LEGAL ASPECTS OF PERIOPERATIVE CARE OF THE PATIENT WITH SLEEP APNEA

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OUTLINE

I. Overview of the Malpractice System
   1. What are the intended purposes of the system
   2. How well does the system fulfill these purposes

II. Elements of a Malpractice Claim

III. Implications for Perioperative Care of the Patient with Sleep Apnea

Societal/Public Health Goals Served (?) by the Malpractice System

- To compensate patients injured as a result of negligence
- To deter unsafe practices by physicians
- To exact corrective justice (to “punish” bad actors)

(1)

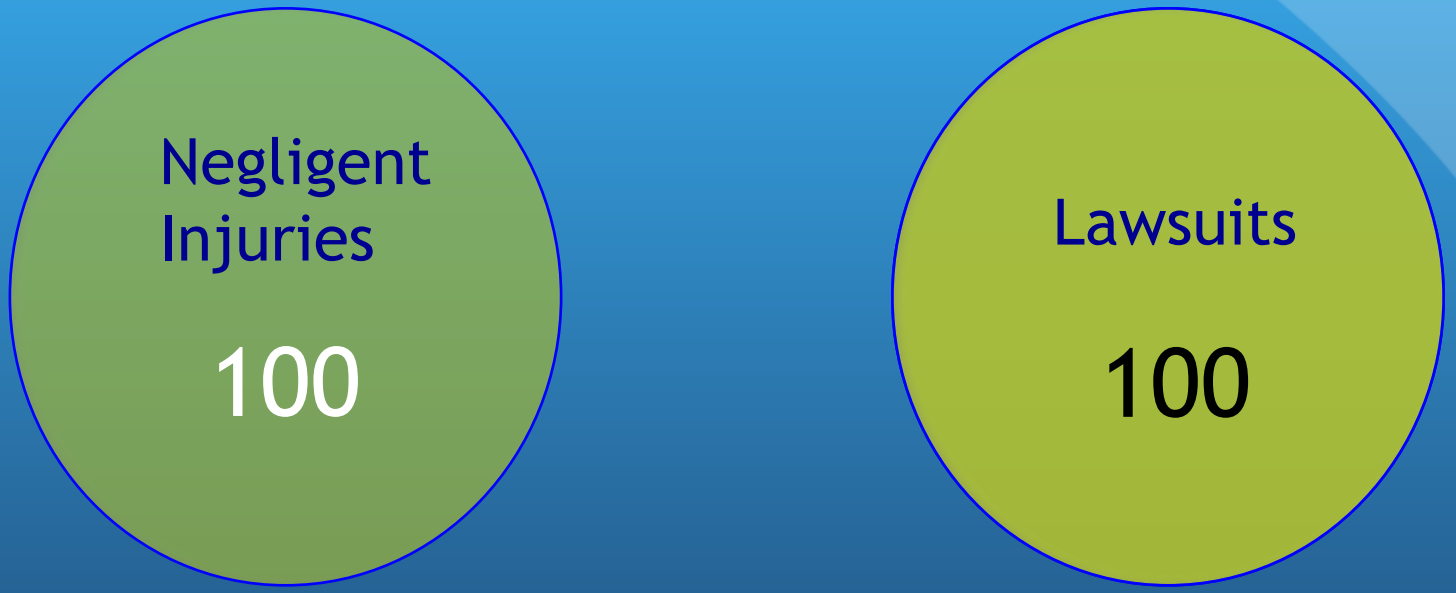
Efficacy of the system at compensating for harm

From studies done in CA, NY, UT and CO in the 80s and 90s:

- Somewhere between 7-10x as many negligent injuries as there are malpractice claims
- Only 2% of negligent injuries resulted in claims
- Only 17% of claims appeared to involve negligent injury

(2-5)

For every 10,000 admissions, if 1% of admissions involves a negligent injury



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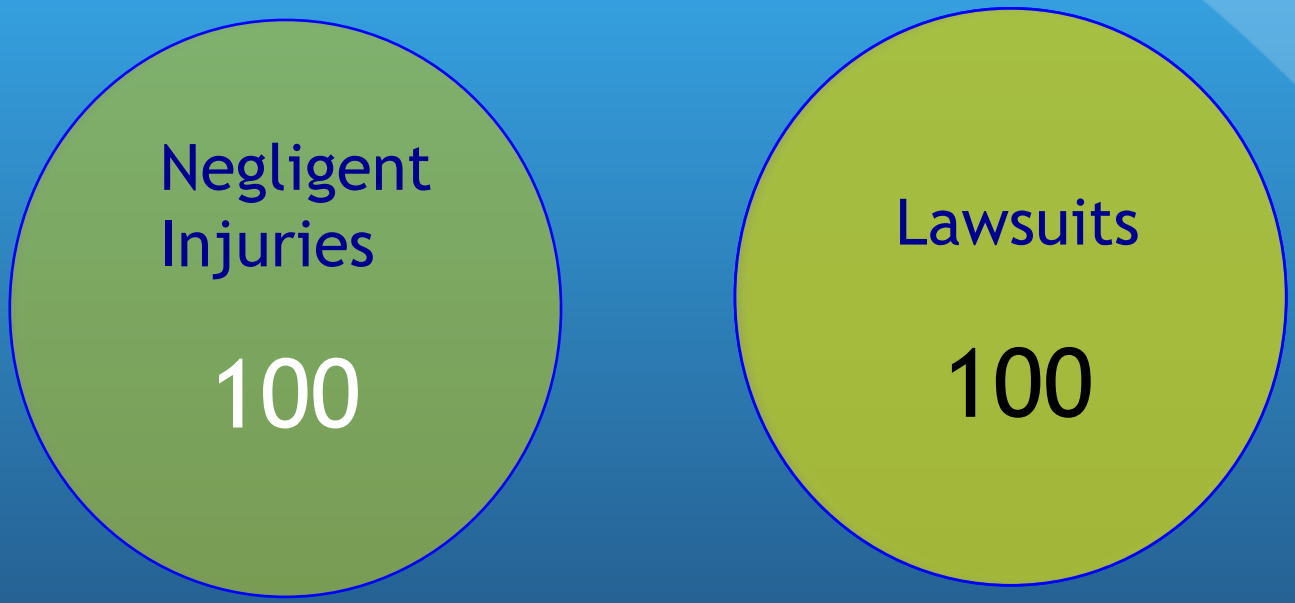

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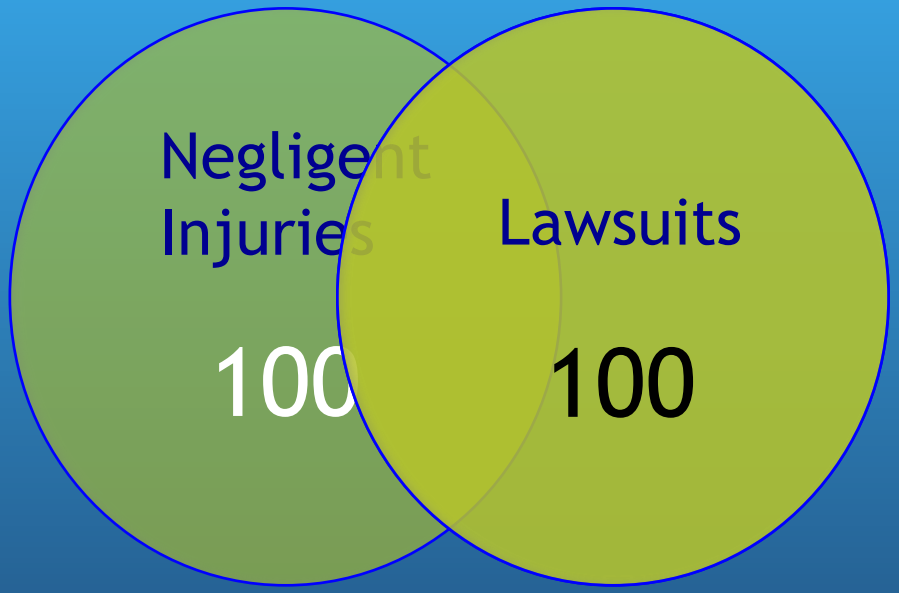

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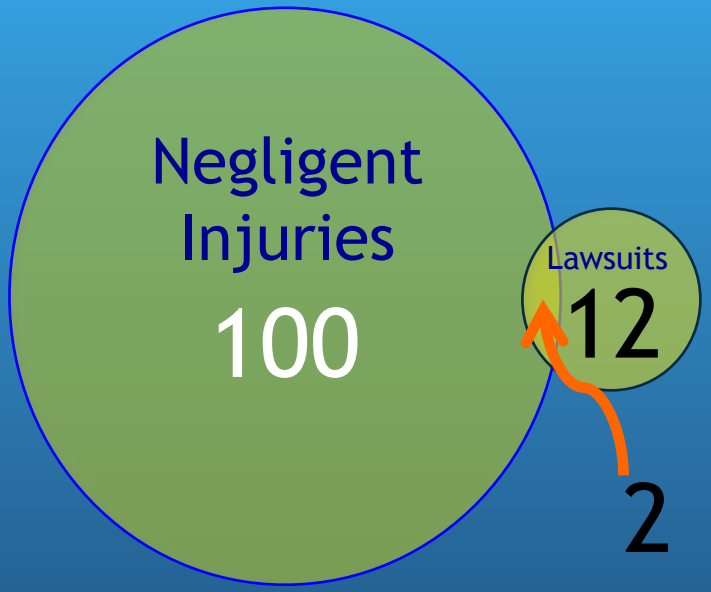

Efficacy of the system for compensating harms

- System may be ok at compensating persons with a negligent injury, when a claim is brought
- However, evidence suggests that the key predictor of payment is the extent of injury, not the presence of negligence

Purposes of the malpractice system

- To compensate persons injured as a result of negligence
  - Most negligently-injured persons don't file a lawsuit
  - The majority of lawsuits that are filed don't involve negligent harms
  - When you do have both a negligent injury and a lawsuit, the system may be ok at compensating the harmed party
  - However, there is evidence that payments correlate with the extent of injury, not the presence of negligence

- To deter unsafe practices
- To exact corrective justice

Efficacy of the system as a deterrent of negligent practices

- Clear evidence of efficacy is lacking
- Best evidence of the effect of liability on practice comes from OB/GYN, and even there the evidence is contradictory
  - Some studies showing that higher liability risk (as measured by premiums, past claims, and perceived risk of being sued) increased the probability of c-section, other studies suggested the opposite, and others have shown no association

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  - Evidence is lacking

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Two Cultures

- The patient safety movement
  - encourages transparency
  - focuses on system rather than individual failures
  - is non-punitive in nature
  - is forward-looking and prioritizes continuous improvement
  - the Swiss cheese model of causation
- The culture of litigation
  - discourages transparency, incentivizes strategic withholding of information
  - focuses on and seeks out entities on which to assign blame and from which to extract payment
  - is punitive in nature
  - prioritizes “winning” a given lawsuit involving a past incident rather than improving the system or the individual with the aim of preventing future harms
  - looks to identify an individual slice on which to lay responsibility for a harm

Effect on healthcare providers

- Concern about litigation risk diminishes interest in patient-safety activities
- Dis-incentivizes reporting to adverse-event reporting systems
- Dis-incentivizes communication to patients about errors
- In one survey, 20% of surveyed physicians admitted not fully disclosing a mistake in the last year, for fear of being sued
- Risk management is typically separated from quality improvement

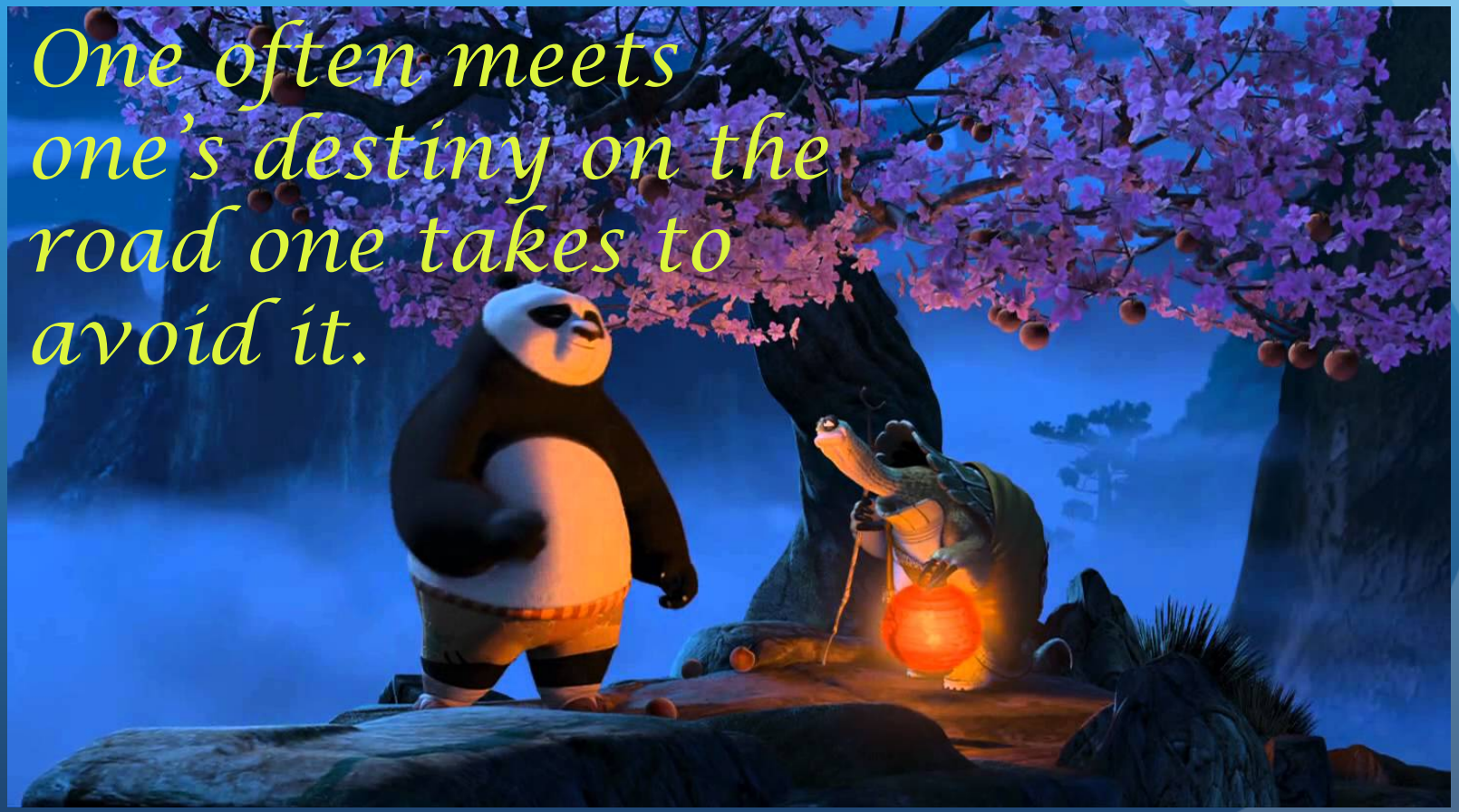
(13-18)

Effect on patients

- There is evidence that in some cases, part of the motivation behind suing is to obtain the “truth” about what took place in an adverse event – to know how the injury happened and why
- Of families of children suffering perinatal injuries who later sued surveyed, 24% cited their suspecting a “cover-up,” and 20% cited wanting more information as reasons for suing

(19-20)

The Kung Fu Panda Effect



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- To exact corrective justice
  - For a physician who has an adverse event, "corrective justice" arguably is the wrong goal

Elements of a Medical Malpractice Claim

1. Duty
    1. In our relationship as physicians to patients, we are "required to exercise the skill and knowledge normally possessed by members of . . . [the medical profession] in good standing …"
2. Breach of Duty
    1. Either an act or an omission to act where there is a duty
3. Causation
    1. The actor's negligent conduct is a legal cause of harm to [a victim] if
        (A) his conduct is a substantial factor in bringing about the harm, and
        (B) there is no rule of law relieving the actor from liability …
4. Damages
    1. Harm resulting to the plaintiff from the breach of duty

Breach of Duty

- Whether a defendant has met the standard of care is an issue of fact to be determined by a jury
- Jury Instructions:
  - “Did the physician in this scenario use the degree of skill and care as would a reasonably competent physician under similar circumstances?”
  - “If no, was this failure a proximate cause of the injury, that is, without the physician’s failure to competently perform, would the injury have taken place?”

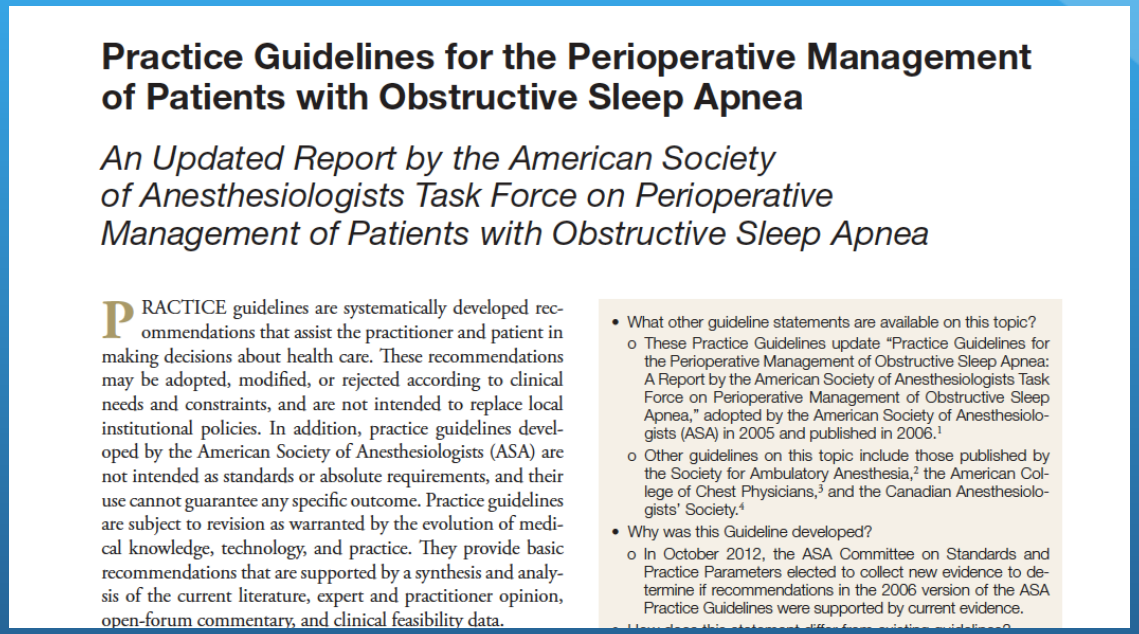
The Standard of Care

- Because “standards” that are adopted by associations or other nongovernmental entities may represent a consensus regarding what a reasonable person in a particular industry would do, **such standards may be helpful to the trier of fact in deciding whether the defendant has met the standard of care in a particular situation.** Hansen v. Abrasive Engineering and Manufacturing, Inc, 856 P.2d 625, 628 (Sup. Ct. Or. 1993)

The Standard of Care

- Evidence of industry standards, customs and practices is "often highly probative when defining a standard of care." 57A Am.Jur.2d Negligence § 185 (2002)
- Such evidence may be relevant and admissible to aid the trier of fact in determining the standard of care in a negligence action "even though the standards have not been imposed by statute or promulgated by a regulatory body and therefore do not have the force of law." Ruffiner v. Material Serv. Corp., 506 N.E.2d 581, 584 (1987); Elledge v. Richland/Lexington School District Five, 534 S.E.2d 289, 291 (Ct. App. S.C. 2000)

ASA Practice Guidelines



Practice Guidelines for the Perioperative Management of Patients with Obstructive Sleep Apnea

An Updated Report by the American Society of Anesthesiologists Task Force on Perioperative Management of Patients with Obstructive Sleep Apnea

PRACTICE guidelines are systematically developed recommendations that assist the practitioner and patient in making decisions about health care. These recommendations may be adopted, modified, or rejected according to clinical needs and constraints, and are not intended to replace local institutional policies. In addition, practice guidelines developed by the American Society of Anesthesiologists (ASA) are not intended as standards or absolute requirements, and their use cannot guarantee any specific outcome. Practice guidelines are subject to revision as warranted by the evolution of medical knowledge, technology, and practice. They provide basic recommendations that are supported by a synthesis and analysis of the current literature, expert and practitioner opinion, open-forum commentary, and clinical feasibility data.

- What other guideline statements are available on this topic?
  - These Practice Guidelines update "Practice Guidelines for the Perioperative Management of Obstructive Sleep Apnea: A Report by the American Society of Anesthesiologists Task Force on Perioperative Management of Obstructive Sleep Apnea," adopted by the American Society of Anesthesiologists (ASA) in 2005 and published in 2006.[1]
  - Other guidelines on this topic include those published by the Society for Ambulatory Anesthesia,[2] the American College of Chest Physicians,[3] and the Canadian Anesthesiologists' Society.[4]
- Why was this Guideline developed?
  - In October 2012, the ASA Committee on Standards and Practice Parameters elected to collect new evidence to determine if recommendations in the 2006 version of the ASA Practice Guidelines were supported by current evidence.

- Society for Ambulatory Anesthesia
- American College of Chest Physicians
- Canadian Anesthesiologists' Society

ASA Practice Guidelines

Intraoperative: “. . .

- Unless there is a medical or surgical contraindication, patients at increased perioperative risk from OSA should be extubated while awake.
- Full reversal of neuromuscular block should be verified before extubation.
- When possible, extubation and recovery should be carried out in the lateral, semiupright, or other nonsupine position.

. . . ”

ASA Practice Guidelines

Post-operative: “. . .

- Hospitalized patients who are at increased risk of respiratory compromise from OSA should have continuous pulse oximetry monitoring after discharge from the recovery room.
- Continuous monitoring may be provided in a critical care or stepdown unit, by telemetry on a hospital ward, or by a dedicated, appropriately trained professional observer in the patient’s room.
- Continuous monitoring should be maintained as long as patients remain at increased risk

. . .”

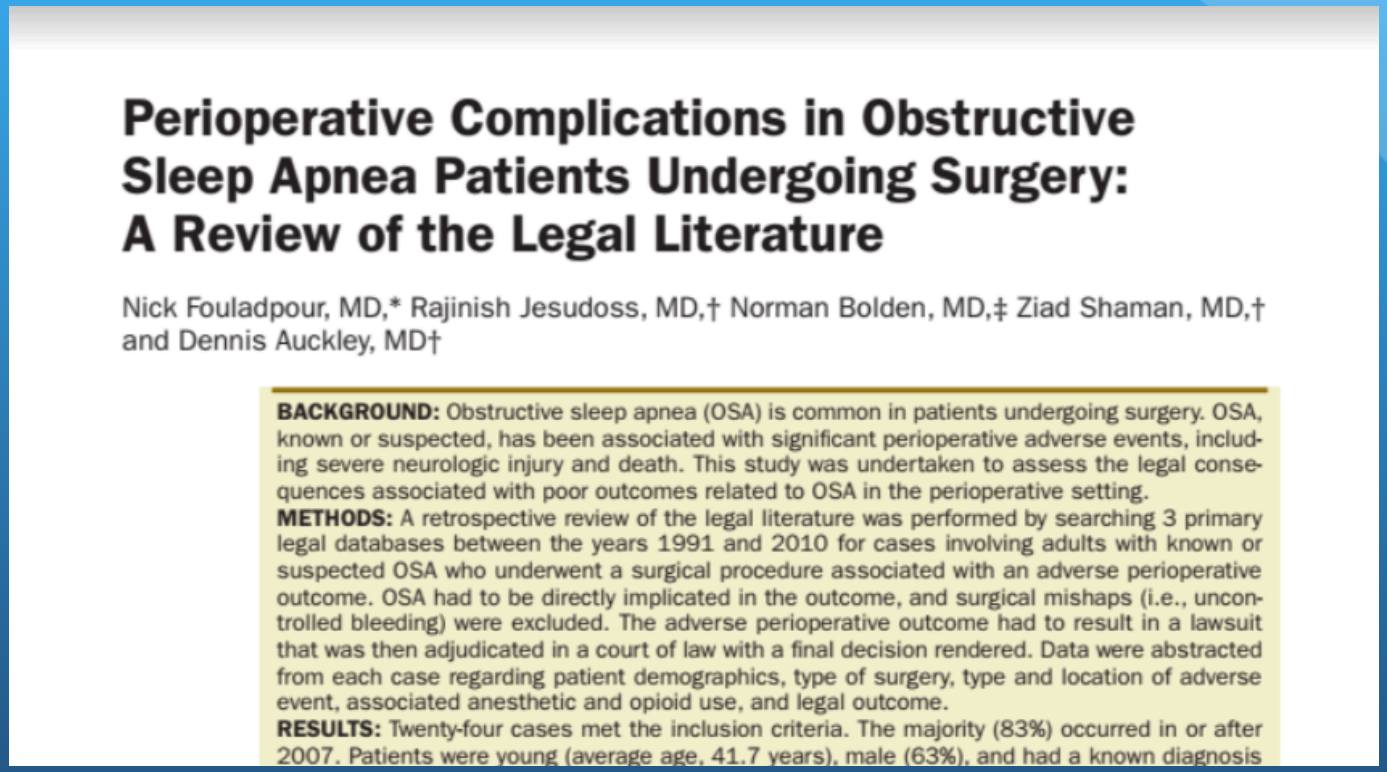
ASA Practice Guidelines

Discharge: “ . . .

- Patients at increased perioperative risk from OSA should not be discharged from the recovery area to an unmonitored setting (i.e., home or unmonitored hospital bed) until they are no longer at risk of postoperative respiratory depression.
- Because of their propensity to develop airway obstruction or central respiratory depression, this may require a longer stay as compared with non-OSA patients undergoing similar procedures.

. . . “

What Perioperative Complications Do We See in Lawsuits?



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

Nick Fouladpour, MD,* Rajinish Jesudoss, MD,† Norman Bolden, MD,‡ Ziad Shaman, MD,† and Dennis Auckley, MD†

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

(23)

Methods

- Searched LexisNexis, Westlaw
- US cases
- 1991-2010
- “obstructive sleep apnea and medical malpractice,” “obstructive sleep apnea and medical negligence,” “sleep apnea and postoperative medical complications,” “sleep apnea and postoperative respiratory complications”

Results

- Plaintiff prevailed 58% of cases found
- Most common complications related to
  - cardiopulmonary arrest in an unmonitored setting
  - difficulty in airway management in OR/PACU
- Common outcomes were death and anoxic brain injury resulting in permanent impairment
- Averaged $2.5m judgments when a financial penalty was rendered in favor of plaintiff

Representative Clinical Scenario

- 48 year-old male with diagnosis of HTN, BMI 42 with large fat deposits around the neck, otherwise in good health, presents for ORIF of wrist fracture.
  - What special considerations pre-op?
  - What anesthetic plan?
  - What post-operative plan?
  - What is the distinction between medical versus medicolegal decision-making here?

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