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Abstract

Purpose  The purpose of this study was to describe the consequences of lawsuits adjudicated in a U.S. court for postoperative complications in patients with obstructive sleep apnea (OSA).

Background  It has been estimated that 24% to 47% of adults presenting for surgery may have Obstructive Sleep Apnea (OSA). A majority of them have never been diagnosed. Patients with OSA are sensitive to anesthetic agents and opioids, and are prone to airway collapse during the perioperative period. Additionally, many OSA patients have comorbid conditions such as hypertension, diabetes, and coronary artery disease. These factors increase OSA patients’ risk of developing postoperative complications, including death. This study sought to examine the ramifications of postoperative complications in patients with OSA.

Methodology  This was a retrospective review of adjudicated lawsuits published in three primary legal databases between the years 1991 and 2010. The cases involved adults with known or suspected OSA who had an adverse perioperative outcome. Only cases in which OSA was directly implicated in the outcome were included. Cases that were settled before going to court were not included since these reports are rarely reported in the legal literature. Descriptive statistics were used to summarize the results.

Result  A total of 24 cases were identified out of 77,630 alleged medical negligence cases reported in the legal literature. The average age was 42 ± 10 years, and a majority were men (63%). Most had known or suspected OSA (96%). Adverse events were most commonly due to difficulty with airway management. The most frequent location of the event was on a surgical ward (46%). Most adverse events involved an unwitnessed respiratory arrest that occurred after the administration of opioids (Table 1 and 2). Only 21% percent of events occurred intraoperatively and 33% occurred in the PACU.

There were 11 patients who died (46%), 11 (46%) who suffered an anoxic brain injury, and 2 (8%) who developed an upper airway complication. Of those patients who suffered an anoxic brain injury, 71% eventually died. Patients who died were more likely to have received opioids and experienced an unwitnessed respiratory arrest. Anoxic brain injury was more likely to have been associated with premature extubation and an inability to reintubate. In 58% of cases the verdict was in favor of the plaintiff. The average financial payment was $2.5 million (range $650,000–$7.7 million), with a higher payment for cases that resulted in an anoxic brain injury compared to death.
Conclusion

OSA is increasingly being reported as the central issue in lawsuits. The most common complications were anoxic brain injury and death, usually as a result of respiratory arrest in an unmonitored setting after opioid administration but also due to inability to reintubate after extubation in a potentially difficult airway. Anesthesia providers should consider following published guidelines for management of patients with OSA, and organizations develop continuous education and monitoring programs.

Table 1. Demographics

<table>
<thead>
<tr>
<th></th>
<th>Death (n = 11)</th>
<th>Anoxic Brain Injury (n = 11)</th>
<th>Airway Complication (n = 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>36.3 ± 7.6</td>
<td>45 ± 10.4</td>
<td>49</td>
</tr>
<tr>
<td>Male gender</td>
<td>73%</td>
<td>64%</td>
<td>0</td>
</tr>
<tr>
<td>Complication</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unmonitored cardiac arrest</td>
<td>73%</td>
<td>36%</td>
<td>50%</td>
</tr>
<tr>
<td>Difficult airway</td>
<td>18%</td>
<td>45%</td>
<td>0</td>
</tr>
<tr>
<td>ICU transfer</td>
<td>0</td>
<td>0</td>
<td>50%</td>
</tr>
<tr>
<td>Ambulatory surgery requiring transfer</td>
<td>9%</td>
<td>9%</td>
<td>0</td>
</tr>
<tr>
<td>Intraoperative arrest</td>
<td>0</td>
<td>9%</td>
<td>0</td>
</tr>
<tr>
<td>Place of complication</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intraoperative</td>
<td>9%</td>
<td>36%</td>
<td>0</td>
</tr>
<tr>
<td>PACU</td>
<td>18%</td>
<td>36%</td>
<td>100%</td>
</tr>
<tr>
<td>Patient’s room</td>
<td>73%</td>
<td>27%</td>
<td>0</td>
</tr>
<tr>
<td>Type of surgery</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General</td>
<td>45%</td>
<td>18%</td>
<td>50%</td>
</tr>
<tr>
<td>ENT</td>
<td>27%</td>
<td>45%</td>
<td>50%</td>
</tr>
<tr>
<td>Other</td>
<td>27%</td>
<td>36%</td>
<td>0</td>
</tr>
</tbody>
</table>

Note: Surgical procedures = bariatric n = 4, laparoscopic cholecystectomy n = 1, colon resection n = 1, appendectomy n = 2, uvulopharyngoplasty n = 7, cholesteatoma removal n = 1, septoplasty n = 1, pacemaker lead revision n = 1, spinal surgery n = 2, dental n = 1, retinal detachment n = 1, gynecology n = 2.

Table 2. Description of Adverse Events

<table>
<thead>
<tr>
<th>Event</th>
<th>n (%)</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sent to ward without CPAP. Opioids administered. Unwitnessed respiratory arrest.</td>
<td>5 (21%)</td>
<td></td>
</tr>
<tr>
<td>Opioids administered. Unwitnessed respiratory arrest.</td>
<td>7 (29%)</td>
<td></td>
</tr>
<tr>
<td>Premature extubation. Unable to reintubate.</td>
<td>7 (29%)</td>
<td>n = 3 of 7 were UPPP</td>
</tr>
<tr>
<td>Opioids given during procedure. Hypoxic arrest.</td>
<td>3 (13%)</td>
<td>n = 1 tooth extraction</td>
</tr>
<tr>
<td></td>
<td></td>
<td>n = 1 episiotomy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>n = pacemaker lead revision</td>
</tr>
<tr>
<td>Postextubation pulmonary edema.</td>
<td>1 (4%)</td>
<td>n = 1 UPPP</td>
</tr>
<tr>
<td>Postoperative hypoxia.</td>
<td>1 (4%)</td>
<td>n = 1 UPPP</td>
</tr>
</tbody>
</table>

Note: UPPP = uvulopalatopharyngoplasty.
postoperative respiratory monitoring protocols for patients with OSA.

**Comment**

These results should be a wake-up call for anesthesia providers! Even though the numbers of cases in this review is very small compared to the millions of anesthetics performed in the United States, the results suggest room for improvement. Our responsibility to the patient should not just end when the patient leaves the operating room. We need to make sure safety measures are in place to protect the patient during the postoperative period. Anesthesia providers should take the lead in developing preoperative screening and postoperative continuous respiratory monitoring protocols (i.e., use of continuous end tidal carbon dioxide and pulse oximetry), and educating surgeons and nurses on the risks and ways to prevent complications in patients with Obstructive Sleep Apnea (OSA). We should also stay up-to-date and proficient with the latest advances in difficult airway management and guidelines for management of OSA. These guidelines include techniques such as extubation when fully awake, full reversal of paralysis, extubating in a non-supine position, minimize long-acting opioids, and continuous respiratory monitoring postoperatively. Taking these steps will help reduce the devastating complications described in this report.

**Dennis Spence, PhD, CRNA**

The views expressed in this article are those of the author and do not reflect official policy or position of the Department of the Navy, the Department of Defense, the Uniformed Services University of the Health Sciences, or the United States Government.
Intraoperative Electroencephalogram Suppression Predicts Postoperative Delirium

Anesth Analg 2016;122:234–42
Fritz BA, Kalarickal PL, Maybrier HR, Muench MR, Dearth D, Chen Y, Escallier KE, Ben Abdallah A, Lin N, Avidan MS

Abstract

Purpose  The purpose of this study was to look for an association between EEG burst suppression during general anesthesia and postoperative delirium.

Background  Delirium is a syndrome of cognitive decline which includes inattention and disorganized thinking. The level of cognitive decline often fluctuates. It may develop over hours or days after surgery and is not uncommon postoperatively. The incidence of postoperative delirium has been reported to be a low of 10% of patients to a high of 70% and depends partly on the type of surgical procedure. Patients with delirium spend longer in the ICU and have an increased cost of care. Patients who develop long-term delirium are more likely to be institutionalized, die, or develop dementia.

Some electroencephalographic (EEG) patterns during anesthesia have been associated with adverse outcomes. For example, patients with increased low-frequency EEG activity during rewarming from cardiopulmonary bypass were more likely to have delirium postoperatively. EEG burst suppression is defined by periods of little to no EEG activity alternating with short periods of high voltage (amplitude) EEG activity. Burst suppression is known to occur during hypothermia, deep general anesthesia, and as the result of pathologic conditions. Few studies have examined risk factors for burst suppression during general anesthesia.

Methodology  This was a prospective, observational study of adult patients who received general anesthesia followed by a planned ICU admission. All patients had their EEG monitored intraoperatively. Neurosurgical patients were not eligible for the study. The general anesthetic technique was not controlled but typically included a propofol induction followed by maintenance with isoflurane, sevoflurane, or desflurane with or without nitrous oxide. EEG was monitored continuously during anesthesia from a single frontal EEG channel (positions FP1 to F7). Data was captured automatically at 1 minute intervals as a “suppression ratio.” Data points with a “signal quality index” of <50% were excluded from analysis as were patients with poor quality data for more than half the duration of surgery. In the ICU, nurses assessed delirium with the Confusion Assessment Method for the ICU (CAM-ICU) twice a day. The CAM-ICU assessment was omitted if the patient was too heavily sedated. A CAM-ICU positive for delirium between post-op days 1 and 5 was the definition of...
postoperative delirium in this study. To make meaningful comparisons of the dose of inhaled anesthetic administered, agent concentrations were converted into age-adjusted MAC values. Cumulative patient burst suppression data was described by dividing the patients into quartiles based upon the total duration of burst suppression observed during their anesthetic. [See Editor’s Note at the end for a description of a quartile.]

**Result**  
Intraoperative EEG data was collected from 727 patients. In 141 of 727 cases (19%), automatic data collection was unsuccessful. In those cases, data was collected manually at 5 minute intervals. Participants were more likely to be male (64%), average age 62 years, and almost all underwent cardiac surgery (87%). The median duration of burst suppression was 4.5 minutes. Assessment for delirium in the ICU was completed in only 619 patients. Of these, 162 patients (26%) experienced delirium. The longer the total duration of burst suppression during anesthesia, the more likely the patient was to experience delirium (P< 0.0001). Periods of burst suppression of a minute or less had little, if any, effect on the incidence of delirium. Burst suppression of 5 minutes or longer was associated with an incidence of delirium about twice that of patients with no burst suppression at all.

Receiving a blood transfusion or undergoing a coronary artery bypass also significantly increased the risk of experiencing delirium. Patients who received lower doses of opioids intraoperatively were more likely to have burst suppression.

**Conclusion**  
In this study, longer durations of burst suppression during general anesthesia were associated with a greater incidence of postoperative delirium. EEG burst suppression can easily be monitored with currently available equipment. However, this study methodology was not designed to determine a cause and effect relationship between EEG burst suppression and postoperative delirium.

**Comment**  
I need to begin by disclosing that I’m not terribly impressed with this study. I’ve chosen the article because I think the topic is important, and I think we are going to be seeing more research in this area. We need to be up-to-date on the scientific evidence surrounding postoperative delirium.
The good news is that burst suppression is fairly easy to monitor with equipment currently available to use in the OR. You don’t need to be able to read an EEG to spot it. And, preventing burst suppression is achievable as well. Using more opioids, nitrous oxide, or anything else that deepens anesthesia and less potent inhalation agent makes burst suppression much less likely. With a little practice it should be possible to eliminate burst suppression completely in most cases. But none of this is important unless burst suppression causes delirium and this study does not show cause and effect.

My Reservations First of all, 15% of patients who had no burst suppression did have delirium so there is obviously something going on to cause delirium other than or in addition to burst suppression. Thus, even if burst suppression causes delirium, preventing burst suppression will only help reduce the incidence of delirium; it won’t eliminate it. Next, since we don’t understand the mechanism by which delirium is produced, right now we’re sort of feeling around in the dark for risk factors. We know, for example, that blood transfusions and coronary artery bypass surgery are also risk factors for delirium. Most of these patients had coronary artery bypass grafts. We’ve long known that this procedure and/or being on bypass increased the risk for cognitive problems postoperatively. So did burst suppression cause delirium or did the CABG or pump time do something to cause delirium and also cause the burst suppression? We don’t know. But if it is the latter, then burst suppression is only a side effect and preventing it won’t prevent delirium. Lastly, there were many patients recruited into this observational study whose data weren’t analyzed, either because they were unable to collect burst suppression data during the anesthetic or because they didn’t perform the delirium assessment. I’m always concerned when too many patients are recruited into a study but then not analyzed, but it is the patients who weren’t assessed for delirium in the ICU I’m most concerned about. I suspect they weren’t assessed because they didn’t stay in the ICU long enough. Who gets discharged from the ICU the fastest? Not the patients with delirium. So, they may have failed to analyze data from a bunch of patients who did have burst suppression but didn’t have delirium.

We here at AnesthesiaAbstracts.com will be on the lookout for other articles on this topic and bring you more information as it is available.

Michael A. Fiedler, PhD, CRNA

Note: Quartiles are a descriptive statistic that divides the data points into four equal parts. In this case, each patient was represented by one data point which was the amount of time during which they experienced burst suppression.
PERIOPERATIVE MORTALITY, 2010 TO 2014: A RETROSPECTIVE COHORT STUDY USING THE NATIONAL ANESTHESIA CLINICAL OUTCOMES REGISTRY

Anesthesiology 2015;123:1312-21
Whitlock EL, Feiner JR, Chen L

Abstract

Purpose The purpose of this study was to present a preliminary analysis of the National Anesthesia Clinical Outcomes Registry which examined factors associated with perioperative mortality – death within 48 hours of surgery.

Background Perioperative mortality has significantly decreased in high-income countries over the last five decades. Much of this improvement is related to advances in anesthesia and surgical techniques. In 2010, the American Association of Anesthesiologists, Anesthesia Quality Institute created the National Anesthesia Clinical Outcomes Registry (NACOR) to collect demographic and outcome data from anesthesia practices across the United States.

The NACOR collects de-identified billing and electronic health records data from anesthesia practices that participate in the registry. Currently, the registry contains over 30 million anesthesia cases from 500 anesthesia practices at more than 2,500 facilities. [Contributing Editors Note: no data is available on provider type, MD or CRNA.]

Methodology This was a retrospective analysis of predictors of perioperative mortality (death within 48 hours) on 2,948,842 cases from 60 practices providing anesthesia at 197 facilities around the country between 2010 and 2014. Anesthesia providers self-reported mortality and other outcomes. Vaginal deliveries were excluded, as were cases without procedure information. Hierarchical logistic regression was used to examine predictors for cases which had information included in the registry on outcome, ASA status, gender, age, emergency case status, time of day, surgery type, and anesthesia technique.

Result The analysis included 2,866,141 cases. The mean age of patients was 50 ± 22 years, and 42% were male. Of the patients included, 28% were ASA 3, 6% ASA 4, and 0.2% ASA 5. Only 3% were emergency procedures, and the majority of surgeries were abdominal or pelvic (34%) performed under general anesthesia (60%). Only 5.5% of cases were performed between 6 pm and 7 am. The geographic distribution of cases within the USA follows:

- 41% South
- 28% Northeast
- 24% Midwest
- 8% West

Seventeen percent were in community hospitals with >500 beds, 14% in University Hospitals, 3% in community hospitals <100 beds, 3% attached surgery centers, 4% freestanding surgery centers, and in 18% the facility type was unknown.
The mortality rate was 33 per 100,000 cases (944 of 2,866,141 cases or 0.033%). The rate was relatively stable over the study period (2010 to 2014). The sickest patients (ASA 4 and 5) had the highest mortality rate. The rate of mortality was 203 per 100,000 for ASA 4 and 5,833 per 100,000 for ASA 5 patients (P < 0.05). Patients under the age of 1 (89 per 100,000 cases) and ≥80 years (75 per 100,000 cases) had the highest mortality rates. Patients under the age of 1 were four times more likely to die within 48 hours of surgery when compared to patients between 19 years and 49 years old (95% CI, 2.38-7.05); patients ≥80 years old were 2.23 times more likely to die within 48 hours (95% CI, 1.62-3.08) compared to those aged 19 years to 49 years. Patients undergoing emergency surgery were 2.7 times more likely to die within 48 hours of surgery compared to those undergoing elective surgery (95% CI, 2.07-3.52). Patients having surgery after 1600 had significantly higher mortality (1600-1759, OR = 1.64, 95% CI, 1.22-2.21; 1800-2259, OR = 1.69, 95% CI, 1.26-2.28; 2300-0659, OR = 1.97, 95% CI, 1.43-2.7) when compared to those undergoing surgery during normal working hours (0700-1559). The rate of mortality between 1800 and 0659 was 87 per 100,000 as compared to 18 per 100,000 from 0700-1559 (Figure 1). Thorax/neck and radiological surgery types had the highest reported mortality (Figure 2).

The most common non-mortality outcomes were major and minor hemodynamic instability (35%), major and minor respiratory complications (8.1%) including airway/intubation (1.7%), upgrade of care (4.2%), and resuscitation (2.8%).

Figure 1. Mortality Rate by Time Period

Figure 2. Mortality Rate by Surgery Type
**Conclusion**

Very sick patients (ASA 4 and 5), extremes of age (<1 or ≥80 years old), and surgical cases starting after 1600 were factors associated with higher rates of perioperative death. Further research is needed to confirm these findings.

**Comment**

Large registry studies are needed to examine relatively rare complications such as perioperative mortality. Findings from studies such as this one can help inform the development of future prospective studies seeking to reduce morbidity and mortality after surgery.

The results of this study are not surprising. Patients that are very sick (ASA 4) and not expected to survive without surgery (ASA 5) had the highest mortality, especially when presenting for emergency surgery after normal working hours (after 1600). This is when there are less personnel and resources available at most facilities, especially at community hospitals, which represented the largest portion of cases included in the NACOR.

So what can you do with these results? Make sure you have all the resources and support personnel needed to take care of patients requiring emergency surgeries after hours. Consider asking the question, “Does this case have to be performed tonight, or can we do it in the morning?” If you take call, make sure to take frequent naps and use fatigue-mitigation strategies to minimize the effects of fatigue on performance.

**Dennis Spence, PhD, CRNA**

The views expressed in this article are those of the author and do not reflect official policy or position of the Department of the Navy, the Department of Defense, the Uniformed Services University of the Health Sciences, or the United States Government.

1. [https://www.aqihq.org/contributors-list.aspx](https://www.aqihq.org/contributors-list.aspx)
**Abstract**

**Purpose** The purpose of this study was to test the hypothesis that exposure to general anesthesia after age 40 was associated with Mild Cognitive Impairment.

**Background** General anesthesia and surgery are associated with temporary “postoperative cognitive dysfunction” in some patients; more commonly the elderly and more commonly after cardiac surgery. It is unknown whether or not such transient postoperative cognitive dysfunction can cause long-term cognitive impairment. Even hospitalization without surgery is associated with an increased risk of dementia in the elderly. Some animal studies suggest that exposure to inhalation agents may result in structural changes in brain cells resulting in some level of dementia. Clinical research has not produced an association between general anesthesia and dementia. “Mild Cognitive Impairment” (MCI) has been suggested as a diagnosis useful to study the effects of general anesthesia on later cognitive changes. Mild Cognitive Impairment has been defined as “a stage of cognitive impairment between normal function and dementia.”

The Mayo Clinic Study of Aging is a long-term prospective study that includes a “rigorous longitudinal assessment of cognitive function” designed to examine cognitive decline in residents of Olmsted County, Minnesota. The Mayo Clinic Study of Aging has identified a number of risk factors for Mild Cognitive Impairment (MCI):

- age
- education level
- gender
- Apolipoprotein E genotype
- diabetes mellitus
- depression
- cardiovascular disease
- stroke

The Rochester Epidemiology Project provides access to medical records of Olmsted County residents.

**Methodology** This study of prospectively collected data combined data sources from the Mayo Clinic Study of Aging and the Rochester Epidemiology Project. Patients had a cognitive evaluation before entering into the Mayo Clinic Study of Aging and all had normal cognition when enrolled. Patients between the ages of 70 years and 89 years at the start of this study of cognitive impairment and general anesthesia were included with their permission. Patients who received only a regional block, only local anesthesia, or only sedation were excluded.
MCI was diagnosed based upon the following criteria:

- impairment in 1 of 4 cognitive domains
- cognitive concerns from patient or examiner
- essentially normal functional activities
- absence of dementia

Participants had a cognitive evaluation at 15 month intervals while in the Mayo Clinic Study of Aging. If they had an acute illness, surgery, or medical procedure the cognitive evaluation was delayed for at least a month. Medical records from the Rochester Epidemiology Project were reviewed for each general anesthetic between age 40 years and either the diagnosis of MCI or the end of the study period.

Anesthetic agents for induction and maintenance were recorded along with surgical procedure and duration of anesthesia. Anesthetic exposure was reported as:

- yes or no
- number of anesthetic exposures (0, 1, 2-3, ≥4)
- cumulative time of exposure

Statistical analysis were conducted unadjusted for MCI risk factors and again adjusted for known MCI risk factors (age, diabetes, cardiovascular disease, etc.). A third analysis was performed including only anesthesia exposures after age 60 years.

**Result**

The analysis included 1,731 participants who had a mean age of 79 years old when enrolled (but data collection began at age 40 years). In this group of 1,731 participants, 85% (N=1,467) had at least one general anesthetic for a total of 4,967 anesthetics. Of those who had surgery after age 40 years; 19% had 1 anesthetic, 35% had 2-3 anesthetics, and 31% had ≥ 4 anesthetics. Almost all anesthetics (89%) included a potent inhalation agent. The median duration of anesthesia was 129 minutes with 50% of general anesthetic times ranging between 77 min. and 195 min. Induction was most commonly with pentothal (58%) or propofol (40%). Nitrous oxide was used in 75% of cases.

Mild Cognitive Impairment (MCI) was diagnosed in 536 participants (31%). According to the plan, data was first analyzed looking at exposure to general anesthesia from age 40 years old onward. When data was analyzed as anesthesia “yes” or “no,” general anesthesia did not correlate with the development of MCI. When data was analyzed as the number of exposures to general anesthesia (0, 1, 2-3, ≥4), general anesthesia did not correlate with the development of MCI. When data was analyzed as the cumulative time of exposure to general anesthesia, it did not correlate with the development of MCI.

In the secondary analysis of anesthesia exposure after age 60 years, exposure to 1, 2, or 3 general anesthetics was associated with an increased likelihood of developing MCI (P=0.03) but exposure to ≥4 general anesthetics was not associated with MCI. Likewise, the cumulative time participants ≥ 60 years old were exposed to general anesthesia was also not associated with MCI (P=0.63).

**Conclusion**

Exposure to general anesthesia after age 40 years was not associated with Mild Cognitive Impairment (MCI) in persons cognitively normal before age 40 years.
Comment

This study may look a little conflicted, but its message is really quite clear. At first glance it may appear to say that exposure to general anesthesia between the ages of 40 years old and 60 years old does not result in Mild Cognitive Impairment (MCI), but exposure after age 60 does result in MCI. What it really says is that the study did not find any link between exposure to anesthesia in adults and later cognitive impairment. The investigators rightly acknowledge this both in their discussion and conclusions.

So what about the part that says “1, 2, or 3 general anesthetics were associated with an increased likelihood of developing MCI (P=0.03)” after 60 years of age? Well, it also says that ≥4 anesthetics after age 60 were not associated with MCI. Did adding a 4th anesthetic “fix” the cognitive impairment caused by the previous 3 anesthetics? Of course not. Likewise, after age 60 years the cumulative exposure to general anesthesia was not associated with MCI. There are always unknown or unaccounted for factors that can affect the outcome of a study. In this case, some of those factors affected the “1, 2, or 3 general anesthetics” analysis but not the other two analyses. These investigators made a good decision to examine the relationship between general anesthesia and MCI in several ways. It saved them from a misleading result.

Michael A. Fiedler, PhD, CRNA
CONTINUOUS SPINAL ANALGESIA FOR LABOR AND DELIVERY: AN OBSERVATIONAL STUDY WITH A 23-GAUGE SPINAL CATHETER

Anesth Analg 2015;121:1290–4
Tao W, Grant EN, Craig MG, McIntire DD, Leveno KJ

Abstract

Purpose The purpose of this study was to examine the complications and pain relief provided by a new 23-gauge continuous spinal catheter in women requesting labor analgesia.

Background Continuous spinal anesthesia can provide effective labor analgesia and be used to achieve rapid surgical anesthesia for a cesarean delivery. Unfortunately, previous “through-the-needle” continuous spinal catheter techniques with a 28 or 32-gauge catheter through a 21 or 22-gauge needle resulted in a high rate of neurological complications. The proposed mechanism of injury was maldistribution of local anesthetic which exposed nerve roots to a toxic concentration of local anesthetic.

A new continuous spinal catheter has been introduced into practice. Called the Wiley Spinal (Epimed Inc., Johnstown, NY), it is a 23-gauge, 10-cm long, continuous spinal catheter made of micro-thin braided wires with a polyamide coating. The tubing and spinal catheter has 0.8 mL of dead space. The investigators in this study sought to examine rates of post-dural puncture headache, pain relief, motor blockade, and the success rate of conversion to cesarean delivery anesthesia with the Wiley Spinal continuous spinal catheter placed for labor analgesia.

Methodology This was a prospective, observational study. Inclusion criteria were women with a term singleton pregnancy and no more than one previous delivery. Exclusion criteria included greater than 6 cm dilation and/or preeclampsia or meconium-stained amniotic fluid. A single, experienced anesthesia provider placed all spinal catheters. Readers are referred to the Wiley Spinal website to review the placement procedure. All catheters were advanced 3-4 cm into the spinal canal. Next 1 mL of 0.25% preservative-free plain bupivacaine [Editor's Note: NOT hyperbaric.] was injected and a patient-controlled epidural analgesia pump was set to deliver 0.0625% plain bupivacaine with fentanyl 2 μg/mL at a rate of 2 mL/h, demand bolus 1 mL, and lockout interval 20 minutes. If breakthrough pain occurred, the anesthesia provider administered a 1 mL bolus of 0.25% plain, preservative-free bupivacaine. The rate was titrated up in 1 mL increments as needed. If cesarean delivery was required, 0.5% plain, preservative-free bupivacaine, up to 25 mg, was administered to achieve a T-4 level. The catheter was left in place at least 12 hours prior to removal.
Result There were 115 women enrolled in the study. One woman delivered before placement and another woman withdrew from the study during catheter placement because of leg pain during insertion. This left 113 women. The mean age of women was 24 years old. Mean body mass index was 31 kg/m$^2$. Mean cervical dilation at enrollment was 4 cm and 64% were nulliparous. There were 83 (73.5%) spontaneous vaginal deliveries, 12 (10.6%) operative vaginal deliveries, and 18 (15.9%) cesarean deliveries.

Outcomes are listed in Table 1. A little less than a quarter of women experienced a paresthesia during placement of the spinal catheter. Catheter placement was unsuccessful in 12 patients, with an 18% failure rate with the first 50 patients, followed by a reduced failure rate to 6% in the next 63 patients. Pain scores on average were 1 out of 10 during labor. Patients experienced mild to moderate motor blockade. Over a third required an anesthesia provider-administered top-up bolus or evaluation of excessive motor block. Only 1 out of 16 spinal catheters failed at the time of cesarean delivery (6%). Three patients (2.6%) experienced a post-dural puncture headache. No neurological complications were reported at the 30-day follow-up.

| Table 1. Outcomes with Wiley Spinal Continuous Spinal Catheter (N = 113) |
|-----------------------------|------------------|
| **Outcome** | **Rate** |
| Paresthesias during catheter insertion | n = 26 (23%) |
| Withdrew because of leg pain with catheter insertion* | n = 1 |
| Mean time to place spinal catheter | 4.9 ± 3.3 minutes |
| Mean pain scores 30 minutes after placement (0-10) | 1 ± 2 |
| Median modified bromage scale 30 minutes after placement (range 1-6) | 4 (detectable weakness of hip flexion) |
| Provider intervention for breakthrough pain or excessive motor block** | n = 36 (36%) |
| Intrapartum temperature ≥38°C attributed to chorioamnionitis*** | n = 14 (14%) |
| Post-dural puncture headache | n = 3 (2.6%) |
| Unsuccessful placement | n = 12 (10.6%) |
| -Failure rate 1st 50 cases | n = 9 (18%) |
| -Failure rate in next 63 cases | n = 3 (6%) |
| Failure rate at cesarean delivery (16 required cesarean) | n = 1 (6%)*** |
| Median 0.5% bupivacaine dose for cesarean delivery | 15 mg (range 10-25 mg) |
| Postoperative paresthesia in left lower extremity <24 duration**** | n = 1 (0.88%) |

*Note: All spinal catheters placed by the same experienced anesthesia provider. *Patient not included in the N = 113. **Total n = 101. ***Spinal anesthesia performed with 0.75% hyperbaric bupivacaine 12 mg and fentanyl 20 μg because 25 mg of 0.5% plain bupivacaine did not result in a surgical block. ****Patient did not report paresthesia during placement; paresthesia completely resolved 24 hours after delivery.
Conclusion

The Wiley Spinal, 23-gauge spinal catheter was used to safely provide labor analgesia and surgical anesthesia quickly. Further research is needed to determine how this catheter compares to traditional epidural techniques.

Comment

As someone who does a lot of obstetrical anesthesia, I am always curious to learn about new labor analgesia techniques. In this study, the investigators sought to examine a new 23-gauge continuous spinal catheter that was recently introduced to the market. As I watched the video on the Wiley Spinal web site the first thing that came to my mind was that there are a lot of steps to placing this catheter. I would be worried I would have a higher failure and complication rate compared to placing a traditional epidural. The investigators found there was a steep learning curve with this device, with 18% failure rate for the first 50 patients, then a 6% failure rate for the next 63 patients. Also they had three patients who experienced a post-dural puncture headache. These rates are not very encouraging to me; a 6% failure rate and 2.6% post-dural puncture headache rate in an experienced anesthesia provider’s hands seems a little high. I would expect an experienced anesthesia provider to have less than a 2% failure rate with traditional epidural techniques, and a low (less than 2.5%) rate of post-dural puncture headache.

Unfortunately, without a comparison group and randomized controlled design, we do not know how these rates would compare to continuous lumbar epidural or combined spinal epidural techniques. If you get these continuous spinal trays at your institution, I strongly recommend you practice on an epidural simulator first!

Dennis Spence, PhD, CRNA


The views expressed in this article are those of the author and do not reflect official policy or position of the Department of the Navy, the Department of Defense, the Uniformed Services University of the Health Sciences, or the United States Government.
Abstract

Purpose  The purpose of this study was to quantify the growth of aerobic bacteria in stopcock dead space after ambulatory procedures with and without propofol anesthesia. The chief purpose was to determine whether or not propofol resulted in greater bacterial contamination through the first 48 hours after administration.

Background  Propofol is suspended in intralipid because propofol is highly hydrophobic. Propofol intralipid contains soy bean oil, egg phospholipid, and glycerin and is nutrient-rich. Bacteria grow well in it. Shortly after propofol was introduced into clinical practice in the USA, the Food and Drug Administration (FDA) required the addition of a preservative, but this only delayed the growth of bacteria once a container of propofol was opened. Open vials and syringes filled with propofol can produce log-rhythmic bacterial growth by 6 hours after opening even with the preservative. When propofol is drawn up into a syringe with aseptic technique, up to 11% of syringes have been shown to be contaminated in less than 6 hours.

Observational studies have shown that the anesthetists' hands are often the final common pathway for bacterial contamination of the IV stopcock. Bacteria from the hands of anesthesia providers have been shown to contaminate IV stopcocks during anesthesia. Thus, while newly opened IV sets are sterile, they quickly become contaminated through normal use and medication injection. Dead space at injection ports and stopcocks can retain propofol and allow bacterial growth even when propofol is not easily visible in the IV tubing. In Vitro investigation has shown that MRSA* grew in stopcock dead space despite preservative in the propofol and a steady flow rate of IV fluid. Despite these facts, the long-term risk of IV stopcock bacterial contamination after propofol injection has not been studied. The investigators hypothesized that bacterial growth in propofol containing IV stopcock dead space could be detected and would reveal the degree of contamination.

Most institutions have a protocol to change IV sets every 3 or 4 days. When the IV set is used for TPN* or a propofol infusion, sets are often changed more frequently.

Methodology  This was a prospective, double-blind study of IV extension tubing used on patients for short procedures with or without propofol. Anesthesia records were reviewed to ensure that propofol was the only nutrient rich substance injected through the IV set (e.g. no blood products or TPN). Extension sets were collected from patients after short anesthetics, ambulatory surgery with propofol vs. cataracts, and electroconvulsive therapy with methohexital. Stopcock dead space was cultured from 50 extension sets from both groups at 6, 24, or 48 hours.
hours postoperatively. Each extension set was cultured only once (total 300 samples). Bacterial counts > 120 CFU (colony forming units)/mL was considered a significant bacterial burden capable of resulting in bacteremia. (This value is 8 times higher than the minimum value previously shown to result in bacteremia.)

**Result** Ambulatory cases where propofol was used were up to 2 hours long with more than 12 uses of the stopcock. Nonpropofol cases were less than 30 minutes long with less than 12 uses of the stopcock.

Positive cultures were obtained from 17% of propofol stopcocks and 19% of nonpropofol stopcocks. At 6 hours after anesthetic induction, the average number of CFU/mL was low and similar in all stopcocks. Comparing samples with positive cultures at 24 and 48 hours after anesthetic induction, stopcocks with propofol had significantly more CFU/mL than nonpropofol stopcocks.

Average bacterial growth at 24 hours from stopcocks with:
- visible propofol 2,361 CFU/mL
- propofol (not visible) 418 CFU/mL
- nonpropofol group 95 CFU/mL

Average bacterial growth at 48 hours from stopcocks with:
- visible propofol 5,066 CFU/mL
- propofol (not visible) 831 CFU/mL
- nonpropofol group 30 CFU/mL

**Notes:** CFU = Colony Forming Unit. Data are mean number of Colony Forming Units/mL.

[Editor’s Note: the threshold for bacteremia was defined as >120 CFU/mL.]

Sources of the bacteria were likely skin flora (patient and care providers) as well as objects in the surrounding environment. Most were gram-positive cocci. [Editor’s Note: frequent causative agents of pneumonia and septicemia.]

**Conclusion** Bacterial growth in IV stopcock dead space occurs quickly (bacterial amplification) starting about 6 hours after propofol induction, whether or not propofol is visible in the IV stopcock dead space. Hand hygiene is even more important when propofol is being used. IV sets probably need to be changed after propofol anesthesia to reduce the risk of bacteremia and systemic infection.

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**Figure 1: Propofol in Dead Space**

**Table 1: Bacterial Growth over Time**

<table>
<thead>
<tr>
<th>SAMPLE TIME</th>
<th>PROPOFOL (VISIBEL)</th>
<th>PROPOFOL (NONVISIBEL)</th>
<th>NONPROPOFOL</th>
<th>P VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 hours</td>
<td>44</td>
<td>42</td>
<td>37</td>
<td>NS</td>
</tr>
<tr>
<td>24 hours</td>
<td>2,361</td>
<td>418</td>
<td>95</td>
<td>0.04</td>
</tr>
<tr>
<td>48 hours</td>
<td>5,066</td>
<td>831</td>
<td>30</td>
<td>0.03</td>
</tr>
</tbody>
</table>
Comment
To review, extension tubing was taken from patients’ IVs after short anesthetics with and without propofol as the induction drug. At 6 hours, 24 hours, and 48 hours after induction, the stopcock dead space was cultured. “Only” about 17% of propofol stopcocks and 19% of nonpropofol stopcocks cultured positive. But of those that did, the results were dramatic. At 6 hours after induction, none of the samples had significant bacterial growth. In the case of propofol this was probably due to the preservative that is designed to inhibit bacterial growth for about 6 hours. But at 24 hours and 48 hours after induction, positive cultures from the propofol group produced far more CFU/mL than positive cultures from the nonpropofol group, whether or not you could see residual propofol in the stopcock. At 48 hours after induction, there were 168 times more CFU/mL in the visible propofol group than the nonpropofol group. This should make us all worry about bacteremia, pneumonia, and septicemia in patients who had a propofol induction.

It is clear that hand hygiene plays a major role in the contamination of the IV system during anesthesia and that this increases the risk of patient morbidity.1,2,3 But it is my belief that normal hand hygiene procedures can’t solve this problem. We simply must interact with the environment and the patient’s IV too frequently during an anesthetic to wash or sanitize our hands often enough.4 Washing and sanitizing more is good, but I don’t believe it can ever solve this problem.

So what can we do? I see three things. 1) Accept that this is a problem. This study convinces me there is a high probability that almost 20% of patients who get a propofol induction will have a bacteremia sometime after the 6-hour point if we do nothing to prevent it. 2) Make certain the IV set down to the IV catheter itself is replaced at the end of the anesthetic. Strong consideration should be given to replacing the IV set intraoperatively during very long cases. 3) Don’t inject propofol through anything you can’t throw away later to eliminate this risk, a port-a-cath for example.

Michael A. Fiedler, PhD, CRNA


MRSA = methicillin- resistant Staphylococcus aureus
CFU = colony forming units
TPN = Total Parenteral Nutrition