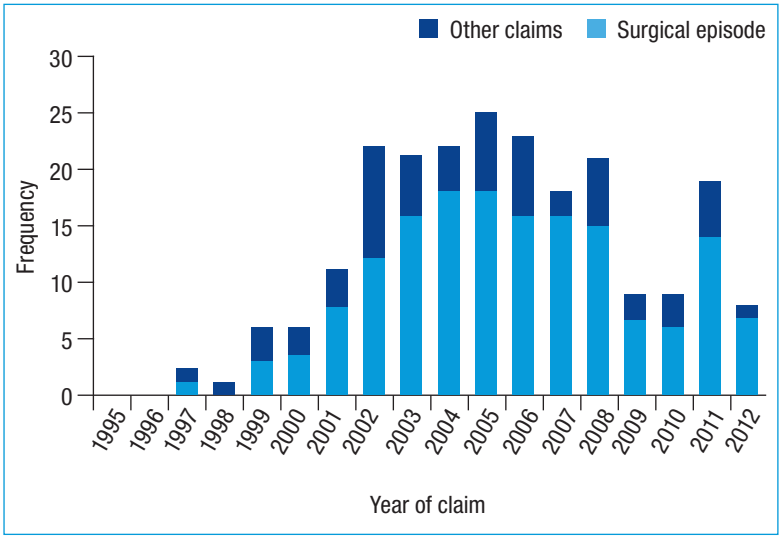

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Table 1. All litigation claims relating to thyroid surgery or the perioperative period reported to the NHS Litigation Authority between 1995 and 2012

Claim category		Total number of claims	Closed cases	Open cases	Successful claims	Average payout	Minimum payment	Maximum payment
Problems with diagnosis	Diagnosis delay	40	35	5	18	£61 106.14	£4496.04	£550 745.00
	Incorrect diagnosis	22	20	2	17	£121 886.10	£9325.00	£1 450 005.26
Problems with consent	Failure of consent	6	3	3	1	£134 046.73		
	Consent taken by separate person to operating surgeon	1	1		1	£73 661.85		
Problems with anaesthesia	Alleged awareness during operation	1	1		1	£623 161.80		
Problems with surgery	Diathermy burns	6	3	3	3	£9265.74	£7354.23	£11 243.00
	Recurrent laryngeal nerve injury	33	33		18	£137 717.26	£8317.50	£945 685.26
	Other nerve injury	5	5		1	£177 177.90		
	Removal of incorrect tissue	3	1	2		£0.00		
	Other surgical problems	5	4	1		£0.00		
Problems with postoperative management	Low serum calcium	6	3	3	2	£23 294.69	£4512.50	£42 076.88
	Wound infection	4	3	1		£0.00		
	Swelling	4	4		2	£63 802.17	£11 534.29	£116 070.05
	Poor care	6	5	1	4	£138 598.07	£26 888.22	£435 843.56
Other	Scarring	7	6	1	2	£15 636.97	£8156.44	£23 117.50
	Negligent treatment	3	3		1	£66 918.11		
Never events		9	7	2	6	£22 672.76	£3393.59	£77 960.50
	Foreign body left in nose after surgery	1	1			£0.00		
	Death following tracheostomy	1		1		Open		
	Loss of specimen	1	1		1	£3393.59		
	Thyroid gland removed in error	1	1		1	£7500.00		
	Swab left in the wound	1	1		1	£8146.25		
	Incorrect surgery	1	1		1	£16 647.31		
	Inappropriate surgery	1	1		1	£22 388.90		
	Death following biopsy	1	1		1	£77 960.50		
	Drain remnant left in wound and found 2 years later	1		1		Open		

the total number of claims for thyroid diagnosis made to the NHS Litigation Authority since 1995 and separates medical claims from those related to the decision to operate or the surgical episode itself. There is an apparent rise in claims filed since 2002 when the NHS Litigation Authority started to handle all litigation claims in England. Before 2002, health-care trusts in England were responsible for claims between £10 000 and £500 000 and information was not recorded by the NHS Litigation Authority unless volunteered by trusts.

Of the 161 claims relating to surgery, 23 claims were still open as of July 2012. A total of 77 claims (47.8%) found in favour of the claimant, costing the NHS £7 649 963.69. The average payout was £99 350.18 per closed case found for the claimant. The mean delay between initiation of a claim and the incident originally occurring was 3.07 years (standard deviation: 2.51 years, range: 0–13 years).

The most common cause for a claim relating to surgery was either a delay or error in diagnosis producing a total of 62 claims (38.5%). Seven claims related to problems

Table 2. The ten largest successful litigation claims relating to thyroid surgery recorded by the NHS Litigation Authority between 1995 and 2012

Claim year	Years from injury to claim	Total amount of claim	Category of claim
2007–8	10	£1 450 005.26	Incorrect diagnosis
2006–7	3	£945 685.26	Surgical injury to recurrent laryngeal nerve
2005–6	0	£623 161.80	Awareness during anaesthesia
2006–7	1	£557 673.89	Not related to surgery
2004–5	9	£550 745.00	Delayed diagnosis
2007–8	1	£435 843.56	Postoperative death as a result of haematoma compressing trachea
2007–8	2	£192 843.80	Surgical injury to recurrent laryngeal nerve
1999–2000	4	£184 128.50	Surgical injury to recurrent laryngeal nerve
2004–5	3	£178 890.49	Surgical injury to recurrent laryngeal nerve
2004–5	1	£177 177.90	Surgical injury to recurrent laryngeal nerve

of consent and one case to anaesthesia. A further 52 claims related to problems attributed to the surgery and 20 cases related to postoperative complications including hypocalcaemia, poor postoperative care and monitoring. Nine cases were reported as 'never events'. These included a case of death following biopsy, two cases of a retained swab, three cases of wrong site surgery, and one case where the tissue for histology was lost following surgery. *Table 1* details the average costs (damages paid and legal fees) for successful claims together with the range of payments for each sub-group of claim.

Table 2 lists the ten highest settlements paid out by the NHS Litigation Authority. The highest claim settled was for a patient who had a right thyroid lobectomy that was initially diagnosed as a follicular adenoma. Subsequently the patient was diagnosed with bone and lung metastases from a follicular thyroid tumour. Five of the highest payments have been for nerve injuries during thyroid surgery (the highest being £945 685.26). The total cost of all ten highest settlements is £5 296 155.46, accounting for 48.42% of the total payout for thyroid-related claims since the beginning of the NHS Litigation Authority in 1995.

Discussion

For negligence to be proven, it must be demonstrated that the doctor owed a duty of care to the patient, that the duty was breached, the care provided deviates from accepted standards of practice and that the patient has suffered harm as a result (Samanta and Samanta, 2003). 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. Multiple strategies are used to try and reduce the possibility of litigation.

Table 3. Thyroid cytology classification

Cytology result	Description	Management
Thy 1/1c	Non-diagnostic	Repeat fine needle aspiration
Thy 2/2c	Benign	Clinical follow up
Thy 3a/3f	Atypia of uncertain significance or follicular lesion	If Thy 3a consider repeat fine needle aspiration Thy 3f consider diagnostic lobectomy
Thy 4	Suspicious of malignancy	Total thyroidectomy or lobectomy
Thy 5	Malignant	Total thyroidectomy or lobectomy

From Cross et al (2016)

Misdiagnosis

The largest number of claims arose from problems with the diagnosis. Incorrect diagnosis accounted for 22 claims of which 17 cases found for the plaintiff. These claims were for incorrect histopathological diagnosis or incorrect radiological diagnosis. Multidisciplinary team case conferences were introduced across the UK to improve the quality of diagnosis and treatment in thyroid surgery in 2004 (Watkinson, 2004; Smith et al, 2012). In addition, the British Thyroid Association and the British Association of Endocrine and Thyroid Surgeons have set standards for best practice which state that all cases of suspected thyroid malignancy should be discussed in a multidisciplinary team meeting (Chadwick, 2012; Perros et al, 2014; Mitchell et al, 2016). The fourth national audit of the British Association of Endocrine and Thyroid Surgeons found that when a postoperative diagnosis of cancer was made, only 50% of cases were discussed preoperatively at a thyroid multidisciplinary team meeting but more reassuringly 98.6% postoperatively (Chadwick, 2012). The British Association of Endocrine and Thyroid Surgeons audit found that 81.7% of Thy5 results were discussed at a

multidisciplinary team meeting (see *Table 3* for explanation of Thy grading). This contravenes British Thyroid Association guidelines suggesting that all of these results should be discussed at a multidisciplinary team meeting to agree a management strategy (Chadwick, 2012; Perros et al, 2014; Mitchell et al, 2016). Similarly only 65.2% of Thy4 results were discussed preoperatively at a multidisciplinary team meeting. The British Association of Endocrine and Thyroid Surgeons audit also found that a Thy4 diagnosis increased the likelihood of surgical intervention, and so suggested that these cases should also have a management plan decided preoperatively at a multidisciplinary team meeting (Chadwick, 2012).

The introduction of multidisciplinary team review together with the development of national external quality assurance carried out by the Royal College of Pathologists aims to minimize errors in diagnosis and delays to treatment and ultimately lead to a decrease in potential litigation related to diagnosis and treatment (Helliwell and Allen, 2009).

Laryngeal nerve injury

Recurrent laryngeal nerve injury accounts for one fifth of litigation claims and is associated with some of the most devastating complications. Unilateral vocal cord paralysis can cause hoarseness, problems with phonation, dysphagia especially with liquids and aspiration pneumonia. Bilateral vocal cord paralysis may cause aphonia, severe breathing difficulties and necessitate a tracheostomy, radically diminishing quality of life.

Several studies have evaluated the use of intraoperative nerve monitoring to reduce recurrent laryngeal nerve injury. The most comprehensive review by Dralle et al (2008) found no difference in outcome in studies of intraoperative nerve monitoring compared to controls. A report by Abadin et al (2010) looked at malpractice litigation in the USA between 1989 and 2009 and found increased use of intraoperative nerve monitoring but no evidence that it reduced malpractice litigation. In another study Dralle et al (2012) reviewed expert opinions from malpractice claims between 1995 and 2010 from a single German hospital. Since 2007, intraoperative nerve monitoring was used in four out of the seven claims where recurrent laryngeal nerve injury was sustained during thyroid surgery. However, none of these cases followed international standards to ensure the intraoperative nerve monitoring was correctly functioning and positioned by stimulating the vagus and recurrent laryngeal nerves before surgery (Poveda et al, 2012). This omission resulted in finding for the claimant in three verdicts. It would seem apparent that while intraoperative nerve monitoring may not reduce the incidence of recurrent laryngeal nerve palsy, if it is used, it must be correctly performed and this in itself may reduce litigation payouts (Dralle et al, 2012). The amount paid by the NHS for recurrent laryngeal nerve injury totalled £2 494 236.20 between 1995 and 2012, roughly one quarter of the total amount settled for all thyroid-related claims.

Never events

The National Patient Safety Agency is part of the Department of Health and leads and contributes to patient care and safety by informing, supporting and influencing the health organizations in England. The National Patient Safety Agency defines never events as:

> **'A serious, largely preventable patient safety incident that should not occur if the available preventative measures have been implemented by healthcare providers' (National Patient Safety Agency, 2012).**

Nine never events were reported to the NHS Litigation Authority as the basis of litigation claims. Of these claims six were successful at court, resulting in £136 036.55 being paid to claimants.

The World Health Organization (2009) introduced a surgical safety checklist as part of the 'Safe Surgery Saves Lives' initiative established by the World Alliance for Patient Safety. The checklist was designed to reduce the number of surgical deaths across the world especially in relation to never events. A study by de Vries et al (2010) from the Netherlands demonstrated that the complication rate decreased from 27.3% to 16.7%, and in-hospital mortality decreased from 1.5% to 0.8% in patients undergoing general surgery operations, following adoption of the World Health Organization surgical safety checklist. The checklist has been adopted throughout the UK since 2009, and its completion by surgical, anaesthetic and nursing practitioners before all operations is now mandatory.

Global comparisons of litigation for thyroid surgery

The Physicians Insurers Association of America handles 25% of all medical malpractice in the USA. Singer et al (2012) reviewed claims made to the Physicians Insurers Association of America between 1985 and 2008; during this 24-year period a total of 380 claims were made, resulting in 128 indemnity payouts (both court settlements and out-of-court settlements). A total of 55 indemnity claims relating to recurrent laryngeal nerve palsy or voice disturbance were made and 21 were settled in the Singer et al (2012) study, compared to 18 found for the claimant out of 38 in the UK. The average payout was £115 701, almost double the average payment paid by the NHS Litigation Authority (£66 781).

Abadin et al (2010) reviewed all USA malpractice cases taken to court and registered on the LexisNexis Academic legal database between 1989 and 2009. A total of 33 cases following thyroid surgery were registered. Fifteen cases (46%) related to recurrent laryngeal nerve injuries of which seven cases were found for the patient (average payout of $1 600 000, range $150 000–3 700 000). These figures are roughly ten times the amount paid by the NHS Litigation Authority for recurrent laryngeal nerve injury in England (*Table 1*). The reviewers also mention that 13 cases of malpractice related to incorrect diagnosis and 13 cases related to delayed diagnosis but no further data were available.

In the previously cited study from Germany, Dralle et al (2012) reviewed 75 medicolegal claims (both court and out-of-court cases) relating to thyroid malpractice between 1995 and 2010 in one tertiary level hospital. A total of 43 cases related to recurrent laryngeal nerve injury, of which 21 found for the claimant, but amounts awarded were not given. This hospital received a relatively high number of claims, approximately half the number of claims made across the whole of England over the same time period, so direct comparison between these countries may not be possible.

These articles demonstrate that litigation following thyroid surgery is also experienced in other countries. The exact levels of payment made for successful litigation are much greater in the USA compared to England. However, it is clear from the German studies that intraoperative nerve monitoring is becoming standard practice to help identify recurrent laryngeal nerve at risk during surgery, but also that when it is not used or is used incorrectly this forms the basis of a successful litigation case. Intraoperative nerve monitoring is not widely used in the UK but is gaining favour, particularly in re-operative cases (Chadwick, 2012).

Volume–outcome relationship

For a legal claim to be upheld, injury must be incurred, therefore any measures to reduce morbidity following thyroid surgery will reduce the number of successful claims. Although it is logical to assume that surgeons with more experience will have a lower complication rate, there is little evidence in the literature to establish an acceptable minimum annual caseload.

Sosa et al (1998) reviewed 5860 discharges relating to thyroidectomy in Maryland, USA between 1991 and 1996. They reported that surgeons who performed more than 100 thyroidectomies in that 6-year period had significantly lower complication rates (5.1% *vs* 8.6%). The group also noted that hospitals with a higher volume had no consistent association with outcomes following thyroid surgery, concluding that surgeon volume appeared to be the only factor impacting outcomes. Stavrakis et al (2007) reviewed 13 997 discharges from all state hospitals in New York and Florida in 2002. They identified that surgeon volume was inversely correlated with complication rate and length of stay and hospital volume did not correlate to either outcome, corroborating the findings of Sosa et al.

A study by Duclos et al (2012) reviewed the relationship between surgeon seniority and complication rate in five academic high volume centres in France between 2008 and 2009. They found that surgeons between the ages of 35 and 50 years had a lower complication rate than those with over 20 years or more surgical experience or those with less than 5 years of surgical experience. Surgeons should engage in a continual audit of their own practice and maintain lifelong learning in order to minimize their rate of adverse outcome.

It appears that high volume surgeons may have lower complication rates. This supports the argument that complex surgery (such as revision thyroidectomy, particularly when a complication has been incurred during the primary surgery) should be performed in specialist centres by experienced surgeons. In the UK, the requirement for consultant level membership of the British Association of Endocrine and Thyroid Surgeons is to perform a minimum of 30 thyroid operations per year and to submit data to their national audit programme (Chadwick, 2012).

Day case thyroidectomy

In the UK and the USA, thyroidectomy has been commonly performed as a day-case procedure, i.e. patients are discharged on the same day as their operation, in practice often within 6 hours following surgery. Doran and colleagues (2012), on behalf of the British Association of Endocrine and Thyroid Surgeons, investigated whether thyroid surgery in patients discharged the same day was safe practice. The principal concern is that of postoperative bleeding. If bleeding is not recognized and stopped, the resultant haematoma may cause external compression of the trachea leading to airway compromise and death. Summarizing the available evidence they cited the incidence of postoperative bleeding at 1–2% with 80% of cases occurring within 24 hours. They also concluded that there is no reliable way to predict which patients are more likely to experience this complication. The authors stated that no other operation with a comparable complication risk profile is currently being performed in the UK as a day-case procedure. As a consequence the British Association of Endocrine and Thyroid Surgeons does not endorse thyroid surgery without an overnight admission in a fully equipped and staffed hospital ward (Doran et al, 2012).

Performing surgery under conditions contrary to those laid out in the 2012 British Association of Endocrine and Thyroid Surgeons consensus position may increase the likelihood of litigation in favour of the plaintiff. English law applies two tests to any medicolegal case, the Bolam test (what would be considered reasonable practice by a responsible body of professionals) and the Bolitho test (the practitioner must be have chosen a logical treatment and have considered the risks and benefits of alternative practice) (Samanta and Samanta, 2003). It could therefore be argued that any patient not receiving the standard of care recommended by the British Association of Endocrine and Thyroid Surgeons, who develops a complication, may be successful in making a legal claim as neither the Bolam nor Bolitho test are fulfilled. A single claim could nullify any potential hospital savings considered likely by adopting day-case thyroid surgery.

Limitations

The NHS Litigation Authority database was designed as a claims management tool rather than for risk management, and case descriptions are limited. Information on patient age, sex, employment status and reasons the claim settled (whichever way) is not provided to protect patient confidentiality. Data were only provided up until 2012 as Freedom of Information requests for data after this date were refused by the NHS Litigation Authority to prevent identification of patients from the case descriptions.

KEY POINTS

- Postoperative thyroid surgery complications can be significant and life-changing.
- Between 1995 and 2012, 77 litigation claims cost the NHS £7.6 million.
- Multiple strategies should be implemented to mitigate litigation claims.
- Implementation of multidisciplinary team working and World Health Organization theatre checklists have helped to prevent diagnostic and surgical errors.
- Intraoperative nerve monitoring can help indicate potential recurrent laryngeal nerve injury but its use is not currently widespread in the UK.
- Day case thyroid surgery is not currently recommended by the British Association of Endocrine and Thyroid Surgeons as a result of serious and life-threatening complications occurring after 6 hours when ambulatory patients may have been discharged.

In addition, before 2002, NHS trusts were not mandated to report all cases of negligence to the NHS Litigation Authority. Therefore the data from this review before 2002 may not reflect the incidence of all injuries and claims related to thyroid surgery, but should act as a guide to litigation practice in the NHS.

Conclusions

To the authors' knowledge this review is the first to present data on litigation regarding thyroid surgery in England. This review has undertaken an analysis of a mandatory national database of claims, detailing causes and payouts that NHS trusts and surgeons may find useful for planning strategies to minimize risk in this area. The introduction of multidisciplinary team meetings, national standards of practice, audit of outcomes, the use of intraoperative nerve monitoring to international standards, the implementation of the World Health Organization surgical safety checklist, and a change towards high volume surgery may reduce litigation in thyroid and parathyroid surgery. This article also draws attention to the British Association of Endocrine and Thyroid Surgeons consensus position against day-case thyroid surgery. Surgeons must be made aware that this could change the way that litigation is viewed by the courts regarding plaintiffs who have suffered complications following same day thyroid surgery. **BJHM**

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