Continuous Spinal Analgesia for Labor and Delivery: An Observational Study with a 23-Gauge Spinal Catheter

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BACKGROUND: The aim of the study was to assess postdural puncture headache, pain relief, motor blockade, and success rate of conversion to cesarean delivery anesthesia of a 23-gauge spinal catheter (Wiley Spinal®) for labor analgesia.

METHODS: After insertion of the spinal catheter, intrathecal bupivacaine 2.5 mg was administered, followed by patient-controlled intrathecal analgesia (basal infusion of 0.0625% bupivacaine with fentanyl 2 μg/mL at a rate of 2 mL/h, demand bolus 1 mL, lockout interval 20 minutes). Bupivacaine 0.5%, up to 25 mg, was administered via the catheter along with fentanyl 20 μg for cesarean delivery anesthesia, if necessary. The catheter was removed after delivery or after 12 hours, whichever was longer.

RESULTS: One hundred thirteen women were enrolled. In 12 women (11%), the catheter was not successfully inserted or maintained in position. Continuous spinal analgesia was used in 101 women. Three women (2.6%, 95% confidence interval, 0.7%–8.1%) developed postdural puncture headache. There were 83 spontaneous, 12 operative vaginal, and 18 cesarean deliveries. Of the 18 cesarean deliveries, 16 had continuous spinal analgesia when the decision was made to perform a cesarean delivery; conversion from labor analgesia to cesarean anesthesia was successful in 15 women (94%, 95% confidence interval, 67.7%–99.7%).

CONCLUSIONS: The 23-gauge spinal catheter can be used for analgesia for labor. It can also be converted to surgical anesthesia for cesarean deliveries. Further studies are warranted to determine whether the spinal catheter will be a useful addition to the neuraxial techniques available for obstetric anesthesia care. (Anesth Analg 2015;121:1290–4)

Continuous spinal analgesia via a spinal catheter offers rapid-onset labor analgesia and the potential to convert to surgical anesthesia for operative vaginal or cesarean deliveries.12 Previous experience with spinal catheters was largely based on the “catheter-through-the-needle” design, with a 28- or 32-gauge catheter through a 21- or 22-gauge needle. The very small internal diameter of the catheters allowed only very low flow rates, which, together with the use of hyperbaric solutions, likely caused laminar flow and pooling of local anesthetics within the intrathecal space. This maldistribution within the cerebrospinal fluid (CSF) exposed nerve roots to locally elevated concentrations of anesthetics, which were widely regarded as the cause of observed neurological complications.3

An alternative spinal catheter design uses the “catheter-over-the-needle” technique, allowing a 22- or 23-gauge catheter to be tacked over a 25- or 27-gauge needle.4 In the current study, we aimed to assess the incidence of postdural puncture headache (PDPH), pain relief, motor block, and the success rate of conversion from labor analgesia to surgical anesthesia, should operative delivery become necessary, of a commercially available 23-gauge spinal catheter.

METHODS

Study Design
This prospective observational cohort study was approved by the IRB of the University of Texas Southwestern Medical Center and performed at Parkland Memorial Hospital, Dallas, Texas. Women presenting to the labor and delivery unit were screened from 7:00 AM to 5:00 PM, Monday through Friday, excluding holidays, when the principal investigator was available. Parturients with a singleton cephalic fetus at 37 weeks or greater gestation with no more than 1 prior birth at a cervical dilation of 6 cm or less at the time of request for analgesia were eligible for inclusion. Women with pregnancy-induced hypertension and meconium-stained amniotic fluid were excluded. Written informed consent was obtained from all women.

Catheter Insertion and Management
The 23-gauge, 10-cm long, continuous spinal catheter is made of micro-thin braided wires with polyamide coating without depth markings (part number 40947, Wiley Spinal®, Epimed Inc., Johnstown, NY). Catheter insertion was performed by one person. Briefly, an 18-gauge

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epidural needle with a peel-way plastic sheath was introduced into the epidural space under local anesthesia. The plastic sheath served as a conduit, allowing the catheter kit to be advanced into the intrathecal space. The catheter kit included the catheter with a 27-gauge internal needle. In our initial experience, we injected 1-mL bupivacaine 0.25% via the needle upon feeling the first “pop” and visualized CSF in the needle hub before advancing the catheter into the intrathecal space. This practice accounted for cases in which the catheter was unintentionally sited in the epidural space. We later changed the practice to advancing the entire kit into the intrathecal space, sensing 2 pops and confirming CSF in the catheter hub before injecting the bupivacaine via the catheter. After the initial bolus injection, the catheter was advanced to 3 to 4 cm into the intrathecal space and connected to an extension tubing set (91 cm). A 2.5-cm-thick, precut support cushion provided housing for the connecting hub to minimize discomfort. An adhesive membrane was placed over a support cushion housing the hub, and the edges of the membrane and the extension tubing were secured with silk tapes. The entire tubing and catheter kit had a deadspace of approximately 0.8 mL. This deadspace was taken into consideration when manual boluses of local anesthetic solution were administered.

Patient-controlled intrathecal analgesia was initiated for maintenance of analgesia (basal infusion of 0.0625% bupivacaine with fentanyl 2 μg/mL at a rate of 2 mL/h, demand bolus 1 mL, lockout interval 20 minutes). If the catheter could not be successfully inserted into the intrathecal space, or if it subsequently became malpositioned, it was removed and conventional epidural analgesia provided. If breakthrough pain was not amendable to patient-controlled demand doses, a provider bolus of 1-mL bupivacaine 0.25% was administered. The infusion rate was adjusted in 1 mL/h increments if warranted.

For operative vaginal delivery, bupivacaine 0.25% was administered in 1-mL increments if necessary. For cesarean delivery, bupivacaine 0.5%, up to 25 mg, was administered incrementally to obtain a T4 dermatome sensory level. The catheter was removed after delivery or after 12 hours, whichever was longer.

**Recorded Variables**

Pain was assessed with a visual analog scale (VAS) score that was illustrated on boards posted in patient rooms (VAS, 0: no pain; 10: worst pain imaginable). Motor function was assessed with a modified Bromage motor score: 1 = complete motor block (unable to move feet or knees); 2 = almost complete block (able to move feet only); 3 = partial block (just able to move knees); 4 = detectable weakness of hip flexion (between scores 2 and 5); 5 = no detectable weakness of hip flexion while supine (full flexion of knees); 6 = able to perform partial knee bend. These variables were also recorded at 30 minutes and 2 hours after catheter insertion and at complete cervical dilation. Maternal temperature was checked every 4 hours with an intact amnion and every 2 hours with a ruptured amnion. Fever was defined as temperature ≥38°C. Catheter insertion time (time from local anesthesia skin infiltration to intrathecal injection) and provider interventions (manual boluses, pump adjustments) were also recorded. Paresthesia and pain upon injection were documented as part of the computerized electronic record. Women were followed daily for PDPH and neurological deficits until discharge. The diagnosis of PDPH was made if the headache was positional and associated with at least one of the following symptoms: photophobia, neck stiffness, tinnitus, hypacusia, or nausea/vomiting. Upon discharge, women were instructed to report to the hospital’s intermediate care center (ICC), a designated urgent/emergent triage and treatment center for women, if symptoms of headache or other neurologic symptoms occurred. Medical records were reviewed 30 days after discharge to determine whether there were return visits to the ICC or other clinics for PDPH or other issues related to analgesia and anesthesia.

**Statistical Analysis**

The primary outcome was the incidence of PDPH. We estimated the sample size based on the most recent study of continuous spinal analgesia, in which the incidence of PDPH associated with a 22-gauge dural puncture was 9%. Because the dural puncture size of the current catheter kit was 23 gauge, and we planned to achieve a minimal catheter dwell time of at least 12 hours, we targeted a 25% reduction in PDPH rate (7%), estimated with 5% precision, leading to a sample size of 100 based on standard methods of rates and proportions.

Continuous (e.g., VAS score) and noncontinuous (e.g., modified Bromage scores) variables were compared across time epochs as a repeated measures analysis of variance with time epochs as a random effect (not all patients had observations at each time point). The pairwise comparison between time points was accomplished using contrasts within the repeated measures random effects analysis of variance. Adjustment for multiple testing was accomplished using the method of Tukey. Data were expressed as frequency (percentage), mean ± SD, or median [first quartile, third quartile] when appropriate. The 95% confidence interval (CI) was obtained with the Newcombe-Wilson method (calculation online at http://vassarstats.net/prop1.html). Statistical analysis was performed using SAS, version 9.3 (SAS Institute, Cary, NC), and statistical tests were evaluated as significant for $P$ values <0.05.

**RESULTS**

From November 9, 2011, through April 12, 2013, 160 women were screened and 115 were enrolled in the study. One woman progressed to complete cervical dilation before the procedure started. Another woman withdrew from the study because of pain in her lower extremities during the initial catheter insertion attempt. In the remaining 113 women, the mean (± SD) age was 24.4 ± 5.2 years, with a body mass index of 30.9 ± 4.8 kg/m². Mean cervical dilation at enrollment was 4.0 ± 0.1 cm. Seventy-two (64%) women were nulliparous.

Three women (2.6%; 95% CI, 0.7%–8.1%) were diagnosed with PDPH; all were among women who had confirmed dural puncture with the spinal catheter and were managed by continuous spinal analgesia. They were treated successfully with single epidural blood patches. No headache
occurred in the 12 women managed with traditional epidural analgesia because of technical failures.

In all women, the intrathecal space was accessed with 1 attempt. The mean (SD) time needed to place the catheter was 4.9 ± 3.3 minutes. During the catheter insertion, paresthesias occurred in 26 (23%) women. No women experienced pain on bupivacaine injection. There were 12 women in whom catheter insertion was performed but who did not deliver with the spinal catheter in place. In 9 women, CSF could not be confirmed via the catheter, and infusion could not be initiated because of high resistance (visual inspection of the catheters after removal indicated kinking). In 3 other women, CSF was observed in the catheter during initial placement, but the patients had breakthrough labor pain a few hours later; inspection of the catheter insertion site showed that the depth of the catheter had changed, suggesting that the catheter tip had migrated out of the intrathecal space. Nine of the 13 unsuccessful cases occurred during first 50 women studied, with success rate of 82% in these women compared with 94% in the subsequent 63 women.

Among the 113 study subjects, there were 83 spontaneous, 12 operative vaginal, and 18 cesarean deliveries. No additional mode of analgesia or anesthesia was required for women with spontaneous and operative vaginal deliveries. Of the 18 women with cesarean delivery, 16 were being managed with continuous spinal analgesia when the decision was made to perform a cesarean delivery. Conversion from labor analgesia to surgical spinal anesthesia was successful in 15 of these women (94%; 95% CI, 67.7%-99.7%). The median dose of the plain bupivacaine was 15 mg [10 mg, 20 mg] (range 10–25 mg). In the remaining patient, single-shot spinal anesthesia was induced with 0.75% hyperbaric bupivacaine 12 mg and fentanyl 20 μg as administration of 0.5% plain bupivacaine 25 mg via the spinal catheter did not result in surgical anesthesia. When the decision was made to perform a cesarean delivery in this woman, the spinal catheter had been in place for 15.5 hours, her VAS pain score was 2 cm, and her modified Bromage score was 2, with a T6 dermatome sensory level, and successful aspiration of CSF before injection. Aspiration of CSF after the injection was not attempted.

The VAS and modified Bromage scores are shown in Table 1. Thirty-six women (36%) required provider interventions to treat breakthrough pain or excessive lower extremity weakness. Fourteen women (14%) had an intrapartum temperature ≥38°C attributed to chorioamnionitis. One woman who did not experience paresthesia during catheter insertion developed paresthesia in her left leg after vaginal delivery, but her symptoms resolved in 24 hours without intervention. The mean spinal catheter dwell time was 13.3 ± 1.9 hours, and the hospital discharge time was 2.4 ± 1.5 days. There were no neurological complications at 30-day follow-up.

**DISCUSSION**

The major concern of using a continuous spinal analgesia for labor is PDPH. The size of the dural puncture, among other factors, plays a role in the rate of PDPH.10,11 The mechanism by which the presence of a spinal catheter may reduce the incidence of PDPH is not clear, and this outcome has not been conclusively proven in a randomized trial. In our previous case series,5 and in the current study, we elected to leave the spinal catheter in place for at least 12 hours in an attempt to further decrease the rate of PDPH. The PDPH rate in our study may have been influenced by this approach.

With the initial intrathecal 2.5-mg bupivacaine bolus, the mean VAS score was significantly reduced within 10 minutes, but it started to increase 2 hours after catheter insertion. Previously, Wong et al.12 showed that the analgesia effect of such a dose of bupivacaine without an opioid was often weak and transient. In our institution, previous study suggested that an opioid administered with the initial intrathecal bolus appeared to be associated with fetal bradycardia.13 For this reason, we elected not to use opioid in the initial bolus, hoping the continuous infusion containing fentanyl plus patient-controlled boluses would render most women pain-free. The concentration of fentanyl in the continuous infusion was based on an expert review.1 We are not certain whether this low dose of fentanyl contributed to analgesia or whether increasing the maintenance fentanyl dose could have reduced the incidence of breakthrough pain and the need for physician intervention. In addition, most women had significant motor weakness; this might

**Table 1. Visual Analog Scale Scores and Modified Bromage Scores for Women with the Continuous Spinal Catheter (n = 101)**

<table>
<thead>
<tr>
<th></th>
<th>At enrollment</th>
<th>10 min</th>
<th>30 min</th>
<th>2 h</th>
<th>At complete cervical dilation</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS</td>
<td>9 ± 1</td>
<td>1 ± 1*</td>
<td>0 ± 1*</td>
<td>1 ± 2*</td>
<td>2 ± 3*</td>
</tr>
</tbody>
</table>

Data shown as mean ± SD for VAS scores, and median [first quartile, third quartile] for Modified Bromage Score. 11-point scale: 0 = no pain and 10 = worst pain imaginable.

VAS = visual analog scale.

*aP < 0.001 versus at enrollment.*
be associated with an increased risk of operative vaginal or cesarean delivery. The optimal drug combination and delivery regimen for continuous spinal analgesia for labor require further study.

The continuous spinal technique could offer rapid conversion from labor analgesia to cesarean anesthesia. This conversion was successful in 15 of 16 cesarean deliveries in the current study, including one emergency cesarean delivery. In the one woman in whom continuous spinal analgesia failed to convert to surgical anesthesia, tachyphylaxis could have been a contributing factor.

All 12 women without successful continuous spinal analgesia were managed with conventional epidural analgesia. In these unsuccessful cases, the failures can be classified into 2 categories: (1) inability to advance the catheter into the intrathecal space during placement, or (2) subsequent catheter migration. The first type of failure was probably related to the blunt taper at the catheter tip, which pushed the dura away (dural tenting) during catheter advancement, resulting in the catheter being placed in the epidural space and a kink. The second type of failure was related to the connecting hub and its support system. Unlike the conventional epidural catheter, a hub was necessary to connect the catheter to the tubing set. The precut support cushion provided a predetermined spacer around the hub. The outward tension created by bending and taping the catheter to skin, along with patient movement, might have contributed to pulling the catheter away from the initial position. We later resolved the catheter migration issue by filling the space around the hub with extra small gauzes or alcohol swabs.

There are several limitations of the study. First, there was a steep learning curve with this catheter design. Since the completion of the study, the original catheter has been replaced by a nylon version with a smoother taper. Second, we did not follow women for 5 days after catheter placement, as suggested by the International Headache Classification, second edition. Most of our patients were discharged before the 5-day window, and telephone follow-up had been unreliable because most of the women were migrants. We therefore relied upon records of their revisit to the ICC to document PDPH that might have developed after discharge. It was possible that some women sought treatment of late-occurring symptoms elsewhere or decided not to seek treatment at all. Our reported PDPH rate could be higher if International Headache Classification, second edition, diagnostic time frame had been strictly followed. The minimum 12 hours of catheter dwell time might have masked the true headache rate with the spinal catheter. Finally, the study was observational and without a proper control group.

We conclude that the 23-gauge spinal catheter can be used for analgesia for labor. It can also be converted to surgical anesthesia for cesarean deliveries. With a continuous infusion and demand dose, most women can be managed with minimal provider intervention. Given the small sample size of this small study, particularly with new catheter design, further studies are warranted to determine safety of the continuous spinal technique and whether it can be a useful alternative to traditional neuraxial labor analgesia.

DISCLOSURES
Name: Weike Tao, MD.
Contribution: This author is the principal investigator; led the study, performed procedures, and prepared manuscript.
Attestation: Weike Tao attests to having reviewed the original study data and to the integrity of the data and the analysis reported in this manuscript. Weike Tao approves the final manuscript and is the archival author.
Conflicts of Interest: Epimed, Inc., provided catheters for the study.
Name: Erica N. Grant, MD, MSc.
Contribution: This author is the co-investigator and participated in study design, patient enrollment and management, data collection and analysis, and helped prepare the manuscript.
Attestation: Erica N. Grant attests to the integrity of the original data and the analysis reported in this manuscript and also attests to having reviewed and approved the final manuscript.
Conflicts of Interest: None.
Name: Donald D. McIntire, PhD.
Contribution: This author is the co-investigator and participated in study design, data collection and analysis, and helped prepare the manuscript.
Attestation: Donald D. McIntire attests to having reviewed the original study data and to the integrity of the data and the analysis reported in this manuscript and also approves the final manuscript.
Conflicts of Interest: None.
Name: Kenneth J. Leveno, MD.
Contribution: This author is the co-investigator and also participated in study design, and helped prepare the manuscript.
Attestation: Kenneth J. Leveno attests to the integrity of the original data and the analysis reported in this manuscript and also attests to having reviewed and approved the final manuscript.
Conflicts of Interest: None.

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