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Lessons from rhinology and facial plastic surgery clinical negligence claims in England 2013–2018

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Main Article

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Abstract

Objective. This study reviewed all rhinology clinical negligence claims in the National Health Service in England between 2013 and 2018.
Method. All clinical negligence claims held by National Health Service Resolution relating to rhinology in England between 1 April 2013 and 1 April 2018 were reviewed.
Results. There were 171 rhinology related claims with a total estimated potential cost of £13.6 million. There were 119 closed claims (70 per cent) with a total cost of £2.3 million, of which 55 claims resulted in payment of damages. Over three quarters of all rhinology claims were associated with surgery ($n = 132$). Claims associated with endoscopic sinus surgery had the highest mean cost per claim (£172 978). Unnecessary pain (33.9 per cent) and unnecessary operation (28.1 per cent) were the most commonly cited patient injuries.
Conclusion. Patient education and consent have been highlighted as key areas for improvement from this review of rhinology related clinical negligence claims. A shift in clinical practice towards shared decision making could reduce litigation in rhinology.

Introduction

The costs associated with clinical negligence claims within the National Health Service (NHS) in England have almost tripled over the last decade, rising from £863 million in the 2004–2005 fiscal year to a projected cost of £2.3 billion for the last fiscal year (2019–2020).[1] Furthermore, there has been an increase of 50 per cent in the number of successful claims in England from 2006 to 2016.[2]

NHS Resolution is a not-for-profit body of the Department of Health and Social Care in England that provides expertise to the NHS on resolving legal concerns and disputes legitimately. National Health Service organisations are provided with indemnity cover for litigation, assistance with risk mitigation and facilitation of learning from claims.[3] All NHS hospitals in England are members of the Clinical Negligence Scheme for Trusts, and each pays an annual contribution based on their clinical negligence claims history and risk profile. Risk is assessed on an individual hospital basis, taking into consideration the type, volume and complexity of clinical activities undertaken. NHS Resolution manages the Clinical Negligence Scheme for Trusts and is responsible for meeting the legal costs and damages arising from clinical negligence claims on behalf of its members through the Clinical Negligence Scheme for Trusts.

Clinical negligence claims are a rich source of learning for surgeons and should be regarded as an opportunity to improve patient care and reduce future litigation. Clinical negligence claims in otolaryngology have been studied extensively in recent years in both the UK[4,5] and internationally.[6] This analysis has identified important targets for improvement in the ENT patient pathway, especially in diagnostic assessment and consent.[7]

However, much of the existing literature has been limited to the examination of legal and insurer databases, which often exclude cases that have settled without the need for court proceedings.[7–9] The data from clinical negligence claims in England through NHS Resolution provides a single national repository for claims information. Analysis of this national data source helps identify important learning points to improve clinical practice.

Rhinology and facial plastic surgery are subspecialties that may be particularly vulnerable to litigation. Complications from endoscopic sinus surgery can potentially result in high morbidity if there is breach of the orbit or anterior skull base.[10,11] Furthermore, facial plastic surgery procedures, such as septorhinoplasty, can be a source of clinical negligence claims owing to patient perceptions of unsatisfactory cosmetic outcomes.[12]

The aim of this study was to review clinical negligence claims in rhinology and facial plastic surgery in England by using the NHS Resolution claims database to identify learning points, improve patient safety and reduce litigation costs.

Materials and methods

The National Health Service Health Authority Research decision tool[13] was used to decide whether ethical approval was required. The decision tool deemed that no ethical approval was necessary for this paper.

A request for information was made to NHS Resolution regarding claims coded under 'otolaryngology' or 'ENT' between 1 April 2013 and 1 April 2018. The information received included the claim status (open or closed), cause of the claim with incident details and the injury related to the claim. The incident year and the year of notification to NHS Resolution were also provided. More than one cause and injury were frequently assigned to each clinical negligence claim.

Information was reviewed for all claims assigned to 'otorhinolaryngology' or 'ENT.' Claims relating to rhinology were identified using incident details and categorised by diagnosis and operation (where sufficient clinical information was available).

For open claims, estimated costs were calculated by NHS Resolution based on the costs already paid on the claim and the outstanding or reserve costs for each claim. For closed claims, the actual cost paid by NHS Resolution was used.

A five-year claims dataset was used for analysis (1 April 2013 to 1 April 2018), unless otherwise stated. Costs presented in this dataset were accurate as of the end of the financial year 2017 to 2018. For example, if the claim was notified to NHS Resolution in financial year 2013 to 2014, the final claim status and cost that was accurate as of April 2018 was used. This allowed for a more precise analysis of actual and potential claims. Costs are stated in British pounds (GBP (£)).

Results

From April 2013 to April 2018, there were 750 claims notified to NHS Resolution that were categorised as 'otorhinolaryngology' or 'ENT' claims. After review of individual claim details, 727 claims were confirmed as correctly being attributed to otorhinolaryngology. A total of 171 claims were identified as being related to rhinology and facial plastic surgery, with a combined cost of both open and closed claims amounting to £13.6 million (Table 1). Of these claims, 52 (30 per cent) were open and 119 (70 per cent) were closed at the end of the 5-year period (Table 2).

In the closed claims group, damages were paid in 55 claims (46 per cent) with an average total claim cost (including legal costs) of £39 899. The average damages paid were £14 586. The highest amount paid for a claim was £149 895, involving orbital injury caused by a microdebrider during endoscopic sinus surgery. Sixty-four claims (54 per cent) in the closed claims group resulted in no damages paid, but 44 (69 per cent) of these incurred defence costs.

Adult rhinology clinical claims ($n = 141$, 82.5 per cent) were of higher cost (mean cost per claim: £90 107) than paediatric rhinology claims ($n = 30$, 17.5 per cent, mean cost per claim: £28 668).

Claims involving an operation ($n = 132$, 77 per cent) were of higher total value (mean cost per claim: £84 560) than claims not involving an operation ($n = 39$, 33 per cent, mean cost per claim: £61 622). The 3 most frequent operations featured in this series included endoscopic sinus surgery ($n = 46$, 27 per cent), septorhinoplasty ($n = 24$, 14 per cent) and septoplasty ($n = 21$, 12 per cent). Endoscopic sinus surgery claims had the highest total mean cost per claim (£172 978). In analysis of closed cases for this group, septoplasty cases represented the lowest proportion of cases with damages paid (4 of 17, 24 per cent; Table 3)

Based on codes assigned by NHS Resolution, the most common causes for litigation included intra-operative complications ($n = 44$, 26 per cent), failure or delay in treatment ($n = 44$, 26 per cent), and consent ($n = 34$, 20 per cent). Claims associated with intra-operative complications incurred the highest costs (mean cost per claim: £153 345). Patient injuries that were commonly cited in rhinology and facial plastic surgery related clinical negligence claims included unnecessary pain ($n = 58$, 34 per cent) and unnecessary operation ($n = 48$, 28 per cent). Claims associated with visual disturbance (including blindness) were found to have the highest mean cost (£197 120; Table 4)

In analysing claims related to the three commonest operations, we observed recurring themes in this subset analysis. Amongst endoscopic sinus surgery claims, eight were associated with orbital injury, five with cerebrospinal fluid leak and five with retained foreign bodies. In septorhinoplasty claims, eight cited unsatisfactory cosmetic appearance, and two claims involved injury to the eyes with aseptic cleaning solution. Septoplasty related claims cited septal perforation ($n = 4$), change in appearance of the nose ($n = 3$) and hyposmia ($n = 3$).

In claims related to failure or delay in treatment, six claims involved nasal fracture management. There were eight claims associated with delays in treatment of chronic rhinosinusitis ($n = 8$) and several claims of missed or delayed diagnosis of sinonasal malignancy ($n = 6$), granulomatosis with polyangiitis ($n = 2$), and meningoencephalocele ($n = 2$).

Table 1. Otolaryngology clinical negligence claims by subspecialty

Parameter	Claims (*n*)	Total cost (£)
Head & neck	313	51.5 million
Otology	171	24.5 million
Rhinology or facial plastic surgery	171	13.6 million
Unspecified	72	18.7 million
Total	727	108.3 million

Values taken from NHS Resolution (April 2013 to April 2018)

Table 2. Summary of rhinology and facial plastic surgery related clinical negligence claims

Rhinology claims	Claims (*n*)	Value (%)	Total cost
Total	171	100.0	£13 565 161
Open	52	30	£11 258 716
Closed	119	70	£2 306 445
Closed claims (% of closed claims)			
– Defence costs paid and damages paid	55	46	£2 194 447
– Defence costs paid and no damages paid	44	37	£111 999
– No costs paid	20	17	

Costs are estimated potential values. Values taken from National Health Service Resolution (April 2013 to April 2018)

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Table 3. Summary of clinical negligence claims for endoscopic sinus surgery, septorhinoplasty and septoplasty

	Endoscopic sinus surgery		Septorhinoplasty		Septoplasty	
Parameter	Claims (*n* (%))	Mean cost per claim (£)	Claims (%)	Mean cost per claim (£)	Claims (%)	Mean cost per claim (£)
All claims (*n* (% of all claims))						
– Total	46	172 978	24	44 614	21	27 646
– Open	15 (33)	465 020	9 (38)	84 617	4 (19)	55 570
– Closed	31 (67)	31 667	15 (62)	20 613	17 (81)	21 076
Closed claims (*n* (% of closed claims))						
– Defence costs paid and damages paid	18 (58)	53 372	8 (53)	37 419	4 (24)	82 909
– Defence costs paid and no damages paid	7 (23)	3000	4 (27)	2462	8 (47)	3331
– No costs paid	6 (19)		3 (20)		5 (29)	

Costs are estimated potential values. Values taken from National Health Service Resolution (April 2013 to April 2018)

Table 4. Most frequent rhinology or facial plastic surgery clinical negligence claim cause code and injury code, as coded by NHS Resolution

Parameter	Claims (*n*)	Percentage of total claims (%)	Total cost (£)	Mean cost per claim (£)
Cause				
– Intra-operative complications	44	26	6 747 164	153 345
– Failure or delay in treatment	44	26	1 203 651	27 356
– Consent	34	20	1 992 277	58 596
– Failure or delay in diagnosis	14	8	1 084 410	77 458
Injury				
– Unnecessary pain	58	34	2 291 210	39 504
– Unnecessary operation	48	28	725 328	15 111
– Cosmetic deformity	16	9	625 183	39 074
– Visual disturbance	13	8	1 187 303	197 120

Each claim will often have more than one cause code and injury code. Costs are estimated potential values. Values taken from National Health Service (NHS) Resolution (April 2013 to April 2018)

Discussion

General trends

Our study demonstrated that the number of rhinology litigation claims in England is on the rise, following the trend of the other clinical specialties. A previous study by Geyton *et al.*[14] reviewed rhinology clinical negligence claims in England using the same claims database as this study. They reported 65 closed claims in the period between 1995 and 2010. When this figure is compared with the 119 closed claims reported in our study's 5-year series, it is evident that litigation activity in rhinology has increased considerably and that surgeons must be aware of the implications.

In this study, rhinology accounted for lower claims costs compared with other otolaryngology subspecialties at almost half the total cost of otology related litigation despite having the same number of claims (Table 1). Although consistent with previous studies analysing rhinology claims in England,[15] it does contrast with the US medicolegal landscape, where rhinology is the most frequently implicated subspecialty[9] and can account for up to two thirds of the total indemnity paid for malpractice claims in ENT.[16] The reasons for these differences are complex owing to contrasting healthcare provider structures, differing legal systems and calculation methods for compensation.

Patient education and consent

Our findings demonstrated that a high proportion of rhinology clinical negligence claims cite 'unnecessary operation' (28 per cent) as the patient injury, and consent is cited as the cause for litigation in one fifth of claims. In a US rhinology malpractice series from 1985 to 2006, informed consent was the subject of 16 per cent of claims.[16] This indicates a failure in the consent process, which relies on effective patient education regarding rhinology procedures and informed decision making.

Ensuring that patients have realistic expectations of the potential outcomes following surgery can be difficult to achieve.[12] The extent of a patient's understanding of their disease can vary widely. With regards to chronic rhinosinusitis, qualitative studies from the UK have demonstrated that patients are often frustrated with their management and seek a better understanding of both their condition and the available treatment options.[17] In facial plastic surgery, psychiatric conditions such as body dysmorphic disorders drastically

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affect patient satisfaction with surgical outcomes[18] and increase the risk of clinical negligence claims.[19]

Rhinology procedures such as endoscopic sinus surgery and septorhinoplasty involve complex anatomy; therefore, it can be difficult for patients to fully comprehend the possible complications of surgery. A survey by Wolf *et al.*[20] of patients who had undergone endoscopic sinus surgery found that the numerous complications, from mild to catastrophic, made the informed consent process especially difficult for this cohort. The study also found that patients wanted to be informed regarding rare but severe complications.[20]

Patient leaflets produced by ENT-UK (the professional body representing ENT surgeons in the UK) have been utilised to inform patients prior to rhinology procedures in the UK.[21] There is also evidence that digital information resources have been beneficial to patients.[22,23] Appropriately guiding patients' decision making processes in rhinology can ensure that patients make the correct decisions based on their personal health beliefs, thereby reducing the chances of an unsatisfactory outcome from treatment. The process can also be aided by the use of validated patient-reported outcome measures, such as Sino-Nasal Outcome Test (SNOT)-22,[24] other shared decision-making tools[25] and the introduction of more objective outcome measurements within rhinology.[26]

Delays in patient pathway

'Failure or delay in treatment' and 'failure or delay in diagnosis' are the first (joint) and fourth most common cause codes respectively in rhinology related litigation in this claims series. Both of these broad categories apply to the entire patient pathway from primary care referral to investigations and definitive treatments performed in secondary care. In these groups of claims, there were six claims citing delay in referral after nasal fracture as the cause. It is well established practice that injuries to the nasal bones have a limited timeframe in which treatment can be administered, and it is essential that there are clear and well reinforced referral pathways for these patients to avoid delay in assessment and treatment.

Furthermore, conditions that have similar symptoms to chronic rhinosinusitis can often be missed or identified late even after review by ENT surgeons. Although rare, primary care and ENT clinicians should have a high index of suspicion for atypical presentations of sinonasal disease, such as unilateral symptoms and additional extra-rhinological manifestations including orbital symptoms (diplopia, reduced visual acuity) and systemic features of vasculitis (arthralgia, haematuria).

Claims associated with operations

Over three quarters of rhinology related clinical negligence claims in this series involved an operation. Intra-operative complications were cited as the most frequent (jointly with failure or delay in treatment) cause for litigation, and claims with this cause 'code' were of the highest value. The frequency of surgery related claims in this subspecialty emphasises the importance of patient safety in surgery. Amongst surgery related claims, the commonest operations were endoscopic sinus surgery, septorhinoplasty and septoplasty.

Endoscopic sinus surgery

Endoscopic sinus surgery is the most common operation associated with rhinology clinical claims in our series, in line with US practice.[27] Considering endoscopic sinus surgery is one of the most common rhinology procedures, with an estimated 19 270 procedures performed in England in the year 2017 to 2018,[28] it is unsurprising that this has featured heavily in the litigation data. From claims associated with surgical procedures, it also had the highest proportion of claims resulting in a payment of damages and the highest mean cost per claim. The amount paid for damages is proportional to the severity of the patient injury,[29] and claims involving complications, such as iatrogenic orbital injury and cerebrospinal fluid leak, resulted in significant costs.[30,31]

As discussed previously, implementing a robust consent process that clearly explains the risks will reduce liability if these recognised complications do occur. In addition, steps to improve patient safety are required to minimise intra-operative complications. For example, image-guided navigation has been shown to improve surgical outcomes,[32] reduce surgical complications[33] and improve surgeon satisfaction[34] in specific types of endoscopic sinus surgery. However, there is no evidence that its routine use minimises medicolegal liability.[35,36] ENT surgeons need to carefully consider the pre-operative, intra-operative and post-operative risk profile for each case in order to reduce the incidence of complications and the potential for litigation.[37]

Facial plastic surgery and septorhinoplasty

Unsatisfactory cosmetic outcome is the predominant reason for litigation in facial plastic surgery[12] and in our series for septorhinoplasty claims. The vast majority of septorhinoplasty operations performed in the NHS are for functional rather than aesthetic indications, but they often have an impact on the cosmetic appearance of the nose. Patient counselling and informed consent both play a vital role in managing patient expectations and guiding the decision-making process for these operations. This is especially pertinent as this patient cohort includes those with concomitant psychiatric disorders, such as body dysmorphic disorder and borderline personality disorder.[18,38]

- Clinical negligence claims are increasing in rhinology in line with trends in otorhinolaryngology
- In this study, over three quarters of clinical negligence claims in rhinology were related to an operation
- In these claims, unnecessary operation and unnecessary pain were frequently cited as reasons for litigation
- Claims associated with endoscopic sinus surgery were associated with the highest costs
- Patient education and shared decision making are key targets for improvement of patient management and selection for surgery and to reduce litigation

The assessment pathway for these patients must include screening tools for related psychiatric disorders owing to the high prevalence of body dysmorphic disorder found amongst septorhinoplasty patients.[39] Such patients need appropriate support from psychologists to ensure that any medical or surgical treatment is the right option considering their overall health needs. In addition, careful patient selection and pre-operative counselling, which explore motivations and expectations of surgery, are necessary in order to reduce patient dissatisfaction and potential clinical negligence claims.

Septoplasty

In our series, septoplasty related claims had the lowest proportion of pay-outs of damages in closed claims. Claims related to

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intra-operative complications seldom resulted in payment of damages unless they were related to unsatisfactory cosmetic appearance. Although septoplasty operations are not intended to change the external appearance of the nose, it must be made clear to patients that this is a potential complication of the surgery.

Limitations

Our study is subject to certain limitations. Firstly, the information for this study was extracted from a claims database, containing limited and variable clinical detail; this restricted our analysis of the clinical aspects of each claim. Additionally, a number of the litigation proceedings from clinical negligence claims in the database remain ongoing. NHS Resolution estimates the costs in these situations; consequently, some figures would require revision once the claim is closed. However, these estimates provide some insight into the potential cost and hence were included in our analysis. Our study did not consider private practice litigation, which would be needed to fully assess the national burden of litigation in rhinology and facial plastic surgery. Furthermore, because of the limitations of the available dataset, a comparison between the relative cost of pre-trial settlements and the damages awarded in court is not possible.

Conclusion

Our study of clinical negligence cases in rhinology and facial plastics has highlighted that patient selection for surgery and the consent process are both key areas to be considered. Ensuring that patients have a clear understanding of both the disease process and the treatment options is crucial. This is the foundation for clear and effective decision making that will improve patient satisfaction and reduce possible litigation in rhinology practice. A shift in clinical practice towards shared decision making could reduce litigation in rhinology and facial plastic surgery.

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