Litigation in Otolaryngology

Minimizing Liability and Preventing Adverse Outcomes

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Preface

Malpractice litigation trends are constantly changing for a variety of reasons including technological innovations and changes in laws. Medicolegal factors contribute to increasing healthcare costs through the direct costs of malpractice litigation, malpractice insurance premiums, and defensive medicine. This textbook, edited by experienced academic and private otolaryngologists at different points in their careers, as well as an attorney, reviews the current literature related to otolaryngology malpractice litigation and discusses strategies to decrease liability and enhance patient safety. Key aspects of this textbook include: a close examination of the most recent trial decisions in otolaryngology, and determining which procedures are most commonly litigated; providing otolaryngologists with tips and pearls on how to prevent malpractice litigation; and discussions of key actions to take when faced with a malpractice suit. The editors hope that this work will be a useful resource for all involved in the care of otolaryngologic patients (physicians, nurse practitioners, physician assistants, etc.), those concerned with the legal aspect of such care (including malpractice attorneys), and healthcare policy makers.

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Chapter 1
Overview of Malpractice Litigation in Otolaryngology

Peter F. Svider, Shawn P. Kelly, Soly Baredes, and Jean Anderson Eloy

Recent decades have witnessed rapidly advancing technologies that significantly reshape the Otolaryngology practice environment. Along with understanding clinical implications stemming from Otolaryngology's versatility, there has been greater recognition of the evolving medicolegal implications of complications, which can add both direct and indirect costs to providing healthcare in the United States. Indirect costs include the practice of defensive medicine, adding $45.6 billion in

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healthcare expenditures annually, while direct costs may be responsible for an additional $10 billion [1]. This textbook is aimed at practicing otolaryngologists as well as Otolaryngology trainees, since having a fundamental understanding of issues raised in proceedings for otolaryngologic-related litigation forms a basis for preventing these adverse events and minimizing liability should an unfortunate event occur. Complications can occur even in the hands of the best surgeons, and risk of malpractice litigation varies significantly by specialty. In an analysis of one large professional liability insurer, physicians in low-risk specialties and high-risk specialties faced a 75% and 99% risk, respectively, of having a malpractice claim by the age of 65 [2]. Nonetheless, the occurrence of an adverse event does not equate to negligence, and there are several basic tenets required for an episode to be considered malpractice and merit payment to a plaintiff (Table 1.1).

This text encompasses several topics serving as the foundation for understanding medical malpractice litigation, with a special focus on Otolaryngology. Most importantly, appropriate and clear communication with one's patient is integral, as many proceedings are initiated not only after an adverse outcome, but specifically following outcomes in which patients claim they were not familiar with specific potential risks [3–21]. For this reason, an entire chapter is dedicated to characterizing what constitutes appropriate informed consent, as well as further detailing the role this has played in prior cases. Further tying into communication, the quality of the physician-patient relationship also plays a key role, as patients are less likely to pursue litigation in situations in which there had been thorough communication and a positive physician-patient relationship. In one study examining this point, the authors evaluated nearly 4000 pages of depositions and noted that the decision to pursue litigation had an association with "a perceived lack of caring and/or collaboration. The issues identified included perceived unavailability, discounting patient and/or family concerns, poor delivery of information, and lack of understanding of the patient and/or family perspective" [22].

Certain themes are pervasive in litigation regardless of the type of procedure or allegation, and these will be emphasized throughout the text. Inadequate informed consent, alleging that surgery was not necessary, requiring additional surgery, and failure to recognize complications in a timely manner are all factors that come up repeatedly when examining past cases [23, 24]. In an analysis evaluating litigation involving cranial nerve injuries, having more of these factors present greatly decreased the likelihood of a decision in favor of a defendant [23]. Nonetheless, there are certainly different considerations based on the intervention being considered. In addition to several foundational topics including informed consent,

Table 1.1 Prerequisites that must be met to award payment in malpractice litigation

1. Duty to act
2. Failure to meet standard of care (breaching duty)
3. Adverse event
4. Evidence of direct causation

Moffett and Moore [60]; Svider et al. [23]

understanding your malpractice policy, differences based on practice setting, expert witness testimony, and a background of the history of malpractice, this text is organized to address various subspecialties comprising Otolaryngology.

Outpatient Otolaryngology

Perhaps surprisingly to some, office-based considerations can lead to significant injuries and consequent litigation. In one review of court records pertaining to otology, alleged injuries sustained from cerumen removal comprised greater than one in five malpractice cases [25], with hearing loss being the most common claimed injury. Furthermore, a significant proportion of cases also stem from myringotomy, an office-based procedure for most adults. These numbers clearly relate to the fact that procedures such as cerumen debridement and myringotomy are among the most commonly performed interventions by otolaryngologists; nonetheless, they illustrate the potential for seemingly routine encounters to develop into full-blown lawsuits.

Several other issues encountered in the outpatient setting can also lead to litigation and merit mention. Laryngoscopy is a mainstay in the otolaryngologist's armamentarium, and multiple patients undergo this procedure every clinic session in most practices. There is a potential, however, to miss suspicious lesions, with devastating consequences [26]. In addition to missing a potential malignancy anywhere in the head and neck examination, radiologic misdiagnosis is another topic that can also lead to medicolegal proceedings. Although this may seem like "common sense" to many practitioners, it cannot be overemphasized that all imaging studies should be reviewed (rather than relying on a report without personally viewing imaging) and that any questions or concerns with radiologic studies should be reviewed with a radiologist. In cases of radiologic misdiagnosis, not only the radiologist but also other treating physicians are frequently named and held liable during litigation [24, 27, 28].

There have been an increasing number of rhinologic procedures being performed in the office setting rather than the operating room. This has been driven by improved visualization with better endoscopes, the development of technologies such as balloon dilation devices, as well as shifting reimbursement structures. Although there is limited information in the literature examining the medicolegal considerations specific to office-based rhinologic procedures, this is a topic that may come up in the future should these trends continue.

Medications prescribed by otolaryngologists can also lead to adverse events that eventually end up in lawsuits. Nash et al. examined court records related to corticosteroid use and medical malpractice, noting alleged negligence, inadequate informed consent, and misdiagnosis as the most common factors brought up in proceedings [29].

In addition to the issues surveyed above, there are several other aspects of outpatient Otolaryngology harboring the potential for litigation, and these are further detailed in Chap. 7.

Head and Neck Surgery

As head and neck procedures encompass some of the most invasive interventions otolaryngologists perform, there is significant opportunity for morbidity and mortality with consequent potential for litigation. Practice setting, training, call responsibilities, and comfort level are the main factors impacting the degree to which head and neck surgery is incorporated into one's practice, and all of these factors may influence the incidence of adverse events. Reviewing the literature and publically available court records, the same themes brought up examining other subfields of Otolaryngology are raised in litigation related to head and neck surgery, including points related to informed consent and failure to recognize a complication in a timely manner. Furthermore, there are unique considerations for various types of surgeries. In a retrospective review involving one tertiary care center in Germany, the majority of claims stemmed from recurrent laryngeal nerve (RLN) injury evenly split between patients with bilateral RLN palsy and those with unilateral injury [30]. As unilateral RLN injury is far more common in the literature, this supports the fact that the far more serious situation of bilateral injury is also far more likely to result in litigation than unilateral injury. The second most commonly cited injury in this series was permanent hypoparathyroidism. Looking at lawsuits from US data, Lydiatt had consistent findings, demonstrating the most common surgical adverse outcome leading to litigation was RLN injury [31]. Factors including inferior voice outcome [32] and requirement of tracheotomy play a significant role in case outcomes. Another review of US thyroidectomy-related malpractice claims noted that the use (or lack of use) of intraoperative nerve monitoring did not play a role in malpractice claims [33], likely due to a lack of consensus regarding its effectiveness (particularly when comparing the general surgery versus Otolaryngology literature).

Far more than thyroid surgery, other head and neck cancers often involve a higher likelihood of perioperative morbidity and present an opportunity for litigation in the event of adverse outcomes. One retrospective review of 50 cases involving patients with oral cavity cancers noted there was a greater chance of litigation being pursued in cases with younger patients, although this analysis focused more on missed/delayed diagnosis than surgical complications [34]. Similar findings have been noted in studies of litigation relating to laryngeal cancer [26]. Numerous studies have also looked at litigation following parotid surgery, with facial nerve injury being the most common injury; one analysis noted an average plaintiff monetary award just under $1 million for patients with facial nerve injury [35]. Issues related to litigation and head and neck surgery are further detailed in Chap. 8, with additional considerations specific to reconstructive surgery in Chap. 15.

Otology

Much like the other practice areas detailed throughout this text, otologic litigation can be roughly split into operative and nonoperative categories. As discussed above, seemingly innocuous outpatient interventions, such as cerumen removal, do have a

potential for harm. Furthermore, missing a diagnosis (largely radiologic misdiagnosis) can lead to medicolegal proceedings.

Among the most commonly claimed injuries following otologic surgeries, hearing loss has been cited in the majority of cases, followed by facial nerve injury and persistent tympanic membrane perforation [25, 36]. Consistent with analyses of court records focusing on different disciplines, Blake et al. noted perceived deficits in informed consent in nearly one-third of cases [25]. Interestingly, hearing loss following stapedectomy resulted in some of the higher payments ($2.7 m) noted in that analysis. Factors relevant to otology are detailed in Chaps. 9 and 10.

Laryngology and Airway Considerations

Myriad factors come into play when evaluating adverse events relating to airway procedures and other aspects of laryngology. While many of the same themes stressed above play important roles, quick and appropriate decision-making is integral particularly during airway emergencies. For this reason, issues relating to informed consent in these situations can be complicated relative to other topics brought up in Otolaryngology litigation. Furthermore, for both larynx-related procedures and all otolaryngologic surgeries, clear communication with the anesthesiologist and anesthesia staff is paramount for ensuring patient safety. Another related issue that is raised in the literature includes concerns around the care of the professional voice, with significant medicolegal implications. Finally, as stressed above, misdiagnosis of aerodigestive tumors as benign entities can result in significant awards [26]. These concerns and strategies to minimize liability are detailed further in Chaps. 11 and 18.

Rhinology

Numerous complications stemming from endoscopic sinus surgeries have been brought up in malpractice proceedings. These include iatrogenic cerebrospinal fluid (CSF) leak due to skull base injury [37] and resultant meningitis [38], intraorbital injury including orbital hematoma [39], and even death. More general themes have been noted; one analysis evaluating 30 US cases noted sustaining allegedly permanent complications (66.7% of cases), requiring additional surgical intervention (63.3%), and inadequate informed consent (40.0%) were repeatedly raised factors [40]. Interestingly, the use or lack of use of image guidance systems (IGS) was not brought up as a reason for litigation. One should note that it often takes many years for cases to proceed from initial injury to medicolegal proceedings and eventually inclusion into publically available court records; consequently, the use or nonuse of IGS may play a role in the future with the popularization of this technology over the past decade. Similarly, the rapidly increasing use of newer technologies such as balloon dilation [41, 42] and newer trends such as the diversion of some rhinologic

procedures to the office-based setting are also considerations that need to be discussed, but the same overall themes of appropriate physician-patient communication, preoperative informed consent, and avoiding unnecessary risks apply to all settings.

In addition to specific rhinologic procedures, an increasing number of otolaryngologists are performing allergy testing and management in the outpatient setting. One study employing the Centers for Medicare & Medicaid Services (CMS) figures noted that otolaryngologists directed care for almost one-third of immunotherapy recipients [43]. Hence, an elementary understanding of the basic safety equipment needed as well as how to recognize and manage complications such as anaphylaxis is important for any practitioners performing this discipline.

Facial Plastic and Reconstructive Surgery

This discipline encompasses a multitude of reconstructive and cosmetic clinical procedures. Although there are shared characteristics among malpractice cases, there are clearly different considerations based on practice setting and the types of procedures performed, and these points are thoroughly explored in this text throughout multiple chapters. Issues brought up by unhappy patients about their appearance following a cosmetic procedure may substantially differ from those raised by head and neck cancer patients with significant functional morbidity following reconstructive surgery.

In one of the largest series of court cases specific to facial plastic procedures, one analysis noted substantial greater than average court settlements and awards ($577,437 and $352,341, respectively) [44]. Rhinoplasty and blepharoplasty were the most litigated entities, perhaps unsurprisingly, as these are among the most commonly performed facial aesthetic procedures. In addition to deficits in informed consent, other issues repeatedly brought up in these proceedings included scarring/disfigurement, functional considerations, and postoperative pain, reinforcing the value of comprehensive preoperative physician-patient discussion of expectations.

Allegations of negligence from patients sustaining facial trauma have also led to litigation. This patient population can differ relative to patients who undergo elective cosmetic procedures, and different points are certainly raised as a result. In addition to complications associated with surgical intervention, the failure to diagnose a fracture is also a common reason for lawsuits [16].

In addition to lawsuits related to aesthetic procedures and facial trauma, there is a tremendous potential for litigation in patients requiring complex head and neck reconstruction, and these patients bring their own unique issues to the table. All of these matters are further detailed in Chaps. 15, 16, and 17.

Pediatric Otolaryngology

Malpractice litigation related to pediatric otolaryngologic procedures and conditions has been previously studied. In a comprehensive analysis by Rose et al.

evaluating 78 cases, median jury-awarded damages were $874,190 [45], generally higher than figures detailed in analyses with adult plaintiffs. This is consistent with evaluations concerning craniofacial surgery and meningitis from otolaryngologic conditions [16, 38] in which proceedings involving pediatric plaintiffs were more likely to be resolved with payment and were resolved with higher payments. Rose et al. reported the most commonly litigated procedure to be adenotonsillectomy [45], with the majority of cases involving intraoperative negligence and 36% of cases involving death. Notably, airway-related adverse events, permanent injury, and plaintiffs being 1–5 years of age were factors significantly increasing the size of payments. These issues are further discussed in Chap. 13.

Special Role of Obstructive Sleep Apnea in Litigation

Malpractice litigation involving plaintiffs with obstructive sleep apnea (OSA) presents challenges in several different ways. There is obviously potential for complications in surgical interventions aimed at addressing OSA, as these surgeries involve the aerodigestive tract and harbor an inherent potential for bleeding and airway swelling with devastating sequelae. Furthermore, there has been an evolution in the types of sleep interventions that are performed [46–50], and for some commonly performed surgeries, there is no consensus as to appropriate specific indications.

It is also important to note that that adult OSA incidence is at 20% and rising in our society [51]. These patients may require close supervision postoperatively after undergoing general anesthesia for any surgeries in Otolaryngology, as 20.4% of cases progressing to litigation in one analysis included allegations of inappropriate postoperative monitoring of patients who simply had OSA in their history [52]. Furthermore, OSA patients are more vulnerable to respiratory depression from opioid medications, reinforcing the importance of conscientious postoperative medication choice and postoperative monitoring. There has been increasing recognition of the availability of evidence supporting the use of opioid alternatives in otolaryngologic surgeries in recent years [53–57], and incorporating these guidelines into one's practice can potentially minimize risks associated with narcotic use in OSA patients.

Summary

The rising threat of medical malpractice in recent decades has impacted the practice of Otolaryngology, as there has been increasing recognition of the personal and financial costs associated with patients who pursue litigation following an undesirable outcome (Fig. 1.1). Familiarity with basic factors required for cases to advance to the level of a lawsuit can be invaluable in developing strategies to avoid adverse medical and legal outcomes. Recurrent themes include the importance of a positive physician-patient relationship, understanding the components of an appropriate

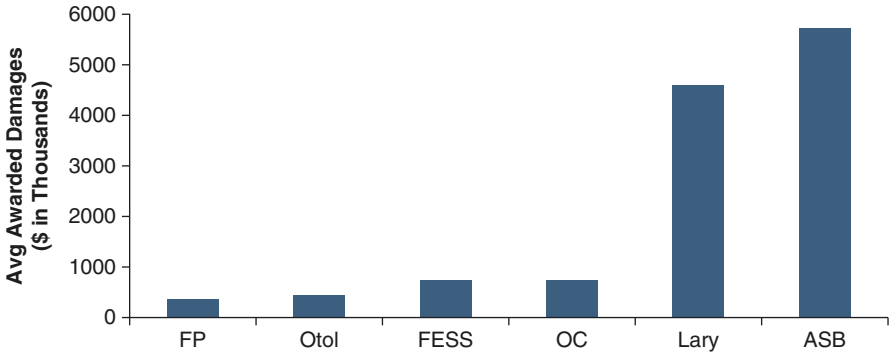

Fig. 1.1 Reported average awarded damages for lawsuits related to select areas in Otolaryngology. FP facial plastic and reconstructive surgery, Otol otology/neurotology, FESS functional endoscopic sinus surgery, OC oral cavity cancer, Lary laryngology, ASB anterior skull base (surgical cases) [21, 25, 34, 44, 58, 59]

informed consent process, and familiarity with other strategies to minimize the incidence of adverse events. Issues raised in proceedings may vary based on practice setting, type of surgery, and severity of complications.

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