Perioperative Complications in Obstructive Sleep Apnea Patients Undergoing Surgery: A Review of the Legal Literature

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BACKGROUND: Obstructive sleep apnea (OSA) is common in patients undergoing surgery. OSA, known or suspected, has been associated with significant perioperative adverse events, including severe neurologic injury and death. This study was undertaken to assess the legal consequences associated with poor outcomes related to OSA in the perioperative setting.

METHODS: A retrospective review of the legal literature was performed by searching 3 primary legal databases between the years 1991 and 2010 for cases involving adults with known or suspected OSA who underwent a surgical procedure associated with an adverse perioperative outcome. OSA had to be directly implicated in the outcome, and surgical mishaps (i.e., uncontrolled bleeding) were excluded. The adverse perioperative outcome had to result in a lawsuit that was then adjudicated in a court of law with a final decision rendered. Data were abstracted from each case regarding patient demographics, type of surgery, type and location of adverse event, associated anesthetic and opioid use, and legal outcome.

RESULTS: Twenty-four cases met the inclusion criteria. The majority (83%) occurred in or after 2007. Patients were young (average age, 41.7 years), male (63%), and had a known diagnosis of OSA (96%). Ninety-two percent of cases were elective with 33.3% considered general procedures, 37.5% were ears, nose and throat procedures for the treatment of OSA, and 29.1% were considered miscellaneous interventions. Complications occurred intraoperatively (21%), in the postanesthesia care unit (33%), and on the surgical floors (46%). The most common complications were respiratory arrest in an unmonitored setting and difficulty in airway management. Immediate adverse outcomes included death (45.6%), anoxic brain injury (45.6%), and upper airway complications (8%). Overall, 71% of the patients died, with 6 of the 11 who suffered anoxic brain injury dying at an average of 113 days later. The use of opioids and general anesthetics was believed to play a role in 38% and 58% of cases, respectively. Verdicts favored the plaintiffs in 58% of cases and the defendants in 42%. In cases favoring the plaintiff, the average financial penalty was $2.5 million (±$2.3 million; range, $650,000—$7.7 million).

CONCLUSIONS: Perioperative complications related to OSA are increasingly being reported as the central contention of malpractice suits. These cases can be associated with severe financial penalties. These data likely underestimate the actual medicolegal burden, given that most such cases are settled out of court and are not accounted for in the legal literature. (Anesth Analg 2016;122:145–51)

Obstructive sleep apnea (OSA) is characterized by repetitive partial or complete obstruction of the upper airway associated with cortical microarousals and oxygen desaturations, leading to disrupted sleep architecture and increased sympathetic neural activity.[1] The prevalence of OSA in the general population is approximately 5%, with most cases remaining undiagnosed.[2,3] Because of the aging of the population and the increasing obesity epidemic, OSA is expected to become more prevalent.

Studies using screening questionnaires to estimate OSA prevalence in patients undergoing elective surgery have found that between 24% and 41% of patients are considered at risk for OSA.[4,5] Most of these patients (81%–87%) have not been diagnosed with OSA at the time of their presentation.[6,7] In certain patient populations, i.e., bariatric surgery candidates, prevalence rates of OSA may reach as high as 70%.[6]

Patients with OSA are at an increased risk for perioperative complications.[8,9] A number of mechanisms for this have been proposed, including difficulty during tracheal intubation and extubation; the effects of anesthetics, sedatives, and narcotics on upper airway muscle tone and ventilatory responsiveness; postoperative supine positioning; and increased rapid eye movement (REM) sleep on the nights following the first postoperative night.[10–16] All these factors can potentially aggravate OSA, leading to worsening nocturnal hypoxia and hypercapnia, which are believed to be the primary mediators for postoperative complications, particularly in an unmonitored setting.[17,18]

Although some of the reported postoperative complications in OSA patients are transient and reversible (i.e., transient hypoxia),[18–20] others can be catastrophic. There are case reports identifying patients suffering major morbidity or

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death in the postoperative setting directly attributable to the presence of OSA.[21,22] The purpose of this study is to describe the reported legal ramifications associated with poor outcomes in OSA patients undergoing surgery and to establish the medicolegal burden of such cases.

METHODS

After consultation with MetroHealth Medical Center's IRB, the study was exempt from requiring informed consent. The study was not registered with Clinicaltrials.gov, because it was a review of the legal literature and did not involve the assignment of patients to treatment groups.

This study is a retrospective review of the legal literature performed by searching the primary legal databases: WestlawNext, Westlaw, LexisNexis, and LexisNexis Academic. LexisNexis and LexisNexis Academic are the world's largest electronic database for legal and public records–related information, containing >5 billion documents of source information. Westlaw and WestlawNext are 2 of the primary online legal research services for lawyers and legal professionals in the United States, containing >28,000 databases of case law, legislation, law reviews, treaties, and directories. It is estimated that approximately 15,000 to 19,000 medical malpractice suits are brought against physicians each year and that the majority of those could be searched and found in both the LexisNexis and the Westlaw databases. Search terms included "obstructive sleep apnea and medical malpractice," "obstructive sleep apnea and medical negligence," "sleep apnea and postoperative medical complications," and "sleep apnea and postoperative respiratory complications." The search was limited to cases in the United States only, and the time period searched included from 1991 through 2010.

Study Population

Inclusion criteria were that cases had to involve adults (>18 years of age) with known or suspected OSA who underwent a surgical procedure that was associated with an adverse perioperative outcome. OSA had to be directly implicated in the outcome, and thus, primary surgical mishaps (i.e., uncontrolled bleeding or postoperative sepsis) were excluded. All other postoperative adverse events, which could include those possibly related to anesthetics and/or the use of opioids or sedatives, were considered. The adverse perioperative outcome also had to result in a lawsuit that was then adjudicated in a court of law with a final decision in the case rendered. Cases settled before going to court were excluded; most of these cases are not reported in the legal literature (personal communications, unpublished data) and often "sealed" from the public, preventing analysis of details from the cases.

Plaintiffs were defined as those bringing the lawsuit against the defendants. Defendants were those on trial in the court of law. Defendants included medical centers/hospitals, physicians, and nurses. More specifically, medical centers/hospitals were named in 41.7% of the cases, surgeons in 37.5% of the cases, anesthesiologists in 33.3% of the cases, other/anonymous physicians in 16.7% of the cases, and nurses in 8.3% of the cases. More than 1 defendant was named in 29.1% of cases.

Using the aforementioned search terms, 50 cases were initially identified. Twenty-six of these were excluded because of being settled out of court (16), not being related to surgery (5), involving a surgical mishap (3), error of informed consent (1), and involving pediatrics (1). This left 24 cases for review and analysis (Fig. 1).

Data Collected

Each case was reviewed, and data were extracted from the records available in the legal posting. Data extracted included age, sex, type of surgery, complication leading to the lawsuit, location where the complication occurred, type of central nervous system depressant (i.e., anesthetics, opioids, benzodiazepines) directly preceding or implicated in the complication, and the final verdict of the case. Of note, none of the records mentioned the use of or implication of benzodiazepines in the case. Where appropriate, the assessment of financial penalties was extracted. All cases were then categorized into the major complication categories of death (11), anoxic brain injury (11), or upper airway (2). Note that 6 of the patients with anoxic brain injury died at later dates, although they were kept in the anoxic brain injury category for purposes of analysis. The upper airway category reflects significant damage to the upper airway leading to disability. In 1 case,

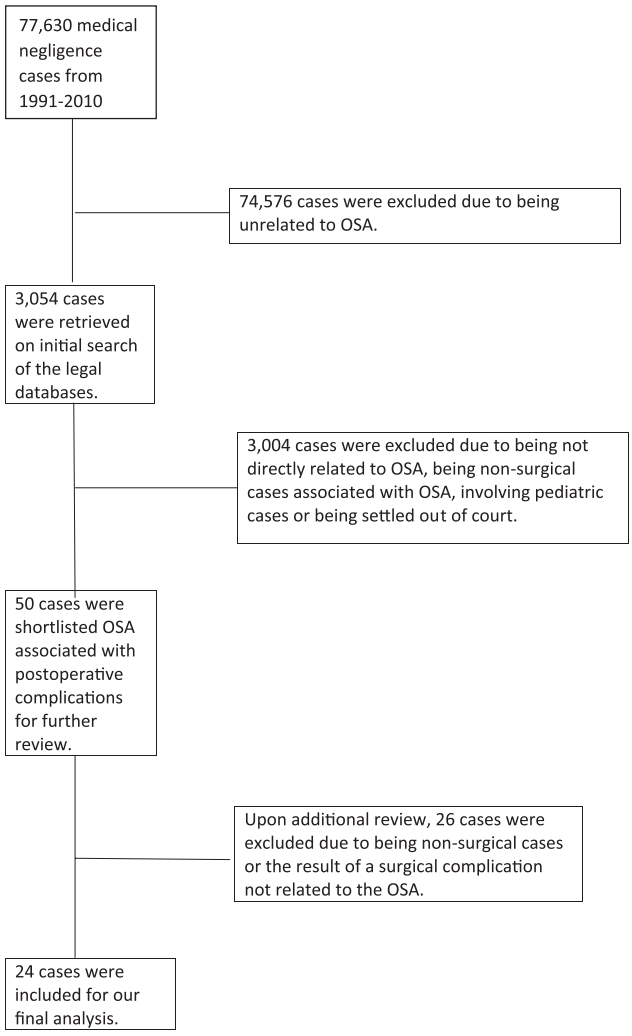


Figure 1. Flowchart for determining the cases for analysis. OSA = obstructive sleep apnea.

an unplanned permanent tracheostomy was placed, and the other resulted from damage to the upper airway from reintubation leading to chronic aspiration problems.

Statistics

Descriptive statistics were used to characterize all cases with means and SDs. Cases were categorized by outcome: death, anoxic brain injury, and upper airway.

RESULTS

Twenty-four cases met criteria for inclusion in the study (Fig. 1). Although cases occurred across the entire search spectrum (1991–2010), 83% of them occurred after the year 2000 and 41% occurred in or after 2007 (Fig. 2).

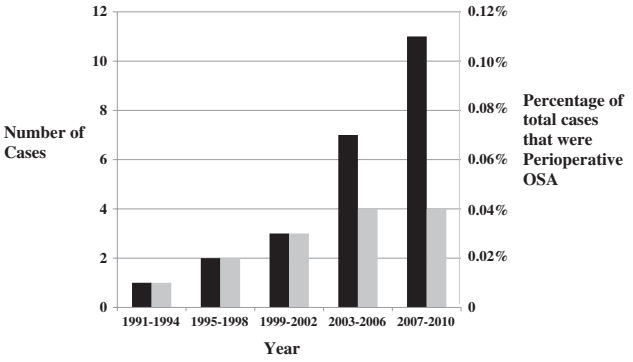


Figure 2. Number of adjudicated lawsuits over time. Black bars represent the number of perioperative OSA cases per time period. Gray bars represent the percentage of the total number of lawsuits that were perioperative OSA cases per time period. OSA = obstructive sleep apnea.

Demographics (Table 1) include an average age of 41.7 years (±9.8 years), 63% male sex, and a known diagnosis of OSA in 96%. Most cases were elective surgeries (92%), with 33.3% considered general surgical procedures (all surgeries were performed below the diaphragm), 37.5% were ears, nose and throat procedures for the treatment of OSA, and 29.1% were considered other or miscellaneous interventions (Table 2). Complications occurred in the following locations: intraoperatively (21%), in the postanesthesia care unit (PACU) (33%), and on the surgical floors (46%).

The most common complications were respiratory arrest in an unmonitored setting and difficulty in airway management, usually in the form of a failed reintubation after premature extubation. Immediate adverse outcomes included death (45.6%), anoxic brain injury (45.6%), and upper airway complications (8%; Table 1). Long term, 71% of the patients died, with 6 of 11 who suffered anoxic brain injury dying at an average of 113 days (±111 days) later. The use of opioids and general anesthetics was believed to play a role in 38% and 58% of cases, respectively.

Patients who died during or immediately after their adverse event, compared with those who suffered anoxic brain injury, were more likely to have an unmonitored arrest on the general ward, although this did not reach statistical significance (Table 1). Those who suffered anoxic brain injury were more likely to have problems with a difficult airway in the operating room or the PACU, although this also did not reach statistical significance (Table 1).

Verdicts were reached in all cases, with 58% in favor of the plaintiff and 42% in favor of the defendant. In cases favoring the plaintiff, the average financial penalty was $2.5 million (±$2.3 million; range, $650,000–$7.7 million), with

Table 1. Comparison of Demographics and Associated Case Factors by Outcome

Outcome[a]	Death (*n* = 11)	ABI[b] (*n* = 11)	Upper airway (*n* = 2)	Total (*n* = 24)
Age[c] (y) ±SD	36.3 ± 7.6	45.0 ± 10.4	49.0	41.7 ± 9.8
Sex, *n* (%)				
Male	8 (73)	7 (64)	0	15 (63)
Female	3 (27)	4 (36)	2 (100)	9 (36)
Complication, *n* (%)				
Unmonitored cardiorespiratory arrest	8 (73)	4 (36)	1 (50)	13 (54)
Difficult airway	2 (18)	5 (45)	0	7 (29)
ICU transfer	0	0	1 (50)	1 (4)
Ambulatory surgery requiring transfer	1 (9)	1 (9)	0	2 (8)
Intraoperative arrest	0	1 (9)	0	1 (4)
Place of complication, *n* (%)				
Intraoperative	1 (9)	4 (36)	0	5 (21)
PACU	2 (18)	4 (36)	2 (100)	8 (33)
Patients' room	8 (73)	3 (27)	0	11 (46)
CNS depressant during complication, *n* (%)[d]				
General anesthesia	7 (64)	6 (55)	1 (50)	14 (58)
Opioids	4 (36)	4 (36)	1 (50)	9 (36)
Type of surgery, *n* (%)				
General	5 (45)	2 (18)	1 (50)	8 (33)
ENT	3 (27)	5 (45)	1 (50)	9 (36)
Other	3 (27)	4 (36)	0	7 (29)
Verdict, *n* (%)				
Defense	3 (27)	6 (55)	1 (50)	10 (42)
Plaintiff	8 (73)	5 (45)	1 (50)	14 (58)

ABI = anoxic brain injury; CNS = central nervous system; PACU = postanesthesia care unit; ENT = ears, nose and throat; ICU = intensive care unit.
[a]Values may not add up to 100% because of rounding.
[b]Six cases died later.
[c]Age missing for 3 cases (2 death and 1 anoxic brain injury).
[d]Type of anesthesia missing for 1 case.

Table 2. Individual Case Descriptions

Case	Age (y)	Sex	Surgery	Anesthetic	Event	Location	Outcome
1	33	F	Gastric bypass	General	Premature extubation. Unable to reintubate.	PACU	Death
2	NA	M	Gastric bypass	General	Sent to floor without CPAP. Opioids given postoperative. Unwitnessed arrest.	Floor	Death
3	25	M	Vertical-banded gastroplasty	General	Opioids given postoperative. Unwitnessed arrest.	Floor	Death
4	51	F	Vertical-banded gastroplasty	General	Opioids given postoperative. Unwitnessed arrest.	PACU	Upper airway
5	33	M	Laparoscopic cholecystectomy	General	Sent to floor without CPAP. Opioids given postoperative. Unwitnessed arrest.	Floor	Death
6	68	F	Colonic resection	General	Opioids given postoperative. Unwitnessed arrest.	Floor	Anoxic brain injury
7	45	M	Appendectomy	General	Opioids given postoperative. Unwitnessed arrest.	Floor	Anoxic brain injury
8	47	M	Appendectomy	General	Premature extubation. Unable to reintubate.	PACU	Death
9	47	F	UP3	General	Postextubation pulmonary edema.	PACU	Upper airway
10	38	M	UP3	General	Premature extubation. Unable to reintubate.	PACU	Anoxic brain injury
11	48	M	UP3	General	Premature extubation. Unable to reintubate.	OR	Anoxic brain injury
12	NA	M	UP3	General	Postoperative hypoxia.	PACU	Anoxic brain injury
13	44	M	UP3	General	Premature extubation. Unable to reintubate.	OR	Anoxic brain injury
14	NA	M	UP3	General	Opioids given postoperative. Unwitnessed arrest.	Floor	Death
15	36	M	UP3	General	Sent to floor without CPAP. Opioids given postoperative. Unwitnessed arrest.	Floor	Death
16	32	M	Cholesteatoma removal	General	Sent to floor without CPAP. Opioids given postoperative. Unwitnessed arrest.	Floor	Death
17	35	F	Septoplasty	General	Premature extubation. Unable to reintubate.	PACU	Anoxic brain injury
18	40	M	Pacemaker lead revision	None	Given opioids during procedure. Hypoxic arrest.	OR	Anoxic brain injury
19	39	F	Hysterectomy	General	Opioids given postoperative. Unwitnessed arrest.	Floor	Anoxic brain injury
20	36	F	Episiotomy	None	Given opioids during procedure. Hypoxic arrest.	OR	Anoxic brain injury
21	57	M	Anterior cervical fusion	General	Premature extubation. Unable to reintubate.	PACU	Anoxic brain injury
22	23	M	Spinal laminectomy	General	Opioids given postoperative. Unwitnessed arrest.	Floor	Death
23	41	F	Tooth extraction	None	Given opioids during procedure. Hypoxic arrest.	OR	Death
24	48	F	Retinal detachment surgery	NA	Sent to floor without CPAP. Opioids given postoperative. Unwitnessed arrest.	Floor	Death

CPAP = continuous positive airway pressure; F = female; M = male; OR = operating room; PACU = postanesthesia care unit.

a higher financial penalty awarded for anoxic brain injury compared with patients who died immediately (Fig. 3). In total, >$32 million was awarded to the plaintiffs, and the largest single settlement was $7.7 million.

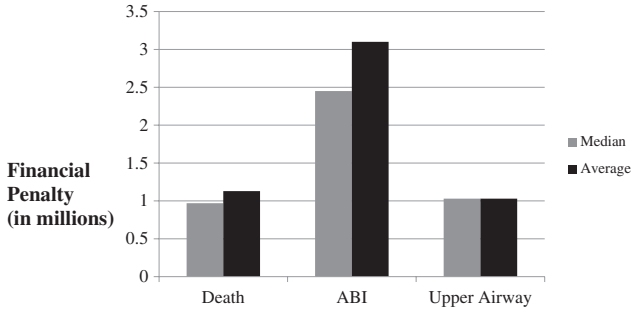
DISCUSSION

There has been an increase in published articles related to excess perioperative morbidity associated with known or suspected OSA.[23–25] However, the medicolegal burden of these perioperative complications has not been fully explored. This study demonstrates that perioperative complications directly related to OSA are increasingly recognized in the legal arena as well as with a growing number of medical malpractice suits reaching the courts. In addition, perioperative OSA cases appear to make up a growing percentage of the total legal cases adjudicated in the court of law, albeit this is a very small percentage of the total cases (Fig. 2). The majority of the cases reported here occurred after the year 2000, and >40% of cases were reported in the most recent 4 years of the study. Of interest, during roughly this same time period (2001–2010), the number of medical malpractice suits in the United States has been declining annually with an overall decrease of 35%.[26]

Medical litigation related to OSA has been previously reported by Svider et al.[27] In that study, similar to our study, cases where a jury verdict was rendered were included for analysis, although some cases settled out of court were also included. In contrast to our study, cases were not limited to the perioperative setting alone. Other studies examining legal issues related to OSA in the perioperative setting focused on surgical factors, primarily tonsillectomy/adenoidectomy, and not the association of OSA with the poor outcome.[28–31] Thus, our study is unique among these studies in that it reports on only surgical cases where OSA was believed to be a contributing factor to the adverse outcome that prompted the litigation.

The majority (58%) of rulings in our study favored the plaintiff. This is in contradistinction to the study by Svider et al.,[27] where 61% of cases ended with a ruling in favor of the defendant. This difference may be related to the reason for litigation, because the cause for litigation in our study was almost exclusively because of either death or anoxic brain injury, whereas there were a large variety of reasons cited for litigation in the study by Svider et al. However, where a financial penalty was rendered, the findings were quite similar, averaging 1.5 to 2.5 million dollars per case with the highest penalties associated with cases involving anoxic brain injury. This likely reflects the expectation of prolonged intensive support and care needed for patients with anoxic brain injury and the high likelihood of subsequent death (6 of the 11 cases of anoxic brain injury in our study ultimately died on average >3 months after the initial complication).

This study carries particular relevance to the field of anesthesiology. More than half of the adverse events occurred intraoperatively or in the PACU and were often related to difficulty with airway management and/or premature extubations. Adverse events that happened intraoperatively or in the PACU were most often associated with a permanent vegetative state or required a permanent tracheostomy. Concerns for such adverse outcomes have been discussed previously and are reflected in recent reviews[32] and recommendations from the American Society of Anesthesiologists for the perioperative management of patients with OSA.[33] Particularly important areas of the American Society of Anesthesiologists guidelines that are relevant to our data are the recommendations for tracheal extubation while the patient is awake, only once neuromuscular blockade has completely resolved, and in the semiupright or lateral position. Following these recommendations may have avoided many of the unfortunate outcomes seen in the cases where premature extubation was believed to be a primary factor in the poor outcome.



*ABI = anoxic brain injury

Death: n=8, range $650,000 to $2 million
ABI: n=5, range $1.5-7 million
Upper airway: n=1, $1 million (only 1 case)

Figure 3. Damages awarded to plaintiffs in millions of US dollars as categorized by major type of injury.

Slightly over half of the complications reported occurred in an unmonitored setting, and a substantial minority involved the use of opioids. These cases were most likely to be associated with death as the outcome. There are controlled data supporting the use of oximetry monitoring to reduce the need for urgent intensive care unit transfers postoperatively, although this study did not specifically examine patients with OSA.[34] Uncontrolled data suggest that implementation of a postoperative monitoring program for OSA patients may improve outcomes, although this requires further study.[35] Most protocols and algorithms now recommend care with the use of opioids in patients with known or suspected OSA, particularly postoperatively, and alternative modes of analgesia should be considered.[19,22,32,33,36–38]

Of note, the cases in this study involved surgeries that were elective and performed on a relatively young patient population, averaging only 42 years of age. In addition, seemingly innocuous procedures such as an outpatient tooth extraction and revision of a pacemaker lead were found in this search. Although numerous perioperative protocols for the management of patients with OSA have been published, it remains to be proven that these protocols and proposed interventions will change the outcomes of OSA patients undergoing elective surgery. Currently, it seems that most institutions do not have policies in place.[39,40] Despite the recent literature suggesting that ambulatory surgery for patients with OSA is safe,[41,42] there were 2 cases of ambulatory surgery that required emergent transfer to a hospital with 1 case resulting in the death of the patient.

Our study is limited in several ways. First, this is a descriptive study and therefore the data presented serve, at best, to expose a previously unexplored area of this subject. Second, the actual medical, legal, and financial burden is undoubtedly significantly underestimated, as most such suits are settled out of court. In these cases, without a court ruling, there are little, if any, record and no reasonable manner by which to gather and analyze the data. Third, although the court findings may have implicated substandard postoperative care of patients with OSA as the reason to rule in the favor of the plaintiff in many of the cases, this study cannot medically verify that this was the case and a cause-and-effect relationship cannot be established. The study reports only on findings as stated in the legal literature. Finally, our study is limited in the presentations of the facts of each case as the medical data available are only that were published in the legal literature and are often devoid of important medical information.

CONCLUSIONS

Surgical patients with known or suspected OSA are at an increased risk for perioperative complications, and such complications are increasingly being reported as the central contention of malpractice suits. The most common

complications are related to cardiorespiratory arrest in an unmonitored setting and difficulty in airway management in the operating room and/or PACU, with both resulting in catastrophic outcomes including death or permanent brain damage. These cases are associated with severe financial penalties. Further research into interventions to reduce postoperative complications is needed. Our data likely underestimate the actual medicolegal burden, given that most such cases are settled out of court, and thus are not accounted for in the legal literature. ■

DISCLOSURES

Name: Nick Fouladpour, MD.
Contribution: This author helped design the study, collect the data, and prepare the manuscript.
Attestation: Nick Fouladpour reviewed the original data and approved the final manuscript.
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Contribution: This author helped design the study and prepare the manuscript.
Attestation: Dennis Auckley reviewed the original data and the analysis of the data, approved the final manuscript, and is also the designated archival author who is responsible for maintaining the study records.
This manuscript was handled by: David Hillman, MD.

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