

Malodorous consequences: What comprises negligence in anosmia litigation?

Peter F. Svider, MD¹, Andrew C. Mauro, BA², Jean Anderson Eloy, MD, FACS^{3,4,5}, Michael Setzen, MD, FACS⁶, Michael A. Carron, MD¹ and Adam J. Folbe, MD¹

Background: Our objectives were to evaluate factors raised in malpractice litigation in which plaintiffs alleged that physician negligence led to olfactory dysfunction.

Methods: We analyzed publically available federal and court records using Westlaw, a widely used computerized legal database. Pertinent jury verdicts and settlements were comprehensively examined for alleged causes of malpractice (including procedures for iatrogenic causes), defendant specialty, patient demographics, and other factors raised in legal proceedings.

Results: Of 25 malpractice proceedings meeting inclusion criteria, 60.0% were resolved for the defendant, 12.0% were settled, and 28.0% had jury-awarded damages. Median payments were significant (\$300,000 and \$412,500 for settlements and awards, respectively). Otolaryngologists were the most frequently named defendants (68.0%), with the majority of iatrogenic cases (55.0%) related to rhinologic procedures. Associated medical events accompanying anosmia included dysgeusia, cerebrospinal fluid leaks, and meningitis. Other alleged factors included requiring additional surgery (80.0%), unnecessary procedures (47.4% of iatrogenic procedural cases), untimely diagnosis leading to

anosmia (44.0%), inadequate informed consent (35.0%), dysgeusia (56.0%), and psychological sequelae (24.0%).

Conclusion: Olfactory dysfunction can adversely affect quality of life and thus is a potential area for malpractice litigation. This is particularly true for iatrogenic causes of anosmia, especially following rhinologic procedures. Settlements and damages awarded were considerable, making an understanding of factors detailed in this analysis of paramount importance for the practicing otolaryngologist. This analysis reinforces the importance of explicitly including anosmia in a comprehensive informed consent process for any rhinologic procedure. © 2013 ARS-AAOA, LLC.

Key Words:

anosmia; hyposmia; malpractice; litigation; negligence; rhinology; rhinologic; informed consent

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¹Department of Otolaryngology–Head and Neck Surgery, Wayne State University School of Medicine, Detroit, MI; ²The University of Michigan Law School, Ann Arbor, MI; ³Department of Otolaryngology–Head and Neck Surgery, Rutgers New Jersey Medical School, Newark, NJ;

⁴Department of Neurological Surgery, Rutgers New Jersey Medical School, Newark, NJ; ⁵Center for Skull Base and Pituitary Surgery, Neurological Institute of New Jersey, Rutgers New Jersey Medical School, Newark, NJ; ⁶Rhinology Section, North Shore University Hospital, Manhasset, NY

Correspondence to: Peter F. Svider, MD, Department of Otolaryngology–Head and Neck Surgery, Wayne State University School of Medicine, 4201 St. Antoine, 5E-UHC, Detroit, MI 48201; e-mail: psvider@gmail.com

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Recent investigation has revealed a potential for olfactory epithelium to regenerate via a variety of mechanisms involving a population of mesenchymal-like stem cells, which have been shown to have a surprisingly broad anatomic distribution.¹ Whereas stem cell–based therapy and other contemporary advances in our understanding of olfaction offer promising future avenues for anosmia management, our current therapeutic repertoire for restoring smell in patients remains limited. Olfactory deficits considerably affect quality of life and may even facilitate adverse health events, ranging from inability to sense environmental cues (such as leaking natural gas, spoiled food) to unsafe losses in weight.^{2–4} Additionally, olfactory function is a critical component of being able to taste, and true anosmia is thus frequently accompanied by dysgeusia.⁵

The profound effects on both health status and quality of life present in patients with olfactory deficits predispose negative outcomes to potential involvement in medicolegal

action. Given the outsize role malpractice litigation and resulting defensive medical practices play in rising healthcare costs,^{6–11} understanding potential sources of medical negligence and iatrogenic injury resulting in anosmia may be useful for the practicing physician. In addition to delineating procedures causing anosmia and resulting in litigation, the objectives of this analysis were to determine alleged causes of negligence in pertinent litigation, case outcomes and awards, and medical specialties affected. Our hope is that physicians will use this information to enhance communication with patients and, ultimately, improve patient safety.

Materials and methods

A computerized legal database, Westlaw, was used to obtain information regarding pertinent cases for the purposes of this analysis. Westlaw is available by subscription and widely used by legal professionals in the United States, and has been invaluable in previous comprehensive examinations of a wide variety of medicolegal topics.^{11–38} This database's advanced search function was used to search for jury verdicts and settlements containing the following combination of terms: "medical malpractice" AND "anosmia" OR "hyposmia" OR "smell" OR "olfaction" OR "olfactory." Out of 49 initial results, cases were excluded for the following reasons: incidental mention of anosmia (ie, anosmia not an alleged injury in litigation) (7), duplicate cases (2), cases that did not involve anosmia or olfactory deficits (14), and congenital anosmia (1).

The 25 pertinent jury verdict and settlement reports with anosmia as an alleged injury were comprehensively evaluated for details regarding outcome, award, defendant specialty, patient demographics, iatrogenic or noniatrogenic cause, procedures involved, allegations involving incomplete informed consent, the requirement of reparative procedures, misdiagnosis/delayed diagnosis leading to injury, dysgeusia, psychiatric/psychological sequelae, depression/loss of enjoyment in life, employment/income affected, and other alleged causes of negligence. Data collection was completed in August 2013.

Statistical analysis

Mann-Whitney U-tests were used for comparison of continuous data, with threshold for significance set at $p < 0.05$. SPSS version 20 (IBM, Chicago, IL) was used for statistical analysis.

Results

The 25 jury verdict and settlement reports containing anosmia occurred between 1989 and 2011. Median patient age was 54 years, with 52.2% male plaintiffs and 47.8% female plaintiffs. The majority of cases included were resolved in

the defendant's favor (60.0%), with remaining cases resolved as out-of-court settlements or with plaintiff verdicts (Fig. 1A). Although considerably large, the median damages awarded by juries did not significantly differ from the 2 out-of-court settlements reporting dollar totals (Fig. 1A) (\$300,000 vs \$412,500, $p > 0.50$). Otolaryngologists were the most frequently named physician defendants (68.0% of cases), followed by oral surgeons (Table 1). Practitioners from several other specialties were also named as defendants (Table 1).

The most frequent procedure performed leading to anosmia litigation was endoscopic sinus surgery (ESS) (7 procedures; Table 2), followed by a variety of other procedures performed by otolaryngologists and oral surgeons. Associated medical adverse events allegedly accompanying anosmia included dysgeusia, cerebrospinal fluid (CSF) leaks, and meningitis (Fig. 1B). Other alleged factors involved in litigation included anosmia being a result of iatrogenic causes (80.0% of all cases), additional surgery being required as a result of an adverse outcome (80.0% of all cases), and a procedure being allegedly unnecessary or inappropriate (9/19 iatrogenic procedural cases); other alleged factors are also shown in Figure 1C. Out of the 20 iatrogenic cases, 19 were related to surgical procedures and 1 was related to medication administration. Specific factors involved in cases resolved with payment are shown in Table 3.

Discussion

Although there have been no formal analyses of anosmia litigation, the possibility of medicolegal action in patients experiencing this complication after undergoing a surgical procedure has been anecdotally reported. In a letter to a journal, 1 otolaryngologist noted hearing of several rhinologic cases in which plaintiffs exploring legal action claimed they had not been informed of anosmia as a potential complication.³⁹ This report was consistent with a survey he had conducted, in which fewer than 50% of otolaryngologists included anosmia in the informed consent process as a potential complication of nasal surgery. Our present analysis reinforces previously described anecdotal findings for the first time, as plaintiffs specifically brought up inadequate informed consent in a significant proportion of iatrogenic cases (35.0%) (Fig. 1C). Perceived deficits in informed consent have been repeatedly cited in a significant proportion of analyses focusing on various procedures and complications.^{14, 16, 24, 33, 34} Rather than physicians not mentioning the possibility of olfactory dysfunction, a significant proportion of these cases may simply relate to patients not comprehending risks explained to them. In addition to documenting specific risks in writing, physicians performing procedures that may potentially result in anosmia may wish to consider providing patient education materials written in a comprehensible manner.^{40–51}

In addition to informed consent, several other previously described considerations were also identified as

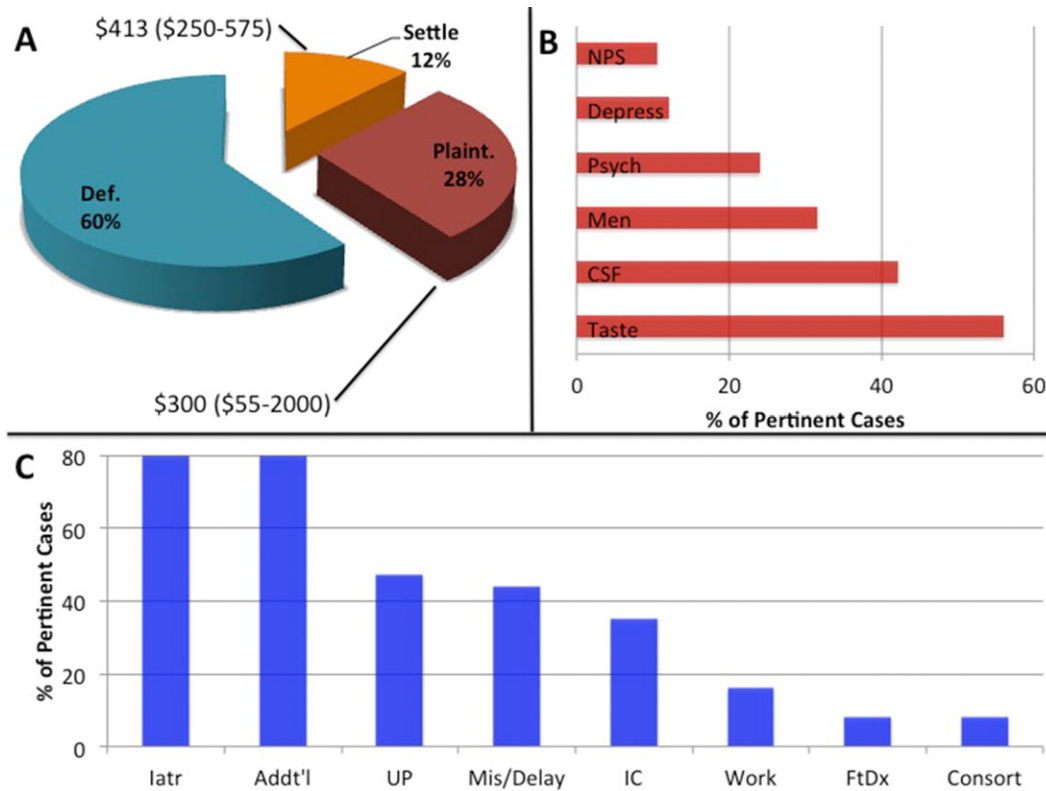


FIGURE 1. (A) Outcome profile of cases included in this analysis, with median and range of settlements and jury awards (in \$1000s). (B) Associated alleged medical adverse events in cases involving alleged anosmia. (C) Alleged factors present in litigation included in this analysis. Results in B and C are illustrated as a percentage of *pertinent* cases; for example, UP is out of cases involving procedures (19 cases), latr is out of all cases. Addt'l = patient required additional surgery as a result of an adverse outcome experience; Consort = loss of consortium; CSF = cerebrospinal fluid leak; Def. = defendant decision; Depress = depression/emotional distress; FtDx = failure to diagnosis cancer; latr = iatrogenic; IC = alleged deficit in informed consent; Men = meningitis; Mis/Delay = failure to diagnosis a complication in a timely manner; NPS = nasopharyngeal stenosis; Plaintiff. = plaintiff verdict; Psych = permanent psychiatric/psychological effects; Settle = out-of-court settlement; Taste = dysgeusia; UP = allegedly unnecessary/inappropriate procedure choice; Work = work/employment allegedly affected by injury.

TABLE 1. Defendant specialty in cases with alleged anosmia

Specialty	Cases, n (%)
Otolaryngology	17 (68.0)
Oral surgery	3 (12.0)
Pathology	1 (4.0)
Neurosurgery	1 (4.0)
Primary care	1 (4.0)
Plastic surgery	1 (4.0)
Psychiatry	1 (4.0)
Radiology	1 (4.0)

recurrent factors in the present analysis. In a previous evaluation of malpractice trials with alleged iatrogenic cranial nerve injuries, the authors found a successive decrease in defendant verdict percentages with the presence of an increasing number of the following factors: (1) informed

TABLE 2. Procedures/conditions involved in litigation

Procedure/condition	Cases (n)
Endoscopic sinus surgery	7
Septorhinoplasty	3
Laryngectomy	2
Adenotonsillectomy	2
Delayed Dx of tumor	2
Voice prosthesis implant	1
Medication-induced	1
Maxillectomy	1
Mandibular/maxillary osteotomy	1
Failed suicide attempt	1
CN V nerve decompression	1
Dental procedure	1

CN = cranial nerve; Dx = diagnosis.

TABLE 3. Characteristics of cases resolved with payment

A/S O	Award	Def	Procedure	Alleged deficit in IC	UP	Taste	Other injuries/comments
60M P	55	NS	CNV decomp.	Y	N	Y	Primary claim that IC did not include anosmia
M P	102	OS	Bridge	N	N	Y	Dental polymeric material retained in sinus
30F P	200	Oto	Septo/rhino	N	N	N	Cribriform plate CSF leak, meningitis
42M P	300	Oto	ESS	N	Y	Y	Olfactory nerves directly damaged, frontal lobe injury, CSF leak, meningitis, cognitive impairment
63F P	925	PCP	Medication	Y	N/A	N	Methadone OD, cognitive impairment
33F P	1900	Oto	ESS	N	Y	Y	Perforated ethmoid sinus, CSF leak, facial paralysis
72M P	2000	Oto	Laryngectomy	N	Y	N	Found no cancer on surgery (postradiation); surgery unnecessary
S	250	Oto	T&A	N	N	N	Nasopharyngeal stenosis
57M S	575	Oto	ESS	N	N	N	CSF leak, meningitis, "mild" brain damage
F S	Conf.	Psych	Failed SA	N/A	N/A	Y	Failed attempt by hanging; anosmia 1 of several alleged injuries due to ABI

Awards are shown in \$1000s.

ABI = anoxic brain injury; A/S O = age/sex of plaintiff and outcome; CSF = cerebrospinal fluid; CNV = cranial nerve V; CNV decomp. = trigeminal nerve decompression; Conf = confidential; ESS = endoscopic sinus surgery; Def = defendant specialty; Failed SA = failed suicide attempt; IC = informed consent; N/A = not applicable; NS = neurosurgery; OD = overdose; OS = oral surgery; Oto = otolaryngologist; P = plaintiff decision; PCP = primary care provider; Psych = psychiatrist; S = settlement; Septo/rhino = septorhinoplasty; T&A = adenotonsillectomy; Taste = taste affected (dysgeusia); UP = allegedly unnecessary or inappropriate procedure.

consent allegations; (2) allegedly unnecessary procedures; (3) additional reparative surgery required; and (4) failure to diagnose a complication in a timely manner.¹⁶ As these general principles appear to be consistent across numerous topics, this highlights the importance of considering an out-of-court settlement in cases where several of these factors are present. Although there was no statistical difference between the size of jury-awarded damages and out-of-court settlements in the current analysis, there are considerably greater costs associated with cases that advance all the way to the courtroom for both sides. In fact, a larger proportion of legal expenditures are related to these "indirect" costs rather than the costs of damages awarded.⁵² Additionally, costs associated with malpractice litigation also involve the significant proportion of time a physician may expend on proceedings in their career, estimated by 1 analysis to encompass as much as 5 years with an open claim for the average physician.⁷ Another indirect effect includes a concern about the impact that involvement in litigation may have on one's reputation, among

both patients and colleagues.^{10,53} Finally, the current medicolegal environment facilitates the practice of defensive medicine. All of these factors, along with sizeable malpractice insurance premiums, increase healthcare costs in the United States by as much as tens of billions of dollars each year.^{6,9,12,35,54-58}

It is important to remember that in order for negligence to be proven, the occurrence of an adverse event alone is not grounds for awarding damages. Other factors must include the presence of a duty, a breach of this duty, and evidence that this breach of duty was directly responsible for causing a harmful event.^{12,19,59} The severity of injuries other than anosmia along with a number of oversights potentially construed as negligence appeared to play a role in the size of damages awarded by juries (Table 3). Several interesting lessons can be gathered from these specific cases. For example, the rhinologic case with the highest damages award resulted in a \$1.9M award (Table 3). In this case, the defendant otolaryngologist allegedly failed to diagnose a postoperative CSF leak, which was eventually picked up

by the plaintiff's primary care doctor. The plaintiff's skull-base defect was deemed not to be amenable to endoscopic management, thus necessitating a craniotomy to repair the leak. In addition to convincing the jury that another otolaryngologist in a similar scenario would have been reasonably more vigilant and would have recognized a CSF leak sooner, the plaintiff alleged that the defendant otolaryngologist failed to pursue conservative treatment with antibiotics and other medications prior to surgery, thus making the ESS not indicated. The size of this judgment was furthermore influenced by permanent deficits from both the initial and reparative procedures, including anosmia and dysgeusia, along with an alleged facial paralysis.

The three ESS cases with anosmia in this analysis that were resolved with a settlement or jury-awarded damages had a median payment of \$575,000 (range, \$300,000-\$1.9M) (Table 3); these cases were resolved in the years 1999 to 2002. The authors have recently examined ESS litigation dating from 2003 to the present,³⁰ and we retrieved our source data from that analysis and compared payments in iatrogenic ESS cases (none of which involved anosmia), which had a median of \$905,000 (range, \$89,000-\$3.9M). This comparison was not statistically significant ($p = 0.67$), demonstrating that the presence or absence of anosmia may not have an obvious effect on the amount of damages awarded, although this is speculative due to the multitude of factors that may be present in all of these cases and which may play a role in compensation totals.

Although plaintiffs initiated litigation in several cases in which a failure to diagnose cancer in a timely manner played a role in the development of anosmia (either through delayed treatment or the cancer itself) (Tables 2 and 3), 1 of these cases is an effective example of the plaintiff failing to prove all of the factors required for a finding of negligence. A patient had seen his dentist several times a year over several years for periodontal cleaning, and on 1 visit a small lip lesion was excised and found to be adenoid cystic carcinoma. The plaintiff alleged that a delay in diagnosis necessitated radiation therapy, which subsequently led to a loss of smell and taste. The defendant argued that perineural invasion, for which this disease process is known,⁶⁰ likely started the moment the cancer started to grow, and most importantly, that a delay in treatment resulted in no difference in the treatment received. Even if the dentist should have detected the lesion earlier, his legal team was able to demonstrate to the jury that this would not have made a difference in the patient's management (and thus on radiation side effects such as anosmia); thus this potential "breach of duty" was not directly responsible for causing any additional harm to the patient, an essential component of attributing negligence.⁵⁹

One case of interest resolved with an out-of-court settlement (Table 3) involved complications stemming from an adenotonsillectomy for chronic hypertrophic adenoiditis, tonsillitis, and sleep apnea. The adult plaintiff alleged that the defendant otolaryngologist removed excessive tis-

sue during surgery that resulted in "excessive scarring and obstruction of the nasal airway." He claimed the "reduction in the ability to smell" contributed to a "diminished ability . . . to enjoy life." No other major injuries were alleged by the plaintiff in this particular case, and it appears that anosmia played a primary role in the defendant's decision to pursue an out-of-court settlement.

We have previously evaluated CSF leaks and their impact on malpractice litigation,³⁷ noting that approximately one-fifth of cases in this previous analysis involved anosmia. Damages awarded and out-of-court settlements were found to be considerably higher in that analysis (\$1.1M and \$966,887, respectively) than those calculated in our current analysis (\$300,000 and \$412,500, respectively), possibly a result of the higher coincidence of intracranial complications associated with patients experiencing iatrogenic CSF leaks.

None of these cases in which plaintiffs attributed anosmia as a result of medical negligence explicitly mentioned the use of objective testing in an attempt to confirm this complaint. We would be remiss not to emphasize the availability of a variety of tools that may be useful in objectively characterizing and confirming the presence of anosmia, including the San Diego Odor Identification Test and the University of Pennsylvania Smell Identification Test.⁶¹ For example, the latter test is based on a 40-point scale and can likely identify many malingerers,⁶² which may be an important point in malpractice litigation.

The present analysis is the first to comprehensively search for and evaluate litigation in which plaintiffs allege anosmia as a result of medical negligence. Despite its potential value in educating physicians about the types of cases and outcomes resulting from these proceedings, there are several limitations inherent to an analysis of this nature. Westlaw is a highly used resource among legal professionals and has shown its value in a multitude of previous medicolegal analyses,^{11-35,37} but this resource is focused on jury verdicts and settlements that advance far enough in proceedings for inclusion into publically available court records. A number of out-of-court settlements may not proceed far enough for inclusion into these records, stressing the point that this resource is far more valuable for its rich detail and discussion of specific factors brought up in litigation than as a tool to estimate the overall prevalence of an injury leading to legal action. While some jury verdict and settlement reports from some jurisdictions are composed of attorney-submitted cases,^{15,17} many jurisdictions also contain involuntarily submitted information; confidential cases from these places are labeled as "confidential," "John/Jane Doe," or "anonymous."

Another potential limitation of this analysis is relevant in the study of malpractice proceedings from any resource: factors affecting the quality of legal representation for defendants and plaintiffs may not be apparent through court records and may play a role in the success of malpractice proceedings. For example, qualitative differences in medical expert witness testimony have been noted among

neurological surgery and otolaryngology proceedings, in which defendant witnesses tend to be more experienced, have higher scholarly impact, and are more likely to be involved in academic practice.^{21,22,26} On the other hand, these analyses suggest those testifying frequently or repeatedly tend to be testifying on behalf of plaintiffs. While it is not entirely clear what effects these phenomena and other differences in legal representation have on outcomes, it is definitely an issue to keep in mind when trying to discern the differences between cases that may be resolved with payment vs those resolved in a defendant's favor. This discussion regarding expert witness qualification is purely speculative in the context of this analysis because these statistics were not examined and would have been unlikely to provide any reliable conclusions, as there were only 25 cases meeting inclusion criteria in the current analysis.

A final limitation is the heterogeneous nature of these cases, specifically relating to the fact that the presence of anosmia may have had varying importance depending on other associated injuries. It may often times be difficult to tease apart the importance of specific injuries when numerous injuries are present, but we feel we have accomplished our objectives of relating the types of cases in which anosmia may be a factor, and which procedures necessi-

tate a comprehensive informed consent process including anosmia.

Conclusions

As olfactory dysfunction can have a significant impact on quality of life, patients experiencing new-onset anosmia as a result of medical care pursue malpractice litigation. This is particularly true for iatrogenic cases, including those stemming from rhinologic procedures. Cases resolved with payment were considerable, with the median damages awarded by a jury totaling \$300,000. Consequently, an understanding of factors critical in initiating litigation is of paramount importance for the practicing otolaryngologist. Other associated injuries frequently experienced in these cases, such as dysgeusia, CSF leaks and meningitis, and psychological effects, should be taken into account. Requiring additional surgery, having undergone an allegedly unnecessary procedure, missed/delay diagnosis leading to anosmia, and perceived deficits in informed consent were present in a significant proportion of cases. Finally, this analysis reinforces the importance of explicitly including anosmia in a comprehensive informed consent process for any rhinologic procedure. 🌐

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