Objective: To evaluate whether maintaining a motor-sparing epidural analgesia infusion affects the duration of the second stage of labor in nulliparous parturients compared with a placebo control.

Methods: We conducted a double-blind, randomized, placebo-controlled trial involving nulliparous women with term cephalic singleton pregnancies who requested epidural analgesia. All women received epidural analgesia for the first stage of labor using 0.08% ropivacaine with 0.4 micrograms/mL sufentanil with patient-controlled epidural analgesia. At the onset of the second stage of labor, women were randomized to receive a blinded infusion of the same solution or placebo saline infusion. The primary outcome was the duration of the second stage of labor. A sample size of 200 per group (400 total) was planned to identify at least a 15% difference in duration.

Results: Between March 2015 and September 2015, 560 patients were screened and 400 patients (200 in each group) completed the study. Using an intention-to-treat analysis, the duration of the second stage was similar between groups (epidural 52 ± 27 minutes compared with saline 51 ± 25 minutes, P = .52). The spontaneous vaginal delivery rate was also similar (epidural 193 [96.5%] compared with saline 198 [99%], P = .17). Pain scores were similar between groups at each measurement during the second stage. More women who received placebo reported satisfaction scores of 8 or less (epidural 32 [16%] compared with saline 61 [30.5%], P = .001).

Conclusion: Maintaining the infusion of epidural medication had no effect on the duration of the second stage of labor compared with a placebo infusion. Maternal and neonatal outcomes were similar. A low concentration of epidural local anesthetic does not affect the duration of the second stage of labor.


A longer duration of the second stage labor is associated with adverse outcomes, including chorioamnionitis, perineal laceration, and postpartum hemorrhage. Thus, any treatment that affects the progress and outcome of the second stage of labor would be of great interest to obstetricians, anesthesiologists, and pregnant women. Epidural analgesia is the most effective method of labor pain relief, but both observational and some randomized studies have found an association with prolonged duration of the second stage of labor and increased rates of instrumental vaginal delivery. During the second stage of labor, some obstetric care providers request a reduction or termination in the rate of epidural infusion to improve maternal expulsive efforts.

The use of a modern low-concentration epidural local anesthetic solution is associated with a low incidence of motor block and can even allow the parturient to ambulate. Despite the minimal motor blockade, many obstetric care providers continue to
request termination of the epidural infusion for the second stage of labor. We hypothesized that when using this management technique of epidural analgesia, the effect on the second stage would be minimal. Therefore, we conducted this trial to estimate the effect of maintaining the epidural analgesic infusion on the second stage of labor.

MATERIALS AND METHODS

This prospective, randomized, placebo-controlled trial was approved by both Human Research Committee–institutional review board for Clinical Research from Nanjing Maternity and Child Health Care Hospital (Nanjing, China) and Beth Israel Deaconess Medical Center (Boston, Massachusetts). The study was registered on December 20, 2014, with the Chinese Clinical Trial Register that participates in the World Health Organization International Clinical Trials Registry Platform (identifier: ChiCTR-15005875) before enrolling the first participant. The study was conducted at the Nanjing Maternity and Child Health Care Hospital between March 2015 and September 2015. The center had approximately 24,000 deliveries in 2015 and approximately 95% of laboring parturients received epidural pain relief.

Participants who were in labor but did not yet have epidural analgesia were screened for study participation. Written informed consent was obtained by a study investigator before enrollment. Inclusion criteria were healthy nulliparous women with term (37 weeks of gestation or greater), live, singleton pregnancies who presented in spontaneous labor and desired neuraxial analgesia. Exclusion criteria included American Society of Anesthesiologists physical status 3 or 4, history of opioid use, receiving magnesium, having received intravenous or oral analgesics during labor, and cervical dilation 6 cm or greater at epidural request. Participants who agreed to participate, but underwent cesarean delivery before full cervical dilation, delivered within 1 hour after epidural catheter placement, or had a nonfunctional epidural catheter that needed to be replaced to provide pain relief were also excluded.

Participation in the study did not alter the obstetric clinical management during labor and delivery. At the time of maternal request for labor analgesia, the patient’s cervix was examined. Thereafter, per hospital practice, the cervix was checked every 2 hours or as indicated. After epidural catheter placement, the patient received a standard protocol for labor epidural analgesia, consisting of an initial bolus of 8–10 mL of 0.08% ropivacaine with sufentanil (0.4 micrograms/mL) followed by an infusion of the same solution at 8 mL/h with a patient-controlled epidural analgesia pump.

At full cervical dilation, remaining eligible, participants were randomized to receive the study solution containing either normal saline (SALINE) or the standard epidural solution (EPIDURAL); both solutions were infused at 8 mL/h. To maintain blinding, the epidural solution containers were labeled only with the study number; thus, parturients, investigators, obstetricians, and midwives were not aware of the group assignment.

The randomization sequence was computer-generated in four equal blocks (100/block) and maintained in the U.S. center, Beth Israel Deaconess Medical Center. Folded note cards with patient allocation were placed in sequentially numbered, sealed, opaque envelopes and delivered to the clinical site. A single study investigator (X.Q.) opened the envelope, prepared the study epidural medications, and had no further participation in the study. To further prevent potential bias, the obstetricians and midwives involved in obstetric management did not participate in data collection.

At the request of the obstetric care provider, participants could have their epidural infusion terminated for clinical indications. There was no standardization of the indication for termination nor was there a specific requirement other than obstetric request. Breakthrough pain during the first or second stage of labor was treated with either patient-controlled epidural analgesia or a physician-administered bolus, as needed. During the second stage of labor, participants with excessive pain were allowed be changed to an unblinded infusion of epidural medication. The blinding of the study was not broken if the epidural infusion was terminated or changed by the obstetric care providers.

The primary outcome was the duration of the second stage of labor, calculated from the time of full cervical dilation until delivery. Secondary outcomes includedpain scores assessed with a visual analog scale (a 100-mm unmarked line with endpoints labeled “no pain” and “worst pain imaginable” in Chinese); motor block measured with a modified Bromage score (Box 1); patient satisfaction with labor analgesia was assessed on a 11-point Likert scale and evaluated at least 1 hour after delivery but before discharge from the labor and delivery unit; the mode of delivery; use of episiotomy; fetal position at delivery; neonatal Apgar scores; and umbilical blood gas results. We also documented the need for supplemental patient-controlled epidural analgesia or physician-administered boluses or a change to the epidural infusion during the second stage.
A pilot observational cohort of 50 participants was used to determine the sample size. We estimated that 154 patients per group would be required to find a 15% increase in the duration of the second stage of labor (as from 60 minutes to 69 minutes) using two-tailed $\alpha=0.05$ and power=0.80. We increased the study size to 200 per group to allow for possible dropouts or patient loss as a result of a clinical situation.

Continuous data are presented as mean±SD, discrete data as median (interquartile range), and frequencies as n (percentage of group). Continuous outcomes were compared using two-sided Student $t$ test or Mann-Whitney $U$ test when not normally distributed. The Shapiro-Wilk test was used to assess the distribution of the data. Categorical data were compared using Fisher exact test. Data were analyzed on an intent-to-treat basis with statistical significance determined at $P\leq.05$.

**RESULTS**

A total of 560 pregnant women were screened for eligibility, and 119 women were excluded based on criteria (Fig. 1). Another 41 patients were excluded because they had a cesarean delivery in the first stage of labor or vaginal delivery within 1 hour of epidural catheter placement. Four hundred parturients reached the second stage of labor, were randomized (200 in each group), and had the epidural solution changed to

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**Box 1. Modified Bromage Score (Intensity of Motor Block)**

1 = Complete 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 3 and 5)
5 = No detectable weakness of hip flexion while supine (full flexion of knees)
6 = Able to perform partial knee bend

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The authors of this article would like to note that the measurement of motor strength is performed with the patient supine and asked to raise her knee (hip flexion). If unable to raise a knee, the patient is asked to move her feet. As a safety measure, testing for orthostatic hypotension must be performed before attempting to stand and test for a deep knee bend (score=6).

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Fig. 1. Flow diagram defining the patient assessment and enrollment numbers in the study.

*Shen. Epidural Analgesia During the Second Stage. Obstet Gynecol 2017.*
the assigned blinded study solution. There were no significant differences in demographic or obstetric characteristics between the EPIDURAL and SALINE groups (Table 1).

The primary outcome, the duration of the second stage of labor, was similar between groups with a 3.3% difference in the duration of the second stage of labor (Table 2). The median times were also similar: EPIDURAL at 45 minutes (range 33–61 minutes) compared with SALINE at 46 minutes (range 34–60 minutes; \( P = .94 \)).

A similar number of fetuses were malrotated at delivery (EPIDURAL 7 [3.5%] compared with SALINE 6 [3%]; \( P = .98 \), difference 0.5%, 95% CI −3.4 to 4.5%). Malrotation was defined as an occiput posterior or occiput transverse presentation at delivery. There was a similar number of cesarean deliveries, forceps deliveries, and episiotomies in both groups (Table 2). The spontaneous vaginal delivery rate was not statistically different between groups (EPIDURAL 193 [96.5%] compared with SALINE 198 [99%], \( P = .17 \) difference 3.5%, 95% CI −0.9 to 5.9%). The neonatal weight was slightly higher in the SALINE group, but there were no other significant differences in the neonatal outcomes (Table 3), including Apgar scores at 1 minute and 5 minutes, umbilical artery pH, and acid base values between groups.

There were no statistical differences in visual analog scale pain scores between groups at any evaluation (Table 2). Pain scores decreased in the EPIDURAL group until the 90-minute mark, whereas pain scores increased in the SALINE group throughout. The maternal satisfaction scores for pain relief were lower in the SALINE group (median 9 [range 8–10]) than in the EPIDURAL group (median 10 [10–10], \( P < .001 \)). In post hoc analysis, only 32 (16%) of the EPIDURAL group had satisfaction scores of 8 or less compared with 61 (30.5%) of the SALINE group (\( P < .001 \)).

The obstetricians requested that the epidural infusion be stopped in 49 (12%) patients; of these, 22 (11%) were in the SALINE group and 27 (13.5%) were in the EPIDURAL group.

Table 1. Baseline Maternal Demographic and Obstetric Characteristics

<table>
<thead>
<tr>
<th>Factor</th>
<th>SALINE Group (n=200)</th>
<th>EPIDURAL Group (n=200)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>28.1±3</td>
<td>28.0±3</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>163±4.4</td>
<td>162±4.4</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>69±7</td>
<td>69±9</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>26.2±2.6</td>
<td>26.3±3.0</td>
</tr>
<tr>
<td>Gestational age (wk)</td>
<td>40 (39 2/7–40 3/7)</td>
<td>39+5 (39 0/7–40 2/7)</td>
</tr>
<tr>
<td>Oxytocin augmentation at 1st stage</td>
<td>91 (45.5)</td>
<td>89 (44.5)</td>
</tr>
<tr>
<td>Cervical dilation at epidural (cm)</td>
<td>2.1±0.4</td>
<td>2.1±0.5</td>
</tr>
<tr>
<td>VAS pain at epidural (cm)</td>
<td>8.0 (7.1–9.2)</td>
<td>8.2 (7.3–9.1)</td>
</tr>
<tr>
<td>Duration of epidural at 1st stage (min)</td>
<td>285±115</td>
<td>290±118</td>
</tr>
</tbody>
</table>

BMI, body mass index; VAS, visual analog scale. Data are mean±SD, median (interquartile range), or n (%). Comparisons were made using \( t \) test for normally distributed variables and Mann-Whitney \( U \) test for gestational age, cervical dilation, and VAS.

Table 2. Maternal Delivery Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>SALINE Group (n=200)</th>
<th>EPIDURAL Group (n=200)</th>
<th>Difference (95% CI)</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of 2nd stage (min)</td>
<td>51±25</td>
<td>52±27</td>
<td>3.3% (−6.8 to 13.5%); 101 sec (−3.5 to 7 min)</td>
<td>.52</td>
</tr>
<tr>
<td>Mode of delivery</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cesarean</td>
<td>0 (0)</td>
<td>2 (1)</td>
<td>0.5% (−0.1 to 0.3%)</td>
<td>.50</td>
</tr>
<tr>
<td>Forceps</td>
<td>2 (1)</td>
<td>5 (2.5)</td>
<td>1.5% (−1.6 to 4.6%)</td>
<td>.25</td>
</tr>
<tr>
<td>Episiotomy</td>
<td>64 (32)</td>
<td>70 (35)</td>
<td>3% (−6.8 to 12.8%)</td>
<td>.52</td>
</tr>
<tr>
<td>VAS pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time 0</td>
<td>1.2 (0.6–2.3)</td>
<td>1.5 (0.7–2.7)</td>
<td>0.3 (−0.6 to −0.2)</td>
<td>.06</td>
</tr>
<tr>
<td>30</td>
<td>1.4 (0.6–2.4)</td>
<td>1.3 (0.8–2.0)</td>
<td>0.1 (−0.2 to 0.4)</td>
<td>.80</td>
</tr>
<tr>
<td>60</td>
<td>1.5 (0.9–1.5)</td>
<td>1.1 (0.5–2.0)</td>
<td>0.4 (−0.1 to 0.9)</td>
<td>.09</td>
</tr>
<tr>
<td>90</td>
<td>3.1 (1.6–3.3)</td>
<td>2.4 (1.2–3.1)</td>
<td>0.7 (−1.2 to 1.9)</td>
<td>.46</td>
</tr>
</tbody>
</table>

VAS, visual analog scale. Data are mean±SD, n (%), or median (interquartile range) unless otherwise specified. Comparisons were made using Fisher exact (mode of delivery) and Mann-Whitney \( U \) test (pain scores).
were in the EPIDURAL group. The indications for stopping the epidural infusion in the EPIDURAL group were poor progress of labor (n=23), high station (n=3), fever (n=1), and fetal heart rate abnormalities (n=2); in the SALINE group, the indications were poor progress of labor (n=17), high station (n=2), and maternal fever (n=3). Most (35 [71%]) of these were stopped before the onset of the second stage of labor and before randomization, and only two were restarted with the initiation of the blinded study solution. The duration of the second stage in this cohort of 35 patients was 54±17 minutes. Among the 14 patients in whom the infusion was stopped after full cervical dilation, 6 were assigned to the EPIDURAL group and 8 were in the SALINE group. The median time from onset of second stage to stopping the infusion was 25 minutes (range 11.25–31.5 minutes). The duration of the second stage in these patients was 98±35 minutes. Breakthrough pain was treated in 10 patients during the second stage (EPIDURAL 6 [3%] and SALINE 4 [2%]). There were no cases in which the epidural infusion was converted to an unblinded, medicated solution.

**DISCUSSION**

We found that exchanging the epidural solution from one containing local anesthesia to a placebo saline control had no effect on the duration of the second stage of labor. Furthermore, we found no effect on the normal vaginal delivery rate, incidence of episiotomy, the position of the fetus at delivery, or any measure of neonatal well-being. We used a very low concentration of ropivacaine (0.8%), which has a relative potency equal to approximately 0.05% bupivacaine.9 This could contribute to less motor block and favor second-stage expulsive efforts. Similarly, Chestnut et al10 found that continuing the epidural infusion of 0.0625% bupivacaine resulted in no effect on the duration of the second stage of labor. Women who had their epidural infusion maintained delivered in 53 minutes (range 5–283 minutes) compared with those who received a saline infusion in 63 minutes (range 16–181 minutes), and instrumental delivery rates were similar between groups; however, their study included only 63 randomized patients.

Some obstetric care providers discontinue epidural pain medication during the second stage of labor. This is a practice that varies considerably from center to center but has been reported as occurring in 40% of deliveries (range 14–85%)7 and anecdotally in up to two thirds of deliveries at the hospital where this study was performed. Ethically, if epidural medications result in a negative effect on the second stage of labor, one could argue that a mild increase in maternal pain or decreased satisfaction with pain control could be balanced by the benefit of a successful vaginal delivery. The potential effect of epidural analgesia on the second stage of labor remains controversial. Most observational studies suggest that women who receive epidural pain medication have a longer second-stage labor and higher rates of assisted vaginal delivery. In a large observational study, Cheng et al15 found the duration of the second stage in nulliparous patients to be 47 minutes without and 120 minutes with epidural pain relief. This increased duration of the second stage of labor among women with epidural analgesia in observational studies is similar to what others have identified.6,11 The potential mechanism by which epidural analgesia would have an effect on the success of the second stage of labor is ill defined. Authors have suggested a decrease in maternal expulsive efforts, reduction in uterine activity, or pelvic floor relaxation, which would interfere with fetal position and rotation.12–14 Presuming these hypotheses have merit, a dose–response relationship between epidural local anesthetic concentration and deleterious effects on the second stage of labor should exist.

The effect of local anesthetic concentration was examined in a prospective, randomized study comparing high (0.25%) and lower (0.1%) concentrations of bupivacaine.15 Of note, the randomization in this study began with initiation of epidural pain relief, not at the start of the second stage. The authors found a lower spontaneous vaginal delivery rate when the

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**Table 3. Neonatal Outcomes**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>SALINE Group (n=200)</th>
<th>EPIDURAL Group (n=200)</th>
<th>Difference (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth weight (g)</td>
<td>3,413±332</td>
<td>3,310±352</td>
<td>103 (36–170)</td>
<td>.003</td>
</tr>
<tr>
<td>pH</td>
<td>7.19±0.08</td>
<td>7.19±0.07</td>
<td>-0.0006 (–0.02 to 0.01)</td>
<td>.94</td>
</tr>
<tr>
<td>Base excess</td>
<td>-7.0±3.3</td>
<td>-6.7±3.0</td>
<td>-0.3 (–0.9 to 0.3)</td>
<td>.36</td>
</tr>
<tr>
<td>Apgar score at 1 min less than 9</td>
<td>1 (0.5)</td>
<td>3 (1.5)</td>
<td>1% (–1.5 to 3.5%)</td>
<td>.62</td>
</tr>
<tr>
<td>Apgar score at 5 min less than 9</td>
<td>0</td>
<td>3 (1.5)</td>
<td>1.5% (–0.7 to 3.7%)</td>
<td>.25</td>
</tr>
</tbody>
</table>

Data are mean±SD or n (%) unless otherwise specified. Comparisons were made using t test for continuous variables and Fisher exact test for incidence.
higher concentration of bupivacaine was used, and this was primarily the result of an increase in instrumental delivery. Interestingly, the instrumental delivery rates among the women who received a low concentration of bupivacaine was 28.5%, which is significantly higher than in our study. Similarly, Chestnut, et al16 studied the effect of maintaining an infusion of 0.125% bupivacaine into the second stage of labor compared with a placebo (saline) in a randomized study including 92 women. These authors found a 24% increase in the duration of the second stage; however, participants were randomized and had their epidural solution exchanged after 8 cm of cervical dilation. It is possible that some of the differences between groups might be the result of the inaccuracy of the timing and measurement of cervical examinations. On the other hand, Craig et al17 randomized 310 women to receive 0.125% bupivacaine with fentanyl compared with a high-dose fentanyl solution. These authors found no difference in the duration of the second stage [median 75 minutes [interquartile range 41–128 minutes] compared with 73 minutes [42–120 minutes]] or in the number of operative vaginal deliveries.

In our study, we found that a number of patients (12%) had their epidural infusion halted before the second stage of labor. Interestingly, the duration of the second stage in these women was the same as those who had their infusion continued. Conversely, several patients had the epidural infusion discontinued after randomization, presumably when being identified as having poor progress of fetal descent. The duration of the second stage of labor was longer in this cohort, suggesting that the obstetricians were correct in their observations; however, it is interesting to note that an equal number of these patients was receiving saline (n=8) and local anesthetic (n=6). Both of these outcomes are secondary findings, thus presented with caution, but they do support the concept of selection bias in the second stage of labor.

We did find an increased incidence of women who reported lower satisfaction scores with pain control (8 or less on the 11-point Likert scale) when the infusion was exchanged for saline. Although the pain scores in our study were not statistically different between groups, the trend of pain scores among women receiving saline infusion was increasing over time, as would be expected. This is consistent with previous studies that demonstrated that withdrawal of local anesthetics from the epidural infusion leads to higher pain scores on average.18 In both groups in our study, the pain scores evaluated at the 90-minute mark were considerably higher, which is consistent with a greater amount of pain found in cases of prolonged labor.19

We can identify several limitations. First, the study was from a single center; therefore, labor and delivery analgesia management may vary from that of other institutes. This might be reflected in the low incidence of assisted vaginal delivery (2%) and the high incidence of episiotomy (33%) in this report. Second, we analyzed data from laboring women with the same ethnicity. It is possible that regional, cultural, or ethnic differences may exist. Similar studies in other countries would be required to determine this. Third, to conduct this study, we were required to allow obstetricians to manage labor as they believed safest. A percentage of the patients had their epidural infusion discontinued in anticipation of the second stage of labor. The rate in which this occurred (12%) was considerably lower than the anecdotal rate at the center, which is likely the result of the patient being included in this study. We used intent-to-treat analysis to correct for this finding. It is also of interest that a similar number of patients in each group had the epidural infusion halted after randomization in both groups. We did not record the time between neonatal delivery and the assessment of maternal satisfaction, so we cannot determine whether there was a difference between groups. It is possible that recall bias could result in the differences we observed. Finally, although the absolute rate of spontaneous vaginal delivery was very high—as would be expected in a study that starts with the onset of the second stage of labor—the rate in the epidural group was slightly lower. This was not our primary outcome; thus, it is possible that our study was underpowered to detect such a small difference in absolute rates.

In summary, stopping the epidural infusion at the start of the second stage of labor does not affect the duration or any other outcome, with the exception of possibly resulting in lower maternal satisfaction.

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analgesia versus intravenous meperidine during labor: impact on cesarean delivery rate. Anesthesiology 1998;89:1336–44.