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Microcatheter Holds Appeal in Continuous Intrathecal Analgesia

Device studied in small series of obstetric cases

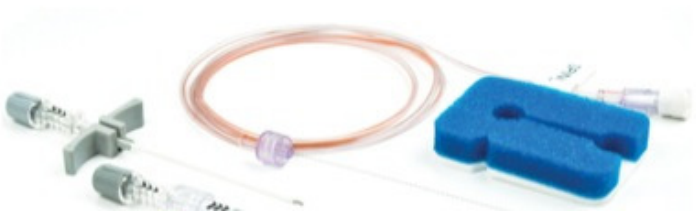
by Karen Blum

A microcatheter approved for regional anesthesia also holds promise for intrathecal labor analgesia, according to researchers at the University of Pennsylvania School of Medicine, in Philadelphia. The findings of the ongoing study, reported at the 2011 annual meeting of the Society for Obstetric Anesthesia and Perinatology, demonstrated successful use of the device in four of six laboring patients (abstract 22).

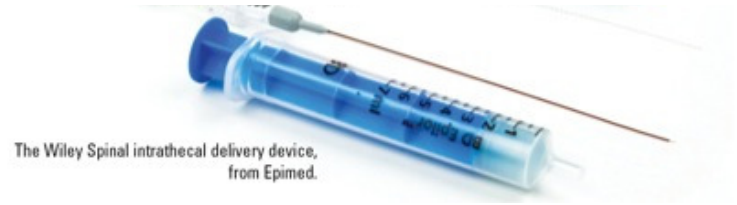
The intrathecal delivery device (Wiley Spinal, Epimed) comprises a 23-gauge end-orifice, Coude-tipped cannula over a 27-gauge pencil-point needle. After identification of the epidural space by the loss-of-resistance technique, the device is inserted through a peel-away plastic introducer. The cannula, inserted into the subarachnoid space similarly to an IV cannula, is connected to infusion tubing at the skin surface via an integrated connector. The device is FDA-approved for intermittent administration of intrathecal medication in regional anesthesia.

The four cases in which the device was used successfully included a patient scheduled for repeat cesarean delivery, a patient undergoing vaginal delivery and induction of labor in two patients—one with gestational hypertension and the other with maternal congenital cardiac disease. The latter two patients eventually had cesarean deliveries. All of these patients reported being “completely satisfied” with their anesthetic and said they would recommend the device, according to the researchers.

In two additional patients, anesthesiologists were unsuccessful in using the device: In one patient, the cannula could not be inserted because of paresthesia; in the second patient, there was no flow of cerebrospinal fluid from the cannula and no anesthetic effect after local injection. Of the total of six patients, none developed postdural puncture headache.



Microcatheters were embraced by the obstetric community in the late 1980s and early 1990s because the amount of anesthetic delivered to



The Wiley Spinal intrathecal delivery device, from Epimed.

patients could be limited and patients could be converted easily from labor delivery to emergency cesarean delivery, according to senior author Valerie A. Arkoosh, MD, MPH, professor of clinical anesthesiology and critical care, and clinical obstetrics and gynecology at Penn.

But in 1991, four cases of cauda equina syndrome—a serious condition caused by compression of the nerves in the lower spinal canal—associated with continuous intrathecal anesthesia in nonobstetric patients were reported to the FDA. After receiving reports of 11 cases of cauda equina syndrome, the FDA in 1992 required the manufacturers of continuous intrathecal catheters, 27-gauge or smaller, to withdraw their products from the market. The drug used in all 11 cases was 5% hyperbaric lidocaine at more than 100 mg, and investigators later concluded that microcatheters were not to blame. Yet since that time, only large-bore epidural catheters have been used to administer continuous intrathecal analgesia.

The FDA recognized that microcatheters would still be helpful for obstetric patients, and Dr. Arkoosh subsequently directed a national study to compare the safety of continuous intrathecal labor analgesia using a 28-gauge catheter with continuous epidural labor analgesia (*Anesthesiology* 2008;108:286-298). The patients who received continuous intrathecal analgesia had better early analgesia, less motor blockade and higher maternal satisfaction with pain relief at 24 hours postpartum; there were no differences in obstetric outcomes or postdural puncture headache between analgesia strategies.

There were some technical difficulties with the microcatheters used in the earlier study, Dr. Arkoosh said. Fluid could not be aspirated with them, and they had a tendency to break easily because they were so thin. She said the long, IV-like Wiley catheter has a large enough diameter to aspirate fluid and does not break as easily.

Dr. Arkoosh, whose group received the catheters from Epimed but no money from the company for their study, said some patients have experienced paresthesia in their legs when the needle is inserted: “It’s not dangerous, but it is something we’re very cautious about.” She said the catheter has been particularly effective in patients with severe heart problems, allowing anesthesiologists to use opioid analgesics that have fewer hemodynamic side effects.

Although Dr. Arkoosh said she believes the design of the device needs refining, she is encouraged by the results so far. “I’m pleased that this catheter is stronger and you can aspirate fluid from it. It helps us know we’re in the right place,” she told *Anesthesiology News*.

Brendan Carvalho, MBBCh, associate professor of anesthesia at Stanford University School of Medicine in Stanford, Calif., started a clinical trial in 2009 of patients scheduled for cesarean delivery to compare the administration of anesthetics by the Wiley Spinal device with typical spinal catheters. He put the study on hold because he and his colleagues encountered technical difficulties with the Wiley device. Dr. Carvalho said he is waiting on a

few minor modifications to the design of the device before resuming his trial. “The appeal with the Wiley is [the] very small gauge—the smaller, the better because of the headache risk,” he told *Anesthesiology News*. “There is definitely a clinical need for an intrathecal catheter and this device has a lot of potential to fill the need.”