

Review Article

Medicolegal issues in otorhinolaryngology: a review

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ABSTRACT

The doctor-patient relationship has undergone a sea change in the past few decades because of the result of fast commercialization and globalization of the medical profession. Miscommunication and lack of patient consent are important points that lead to complaints against surgeons in otorhinolaryngology and other medical specialties. Otolaryngology is a dynamic field, with standards of care changing with the advent and popularization of numerous technological innovations. Inadequate documentation and using unusual terminologies are the well-known reason for errors in Otorhinolaryngology. The treatment has the potential to affect the ability for getting hearing, smelling, talking, swallowing, and breathing. So, any event that affects adversely results in a dramatic impact on quality of life. This specialty typically also involves the face and the part of the body that most people associate with one's identity. Most complications due to otorhinolaryngological surgeries may not result in litigation, however, management of the post-complication period is important to prevent lawsuits. Adequate awareness of the factors involved in lawsuits in Otorhinolaryngology allows surgeons to reduce their risk of prosecution.

Keywords: Otorhinolaryngology, Malpractice, Litigation, Medical negligence

INTRODUCTION

Otorhinolaryngology is one of the leading medical specialties which subject to malpractice lawsuits. Malpractice and related lawsuits are increasing among clinicians and attorneys. Surgeons like otorhinolaryngologists may feel pressured to refrain from requisite surgeries or requesting for unnecessary radiological or laboratory investigations. The medicolegal process can last for years and often take a personal and financial toll, as Otorhinolaryngologists undergo lawsuits and exhibit symptoms of depression and burnout.¹ This type of attitude is usually brought about by the lack of awareness regarding legal aspects of the medical curriculum and fear of litigation. Differences among legal systems, laws, and the socioeconomic status of countries, as well as differences in education status, may affect the distribution and characteristics of lawsuits. The definition

of standard of care, the patient's expectation of a surgical outcome, and the psychological consequence that results from the surgical complications are unique to this especially. As Otorhinolaryngology specially deals with one of the most sensitive parts of the human body, the patient's expectations of any treatment are bound to differ from that of the doctor.² Unlike other fields, the definition of standard of care is constantly evolving due to continuous introduction and modification of the techniques and instruments.

LITERATURE SEARCH

Multiple systematic methods were used to find current research publications on the medicolegal issues in otorhinolaryngology. We started by searching the Scopus, PubMed, Medline, and Google Scholar databases online. A search strategy using PRISMA (Preferred reporting

items for systematic reviews and meta-analysis) guidelines was developed. This search strategy recognized the abstracts of published articles, while other research articles were discovered manually from the citations. Randomized controlled studies, observational studies, comparative studies, case series, and case reports were evaluated for eligibility. There were a total number of articles 48 (12 case reports; 14 cases series; 22 original articles) (Figure 1). This paper focuses only on medicolegal issues in otorhinolaryngology. This analysis provides a better understanding of medicolegal issues in otorhinolaryngology. It will also catalyse further study and better awareness of medicolegal issues in otorhinolaryngology.

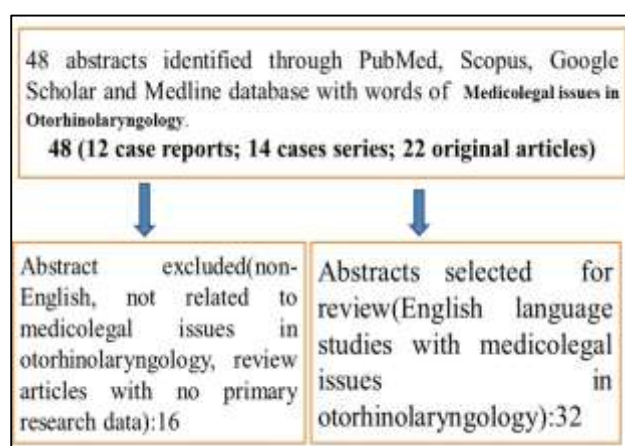


Figure 1: Method of literature search.

OTORHINOLARYNGOLOGY AND MEDICOLEGAL ISSUES

Throughout the world, otorhinolaryngology-related lawsuits are increasing rapidly nowadays, because the patient's expectations of any surgical outcome are often more optimistic and different from that of the physicians. Otorhinolaryngology treatment has the potential to affect the ability to affect hearing, smelling, talking, swallowing, and breathing.³ So, any event that affects adversely results in a dramatic impact on quality of life. This specialty typically involves the face and the part of the body that most people associate with one's identity.⁴

GLOBAL SCENARIO

Legal regulations in medical malpractice vary from country to country, and disparities in terms of compensation make comparison difficult. As the World Health Organization states, a difference between malpractice and untoward results that occur in the period of treatment should be made, as the latter may not indicate the fault of the clinician.⁵ In a review of a random sample of malpractice claims, approximately 37% of the claims were seen to be frivolous and accounted for 15% of the total estimated cost.⁶ Approximately 75% of clinicians in low-risk specialties

and nearly all clinicians in high-risk specialties are at risk of facing malpractice litigation during their professional career; however, the majority of claims favor the defendant clinician.⁷ Differences among legal systems, laws, and the socioeconomic strata of different countries, as well as educational differences, may affect the distribution and characteristics of lawsuits.

MEDICAL NEGLIGENCE

Medical negligence claims fall into three broad groups (Table 1): Delay in or failure to make a diagnosis; A recognized complication that occurs after a surgical procedure and an adverse outcome of treatment (both medical and surgical).

Table 1: Classification of allegations.

Group	Type of allegation
1	Failure or delay in diagnosis
2	Improper performance (Surgery or medical treatment)
3	Complication of surgery
5	Improper post-operative care

Delay/failure to make a diagnosis

In this group, the typical scenarios include a patient with vague otological symptoms later found to have an acoustic neuroma. Patients with globus-like symptoms are subsequently found to have esophageal cancer.⁸ Otalgia may be manifestations in the case of tongue base or tonsillar carcinoma. Failure to diagnose early was frequently complained about in most cancer-related diseases. Failure to advise biopsy was singled out in many instances. Similarly, an inadvertent diagnosis of a cancer may be associated with a lawsuit for causing mental agony and the plaintiff may ask for compensation in terms of damages. The courts often held that histological proof of malignancy is the cornerstone of diagnosis and treatment. But, in reality, establishing the type of tumor and determining whether it is benign or malignant is not an exact science. Errors may occur in sampling, processing, and interpreting specimens. A doctor should never accept a histological diagnosis as unequivocal and should not act on verbal reports from anyone.⁹ Surgeons must ensure that the pathologist is provided with sufficient tissue samples both for routine histopathology and for special studies. When the histological diagnosis does not correlate with the clinical course, the surgeon should review the clinical data about the patient with the pathologist. If the pathologist's diagnosis is still equivocal, he/she may obtain an opinion from another consultant pathologist.

Complications during surgery

In this group, the case may be argued on the point that the surgeon's skills were inadequate but are more normally fought around the quality and content of the consent

process. Typical scenarios include recurrent laryngeal nerve damage following thyroid surgery, facial nerve damage following parotid or mastoid surgeries, and accessory nerve damage in neck dissection. Orbital complications and cerebrospinal fluid (CSF) leaks may occur following endoscopic sinus surgery. Reactionary or secondary haemorrhage may happen following tonsillectomy.¹⁰ Loss of taste sensation may occur following ear surgery by damage to the chorda tympani nerve. Vertigo may occur following ear surgery due to labyrinthine injury.¹¹ Loss of voice occurs after thyroid surgery due to injury to the recurrent laryngeal nerve. Hearing loss is more following ear surgery.

Adverse outcome of treatment

Finally, the third group represents a more difficult area and mostly due to a lack of communication between the clinicians and patients. There are often unrealistic expectations of outcome and a subsequent failure to acknowledge this in an angry patient. Typical scenarios include dissatisfaction with appearance after cosmetic surgery or rhinoplasty. Failure to address the symptoms with nasal surgery often creates a challenge for the surgeon.¹² Poor hearing after ear surgery may occur due to injury of the cochlea.

OTORHINOLARYNGOLOGICAL PROCEDURES

Rhinological surgery

Among otorhinolaryngology, head and neck surgery malpractice claims, poor performance in rhinological surgeries accounted for two-thirds of all cases in terms of paid indemnity.¹³ Functional endoscopic sinus surgery is the foremost litigated surgical procedure in rhinology. Endoscopic sinus surgery constitutes a large part of routine operations performed by an otolaryngologist for chronic rhinosinusitis. Furthermore, endoscopic sinus surgery has undergone an enormous expansion of its reach and its indications.¹⁴ The most frightening condition during rhinological surgery is certainly death. Although death during surgery may be related to anesthesia, the surgeon often carries responsibility. Maxillofacial structural abnormalities may cause a difficult airway where a tracheostomy is needed to perform sinonasal surgery. It may land in a fatal situation if the airway is properly managed intraoperatively or postoperatively. Nasal surgery under local anesthesia may be done but can result in aspiration of blood. Although in this situation anesthesiologists may switch to endotracheal anesthesia intra-operatively, the patient develops pneumonia, and is followed by death.

Cosmetic septoplasty

Cosmetic rhinoplasty surgeons have long advocated patient screening to identify specific personality traits, anxiety, and body dysmorphic disorders with new referrals. Careful patient selection and communication are

key to preventing patient dissatisfaction cumulating in hours of unhappy consultation, poor surgical outcomes, and medicolegal concerns. The mnemonic "SIMON": single, immature, male, overly expectant, narcissistic was coined by Gorney to warn against operating on this particularly difficult patient.¹⁵

Sinonasal and skull base surgery

The complex anatomy and close proximity to critical areas surrounding the paranasal sinuses create numerous opportunities for the compromise of orbital and/or intracranial structures.¹⁶

Cochlear implants

Cochlear implants are the best treatment for congenital profound deafness.¹⁷ Parents/guardians usually have high expectations for the outcome of the procedure in improving areas such as communication, education, socialization, and future employment possibilities for their children. Many times, unmet expectations may lead to conflict.

Recurrent laryngeal nerve injury

Damage to the recurrent laryngeal nerve can cause a change in voice and also life-threatening manifestations like aspiration and airway obstruction. Iatrogenic dysphonia may not be a life-threatening situation but it can greatly affect the quality of life which reduce employment, withdrawal from social life, and decreased general health.¹⁸ The iatrogenic damage to the recurrent laryngeal nerve concern not only Otolaryngologists but also other specialties and health care professionals who perform procedures on the larynx.¹⁹ For instance, anesthesiologists have a risk to injure the glottic and recurrent laryngeal nerve due to high cuff pressure of the endotracheal tube during intubation. General surgeons who are doing thyroid and parathyroid surgery, spine surgeons using cervical spine instrumentations, and thoracic surgeons who perform carotid endarterectomies are also at risk.

WRONG DIAGNOSIS

Failure to diagnose early was frequently complained about in most cancer-related diseases. Failure to advise biopsy was singled out in many instances. Similarly, an inadvertent diagnosis of a cancer may be associated with a lawsuit for causing mental agony and the plaintiff may ask for compensation in terms of damages. The courts often held that histological proof of malignancy is the cornerstone of diagnosis and treatment. But, in reality, establishing the type of tumor and determining whether it is benign or malignant is not an exact science. Errors may occur in sampling, processing, and interpreting specimens. A doctor should never accept a histological diagnosis as unequivocal and should not act on verbal reports from anyone. He must ensure that the pathologist

is provided with sufficient tissue samples both for routine histopathology and for special studies. When the histological diagnosis does not correlate with the clinical course, he should review the clinical data about the patient with the pathologist. If the pathologist's diagnosis is still equivocal, he may obtain an opinion from another institution or obtain another biopsy.

WRONG SIDE SURGERY

Wrong-side surgery is directly a medicolegal issue even in routine ear or sinus surgery.²⁰ Generally 10% of active Otolaryngologists have experienced such types of cases.²¹ A strict, direct, systematic analysis of preoperative imaging of each patient by the surgeon just before surgery in the operation room is recommended. Special otorhinolaryngology imaging or general checklists can be used for consideration of the inevitable additional organizational load.²¹

MEDICAL RECORDS

The primary purpose of medical records is to support ongoing patient care, and provide a crucial source of information in the health care system. The medical record must be clear, accurate, and legible including date and time, and duly signed by the doctor. The record should be made during or after each episode of patient care. Every consultation, discussion about patients, care, possible complications of the surgery, treatment outcome, any alternative to surgery, future management plan, palliative care, etc. must be recorded. The record should not be altered, amended, or added after the original episode of care. Abbreviations should be avoided in the medical record. Abnormal test results should be documented in the medical record. The records must be stored and retained for future use or research.

DOCUMENTATION AND CHECKLIST

It is customary to retrieve routine surgical procedures by specific preoperative checklists before and during surgery. Operative reports should be written within 24 hours, and should not be modified at a later stage.²² Standards of care in documentation and cooperation should be followed in Otorhinolaryngological surgeries. A special checklist must be adopted for the specific needs of surgery. During the entire hospital stay flaws in communication between surgeons, patients, and nurses or among physicians can lead to significant therapeutic and medico-legal problems.²³ Surgical or clinical procedures must be planned, secured, and controlled taking into consideration of the fact that monitoring and patient care are shared.²⁴ If complications occur, the attending surgeons are well advised to pay attention to document all measures of diagnosis and treatment intensely. An Otolaryngologist is personally obliged to accurately inform all the team involved in patient care even at inconvenient times.

OPERATIVE NOTES

The handwritten notes, when incomplete and illegible often weaken a surgeon's defense. An operating note is an important document, which is often produced in a court of law as documentary evidence, either by the plaintiff or the defendant. Therefore, the operative note has to be legible and comprehensive. It should include diagrams, if this explains the procedure. It must contain the names of the surgeon, assistants, and the anesthetist who conducted the procedure. The indication for the surgery must be mentioned before the procedure. If the surgery has a name, it should be written there. Description of the position of the patient should be documented, as it may be an important source of defense in cases of claims arising from complications in that position. It is always best to describe the size, shape, and length of the incision and the structures that were divided to obtain access. The pathology needs to be described as seen in the operating field. The exact procedure should be described step by step. Any special procedure done or any special instruments used should also be documented. The method used for closure needs to be mentioned. The instructions regarding postoperative care are an important part of the note and must be clearly written. Any complications that may follow must be documented clearly. At the end of the operating note, the surgeon must sign it with his name and date. Like all medical records, the operating note has to be preserved for at least three years.

POST-OPERATIVE CARE

The operating surgeon is responsible for the postoperative care of the patient. Without the patient's consent, a surgeon, after the operation cannot hand over a patient to some other doctor having lower qualification to take postoperative care. Even when some aspects of postoperative care may be best delegated to others, the surgeon must maintain an essential coordinating role. The surgeon is responsible for determining when the patient should be discharged from the hospital.

REFERRAL

Patient referral is a common and important medical practice. Sometimes, the condition of the patient is outside a doctor's expertise which requires referring the patient to a specialist who is more knowledgeable or experienced in treating such condition. Every referral is meant to ensure the best outcome for the patient. It is the basic duty of the doctor to handle only those cases which are within the limit of his skill, knowledge, and experience. Moreover, he or she must take into consideration the availability of equipment, staff, medicine, and other circumstances also. Once a patient is under his care, it is negligence to leave the treatment halfway, especially when the patient's condition is deteriorating. Therefore, if a doctor finds on preliminary examination that, the case is beyond his capacity, it is better to refer it to the consultant or a hospital earliest

after giving primary treatments only. Sometimes before admission, the doctor takes the signature of the patient on a printed consent form authorizing him to shift the patient to another hospital as and when it becomes necessary in his opinion. If the doctor is aware from the beginning that it is beyond his capacity to treat that patient, the consent taken is no defense. Of course, if because of natural consequences, the patient's condition deteriorates, and shifting is required, it is not negligence.

OTORHINOLARYNGOLOGISTS AND THEIR ROLE

Otorhinolaryngologists should be aware of the anatomical limits of their surgical field and the consequences of it if cross the limits. Optic nerve injury is an extremely uncommon and disastrous situation during septoplasty. Aggressive removal of vomer during septoplasty may result in optic nerve injury by a small fragment of bone penetrating the dehiscence of the optic nerve within the sphenoid sinus.²⁵ During the removal of the maxillary crest, an inadvertently placed chisel slipped off the bone of the nasal floor and injured the apex of the orbit. This can result in orbital hematoma and ischemia of the optic nerve. Surgeons must avoid brutal or unnecessary maneuvers during the surgery, because of the close relationship with vital structures such as the optic nerve, carotid artery, orbit, or skull base. The co-operation between anesthesiologist and surgeon is very important, during and after the operation, particularly when the airway is involved in the surgery.²⁶

MEDICAL BEHAVIOR

In case complications occur during surgery, the surgeon should try to maintain calmness and review the situation. The goal is to assess whether continuing the treatment with resources at hand is still possible and reasonable and also any additional medical specialties involved or an emergency measure.²⁷ After the operative procedure, immediately communicated with the patient and his/her relatives about the complications. A complete explanation of the complication should be informed.

CONCLUSION

The medical malpractice system is intended to discourage negligent care. Otorhinolaryngologists should be educated in the medicolegal aspects of malpractice and awareness must be raised accordingly. Although increasing number of studies, more research and collaboration with legists in this specialty are required. All Otorhinolaryngologists should at least be aware of common legal terms and medicolegal aspects of their specialty, and duties that both a plaintiff and a defendant have in a case of malpractice. Surgeons should take time to explain the diagnosis and treatment plans and patients also should understand that. Informed consent should be taken in every stage of treatment. Patients should not be forced for doing surgery even it is a right decision.

Otorhinolaryngologist should document everything and store it for future reference.

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REFERENCES

- Balch CM, Oreskovich MR, Dyrbye LN, Colaiano JM, Satele DV, Sloan JA, et al. Personal consequences of malpractice lawsuits on American surgeons. *J Am College Surg.* 2011;213(5):657-67.
- Ta JH, Liu YF, Krishna P. Medicolegal aspects of iatrogenic dysphonia and recurrent laryngeal nerve injury. *Otolaryngol Head Neck Surg.* 2016;154(1):80-6.
- Swain SK. Age related hearing loss and cognitive impairment—A current perspective. *Int J Res Med Sci.* 2021;9(1):317-21.
- Swain SK, Behera IC, Mohanty JN. Mucormycosis in head-and-neck region—Our experiences at a tertiary care teaching hospital of Eastern India. *Ann Indian Academy Otorhinolaryngol Head Neck Surg.* 2019;3(2):58-62.
- World Medical Association. WMA Statement on Medical Liability Reform. In: <http://www.wma.net/en/30publications/10policies/l5/>. Accessed on 25 July, 2023.
- Studdert DM, Mello MM, Gawande AA, Gandhi TK, Kachalia A, Yoon C et al. Claims, errors, and compensation payments in medical malpractice litigation. *N Engl J Med.* 2006;354:2024-33.
- Jena AB, Seabury S, Lakdawalla D, Chandra A. Malpractice risk according to physician specialty. *N Engl J Med.* 2011;365: 629-36.
- Swain SK, Choudhury J. Experience with the management of pediatric laryngopharyngeal reflux in an Indian teaching hospital. *J Clin Sci.* 2020;17(3):61-5.
- Crowson AN. Medicolegal aspects of neoplastic dermatology. *Modern Pathol.* 2006;19:148-54.
- Swain SK. Post-tonsillectomy pain management in paediatric patients—a review. *Int J Contemporary Pediatr.* 2021;8(9):1637-42.
- Swain SK, Samal R, Pani SK. Effect of smoking on outcome of tympanoplasty. *Indian J Otol.* 2011;17(3):120-2.
- Swain S, Mohanty J. Chondroma of the nose. *Libyan J Med Sci.* 2020;4(2):87-9.
- Dawson DE, Kraus EM. Medical malpractice and rhinology. *Am J Rhinol.* 2007;21:584-90.
- Cohen SM, Kim J, Roy N, Asche C, Courey M. The impact of laryngeal disorders on work-related dysfunction. *Laryngoscope.* 2012;122(7):1589-94.
- Swain SK, Debta P, Samal S, Mohanty JN, Debta FM, Dani A. Endoscopic treatment of sinonasal ossifying fibroma: A case report. *Indian J Public Health.* 2019;10(09):1697-700.

16. Castelnovo P, Dallan I, Battaglia P, Bignami M. Endoscopic endonasal skull base surgery: past, present and future. *Eur Arch Otorhinolaryngol.* 2010;267(5):649-63.
17. Swain SK. Cochlear implant and tinnitus: a review. *Int J Otorhinolaryngol Head Neck Surg.* 2021;7(12):1960-4.
18. Matin MA. Medicolegal Issues in ENT Practice. *Bangl J Otorhinolaryngol.* 2021;27(1):1-3.
19. Swain SK, Behera IC, Sahoo L. Hoarseness of voice in the pediatric age group: Our experiences at an Indian teaching hospital. *Indian J Child Health.* 2019;6(2):74-8.
20. Becker SS, Duncavage JA. Malpractice claims in nasal and sinus surgery: a review of 15 cases. *Otolaryngol Clin North Am.* 2010;43(4):929-32.
21. Shah RK, Nussenbaum B, Kienstra M, Glenn M, Brereton J, Patel MM et al. Wrong-site sinus surgery in otolaryngology. *Otolaryngol Head Neck Surg.* 2010;143(1):37-41.
22. Stankiewicz JA, Lal D, Connor M, Welch K. Complications in endoscopic sinus surgery for chronic rhinosinusitis: a 25-year experience. *Laryngoscope* 2011;121(12):2684-701.
23. Shah RK, Kentala E, Healy GB, Roberson DW. Classification and consequences of errors in otolaryngology. *Laryngoscope.* 2004;114(8):1322-35.
24. Katzenmeier C. Grundlagen und Entwicklungen des Organisationsverschuldens. *Z Ärztl Fortbild Qual Gesundheitswes.* 2007;101:531-5.
25. Khanna A, Sama A. Managing complications and revisions in sinus surgery. *Curr Otorhinolaryngol Rep.* 2019;7:79-86.
26. Swain SK, Choudhury J. Pediatric airway diseases. *Indian J Health Sci Biomed Res Kleu.* 2019;12(3):196-201.
27. Stankiewicz JA, Chow JM. The low skull base: an invitation to disaster. *Am J Rhinol.* 2004;18(1):35-40.

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