Toward Safer Practice in Otology: A Report on 15 Years of Clinical Negligence Claims

Rajeev Mathew, MA, MBBS; Eleni Asimacopoulos, BSc, MBBS; Peter Valentine, MBBS, FRCS

Objectives/Hypothesis: To determine the characteristics of medical negligence claims arising from otological practice.

Study Design: Retrospective analysis of medical negligence claims contained in the National Health Service Litigation Authority (NHSLA) database.

Methods: Claims relating to otology and neurotology between 1995 and 2010 were obtained from the NHSLA database and analyzed for cause of injury, type of injury, outcome of claim and costs.

Results: Over 15 years there were 137 claims in otology, representing 26% of all the claims in otolaryngology. Of these, 116 have been closed, and 94% of closed claims resulted in payment. Of the 97 successful claims, 63 were related to operative complications. This included six cases of wrong side/site surgery, and 15 cases of inadequate informed consent. The most common injuries claimed were hearing loss, facial paralysis, and additional/unnecessary surgery. Middle ear ventilation and mastoid surgery were the procedures most commonly associated with a successful claim. There were 15 successful claims of misdiagnosis/delayed diagnosis, with chronic suppurative otitis media the condition most frequently missed. There were nine successful claims related to outpatient procedures, of which seven were for aural toilet and six claims of medical mismanagement, including three cases of ototoxicity from topical medications. There were also four successful claims for morbidity due to delayed surgery.

Conclusions: This is the first study to report outcomes of negligence claims in otology. Claims in otology are associated with a high success rate. A significant proportion of claims are not related to surgery and represent areas where safety should also be addressed.

Key Words: Malpractice, litigation, otology, neurotology.

Level of Evidence: 4.

INTRODUCTION

In the United Kingdom, litigation places a substantial burden on the National Health Service (NHS). Successful claims from 2009 to 2010 cost the NHS approximately 787 million Great British pounds (GBP) (1.20 billion United States dollars [USD]). A recent report from the United States estimated the annual cost of malpractice claims at 9.85 billion USD. Medical malpractice is, therefore, a significant driver of healthcare costs, and in both countries there has been much interest in medical liability reform to address this problem.

Irrespective of these developments, it is the clinician's duty to ensure that their practice is as safe as possible. In this respect litigation analysis can help to educate physicians and reduce the burden of claims.

There have been a number of reviews of malpractice cases within the field of surgery, which have focused on operative errors. A review of 444 malpractice claims found that most technical errors occur in routine operations with experienced surgeons, under conditions of increased patient complexity or systems failure. The authors suggested that the focus of surgical safety should, therefore, be on improving decision making and performance in routine operations for complex patients and circumstances.

Given the high case load of routine procedures, such as ventilation tube insertion and the possible devastating complications of advanced otological surgery, the potential for litigation in otological practice is high. To date, however, there have been no published reports of negligence claims in the field. The present study analyzes negligence claims related to all aspects of otological practice on a national basis over the last 15 years. Our aim was to highlight potential sources of error to enable surgeons to make their practice safer and thereby reduce litigation.

MATERIALS AND METHODS

Our data was obtained from the National Health Service Litigation Authority (NHSLA). This body was created in 1995 to manage negligence claims within the public sector in England. Since April 2002, all clinical negligence claims have been managed by the NHSLA. From 1995 to 2002, individual
hospital trusts managed small claims, but it is estimated that 90% of claims entered the NHSLA database during this period.6

A data request for all claims in otolaryngology between 1995 and 2010 was made to the NHSLA. Claims were grouped according to subspecialty, and only those relating to otology or neuro-otology were analyzed. Information provided in the NHSLA data set included whether the claim was open or closed, a brief description of clinical events, injury claimed, and costs to the NHS. All closed claims that resulted in payment of damages were categorized according to cause of injury, which included 1) misdiagnosis/delayed diagnosis, 2) outpatient procedure, 3) complication of surgery, 4) delayed surgery, or 5) medical mismanagement. Each group was then analyzed for injuries claimed and associated costs. Costs are stated in GBP, and conversion to USD is based on the April 2010 exchange rate.7

RESULTS

There were a total of 137 claims in otology over a 15-year period, representing approximately 26% of all claims in otolaryngology. Of these, 116 were closed at a total cost of 6.10 million GBP (9.33 million USD). Ninety-seven of the closed claims (84%) resulted in damages being paid at an average cost of 62,700 GBP per claim (95,000 USD). This included an average of 34,300 GBP (52,400 USD) for damages paid, 8,900 GBP (13,500 USD) for defense costs, and 19,500 GBP (29,600 USD) for claimant costs.

The causes of successful claims are shown in Table I. In total there were two fatalities; one followed a dural tear during mastoid surgery and the other was due to delayed diagnosis of malignant otitis externa. The individual cases with highest payout were in the surgical complications group. The first was for acoustic neuroma surgery complicated by loss of visual acuity, tinnitus, and imbalance. The cost for this case was 361,000 GBP (553,000 USD). The second was for facial palsy following myringoplasty; the cost for this case was 330,000 GBP (505,000 USD).

Complications of surgery accounted for 65% of successful claims (Fig. 1). The most common injuries claimed were hearing loss and facial palsy. There were 12 claims of additional/unnecessary surgery, including five cases of wrong-side surgery, three of which were for insertion of a ventilation tube; one for removal of a ventilation tube, and one that was unknown. There was one case of wrong-site surgery when the wrong lesion was removed from an ear and one claim of surgery for the wrong diagnosis, when grommets were inserted for a presumed diagnosis of middle ear effusion. There was also a case where a procedure was started by a trainee in preparation for the attending who turned out to be away. The incision had to be closed and the surgery terminated. Lack of informed consent was claimed in 15 out of 63 cases (Table II).

Ventilation tube surgery/myringotomy (10 grommets, two myringotomies, and two T tubes) was the procedure with the most successful claims. Hearing loss

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**Table I.** Cause of Successful Closed Claims and Associated Costs.

<table>
<thead>
<tr>
<th>Cause of Claim</th>
<th>No.</th>
<th>Mean Cost Per Claim, GBP/USD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Misdiagnosis/delayed diagnosis</td>
<td>15</td>
<td>80,300/123,000</td>
</tr>
<tr>
<td>Outpatient procedure</td>
<td>9</td>
<td>59,300/90,700</td>
</tr>
<tr>
<td>Complication of surgery</td>
<td>63</td>
<td>58,300/89,200</td>
</tr>
<tr>
<td>Delayed surgery</td>
<td>4</td>
<td>49,000/75,000</td>
</tr>
<tr>
<td>Medical mismanagement</td>
<td>6</td>
<td>78,700/120,000</td>
</tr>
<tr>
<td>Total</td>
<td>97</td>
<td>62,700/95,000</td>
</tr>
</tbody>
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GBP = Great British pound; USD = United States dollar.
was claimed in five cases; severe sensorineural hearing loss was alleged to have occurred in three of these. Other injuries claimed included recurrent infections and pain. There were 12 successful claims relating to mastoid surgery. The most common injuries were facial palsy (five cases) and hearing loss (three cases). Other complications included ear infection as a result of retained BIPP, aural fistula, cervical spine dislocation, tinnitus, imbalance, and death following a dural tear.

Details of claims not related to complications of surgery are shown in Figures 2 to 5.

DISCUSSION

It is clear that only a small proportion of otological cases result in malpractice claims. In 2009 to 2010 alone, there were 93,163 otological operations performed in the NHS in England. However, malpractice claims represent only the tip of the iceberg with respect to events of medical negligence. In a study of 14,700 medical records, it was found that 97% of patients who suffered negligent injury did not claim compensation. Adverse events due to negligence in otology are, therefore, likely to be much more common than indicated in this report, and it is important that otologists adjust their practice not only to reduce the chance of litigation but more importantly to improve patient safety.

There are a number of findings of note from this study. A significant proportion (35%) of successful claims are not related surgical complications and represent areas where safety should be addressed. In addition, 84% of closed claims in otology result in payment of damages. This is particularly high and compares to a figure of 73% in anesthesia and 44% for cataract surgery.
This may relate to the high prevalence of objective injuries, such as hearing loss and facial paralysis in otology claims. In malpractice lawsuits, it has been shown that the severity of the patient’s disability, not the occurrence of an adverse event due to negligence, was predictive of payment to the plaintiff. In our series, lack of informed consent was alleged in 24% of successful claims related to surgical procedures. This compares to a rate of 37% for claims related to endoscopic sinus surgery and 30% for claims following iatrogenic facial nerve paralysis. As seen in Table II, most of the injuries claimed are well-recognized complications of otological surgery, and it is somewhat surprising that consent was inadequate in these cases. Adequate consent requires that physicians provide information that a patient could reasonably expect to receive and that the disclosure is consistent with a professional standard of care. Certainly, in the United Kingdom there has been a shift in the standard for consent from what a reasonable doctor would do to what a reasonable patient would expect.

Informed consent should not only include the details of a procedure and risks but also viable alternative treatment options. In one successful claim of stapedectomy surgery, the patient alleged that they were not given the option of a hearing aid. In addition, it is good practice to have the discussion of informed consent on a number of occasions and document this in the patient’s charts. In a study of informed consent for reduction mammoplasty, it was found that only 25% of patients retained the risks of complications. It is our practice to take informed consent in the outpatient clinic.

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**Fig. 3.** Successful claims due to delayed surgery and associated injuries. In one case of chronic suppurative otitis media (CSOM), it was claimed that delayed surgery occurred due to a delay in the follow-up appointment.

**Fig. 4.** Successful claims due to outpatient procedures and associated injuries. Cases of hearing loss included a dead ear and dislodged middle ear prosthesis due to microsuction.

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<table>
<thead>
<tr>
<th>Injuries claimed</th>
<th>No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hearing loss</td>
<td>4</td>
</tr>
<tr>
<td>Facial palsy</td>
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</tr>
<tr>
<td>Additional surgery</td>
<td>1</td>
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</table>

<table>
<thead>
<tr>
<th>Injuries claimed</th>
<th>No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hearing loss</td>
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</tr>
<tr>
<td>Perforation</td>
<td>4</td>
</tr>
<tr>
<td>Pain</td>
<td>4</td>
</tr>
<tr>
<td>Infection</td>
<td>1</td>
</tr>
<tr>
<td>Imbalance</td>
<td>1</td>
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at preoperative assessment and on the day of surgery. Patients should also be provided with a copy of the consent form.

Although adequate consent is essential, it does not prevent successful claims from arising. In fact, most of the successful claims of surgical complications in our series relate to negligent technique or surgical misadventure. The first question that often arises in claims of surgical misadventure is whether the surgeon was competent to perform the procedure. The Good Surgical Practice Guidelines published by the Royal College of Surgeons of England state that surgeons should only carry out procedures that “lie within the range of the surgeon’s routine practice.” What is and should be, a surgeon’s routine practice is demonstrated by a logbook of surgical procedures and audit of long term outcomes. In addition, trainees should only be allowed to do procedures appropriate to their level of competence, and there must be adequate supervision.

Facial nerve injury is one of the most common postoperative injuries associated with a successful claim in this series. Certain errors are indefensible; this includes thermal injury as a result of drilling with inadequate irrigation, failing to find the nerve in an area of normal anatomy and following it into the area of disease, and inexperience at recognizing the key anatomical landmarks in the temporal bone. On the other hand, if the nerve is in a congenitally abnormal position or disease has exposed the nerve, then a defense can be mounted, but it is important to document these findings with photographic evidence if possible. If facial paralysis occurs, then it is prudent to discuss management with a colleague. Early assessment with neuronography or decompression/repair should be performed when indicated.

There were six cases of wrong-side and site surgery in this series. Otologists should routinely check the patient's notes and audiogram preoperatively to avoid this error. The World Health Organization surgical safety checklist is a useful adjunct in this respect. As part of this checklist, the surgeon should specifically check for iodoform allergy to avoid reaction to bismuth iodoform paraffin paste dressing. Preoperative patch testing to prevent hypersensitivity reactions has been advocated by some. Care must also be taken with patient transfer and positioning in the operating room. There was one case of back injury as a result of a patient falling off the operating table during surgery and one case of cervical subluxation during mastoid surgery in this series. Use of a contralateral pelvic support and chest straps can potentially improve safety during canal wall up mastoid surgery. This allows the table to be tilted away without the patient falling and avoids the need for excessive rotation of the cervical spine, which can cause vertebral subluxation particularly in children.

Chronic suppurative otitis media (CSOM) is the condition that was most frequently associated with misdiagnosis/delayed diagnosis. Accurate diagnosis depends on a high index of suspicion, micro-otoscopic examination, and judicious use of imaging. There were also two cases of delayed diagnosis of vestibular schwannoma. In one case of missed vestibular schwannoma, an magnetic resonance imaging scan was performed but not reported, resulting in a 4-year delay in diagnosis. It is the clinician's responsibility to ensure that requested scans are performed and reported; it is our practice to keep a record of all requested investigations, and these are followed up by a dedicated member of staff.

There were three successful claims for ototoxicity from ear drops in our series. Ototoxicity from aminoglycoside drops has been documented in a number of reports. Current UK guidelines state that in the presence of infection, aminoglycoside drops should be used for no longer than 2 weeks, that the justification for the use of the drops be explained to the patient, and that baseline audiometry should be performed if possible. There were four successful claims for complications due to delayed surgery, with four claims of hearing loss and one claim of facial palsy. The question that follows is...
which cases of CSOM should the otologist prioritize for surgical treatment? Clearly, cases with evidence of intra- or extracranial complications need early treatment; we would also recommend early surgical treatment of CSOM in an only hearing ear.

There are a number of limitations to this study. First, these claims only represent those made against the NHS in England and do not contain information on claims from the private sector. Second, the NHSLA database has been constructed for claims analysis. As a result, the clinical information provided is limited, and information such as type of surgery or diagnosis is missing in a number of cases. Third, injuries in the database represent what was claimed by patients and not necessarily what happened.

CONCLUSION
The relative numbers of clinical negligence claims in otology are small according to these data. However, when a claim is made there is a high chance that it will result in payment of damages. A significant proportion of claims in otology are not related to complications of surgery and represent areas where safe clinical practice should also be addressed.

Acknowledgments
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BIBLIOGRAPHY