Pituitary and skull-base lesions and the litigious patient

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Background: **The objective of this research was to evaluate litigation relating to the diagnosis and management of pituitary and ventral skull base lesions and delineate allegations involved in the decision to pursue medicolegal proceedings.**

Methods: **Publically available federal and court records were accessed via the Westlaw Next database. Jury verdict and settlement reports relevant to pituitary and anterior skull-base lesions were accessed, and litigation was reviewed for alleged injuries, defendant specialty, patient demographics, and other factors raised in proceedings.**

Results: **Of 75 cases included, 50.7% were resolved in the defendant's favor. The most frequent physician specialties cited as defendants included primary care (20%), neurosurgery (17%), and radiology (16%), while otolaryngologists were defendants in only 5% of cases. Fifty-two (69%) did not involve surgical intervention; the most common allegations in these proceedings were misdiagnosis, permanent injury (19%), requiring additional procedures as a result of misdiagnosis (17%), permanent endocrine dysfunction (14%), and visual sequelae (12%). Among surgical cases, the most common allegations raised included permanent injury (17%), postoperative complications (14%), intraoperative complications (13%), and death (10%). Among cases resolved with payment, there was no statistical difference in payment between surgical cases ($5.7M) and nonsurgical cases ($4.8M).**

Conclusion: **Misdiagnosis of endocrinopathy, failure to appropriately workup patients presenting with neurologic complaints, and radiologic misdiagnosis play important roles in the pursuit of litigation in nonsurgical cases. Sustaining permanent sequelae including endocrine and visual injury play an important role in surgical cases. Postoperative management appears to play just as important a role in the decision to pursue litigation as intraoperative considerations.**

Key Words:
pituitary; anterior skull-base; ventral skull-base; skull-base surgery; transsphenoidal; pituitary adenoma; meningioma; malpractice; litigation; informed consent

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One of the most dreaded consequences of practicing medicine remains being named a defendant in malpractice litigation. This trepidation is not unwarranted, as medicolegal litigation harbors considerable costs in money, time, and in some cases, reputation and ability to practice. On a national level, malpractice claims cost an estimated $9.85 billion in 2008.[1] The threat of malpractice looms most heavily on the high-risk specialties; it is estimated that 99% of physicians in high-risk specialties will face a malpractice claim in their career, compared with 75% of physicians in low-risk specialties.[2] Medical malpractice cases are often heavily studied in these high-risk specialties and procedures,[3] in order to identify common medicolegal risks,[4] and thus help physicians develop strategies to minimize malpractice claims and reduce patient harm.[5–11]

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Although factors that confer legal risk in otolaryngology and neurosurgery have previously been studied, a review of the literature yields no studies of malpractice claims focusing on pituitary and anterior skull-base lesions. These are of potential interest to a wide variety of physicians, including primary care physicians, endocrinologists, neurosurgeons, and otolaryngologists. The diagnosis and management of processes involving the skull base is often considered high risk, as a consequence of their anatomical location and close proximity to crucial structures, which renders the physicians treating these lesions potentially more susceptible to medicolegal involvement in any scenarios involving adverse events. Although historically recent advances in surgical management, such as transsphenoidal (TSS) approaches, have reduced adverse outcomes when compared to the traditional open craniotomy, significant litigation risk endures for the physicians treating these conditions.[12–15] The objective of this study is to comprehensively analyze malpractice claims involving the diagnosis and management of skull-base lesions in order to recognize common trends, which may be useful in producing standards that minimize litigation risk and improve patient outcomes.

Materials and methods

The Westlaw legal database (Thomson Reuters, New York, NY) was used to identify jury verdict and settlement reports from 1985 to 2016 for topics relevant to physicians involved in the management of pituitary skull-base lesions, using the term "medical malpractice" in combination with the following:

> "pituitary gland tumor" OR "pituitary tumor" OR "pituitary adenoma" OR "meningioma" OR "transsphenoidal" OR "trans sphenoidal" OR "trans-sphenoidal" OR "hypophysectomy" OR "pituitary" OR "cerebrospinal fluid" OR "cerebrospinal leak" OR "clivus" OR "clival" OR "juvenile nasopharyngeal angiofibroma" OR "skull base tumor" OR "encephalocele" OR "pituitary surgery" OR "craniopharyngioma" OR "anterior skull base resection" OR "esthesioneuroblastoma" OR "olfactory groove" OR "cribriform."

The Westlaw database draws from court proceedings from publically available federal and state court documents from most jurisdictions in the United States, as well as voluntary reports by attorneys. Publically available court documents that are nonvoluntary or confidential are labeled as "confidential," "anonymous," or "Jane/John Doe." Westlaw is commonly utilized by attorneys to characterize and discover predictive factors in preparation for legal cases. Outside of the legal community, this database has also been validated to describe and analyze medicolegal issues.

We collected and analyzed data on outcomes, patient demographics, award amount, alleged causes of malpractice (both surgical and nonsurgical cases), defendant, procedure type, surgical indication, and other relevant factors found in these documents. Our initial search yielded 139 results. A total of 64 cases were excluded for the following reasons: duplicates (n = 7), sinus procedures (n = 11), spine-related procedures (n = 22), orthopedic-related procedures (n = 2), lateral skull-base procedure (n = 5), medical treatment (n = 7), hydrocephalus, and ventriculoperitoneal shunt malfunction not related to adenomas or complications of anterior skull-base procedures (n = 10). All data was collected in April 2017.

Statistical analysis

SPSS version 20 (IBM Corp., Armonk, NY) was used for statistical analysis, with *t* tests and chi square tests used for comparison of continuous and categorical variables, respectively.

Results

Seventy-five cases were included in this analysis, and of these cases, 50 (67%) cases reported the age and 73 (97%) cases reported the gender of the plaintiff. The mean plaintiff age was 42.4 years (range, 10 to 74 years). There were 30 male plaintiffs (41%) and 43 female plaintiffs (59%). Greater than one-half of the cases included were resolved in the defendant's favor (50.7%), with 16 cases (21.3%) resolved with a plaintiff decision, and 17 cases (22.7%) that reached a settlement (Fig. 1). Fifty-two cases (69%) did not involve a surgical intervention, while the other 23 (31%) involved a surgical intervention. Among cases resolved with payment (either settlement or jury awarded damages), there was no statistical difference between surgical ($5.7 million) and nonsurgical ($4.8 million) payments ($p = 0.83$). The most frequent physician specialty involved was primary care (20%, n = 15) followed by neurosurgery (17%, n = 13) and radiology (16%, n = 12). There were 3 cases involving non-physician hospital staff (4%) (Fig. 2).

Nonsurgical litigation

In cases without surgical intervention, the plaintiffs were awarded on average $4.97M (n = 13, 27%) when the case was found in the plaintiff's favor, compared to an average of $4.03M (n = 11, 21%) when a settlement was reached, with 27 cases resolved in favor of the defendant. The most common allegations raised in these cases were misdiagnosis (either radiologic or failure to pursue appropriate imaging studies), followed by sequelae occurring as a result of misdiagnosis, including permanent injury (19%), requiring additional procedures as a result of misdiagnosis (17%), permanent endocrine dysfunction (14%), and visual sequelae (12%) (Table 1).

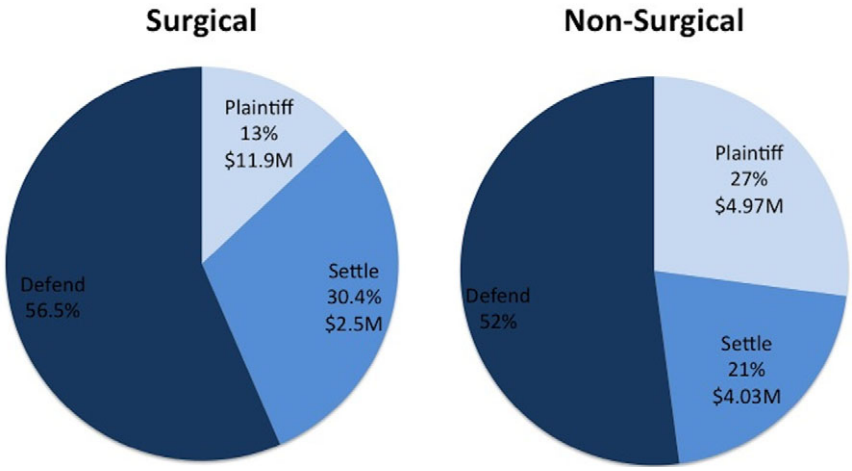

FIGURE 1. Outcomes of litigation included in this analysis.

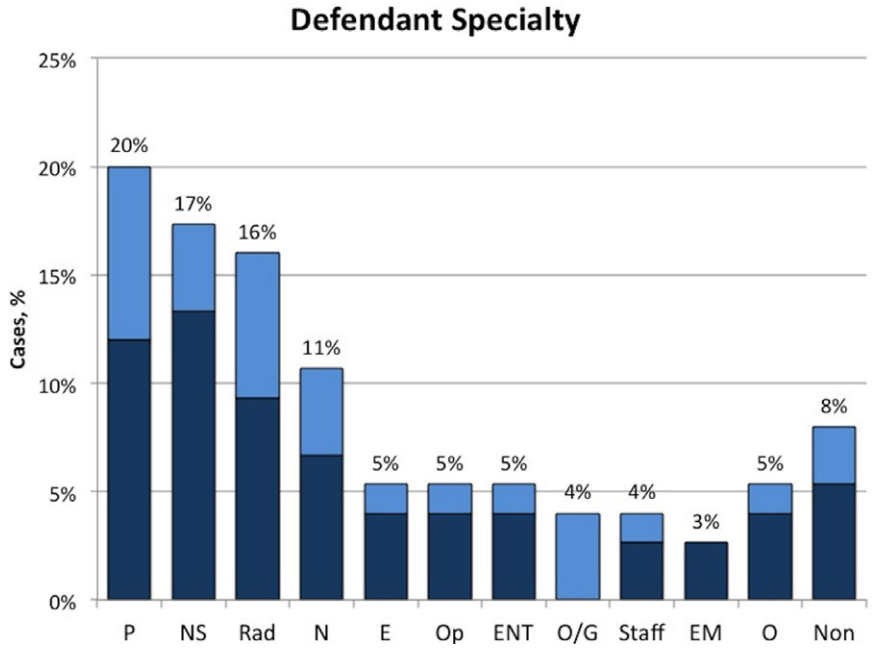

FIGURE 2. Defendant specialty. Dark blue = plaintiff verdict; light blue = settlements. E = endocrinology; EM = emergency medicine; ENT = otolaryngology; N = neurology; Non = non-specified specialty; NS = neurosurgery; O = other; O/G = obstetrics and gynecology; Op = ophthalmology; P = primary care; Rad = radiology; Staff = hospital and hospital staff.

Surgical litigation

In the cases with surgical intervention, the jury awarded damages averaged $11.9M (n = 3, 13%), compared to an average of $2.5M (n = 7, 30.4%) when a settlement was reached, with 13 (56.5%) cases resolved in the defendant's favor. The most common for surgical interventions were pituitary adenoma (39.13%, n = 9), meningioma (34.78%, n = 8), cerebrospinal fluid leak (4.35%, n = 1), craniopharyngioma (4.35%, n = 1), and unspecified tumors (17.39%, n = 4). Specific considerations in intraoperative cases involving neurological surgeons and otolaryngologists are illustrated in Table 2 and Table 3, respectively.

The most common allegations raised in surgical litigation included permanent injury (17%), complications related to postoperative care (14%), intraoperative complications (13%), death (10%), and requiring additional procedures as a result of injuries (9%) (Table 1). Inadequate informed consent, visual sequelae, and permanent endocrine dysfunction were each alleged in 7% of cases. Postoperative cerebrospinal fluid (CSF) leak and infection were only raised as factors in litigation in 1% of cases proceeding to litigation.

Allegations involving cases with pituitary adenomas resulting in monetary awards to the plaintiff are summarized in Table 4. The approaches to these surgeries were either TSS or craniotomy. Of the 16 cases that reached a jury

TABLE 1. Allegations in surgical cases vs nonsurgical cases

Allegations in surgical cases	%	Allegations in nonsurgical cases	%
Permanent injury	17.39	Misdiagnosis	22.81
Postoperative complication	14.49	Permanent injury	19.30
Intraoperative complication	13.04	Additional procedures required	16.67
Death	10.14	Endocrine dysfunction (permanent)	14.04
Additional procedures required	8.70	Visual sequelae	12.28
Informed consent	7.25	Death	4.39
Visual sequelae	7.25	Postoperative hearing loss	2.63
Bleeding	5.80	Unnecessary procedure or procedure not indicated	1.75
Misdiagnosis	4.35	Postoperative complication	1.75
Unnecessary procedure or procedure not indicated	4.35	Postoperative cerebrospinal fluid leak	1.75
Endocrine dysfunction (permanent)	4.35	Bleeding	0.88
Postoperative cerebrospinal fluid leak	1.45	Informed consent	0.88
Postoperative infection	1.45	postoperative anosmia	0.88

verdict and reported a specific surgical approach, 43.75% of the cases were TSS (n = 7) and 56.25% were craniotomies (n = 9). In TSS cases, 28.6% of plaintiffs were awarded a verdict in their favor, with an average amount of $16M (n = 2). Defendants were awarded a verdict in their favor in 71.4% of cases involving TSS (n = 5). With respect to craniotomies, in 1 case (11.1%) the plaintiff was awarded a verdict in their favor ($3.6M); defendants were awarded a verdict in their favor in 88.9% of cases involving craniotomies (n = 8).

Discussion

The litigious nature of the U.S. healthcare system is widely seen as a divisive force between patient and physician.[16] Medical malpractice claims add to rising healthcare costs, both directly through indemnity awards and by contributing to the phenomenon of defensive medicine. Importantly, a preponderance of cases identified using our search strategy were nonsurgical, emphasizing that inappropriate workup of patients with pituitary and skull-base lesions plays a greater role in facilitating malpractice litigation. Consequently, primary care physicians (20% of all cases), radiologists (16%), neurologists (11%), endocrinologists (5%), and ophthalmologists (5%) were the most common specialists named as defendants.

As noted above, misdiagnosis was the most common allegation raised in nonsurgical cases, and nearly all nonsurgical cases fell into the following categories: (1) failure to investigate presenting signs and symptoms that were consistent with endocrine dysfunction (20.8%, n = 10); (2) failure to pursue imaging for neurologic signs and symptoms (31.3%, n = 15); and (3) radiologic misdiagnosis (22.9%, n = 11). Failure to diagnose these lesions in a timely manner harbors potentially serious consequences, as 19% of patients in these nonsurgical cases allegedly experienced permanent injury. Furthermore, even when lesions are identified by a radiologist, it is still important to communicate these findings to the referring physician and the plaintiff, as seen in the 1 case resulting in anosmia—the plaintiff claimed that the resulting 3-year delay in the communication of diagnosis resulted in permanent loss of smell. Hence, these findings may be of great interest to physicians in a variety of specialties beyond those involved in the surgical management of these lesions (neurosurgeons and otolaryngologists).

Prior medicolegal analyses have reported that allegedly inadequate informed consent plays a significant role in facilitating malpractice litigation. In a prior analysis of litigation related to cranial nerve injury, perceived deficits in informed consent, requiring additional surgery, failure to recognize complications, and allegedly unnecessary surgical intervention were noted to cause a stepwise increase in the likelihood of cases being resolved with payment.[17] In contrast, allegedly inadequate informed consent was raised in only 7% of surgical cases included in this analysis, suggesting that the serious injuries sustained played more of a factor. Nonetheless, this analysis identifies numerous factors that were raised in surgical cases, and these considerations may likely be beneficial to include in a comprehensive informed consent process, as patient-physician communication and a thorough understanding of potential risks has been noted to be an important factor in the decision to pursue litigation.[18–20]

TSS approaches re-emerged in the last 2 decades of the 20th century as a favored approach for pituitary and skull-base lesions, and recent decades have witnessed the

TABLE 2. Alleged intraoperative injuries for neurosurgeons resulting in monetary awards to plaintiff

Patient age (years)/sex (male/female)[a]	Award (S/P)	Procedure/underlying condition	MDX	P/O	U	E	Add	IC	P	B	ID	D	VS	Alleged injury
35 / –	$5.14M (P)	Benign brain tumor/TSS	N	Y	N	N	N	N	Y	Y	N	Y	N	Cribriform plate puncture led to cerebral hemorrhage and death
39 / female	Unspecified (S)	Craniopharyngioma/TSS	N	N	Y	Y	N	Y	Y	N	N	N	N	Diabetes insipidus and hypothyroidism could have been managed medically with bromocriptine
35 / female	$26.98M (P)	Meningioma/TSS	Y	N	Y	Y	N	N	Y	N	N	N	Y	Misdiagnoses resulted in suboptimal surgical approach and surgery caused CVA, right eye vision loss, paralysis, endocrine dysfunction
62 / female	$811K (S)	CSF leak/TSS	Y	N	Y	N	N	N	Y	Y	N	Y	N	Undiagnosed mass removed during procedure which was later identified as brain tissue; patient died
30s / female	$160K (S)	Adenoma/craniotomy	N	Y	N	N	N	N	N	N	N	Y	N	Failure to recognize postoperative pulmonary embolism

[a]Gender or age were not available for some patients.
Add = additional procedure required; B = bleeding complications; CSF = cerebrospinal fluid; CVA = cerebrovascular accident; D = death; E = endocrine dysfunction (permanent); IC = alleged deficits in informed consent; ID= infection; MDX = misdiagnosis; P = permanent injury; P/O = postoperative negligence; S/P = settlement verdict/ plaintiff verdict; TSS = transsphenoidal surgery; U = unnecessary procedure or procedure not indicated; VS = visual sequelae.

TABLE 3. Alleged intraoperative injuries for otolaryngologists resulting in monetary awards to plaintiff

Patient age (years)/sex (male/female)[a]	Award (S/P)	Procedure/underlying condition	MDX	P/O	U	E	IC	P	B	D	Alleged injury
35 / –	$5.14M (P)	Benign brain tumor/TSS	N	Y	N	N	N	Y	Y	Y	Cribriform plate puncture led to cerebral hemorrhage and death
39 / female	Unspecified (S)	Craniopharyngioma/TSS	N	N	Y	Y	Y	Y	N	N	Diabetes insipidus and hypothyroidism could have been managed medically with bromocriptine
62 / female	$811K (S)	CSF leak/TSS	Y	N	Y	N	N	Y	Y	Y	Undiagnosed mass removed during procedure which was later identified as brain tissue; patient died

[a]Gender and/or age was not available for some patients.
B = bleeding complications; CSF = cerebrospinal fluid; D = death; E = endocrine dysfunction (permanent); IC = alleged deficits in informed consent; MDX = misdiagnosis; P = permanent injury; P/O = postoperative negligence; S/P = settlement verdict/plaintiff verdict; TSS = transsphenoidal surgery; U = unnecessary procedure or procedure not indicated.

TABLE 4. Alleged injuries for adenomas resulting in monetary wards to plaintiff

Patient age (years)/sex (male/female)[a]	Award (S/P)	Procedure/underlying condition	MDX	P/O	E	P	D	VS	Alleged injury
33 / female	$160K (S)	Craniotomy/adenoma	N	Y	N	N	Y	N	Failure to recognize postoperative pulmonary embolism
30s / female	$250K (P)	NS/adenoma	Y	N	Y	Y	N	Y	Failure to investigate plaintiff's absence of menstruation >2 years; late adenoma diagnosis
– / female	$325K (S)	NS/adenoma	N	Y	N	Y	Y	N	Failure to recognize shunt malfunction and increased intracranial pressure as complications of adenoma resection procedure
29 / female	$250K (P)	NS/adenoma	Y	N	Y	N	N	Y	Failure to diagnose adenoma causing amenorrhea
44 / male	$10.8M (S)	Craniotomy/adenoma	N	Y	N	Y	N	Y	Postoperative complication of underventilation in recovery room resulting in cortical blindness

[a]Gender and/or age was not available for some patients.
B = bleeding complications; CSF = cerebrospinal fluid; D = death; E = endocrine dysfunction (permanent); IC = alleged deficits in informed consent; MDX = misdiagnosis; NS= no surgical procedure performed; P = permanent injury; P/O = postoperative negligence; S/P = settlement verdict/plaintiff verdict; TSS = transsphenoidal surgery; U = unnecessary procedure or procedure not indicated; VS= visual sequelae.

increasing popularity of endoscopic techniques over microscopic approaches specifically for pituitary lesions.[21] There were several interesting findings when comparing cases involving craniotomy vs those with TSS approaches. TSS was associated with a 2-fold risk of the plaintiff winning (12.5% in TSS cases vs 6.25% in craniotomy cases, $p = 0.55$). On the surface, this finding seems completely unexpected, as successive improvements to TSS technology have led to more complete resections and higher remission rates compared with craniotomy.[13,15] Additionally, TSS holds numerous other benefits over craniotomy, including increased patient safety, less complications, less postoperative pain, and quicker recovery. We postulate that this paradoxical finding regarding TSS and craniotomy could possibly be explained by the patient informed consent process. Craniotomies are seen as relatively higher risk, and physicians would take care to fully expound on all the risks associated with it. However, it is possible that the knowledge of the relative safety of TSS may falsely lead patients to underappreciate associated risks. When the patient who has undergone a minimally invasive approach does experience a complication, they may be more apt to claim that their physician failed to warn them.[22] Both our data and the literature stresses the importance of stating all possible risks in the informed consent process, even with relatively safer procedures such as TSS.[22,23]

To our knowledge this is the first focused analysis examining litigation related to the diagnosis and management of pituitary and skull-base lesions. Nonetheless, there are several limitations inherent to our study design. As it is primarily a legal database, Westlaw reported limited medical details in many cases; for example, it was difficult to characterize whether TSS in many cases was done via an endoscopic or microscopic approach. Hence, since the target audience for these reports was not physicians or medical professionals, all medical details in Westlaw are written at a layperson level. Furthermore, Westlaw is not a comprehensive database of all cases; individual vendors collect data from various jurisdictions, and reporting requirements vary by jurisdiction. Hence, the only cases included were ones that progressed to the point of inclusion in publically available federal and state court records. This includes cases that progressed to jury-mediated proceedings; however, it is well known that the majority of cases are settled out of court out of the public eye. Hence, this analysis may be more valuable for considerations raised within these proceedings, but is not appropriate for use in measuring the total incidence of pursuing litigation and out of court mediation in the United States. Hence, due to these limitations on cases involving settlements, statistical analysis involving monetary awards of settlements and prevalence cannot be estimated. Despite these limitations, this resource has demonstrated its unique value in many prior analyses, and the factors we report certainly fill a void in the literature regarding this important topic.

Conclusion

Physicians in a variety of specialties are impacted by litigation related to the diagnosis and management of pituitary and skull-base lesions. Importantly, critical anatomic structures in close proximity to these locations suggest that failure to recognize these pathologies may lead to permanent sequelae, a common factor facilitating litigation in nonsurgical cases. Importantly, misdiagnosis of patients presenting with endocrinopathy, failure to appropriately workup patients presenting with neurologic complaints, and radiologic misdiagnosis play important roles in the pursuit of litigation in nonsurgical cases. Furthermore, sustaining permanent sequelae including endocrine and visual injury play an important role in surgical cases. Postoperative management appears to play just as important a role in the decision to pursue litigation as intraoperative considerations. Our hope is that the findings noted in this analysis can be helpful for physicians involved in the initial diagnosis and management of patients with pituitary and skull-base disorders, and surgical allegations can be included in a preoperative informed consent process by neurological surgeons and otolaryngologists involved in the surgical management of these patients.

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