Failed Spinal Anesthesia Tied to Cold Temperature

BY MIRIAM E. TUCKER

FROM THE ANNUAL MEETING OF THE SOCIETY FOR OBSTETRIC ANESTHESIA AND PERINATOLOGY

SAN ANTONIO — A cluster of 14 cases of failed spinal anesthesia among women undergoing C-sections in Pittsburgh during the winter of 2008-2009 was linked to chemical alteration that is believed to be the result of exposure of the anesthetic to subfreezing temperatures during the shipping process.

Failed spinal anesthesia can have significant clinical consequences, possibly necessitating redosing, conversion to general anesthesia, or pain during surgery.

"Efforts to identify and reduce the incidence of failed neuraxial anesthesia are of utmost importance, considering the increased use of these techniques in obstetric cases," Dr. Manuel C. Vallejo Jr. said at the meeting.

The 14 cases, spanning an 8-week period, were all associated with three particular lots of unexpired BD spinal anesthesia trays. The cases were all under the care of experienced staff anesthesiologists and were associated with standardized neuraxial technique using hyperbaric bupivacaine 12 mg (0.75% with dextrose 8.25%) plus 20 mcg fentanyl plus 0.2 mg Duramorph (morphine). A 25-gauge Whitacre needle was used, and the free flow of cerebrospinal fluid was confirmed before and after the intrathecal drug placement, Dr. Vallejo reported.

His team at Magee-Women's Hospital contacted the bupivacaine manufacturer, Hospira Inc.; the spinal kit manufacturer, BD (Becton, Dickinson, and Co.); and the Food and Drug Administration, noting that the clustering of failures suggested problems with concentration/formulation or drug stability. Hospira tested samples from the drug lot and found no formulation or concentration issues.

VITALS

Major Finding: Fourteen cases of failed spinal anesthesia were attributed to chemical alteration from cold temperature exposure.

Data Source: Experience at Magee-Women's Hospital, Pittsburgh.

Disclosures: None was reported.

For its part, BD replied that Hospira's testing showed that "all testing was within specification," and that "we were unable to find the cause of the insufficient anesthesia identified in your report."

The company also said that the drug supplier would "continue to monitor for the complaint condition through normal inspection and sampling procedures."

The negative batch analysis, normal product potency, and unremarkable testing of retained samples by Hospira led Dr. Vallejo and his team to suspect that the problem was related to drug stability issues in transit and/or storage of the spinal kit.

There had been a cold spell starting during the first week of December, during which the temperature was never above freezing, ranging from 15.4° to 30.9° F.

The bupivacaine is made in Indianapolis by Hospira and is shipped to BD in New Jersey, where the spinal kits are assembled. The suspect kits had been shipped to a warehouse in Pittsburgh, loaded onto a nonenvironmentally controlled truck in the evening, and unloaded at Magee the following morning, thus having been stored for more than 9 hours at temperatures below freezing before delivery, Dr. Vallejo said.

A mass spectrometric analysis done at the University of Pittsburgh demonstrated that there had been chemical alteration of the bupivacaine involved. The suspect sample had a molecular mass to charge ratio of 276, compared with 289 for normal bupivacaine.

They suspected the problem was related to drug stability issues in transit and/or storage of the spinal kit after a cold spell with temperatures below freezing.

As a temporary solution, a separate bupivacaine ampule was affixed to the suspect spinal kits, and temperature indicator strips were used.

All 14 of the women and newborns were fine with no long-term problems, he noted.

BD now directly drop ships the packaged spinal kits to Magee-Women's. These measures have dramatically decreased but not eliminated the rate of failed spinal anesthetics, Dr. Vallejo commented, adding that other factors may also contribute, including technical failure, inadequate patient position, inadvertent subdural or epidural injection, inadequate intrathecal dose, and "rachiresistance," a phenomenon described in 1934 in which patients are "hyperresistant" to spinal anesthesia, possibly because of insensitive nerve roots.

"I think it's multifactorial, but we definitely showed a chemical alteration," he noted.

During the question and answer period, an audience member from Toronto said that approximately 400 cases of failed spinal anesthesia had been reported in the province of Ontario in October 2009 and were also suspected to be a result of cold temperature exposure.

"There's definitely a problem," Dr. Vallejo replied.

Asked to comment specifically for this story, BD replied in part: "Patient safety and quality of our products are BD's foremost priorities. The causes of failed regional anesthesia are multifactorial and an industrywide phenomenon. They are typically not associated with any single manufacturer's product.

"Evaluations of our complaint records do not show a correlation between the shipment of product during cold or hot months and complaint rates. The rate remains stable across the year.

"We are conducting a more extensive, controlled study to evaluate this hypothesis. When this investigation is completed, BD will take all actions deemed necessary and appropriate by the study, if any." ■

Obstetric Anesthesia Complications Database Is Established

BY MIRIAM E. TUCKER

FROM THE ANNUAL MEETING OF THE SOCIETY FOR OBSTETRIC ANESTHESIOLOGY AND PERINATOLOGY

SAN ANTONIO — Serious obstetric complications occur in approximately 1 in 1,900 deliveries and serious anesthesia-related complications in about 1 in 3,000, according to data from a large multisite repository.

The Society for Obstetric Anesthesia and Perinatology Serious Complication Repository (SOAP SCORE) project was established in 2004 with the aim of gathering accurate data on the incidence of both overall obstetric- and obstetric anesthesia–related complications, as well as additional information about the complications that could inform future obstetric anesthesia practice.

Until now, complication rates reported in the literature have varied dramatically. "From this database, we can tell you that the rate of serious anesthesia-related obstetric complications is very low," said Dr. Robert D'Angelo, professor of anesthesiology at Wake Forest University, Winston-Salem, N.C.

Data were collected on a quarterly basis from 25 institutions between Oct. 1, 2004, and June 30, 2009. Of a total 307,500 deliveries, approximately 257,000 (84%) involved anesthesia and 96,000 were cesarean sections. Regional anesthesia was used in about 76% of the vaginal deliveries and in 69% of the C-sections. There were a total of 158 serious complications, for a rate of 1 in 1,900 deliveries. Of those, 84 were deemed to be related to anesthesia, for a rate of 1 in 3,000. Failed regional anesthesia occurred in 1.7%.

VITALS

Major Finding: High spinal block occurred with 1 of every 4,300 regional anesthetics. Other anesthesia-related serious complications were far less common, including respiratory distress during labor and delivery in 1 in 10,000, unrecognized spinal catheter in 1 in 15,000, and severe neurologic injury in 1 in 36,000.

Data Source: The Society for Obstetric Anesthesia and Perinatology Serious Complication Repository.

Disclosures: None was reported.

Failed intubation occurred with 1 of every 533 general anesthetics, and high spinal block in 1 of every 4,300 regional anesthetics. Other anesthesia-related serious complications were far less common, including respiratory distress during labor and delivery in 1 in 10,000, unrecognized spinal catheter in 1 in 15,000, and severe neurologic injury in 1 in 36,000. The rate of epidural abscess/meningitis related to anesthesia was 1 in 63,000, while the rates of anesthesia-related myocardial infarction and cardiac arrest were both just 1 in 128,000. Rarest of all was epidural hematoma, in 1 in 250,000.

'The rate of serious anesthesia-related obstetric complications is very low.'

DR. D'ANGELO

There were 30 maternal deaths and 5 cases of anaphylaxis, but none was deemed to be anesthesia related. There were no aspirations, Dr. D'Angelo said.

High spinal block was the only anesthesia-related complication reported in large enough numbers to allow for generalizations regarding associated risk factors. Of the 58 high spinal blocks reported, 14 were the result of an unrecognized spinal catheter. Of the remaining 44, known risk factors were identified in 32. The most common of these were obesity and spinal anesthesia following failed epidural.

Data were also collected on postdural puncture headaches (PDPH). Of the 1,647 reported PDPH, 917 (56%) were treated with epidural blood patch, and 98 (11% of EBP) required a repeat blood patch.

In October 2008, the American Society of Anesthesiologists formed the Anesthesia Quality Institute (www.aqihq.org), a large national database that is currently gathering information on all anesthesia practice, including obstetric.

They plan to publish their first set of findings by January 2011, Dr. D'Angelo said in an interview. ■