ANESTHESIOLOGY

Quality of Labor Analgesia with Dural Puncture Epidural *versus* Standard Epidural Technique in Obese Parturients: A Double-blind Randomized Controlled Study

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EDITOR'S PERSPECTIVE

What We Already Know about This Topic

- The "dural puncture epidural technique" is performed by puncturing the dura with a spinal needle but without injecting medications intrathecally.
- Dural puncture epidural has been suggested to improve the efficacy of labor epidural analgesia, potentially by increasing the likelihood of midline placement or by facilitating the translocation of medication from the epidural to intrathecal space. However, data regarding the efficacy of this technique are mixed.
- Obese patients are at higher risk for epidural failure, so the dural puncture technique may have particular utility in this population.

What This Article Tells Us That Is New

- A total of 132 term parturients with body mass index of 35 kg · m^{-2} or greater were randomized to either a dural puncture epidural using a 25-gauge Whitacre needle or a standardized epidural technique. This was followed, in both groups, by maintenance with programed intermittent boluses and patient-controlled epidural analgesia.
- The primary outcome was a composite of five outcomes indicating lower quality of labor analgesia. There was no meaningful difference between the two groups (52 *vs.* 49%; absolute risk difference, 3.0%; 95% CI, –14.0 to 20.1%) in the primary outcome or the secondary outcomes assessed.
- The study excludes a large benefit for dural puncture epidural in improving labor analgesia in obese parturients, although CI ranges for the primary outcome were wide and do not fully exclude the potential for a clinically meaningful effect.

ABSTRACT

Background: The dural puncture epidural technique may improve analgesia quality by confirming midline placement and increasing intrathecal translocation of epidural medications. This would be advantageous in obese parturients with increased risk of block failure. This study hypothesizes that quality of labor analgesia will be improved with dural puncture epidural compared to standard epidural technique in obese parturients.

Methods: Term parturients with body mass index greater than or equal to 35 kg · m^{-2}, cervical dilation of 2 to 7 cm, and pain score of greater than 4 (where 0 indicates no pain and 10 indicates the worst pain imaginable) were randomized to dural puncture epidural (using 25-gauge Whitacre needle) or standard epidural techniques. Analgesia was initiated with 15 ml of 0.1% ropivacaine with 2 μg · ml^{-1} fentanyl, followed by programed intermittent boluses (6 ml every 45 min), with patient-controlled epidural analgesia. Parturients were blinded to group allocation. The data were collected by blinded investigators every 3 min for 30 min and then every 2 h until delivery. The primary outcome was a composite of (1) asymmetrical block, (2) epidural top-ups, (3) catheter adjustments, (4) catheter replacement, and (5) failed conversion to regional anesthesia for cesarean delivery. Secondary outcomes included time to a pain score of 1 or less, sensory levels at 30 min, motor block, maximum pain score, patient-controlled epidural analgesia use, epidural medication consumption, duration of second stage of labor, delivery mode, fetal heart tones changes, Apgar scores, maternal adverse events, and satisfaction with analgesia.

Results: Of 141 parturients randomized, 66 per group were included in the analysis. There were no statistically or clinically significant differences between the dural puncture epidural and standard epidural groups in the primary composite outcome (34 of 66, 52% *vs.* 32 of 66, 49%; odds ratio, 1.1 [0.5 to 2.4]; $P = 0.766$), its individual components, or any of the secondary outcomes.

Conclusions: A lack of differences in quality of labor analgesia between the two techniques in this study does not support routine use of the dural puncture epidural technique in obese parturients.

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Neuraxial analgesia is considered the accepted standard technique for labor pain relief, owing to its excellent efficacy and low risk of adverse effects.[1] Dural puncture epidural involves dural puncture with a spinal needle but without administration of intrathecal drugs. Neuraxial analgesia is then initiated by medications given through an epidural catheter.[2] The purported advantages of dural puncture epidural over the standard epidural technique stem from a clear and definitive endpoint of cerebrospinal fluid (CSF) return *via* the spinal needle. This confirms midline placement of the Tuohy needle and may increase transfer of epidural medications through the dural puncture into the intrathecal space, thereby hastening analgesic onset and improving the quality of analgesia.[2–5] However, available data comparing dural puncture epidural and standard epidural techniques

are sparse, with two recent systematic reviews reporting no clear evidence of clinical benefit associated with the dural puncture epidural technique.[3,4]

The ostensible advantages of the dural puncture epidural technique would especially benefit obese parturients, in whom difficulty with palpating anatomical landmarks and possible false loss of resistance from increased adipose tissue may make neuraxial placement challenging and increase the epidural catheter failure rate.[6] Moreover, obese parturients are at higher risk of intrapartum cesarean delivery,[7] during which a well-functioning epidural catheter can be used to administer regional anesthesia. This would avoid general anesthesia and its associated risks, such as failed intubation and pulmonary aspiration of gastric contents, which are of particular relevance in obese parturients.[8,9] Hence, we performed this double-blind randomized controlled study to compare dural puncture and standard epidural techniques for neuraxial analgesia in obese parturients, with the hypothesis that the dural puncture epidural technique will be associated with improved quality of labor analgesia compared to the standard epidural technique.

Materials and Methods

After approval by the Duke University Institutional Review Board (Durham, North Carolina; approval No. PRO00079368) and registration on Clinicaltrials.gov (NCT03074695, posted on March 9, 2017; Principal Investigator, Ashraf Habib), this superiority, parallel group, randomized controlled study was conducted from April 2017 to November 2020 at Duke University Medical Center. Written informed consent was obtained from all enrolled parturients.

A convenience sample of women admitted for spontaneous or induced labor was screened for enrollment and approached by investigators. We included English-speaking, nulliparous or multiparous, obese (body mass index greater than or equal to 35 $kg \cdot m^{-2}$) adult parturients (age, 18 to 45 yr) with singleton vertex fetuses at 37 to 41 weeks' gestation, cervical dilation 2 to 7 cm, and with numeric rating scale (0 to 10, where 0 indicates no pain and 10 indicates the worst pain imaginable) pain score greater than 4. We excluded parturients with major cardiac disease, chronic pain, chronic opioid use, previous cesarean delivery, and maternal pelvic/hip disease. The protocol was amended after initiation of the study to allow inclusion of parturients with body mass index greater or equal to 35 $kg \cdot m^{-2}$, whereas the original protocol was limited to parturients with body mass index greater or equal to 40 $kg \cdot m^{-2}$.

One of the study investigators evaluated eligibility, obtained informed consent, and enrolled the participants. After signing the written informed consent, parturients were randomized (1:1 ratio) to receive the dural puncture epidural or standard epidural technique using a computer-generated random number generator, stratified by class of obesity (body mass index 35 to 39.9, 40 to 49.9, and greater or equal to 50 $kg \cdot m^{-2}$) and by parity (nulliparous or multiparous). The allocation sequence was created by the study statistician. Allocation was concealed using sequentially numbered opaque sealed envelopes. Upon request for labor analgesia, the proceduralist opened the envelope containing the group allocation. Parturients, obstetricians, nurses, and anesthesia providers involved in labor analgesia management and data collection were blinded to the group allocation. Neuraxial procedures were performed by the attending anesthesiologist or by senior residents, fellows, or certified registered nurse anesthetists under the supervision of an attending anesthesiologist. The proceduralist and supervising attending anesthesiologist (if applicable) were not involved in subsequent management of labor analgesia.

Parturients received 500 to 1,000 ml of intravenous crystalloid hydration, and a 17-gauge Tuohy needle was sited at the estimated L3–L4 or L4–L5 interspace using loss of resistance to saline, with the parturients in the sitting flexed position. Preprocedure ultrasound was allowed at the discretion of the anesthesiologist. In the dural puncture epidural group, dural puncture with a 25-gauge Whitacre needle was performed using the needle-through-needle technique, and the spinal needle was withdrawn after confirmation of free-flowing CSF. A second attempt would be made, either at the same or at a different space, if CSF return was not observed. In both groups, a 19-gauge Duraflex wire-reinforced multiport catheter (Smith Medical, USA) was threaded 5 cm into the epidural space and secured in the sitting upright position with Tegaderm clear occlusive dressing (3M, USA). After negative aspiration for blood or

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CSF, analgesia was initiated with divided doses of 15 ml of epidural medication (0.1% ropivacaine with 2 μg · ml^{-1} fentanyl) over 6 min as per standard practice. The end of administration of the loading dose was time zero. At that time, the blinded investigator was called into the room to start data collection. Pain with the preceding contraction was assessed at 3-min intervals for 30 min or until a pain score of 1 or less was achieved. At 30 min, the upper and lower sensory levels were assessed bilaterally using temperature discrimination to ice (defined as the dermatomal level at which the parturient reported the same cold sensation to ice compared to the shoulder), along with the modified Bromage score. Subsequently, pain scores and modified Bromage scores were collected every 2 h until delivery. Thoracic dermatomal sensory levels were assessed along the midclavicular line, in addition to the inguinal crease (L1), anterior thigh (L2), medial knee (L3), medial malleolus (L4), between the great and second toe (L5), lateral heel (S1), and medial popliteal fossa (S2), bilaterally. Motor block was assessed using the modified Bromage score (where 1 indicates unable to flex feet or knees, 2 indicates able to flex feet only, 3 indicates able to flex knees, 4 indicates detectable weakness in hip flexion, and 5 indicates no weakness with hip flexion).[10]

Labor analgesia was maintained with programed intermittent boluses of 6 ml of epidural medication every 45 min initiated 30 min after the loading dose, with the addition of patient-controlled epidural analgesia set at 8 ml per demand dose, lockout for 10 min, and maximum dose of 45 ml · h^{-1}. Breakthrough pain (defined as parturient request for supplemental analgesia beyond self-administered boluses) was managed as follows: asymmetric sensory levels (difference of more than 2 dermatomal levels) were treated by withdrawing the catheter 1 cm, administration of 5 ml of epidural medication, and repositioning of the parturient lateral with the lower sensory block side in the dependent position. Parturients with inadequate block height (bilateral sensory levels below T10) were given 5 ml of epidural medication, with up to 15 ml permitted over 15 min. Parturients with breakthrough pain despite adequate sensory levels (above T10 bilaterally) were treated with 100 μg of epidural fentanyl. Last, breakthrough pain persisting despite these interventions was assessed by the attending anesthesiologist for subsequent management.

In addition to pain scores, sensory levels, and modified Bromage scores, the following data were recorded every 2 h until delivery: presence of hypotension (systolic blood pressure less than 20% from admission blood pressure of less 90 mmHg), nausea, pruritus, asymmetric sensory block, need for epidural top-up, and catheter adjustment or replacement. On postpartum day 1, parturients were assessed for postdural puncture headache and were asked about their satisfaction with labor analgesia (where 0 indicates very dissatisfied and 10 indicates very satisfied). An obstetrician blinded to group assignments reviewed tocometry and continuous fetal monitoring stored on the hospital electronic medical system. Uterine contraction and fetal heart rate monitoring patterns were extracted in 10-min epochs, for the periods of 1 h before and 1 h after initial dosing of epidural analgesia. Baseline heart rate was the mean of the six 10-min epochs before and after epidural catheter placement. Quantitative assessment of fetal heart tracings also included variability (minimal, moderate, or marked) and decelerations (late or variable). The obstetrician also assigned a category to the fetal heart tracings before and after the epidural catheter placement based on the three-tier National Institute of Child Health and Human Development (Bethesda, Maryland) system.[11]

The primary outcome of the study was the quality of labor analgesia defined as a composite of (1) asymmetrical block (difference in sensory level of more than 2 dermatomes), (2) epidural top-ups, (3) catheter adjustments, (4) catheter replacement, and (5) failed conversion to regional anesthesia requiring general anesthesia or replacement neuraxial anesthesia in the event of cesarean delivery. All components of the primary composite outcome were treated as binary measures, and the presence of one or more of these components was considered positive for the primary composite outcome. Secondary outcomes included time to adequate analgesia (pain score less than or equal to 1), upper and lower sensory block levels at 30 min, modified Bromage score at 30 min and during labor, maximum pain score during labor, number of patient-controlled epidural analgesia demand and successful boluses, duration of neuraxial analgesia, total epidural medication consumption per hour, duration of second stage of labor, mode of delivery, fetal heart tones (heart rate, decelerations, variability, and National Institute of Child Health and Human Development system classification), Apgar scores at 1 and 5 min, maternal adverse events (hypotension, nausea, pruritus, and postdural puncture headache), and maternal satisfaction with labor analgesia.

Statistical Analysis

Based on a retrospective study by our group,[12] we anticipated that our primary outcome will occur in 35% of parturients assigned to the standard epidural group. Based on the findings by Hess *et al.*[13] of a 62% relative reduction in breakthrough pain with the combined spinal–epidural compared to the standard epidural technique, we defined a clinically meaningful effect as a similar reduction in the composite outcome to 14% in the dural puncture epidural group, which corresponds to an odds ratio of 0.30. A two-sided chi-square test for the difference in primary outcome incidence at an α level of 0.05 had 80% power to detect an odds ratio of 0.30 comparing the dural puncture epidural to the epidural technique in a study of 130 patients (65 per group). We planned to enroll up to 150 parturients to account for possible dropouts, with a goal to stop enrollment once our target sample size was achieved.

The data are reported as median [interquartile range] or number (%) as appropriate. Baseline characteristics were compared between groups using standardized mean difference. The primary composite outcome was analyzed using univariate logistic regression with *post hoc* sensitivity multivariable logistic regression analysis. The multivariable logistic regression included adjustment terms for baseline demographics and obstetric characteristics with standardized mean differences of more than 0.2 between the two groups. Secondary outcomes, such as time to adequate analgesia, sensory block levels, modified Bromage score, maximum pain score during labor, number of patient-controlled epidural analgesia demand and successful boluses, duration of neuraxial analgesia, total epidural medication consumption per hour, duration of second stage of labor, mode of delivery, fetal heart tones, Apgar scores, maternal adverse events, and maternal satisfaction were assessed using Fisher exact tests with associated risk differences for categorical measures and Mann–Whitney U tests with Hodges–Lehman shift for continuous measures. We report group differences with 95% CI, univariable directly calculated, and multivariable based on bootstrapping, in addition to *P* values. A *post hoc* sensitivity analysis excluding epidural top-ups from the composite outcome definition was conducted to explore the impact of including epidural top-ups on the overall study conclusions.

The data were analyzed on an intention-to-treat basis. All *P* values for the secondary outcomes were adjusted for multiple comparisons using the false discovery rate method, and the resulting Q values are presented. Additionally, time to adequate analgesia was compared between the groups *via* Kaplan–Meier estimates and log-rank tests. *P* values and adjusted Q values of less than 0.05 were considered statistically significant. Analysis was performed using *R* 4.0.0, with power calculations performed using NQuery. The detailed trial protocol can be obtained from the corresponding author upon request.

Results

A total of 204 parturients were screened for eligibility, of whom 141 were enrolled. Enrollment ceased after achieving our target sample size. Of the 141 parturients enrolled, 9 patients were excluded due to cesarean delivery before receipt of labor analgesia (n = 2), nonreceipt of labor analgesia (n = 4), or unavailability of research staff (n = 3). In total, 132 parturients completed the study, with 66 randomized to receive dural puncture epidural and 66 to receive standard epidural technique (fig. 1). CSF return was successfully confirmed in all parturients receiving the dural puncture epidural technique. Preprocedure ultrasound was utilized in three patients in the standard epidural group and none of the patients in the dural puncture epidural group. There were no missing data except for fetal heart tones as highlighted in tables 1 and 2. Baseline parturient and obstetric characteristics are summarized in table 1. The dural puncture epidural group had a greater proportion of self-identified Hispanic/Latino parturients, parturients who underwent induction of labor, and taller parturients compared to the standard epidural group.

There were no significant differences between the dural puncture epidural and standard epidural groups in our primary composite outcome of quality of analgesia (34 of 66, 52% *vs*. 32 of 66, 49%; absolute risk difference [95% CI], 3.0% [–14.0 to 20.1%]; odds ratio [95% CI], 1.1 [0.5 to 2.4]; $P = 0.766$, when adjusted for baseline characteristics with a standardized mean difference of more than 0.2 [parturient race, ethnicity, height, and induction status]). A *post hoc* sensitivity analysis excluding epidural top-ups from the primary composite outcome also revealed no significant differences between the groups (20 of 66, 30% *vs.* 17 of 66, 26%; odds ratio [95% CI], 1.09 [0.53 to 2.37]; $P = 0.846$). Details of the primary composite outcome and breakdown of its individual components are summarized in figure 2 and the Supplemental Digital Content (http://links.lww.com/ALN/C788). During labor, three catheters in the dural puncture epidural group needed replacement due to ineffective analgesia, whereas in the standard epidural group, two catheters were replaced due to ineffective analgesia, one catheter was replaced due to asymmetric block, one catheter migrated out of the epidural space, and one catheter was replaced due to disconnection. In both groups, two catheters were replaced for cesarean delivery, with each group having one catheter replaced with another neuraxial block and one converted to general anesthesia. Our secondary outcomes are summarized in table 2. There were no significant intergroup differences in upper and lower sensory block levels at 30 min, modified Bromage score at 30 min or during labor, maximum pain score during labor, number of patient-controlled epidural analgesia demand and successful boluses, duration of neuraxial analgesia, total epidural medication consumption per hour, duration of second stage of labor, mode of delivery, fetal heart tones, Apgar scores at 1 and 5 min, maternal adverse events, and maternal satisfaction with labor analgesia. A log-rank test analyzing the time to pain score 1 or lower showed no significant differences between the groups ($P = 0.650$; data not shown).

Discussion

In this randomized study, we compared the dural puncture epidural and standard epidural techniques for the initiation of neuraxial labor analgesia in obese parturients and found no significant differences in quality of analgesia between the two techniques. Unlike the standard epidural technique, dural puncture epidural involves dural puncture and confirmation of CSF return through the spinal needle. Purportedly, this indirectly confirms correct identification of the epidural space, increases the likelihood of midline Tuohy needle placement, and enhances the transfer of epidural medications into the intrathecal space. However, previous studies comparing dural puncture epidural *versus*

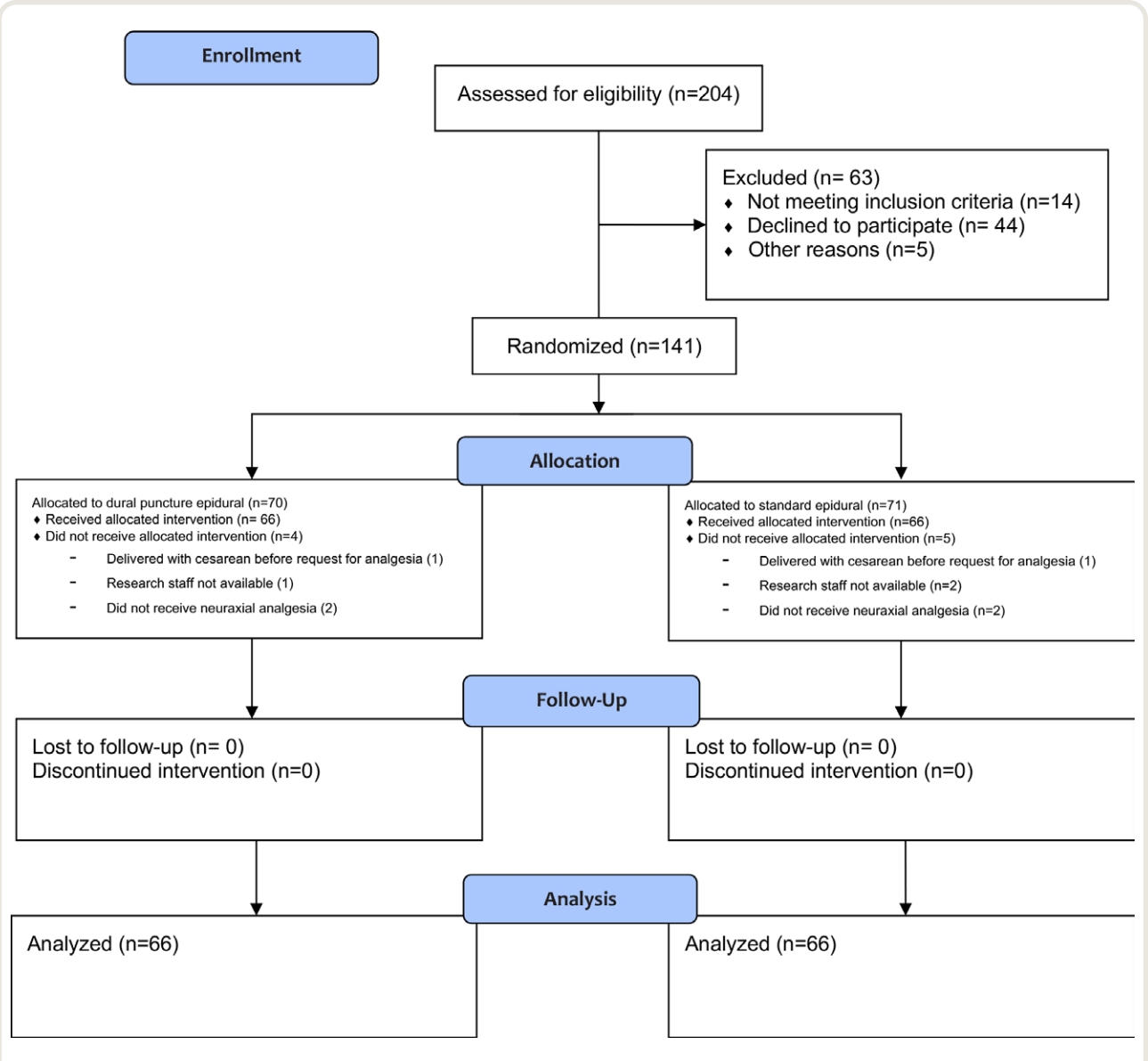

Fig. 1. Consolidated Standards of Reporting Trials flow diagram.

standard epidural techniques for labor analgesia reported conflicting results. Compared to the standard epidural technique, dural puncture epidural with 27-gauge spinal needles did not significantly alter the incidence of catheter manipulation or replacement, sacral block sparing, asymmetrical block, or the need for epidural top-up in one study,[14] while another study also using a 27-gauge spinal needle reported lower pain scores within the first 10 min and faster time to onset of analgesia with the dural puncture epidural compared to standard epidural technique.[15] With 26-gauge spinal needles, dural puncture epidural was associated with faster analgesic onset compared to the standard epidural technique.[16] Using larger 25-gauge spinal needles, both Cappiello *et al.*[17] and Chau *et al.*[5] reported lower incidence of sacral block sparing and asymmetric block with dural puncture epidural compared to the standard epidural technique but detected no significant difference in the time to onset of analgesia. Additionally, Chau *et al.*[5] noted that dural puncture epidural was associated with lower need for epidural top-ups than the standard epidural technique.

Notably, none of these studies specifically investigated the use of the dural puncture epidural technique in obese parturients. Those parturients would particularly benefit from indirect confirmation of Tuohy needle placement within the epidural space, given the increased difficulty in palpating anatomical landmarks and potential for false loss

Table 1. Baseline Demographic and Obstetric Characteristics

Characteristic	Dural Puncture Epidural (n = 66)	Standard Epidural (n = 66)	Standardized Mean Difference
Age, yr (median [interquartile range])	29 [25–34]	30 [25–34]	0.066
Height, cm (median [interquartile range])	165 [160–168]	162 [158–168]	0.212
Weight, kg (median [interquartile range])	115 [104–132]	112 [102–130]	0.007
Body mass index, kg · m^{-2} (median [interquartile range])	41 [39–48]	42 [38–46]	0.132
Body mass index strata			0.054
35–39.9 kg · m^{-2} nulliparous, n (%)	11 (17)	11 (17)	
35–39.9 kg · m^{-2} multiparous, n (%)	11 (17)	12 (18)	
40–49.9 kg · m^{-2} nulliparous, n (%)	19 (29)	19 (29)	
40–49.9 kg · m^{-2} multiparous, n (%)	11 (17)	11 (17)	
≥ 50 kg · m^{-2} nulliparous, n (%)	10 (15)	9 (14)	
≥ 50 kg · m^{-2} multiparous, n (%)	4 (6)	4 (6)	
Race			0.377
White, n (%)	26 (39)	26 (39)	
Black, n (%)	22 (33)	31 (47)	
Other, n (%)	17 (26)	9 (14)	
Ethnicity			0.527
Hispanic or Latino, n (%)	10 (15)	1 (2)	
Non-Hispanic, n (%)	50 (77)	61 (92)	
Unknown, n (%)	6 (8)	4 (6)	
Gravida (median [interquartile range])	2 [1–3]	2 [1–3]	0.106
Parity (median [interquartile range])	0 [0–1]	0 [0–1]	0.031
Nulliparous, n (%)	39 (59)	40 (61)	
Multiparous, n (%)	27 (41)	26 (39)	
Gestational age, wk (median [interquartile range])	39 [38–40]	39 [38–40]	0.109
Pain score at time of neuraxial analgesia (0–10; median [interquartile range])	8 [6–9]	8 [7–9]	0.112
Cervical dilation at time of neuraxial analgesia in cm (median [interquartile range])	4 [4–5]	4 [3–5]	0.129
Proceduralist, n (%)			0.113
Attending	28 (41)	29 (44)	
Certified registered nurse anesthetist	8 (12)	10 (15)	
Fellow	6 (9)	5 (8)	
Resident	24 (36)	22 (33)	
Induction of labor, n (%)	64 (97)	58 (88)	0.349
Fetal heart rate, beats/min (median [interquartile range])	135 [125–140]	135 [125–145]	0.002
Fetal heart rate decelerations, n (%)			0.442
Variable	6 (9)	1 (2)	
Late	6 (9)	3 (3)	
Fetal heart rate variability, n (%)			0.212
Moderate	58 (88)	62 (94)	
Minimal	2 (3)	1 (2)	
Marked	2 (3)	1 (2)	
Missing or not assessed	4 (6)	2 (3)	
National Institute of Child Health and Human Development fetal heart rate classification, n (%)			0.389
Category 1	48 (73)	58 (79)	
Category 2	14 (21)	6 (9)	
Missing or not assessed	4 (6)	2 (3)	

of resistance resulting from adipose tissue. Furthermore, in the case of emergency cesarean delivery, a well-positioned epidural catheter may be used to achieve surgical anesthesia and potentially avoid severe morbidity from failed intubation or pulmonary aspiration that may occur during general anesthesia. However, our results suggest that the dural puncture epidural technique was not associated with significant improvement in our primary and secondary outcomes compared to the standard epidural technique.

In addition to indirect confirmation of midline epidural placement, dural puncture is hypothesized to increase the transfer of epidural medications into the intrathecal space, thereby hastening block onset while improving analgesia quality and sacral blockade.[3] However, the mechanisms governing flux through the meninges are dependent on multiple factors including total epidural drug mass, size of the dural puncture, and inherent rate of drug transfer through the intact meninges.[4,18–20] The effects of epidural drug mass could have contributed to the lack of analgesic benefit of the dural puncture epidural compared to standard epidural technique in our study. Layera *et al.*[4] postulated that the diffusion gradient generated by dilute epidural solutions and smaller drug masses may be insufficient to drive drug transfer across the meninges or dural

Table 2. Secondary Outcomes Associated with Dural Puncture Epidural *versus* Standard Epidural Techniques

Outcome	Dural Puncture Epidural (n = 66)	Standard Epidural (n = 66)	Difference Measure [95% CI]	*P* Value	Adjusted Q Value
Time to pain score ≤ 1, min (median [interquartile range])	12 [9 to 18]	15 [9 to 21]	3 [–3 to 6]	0.367	> 0.999
Upper sensory block height at 30 min*					
Left (median [interquartile range])	T8 [T7 to T10]	T10 [T8 to T10]	1 [0 to 2]	0.016	0.253
Right (median [interquartile range])	T8 [T7 to T10]	T9 [T7 to T10]	0 [0 to 1]	0.301	> 0.999
Lower sensory block height at 30 min*					
Left (median [interquartile range])	S2 [S1 to S2]	S2 [S1 to S2]	0 [0 to 0]	0.509	> 0.999
Right (median [interquartile range])	S2 [S1 to S2]	S2 [S1 to S2]	0 [0 to 0]	0.766	> 0.999
Bromage score at 30 min†					
Left (median [interquartile range])	5 [5 to 5]	5 [5 to 5]	0 [0 to 0]	0.793	> 0.999
Right (median [interquartile range])	5 [5 to 5]	5 [5 to 5]	0 [0 to 0]	0.398	> 0.999
Lowest Bromage score during labor†					
Left (median [interquartile range])	5 [5 to 5]	5 [5 to 5]	0 [0 to 0]	0.484	> 0.999
Right (median [interquartile range])	5 [5 to 5]	5 [5 to 5]	0 [0 to 0]	0.348	> 0.999
Maximum pain score during labor (median [interquartile range])	0 [0 to 4]	1 [0 to 5]	0 [0 to 1]	0.224	> 0.999
Number of patient-controlled epidural analgesia demands per hour (median [interquartile range])	0.8 [0.3 to 1.3]	0.8 [0.4 to 1.4]	0.1 [–0.1 to 0.2]	0.674	> 0.999
Number of patient-controlled epidural analgesia successful boluses per hour (median [interquartile range])	0.5 [0.2 to 0.9]	0.5 [0.3 to 1.0]	0.1 [–0.2 to 0.3]	0.543	> 0.999
Patient-controlled epidural analgesia successful/demand ratio (median [interquartile range])	0.7 [0.5 to 1.0]	0.7 [0.5 to 1.0]	0.0 [–0.1 to 0.1]	0.916	> 0.999
Time to first patient-controlled epidural analgesia dose, h (median [interquartile range])	1.0 [0.5 to 3.5]	1.9 [0.8 to 4.0]	0.2 [–0.4 to 1.0]	0.597	> 0.999
Duration of neuraxial analgesia, h (median [interquartile range])	8.9 [3.0 to 16.5]	8.9 [5.5 to 14.7]	0.5 [–2.4 to 3.1]	0.728	> 0.999
Total epidural medication consumption, ml · h^{-1} (median [interquartile range])	10.8 [8.5 to 14.8]	10.8 [8.2 to 16.3]	0.3 [–1.3 to 2.1]	0.961	> 0.999
Duration of second stage of labor, h (median [interquartile range])	0.6 [0.2 to 1.2]	0.3 [0.2 to 1.5]	0.0 [–0.3 to 0.2]	0.900	> 0.999
Mode of delivery, n (%)				0.925	> 0.999
Spontaneous vaginal	39 (59)	40 (61)	Reference		
Operative vaginal	4 (6)	3 (5)	1.4 [0.3 to 7.3]		
Cesarean	23 (35)	23 (35)	1.0 [0.5 to 2.2]		
Apgar scores					
1 min (median [interquartile range])	8 [7 to 8]	8 [8 to 8]	0 [0 to 0]	0.735	> 0.999
5 min (median [interquartile range])	9 [9 to 9]	9 [9 to 9]	0 [0 to 0]	0.657	> 0.999
Hypotension, n (%)	2 (3)	6 (9)	0.3 [0.1 to 1.4]	0.274	> 0.999
Nausea, n (%)	11 (17)	11 (17)	1.0 [0.4 to 2.5]	> 0.999	> 0.999
Pruritus, n (%)	27 (41)	25 (38)	1.1 [0.6 to 2.3]	0.859	> 0.999
Postdural puncture headache, n (%)	0	0			
Maternal satisfaction (median [interquartile range])	10 [8 to 10]	9 [8 to 10]	0 [–1 to 0]	0.022	0.253
Fetal heart rate, beats/min (median [interquartile range])	135 [125 to 140]	135 [125 to 140]	0 [–5 to 5]	0.790	> 0.999
Fetal heart rate decelerations, n (%)				0.785	> 0.999
Variable	4 (6)	2 (3)	0.5 [0.1 to 2.6]		
Late	7 (11)	9 (14)	0.4 [0.1 to 2.6]		
Fetal heart rate variability, n (%)				0.435	> 0.999
Moderate	61 (92)	61 (92)	Reference		
Minimal	1 (2)	3 (5)	0.3 [0.2 to 2.7]		
Missing or not assessed	4 (6)	2 (3)	2.0 [0.4 to 14.8]		
National Institute of Child Health and Human Development fetal heart rate classification, n (%)				0.596	> 0.999
Category 1	51 (77)	50 (76)	Reference		
Category 2	11 (17)	14 (21)	0.8 [0.3 to 1.9]		
Missing or not assessed	4 (6)	2 (3)	2.0 [0.4 to 14.6]		

Difference measures correspond to the Hodges–Lehman shift for continuous variables and the risk difference for categorical variables.

*Sensory block height assessed with temperature discrimination using ice. Sensory level was tested to the S2 dermatome in the caudad direction, but no limit was imposed on sensory block height assessment in the cephalad direction.

†Modified Bromage score, where 1 indicates unable to flex feet or knees, 2 indicates able to flex feet only, 3 indicates able to flex knees, 4 indicates detectable weakness in hip flexion, and 5 indicates no weakness with hip flexion.

puncture, which may explain why the use of dilute ropivacaine 0.1% in our study produced similar results to those of Thomas *et al.*,[14] who reported no improvement in analgesia quality or reduction in catheter manipulation or replacement with dural puncture epidural compared to the standard epidural technique using 0.11% bupivacaine. Interestingly, a recent study comparing dural puncture epidural plus continuous infusion, dural puncture epidural

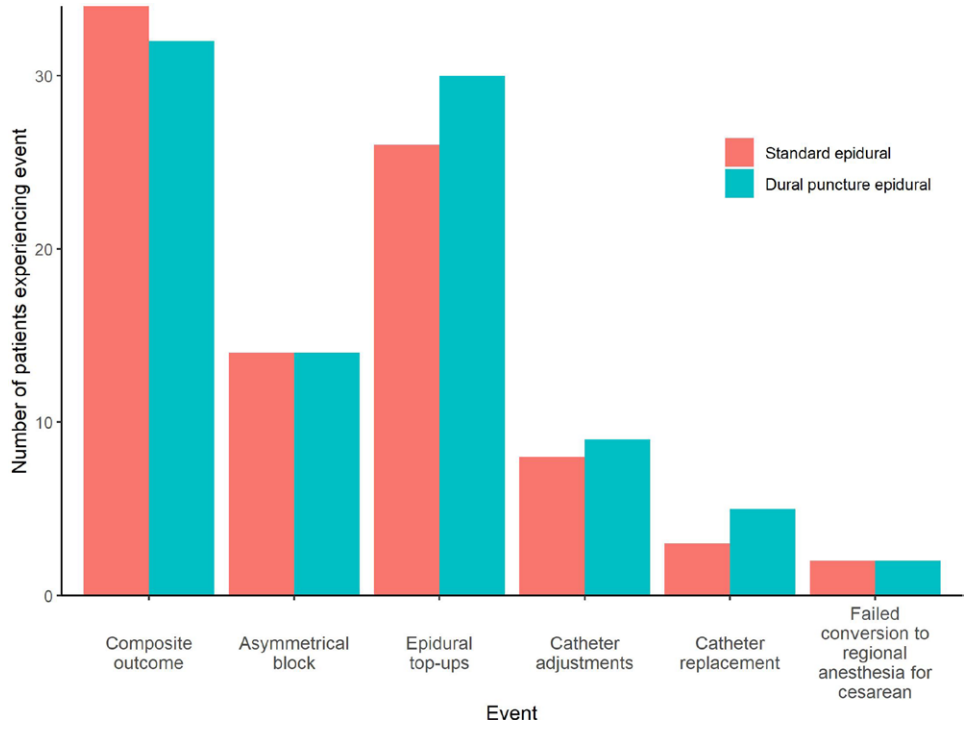

Fig. 2. Primary composite outcome and its individual components. The primary outcome was the quality of labor analgesia defined as a composite of (1) asymmetrical block (difference in sensory level of greater than 2 dermatomes using temperature discrimination to ice), (2) epidural top-ups, (3) catheter adjustments, (4) catheter replacement, and (5) failed conversion to regional anesthesia requiring general anesthesia or replacement neuraxial anesthesia in the event of cesarean delivery. There were no statistically significant differences between the groups in the composite outcome or its individual components. Further details are provided in the Supplemental Digital Content (http://links.lww.com/ALN/C788).

plus intermittent boluses, and standard epidural plus continuous infusion reported that treatment with dural puncture epidural plus intermittent boluses was associated with the greatest analgesia quality and drug-sparing effect compared to the other two techniques.[21] It is possible that the higher injectate pressures used in the intermittent bolus technique may increase drug transfer through the dural puncture, although this technique did not significantly increase analgesia efficacy with dural puncture epidural compared to standard epidural in our study. Another possibility is that the increased epidural drug spread associated with the intermittent bolus technique[1] may obscure any analgesic improvement resulting from increased drug transfer through the dural conduit with the dural puncture epidural technique.

Dural punctures were performed with 25-gauge spinal needles, similar to previous studies that reported reduced sacral block sparing and asymmetrical block with dural puncture epidural compared to standard epidural technique.[5,17] Hence, the size of the dural puncture is unlikely to explain the lack of analgesic benefit of dural puncture epidural compared to standard epidural technique in our study. Finally, the presence of a dural puncture will have greater effect on the rate of transmeningeal drug transfer in medications with inherently slow diffusion rates through intact meninges such as lidocaine or morphine compared to medications that easily diffuse across the intact meninges such as bupivacaine or ropivacaine[20] and may have contributed to the absence of significant analgesic improvement with the dural puncture epidural technique when ropivacaine was used.

In our study, dural puncture with 25-gauge spinal needles did not significantly increase the incidence of adverse effects compared to the standard epidural technique, consistent with the findings of Cappiello *et al.*[17] and Chau *et al.*[5] It is likely that the rate of transmeningeal transfer of epidural medications is slow enough to avoid complications such as hypotension, uterine tachysystole, and fetal bradycardia that are associated with the combined spinal epidural technique.[22] Also, no difference in the incidence of postdural puncture headache was detected. However, it is possible that our study was not sufficiently powered to detect small changes in these rare outcomes.

The main strength of our study is the randomized, double-blind design that minimizes bias and influence of known and unknown confounders. In addition, the composite primary outcome increases study power to detect clinically

relevant differences in overall quality of analgesia. However, we acknowledge several potential limitations. While we found no statistically significant differences between the groups in our primary outcome, it should be noted that the 95% CI ranges were wide and contained potentially clinically relevant differences. Given our observed difference and variability of outcome rate, future large studies would be required to rule out a smaller but clinically relevant difference. The onset of adequate analgesia is challenging to measure given the cyclical nature of labor pain. We attempted to control for this by assessing pain with the preceding contraction and enrolling parturients with moderate to severe labor pain. However, as the frequency of uterine contractions vary during labor, it is possible that adequate analgesia was obtained earlier than what was documented. We included a wide range of cervical dilatation in our study, although cervical dilatation and pain scores at request of analgesia were comparable between the two groups. In addition, maintenance of labor analgesia was achieved *via* intermittent boluses of epidural medications, which may have influenced our findings and reduced the generalizability of our results compared to other studies utilizing continuous infusion of epidural medications. We note that the incidence of our composite outcome was higher than anticipated. This discrepancy may be attributed to the prospective collection of data in this study, which might have captured more interventions compared to the retrospective study that was used for the power analysis, which also used a more concentrated solution compared to the one used in this current study. Furthermore, the long duration of labor in parturients with obesity might lead to increased need for interventions. Finally, the need for epidural top-ups was included in our composite outcome, but it might not indicate definitive catheter failure such as need for catheter replacement during labor or for cesarean delivery. However, it reflects the presence of breakthrough pain and therefore is a measure of inadequate labor analgesia. This has a clinically significant impact on parturient satisfaction and anesthesia provider workload. While epidural top-ups were the predominant component of our composite outcome, our *post hoc* sensitivity analysis indicated that our findings were consistent with or without the inclusion of epidural top-ups in our composite outcome.

In conclusion, we did not find significant differences in quality of analgesia or the incidence of adverse effects between dural puncture epidural and standard epidural techniques for labor analgesia in obese parturients. Those findings do not support routine use of the dural puncture epidural technique for labor analgesia in obese parturients.

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Competing Interests

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Reproducible Science

Full protocol available at: ashraf.habib@duke.edu. Raw data available at: ashraf.habib@duke.edu.

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