Published in final edited form as:

Anesth Analg. 2018 February ; 126(2): 545–551. doi:10.1213/ANE.0000000000002129.

Labor Analgesia Onset With Dural Puncture Epidural Versus Traditional Epidural Using a 26-Gauge Whitacre Needle and 0.125% Bupivacaine Bolus: A Randomized Clinical Trial

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Abstract

BACKGROUND: Lumbar epidurals (LEs) provide excellent analgesia. Combined spinal epidural and dural puncture epidural (DPE) are 2 techniques to expedite neuraxial analgesia onset. In DPE, dura is punctured but medication is not administered in the cerebrospinal fluid. Expedited analgesia onset has been demonstrated with DPE, using 0.25% bupivacaine; however, this concentration may impede an unassisted vaginal birth and is not currently used for induction and maintenance of labor analgesia. The primary goal of this study was to compare the percentage of patients who achieved adequate labor analgesia following DPE or LE with an epidural bolus of 0.125% bupivacaine. Adequate labor analgesia was defined as Visual Analog Scale (VAS) measurement ≤ 10 mm on a 100-mm scale during active contractions, measured 10 minutes after epidural bolus initiation.

METHODS: Laboring patients were randomly assigned to receive LE or DPE. Immediately before epidural placement, subjects marked a VAS score during an active contraction and parturients with VAS < 50 mm were excluded. The epidural space was identified by a loss of resistance technique to saline (17G Tuohy needle [Arrow International, Inc, Redding, PA]). In the DPE group, dura was punctured with a 26G Whitacre needle (Arrow International, Inc). In all

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This manuscript was handled by: Jill M. Mhyre, MD.

The authors declare no conflicts of interest.

Reprints will not be available from the authors.

participants, a 19G epidural catheter (Arrow International, Inc) was inserted. An epidural bolus was then administered over 3 minutes (12 mL, 0.125% bupivacaine, 50 μg fentanyl) followed by infusion (0.1% bupivacaine, 2 μg/mL fentanyl). After initiation of epidural bolus (time zero), VAS measurements were collected at 2-minute intervals for up to 20 minutes. Median time to achieve adequate analgesia by treatment group was assessed by Kaplan-Meier analysis. Time to achieving adequate analgesia was evaluated using a Cox regression model. All analyses were conducted in SAS version 9.4. (SAS Institute, Cary, NC)

RESULTS: Data were analyzed from 80 participants (40 per group). Adequate analgesia at 10 minutes did not differ by neuraxial technique (DPE = 55.3% vs LE = 44.7%; $P = .256$). However, parturients receiving DPE had shorter median times to adequate analgesia (median [95% confidence interval], 8 minutes [6–10] vs 10 minutes [8–14]) and a 67% increase in the relative risk of achieving adequate analgesia compared to LE (relative risk = 1.67; 95% confidence interval, 1.02–2.64; $P = .042$).

CONCLUSIONS: Although the percentage of parturients achieving adequate labor analgesia at 10 minutes after epidural bolus did not differ by technique, DPE was associated with faster time to VAS ≤ 10 mm compared with LE.

Lumbar epidural (LE) is the standard technique for providing labor analgesia. However, time to onset of adequate pain relief may be 15 to 20 minutes as the medication traverses the meninges to anesthetize the nerve roots. In combined spinal epidural (CSE), the dura mater is punctured using a spinal needle and medication is deposited in the subarachnoid space for expedited labor analgesia onset.[1] Disadvantages to the CSE technique include potential maternal hemodynamic instability and fetal bradycardia.[2,3] Dural puncture epidural (DPE) is a distinct technique where the dura mater is punctured using a spinal needle, but medication is not directly introduced into the intrathecal space.[4] Medication is administered into the epidural space through the epidural catheter, and the dural puncture facilitates migration of some medication intrathecally.

Previous studies have explored the efficacy of DPE in the setting of surgical and obstetric procedures.[4–9] To minimize motor blockade while maximizing possibilities for the rapid onset of labor analgesia, our primary aim was to evaluate neuraxial labor analgesia onset following epidural catheter bolus with a dilute local anesthetic solution (0.125% bupivacaine with 50 μg fentanyl) in active laboring parturients with and without DPE. Prior work examining 25, 26, and 27G Whitacre needles for spinal anesthesia in parturients found 27G needles to have lower rates of successful dural puncture; however, no difference in dural puncture success rates were noted between 25 and 26G needles.[8] A 26G Whitacre needle was selected for the dural puncture to minimize the possibility of postdural puncture headache while maximizing successful puncture of the dura mater. Our primary outcome was comparison of the percentage of parturients in each group with Visual Analog Scale (VAS) scores ≤ 10 mm on a 100-mm scale during an active contraction 10 minutes after initiating the epidural catheter bolus. We hypothesized that DPE would result in a faster onset and therefore a greater percentage of parturients with adequate analgesia at 10 minutes.

METHODS

Following approval by the institutional review board and written informed consent, parturients admitted to the labor and delivery unit for childbirth and planning to request neuraxial labor analgesia were enrolled in this single-blinded randomized study. Patients were consented for enrollment during their initial anesthesia evaluation on admission to the labor and delivery floor. Subject randomization was based on a computer-generated list created by the statistician before study initiation. Exclusion criteria included any contraindication to neuraxial anesthesia, non-English speaking, body mass index > 50 kg/m^2, patient refusal, and VAS < 50 mm during an active contraction on request for neuraxial analgesia. The study was registered at ClinicalTrials.gov (NCT#02412969) before patient enrollment, and this article adheres to the applicable Equator guidelines.

After verification of study eligibility and completion of written consent, the study personnel referred to the subject randomization list and informed the clinician performing the neuraxial procedure. All procedures were performed by senior anesthesia residents who had previously completed over 50 neuraxial procedures. Parturients were blinded to the type of neuraxial procedure. All neuraxial procedures were performed in the L3-L4 or L4-L5 interspace using a 17G Tuohy needle. DPE subjects received a dural puncture using a 26G Whitacre needle through the Tuohy needle and free flow of CSF was observed but no medication was administered into the subarachnoid space. All epidural catheters (19G) were inserted 4 to 5 cm into the epidural space. After negative aspiration for blood and CSF, a 3-mL test dose was administered (1.5% lidocaine with epinephrine 5 μg/mL) to check for intravascular or subarachnoid catheter placement. Epidural catheters were then dosed with a 12-mL bolus (0.125% bupivacaine with 50 μg fentanyl), in 4-mL aliquots administered every minute over 3 minutes. Patient-controlled epidural analgesia infusions were then started (bupivacaine 0.1% with 2 μg/mL fentanyl) at 10 mL/h with the ability for patient-administered bolus (5 mL every 10 minutes; 32 mL/h maximum). Patients or providers did not administer additional epidural boluses during the initial 20 minutes. Sensory and motor block was assessed by a member of the study team 20 minutes after epidural bolus. Sensory block was assessed to blunt pinprick. Motor block was assessed by modified Bromage score.[10] The study team member performing the assessment did not perform the block; however, they were not blinded to the assignment group.

Adequate analgesia was defined as VAS score ≤ 10 mm in the presence of contraction or a VAS score ≤ 10 mm in the absence of contraction provided that the VAS score was still ≤10 mm during the next contraction. The timing of data collection is detailed in Figure 1. Patients marked their “level of pain” on a 100-mm VAS scale on request for neuraxial labor analgesia. Following neuraxial analgesia placement, administration of the first 4-mL aliquot for epidural catheter bolus dosing marked time zero. Parturients were then instructed to mark their “level of pain” on a VAS 100-mm scale every 2 minutes up to 20 minutes to determine the time at which adequate pain control (VAS ≤ 10 mm) was achieved. Every time they marked on the VAS scale, they were asked if they were having a contraction or not. Contractions were confirmed by the tracing on the tocodynamometer, and these data were noted. Because it was anticipated that contraction frequency would vary with each

parturient, the 2-minute time interval was chosen to capture many data points and detail the improvement of analgesia with time.

Other collected data included demographic data, obstetric variables, procedural variables, occurrence of side effects, and patient satisfaction. Demographic data collected included maternal age, height, weight, body mass index, race, and American Society of Anesthesiologists score. Obstetrical data collected included parity, gestational age, cervical dilation at time of neuraxial placement, and labor augmentation. Procedural variables included time to pain relief, maternal heart rate (pre and post), and fetal heart rate (pre and post). Potential side effects examined included hypotension, fetal bradycardia, nausea, pruritus, occurrence of headache characteristic of postdural puncture at 24 and 48 hours, and occurrence of nerve injury as evidenced by sensory or motor involvement or patient complaint at 24 and 48 hours. Maternal hypotension, fetal bradycardia, and nausea were assessed in the initial 20-minute period. Maternal hypotension was defined as a decrease in mean arterial pressure greater than 20% of baseline, systolic blood pressure less than 90 mm Hg, or other drop in blood pressure requiring pharmacologic administration. Fetal bradycardia was defined as a rate of less than 110 bpm. The presence of nausea or fetal bradycardia was collected as a yes or no answer. Occurrence of pruritus, headache, or nerve injury was collected by patient follow-up with a verbal interview at 24 and 48 hours postpartum. Patient satisfaction was assessed by verbal interview at 24 to 48 hours postpartum by having the patient mark their satisfaction on a 100-mm scale (left “very dissatisfied” and right “very satisfied”) for satisfaction pertaining to neuraxial analgesia placement, speed of neuraxial analgesia placement (how quickly procedure was completed), time to pain relief, and overall satisfaction with analgesia. The need for additional neuraxial catheter boluses during labor (after the initial 20-minute period) was determined by the anesthesia team caring for the patient during labor.

Statistical Analysis

The primary outcome of interest was the percentage of parturients in each group with adequate analgesia 10 minutes after epidural bolus initiation. Adequate analgesia was defined as VAS score ≤ 10 mm in the presence of contraction or a VAS score ≤ 10 mm in the absence of contraction provided that the VAS score was still ≤10 mm during the next contraction. Descriptive statistics were calculated for all variables in the data set across all patients, within neuraxial technique, and within analgesia group (adequate analgesia at 10 minutes versus not). Secondary outcomes included time to achieve adequate analgesia, VAS scores in the presence of contractions over the 20-minute time period following epidural catheter bolus, need for physician-administered epidural boluses during labor, patient satisfaction, side effects, and block characteristics (sensory and motor) 20 minutes after epidural catheter bolus. Median time to achieving pain control by neuraxial technique was estimated using a Kaplan-Meier approach, and log-log confidence intervals around the median were reported. The relative risk of achieving adequate pain control by neuraxial technique was also evaluated using a univariate Cox regression model. The proportional hazards assumption for the Cox model was checked using the Grambsch-Therneau test. The association between VAS scores in the presence of an active contraction over time and neuraxial technique was evaluated using a generalized linear mixed model assuming a β

distribution with a logit link. The β distribution was selected since VAS scores were treated as proportions ranging between 0 and 1. The model included fixed effects for neuraxial technique, time, the interaction between neuraxial technique and time, and a random subject effect to account for repeated measures on the same parturient. Effect size was calculated from the mixed effects β-regression model of VAS score over time in contracting parturients. Model assumptions were checked graphically and found to be met. All analyses were conducted in SAS version 9.4.

Assuming that 50% of patients receiving an LE will have a VAS ≤ 10 mm at 10 minutes compared to 80% receiving DPE, an a priori power analysis found a sample size of 40 per group would provide 80% power at significance level $\alpha = .05$.

RESULTS

Patient enrollment took place between August 2014 and January 2016 and is detailed in Figure 2. One hundred one patients were consented for enrollment on admission to the labor and delivery unit for childbirth and before request for neuraxial analgesia placement. While 101 were randomly assigned to LE or DPE, 21 were excluded from data collection after randomization (Figure 2). Reasons for exclusion included delivery, withdrawal, protocol violation, or VAS < 50 mm on neuraxial analgesia request. Data were collected on 80 parturients. Patient characteristics by neuraxial technique appeared relatively balanced (Table 1).

Primary Outcome

The primary outcome, the percentage of parturients with adequate labor analgesia 10 minutes after the initiation of the epidural catheter bolus as defined as a VAS ≤ 10 mm on a 100 mm scale during an active contraction, did not differ by neuraxial technique (Table 2). A majority of the parturients, 58.8%, reported adequate analgesia within 10 minutes.

Secondary Outcomes

Figure 3 shows the Kaplan-Meier curves for time to achieving adequate analgesia by neuraxial technique. Parturients receiving DPE had shorter median times to adequate analgesia (Table 2). The relative risk of achieving pain control at any collected time point in parturients receiving DPE was 1.7 times greater than in those receiving LE in a Cox proportional hazards model (relative risk = 1.67; 95% confidence interval, 1.02–2.64; $P = .042$). Figure 4 shows the observed median VAS scores at each data collection point in all patients (Figure 4A) and in patients experiencing an active contraction (Figure 4B). VAS scores decreased with time ($P < .001$). When examining the interaction between neuraxial technique and time, VAS scores decreased faster with DPE versus LE, regardless of the presence of a contraction ($P = .003$; Figure 4A). If only contracting parturients were examined, this difference was confirmed ($P = .001$; Figure 4B). The observed effect size for the interaction between neuraxial technique and time was 2.7. The requirement for additional, physician-administered epidural boluses during the course of labor and patient satisfaction measurements were not significantly different by neuraxial technique (Table 2).

Block characteristics (degree of motor block and sensory level) and side effects did not differ by neuraxial technique (Table 3).

Nine patients (9%), 7 LE (17.5%) and 2 DPE (5%), did not achieve consistent VAS ≤ 10 mm in the 20-minute study period. Despite this, all parturients were satisfied with their neuraxial analgesia, and no epidural catheters required replacement.

DISCUSSION

This randomized clinical trial examined the onset of adequate analgesia in laboring parturients receiving neuraxial analgesia by LE or DPE utilizing a 26G Whitacre needle for dural puncture and epidural catheter bolus with 12 mL of 0.125% bupivacaine with 50 μg fentanyl. Although the percentage of parturients with adequate analgesia did not differ by neuraxial technique 10 minutes following the initiation of the epidural bolus, DPE was associated with reduced time to adequate analgesia.

DPE has been found to improve neuraxial medication delivery in the past. Suzuki et al[4] investigated DPE in patients having lower abdominal surgery. They utilized a 26G Whitacre for dural puncture and bolused 15 mL of 2% mepivacaine over 1 minute through the epidural catheter. They noted improved sacral spread and hypothesized that a small amount of local anesthetic spread into the subarachnoid space through the dural hole to anesthetize the caudal nerves. In contrast, the first study of DPE in laboring parturients examined a smaller spinal needle, 27G Whitacre, without an epidural bolus.[5] Rather, an infusion of 0.11% bupivacaine with 2 μg/mL fentanyl was started (10 mL/h with 5 mL demand every 10 minutes) and physician-administered rescue boluses of 0.25% bupivacaine (5–15 mL) were given throughout labor for inadequate analgesia.

They concluded DPE did not improve the quality of analgesia compared with a traditional labor epidural. In 2008, Cappiello et al[6] reexamined DPE for labor analgesia with a 25G Whitacre needle for dural puncture and epidural catheter bolus administered over 5 minutes (12 mL, 0.25% bupivacaine) followed by epidural infusion (0.125% bupivacaine with 2 μg/mL fentanyl). They found DPE to improve sacral spread and bilateral pain relief; however, DPE was also associated with increased instrumental vaginal delivery rates. Recently, Chau et al[9] utilized a low-concentration epidural catheter bolus (20 mL, 0.125% bupivacaine, 2 μg/ mL fentanyl) over 5 minutes. They found DPE to improve block quality over LE with improved sacral coverage, fewer asymmetric blocks, and less need for physician bolus inter-vention; however, they did not find a difference in time to numeric pain rating scale ≤1 between groups.[9] Further, they noted DPE to have fewer maternal and fetal side effects than CSE. Similar to these prior studies, our data demonstrate that DPE appears to be a successful technique with 26G needles if an epidural bolus is administered and may offer certain clinical advantages over LE for labor analgesia.

Our data also indicate that a less concentrated local anesthetic (bupivacaine 0.125%) may be effective for epidural catheter dosing following DPE without compromising motor function. Both DPE and LE techniques demonstrated similar degrees of motor block and achievement of bilateral sensory levels. However, DPE was associated with a decreased median time to

adequate analgesia. Our protocol specifically included dilute concentrations of local anesthetics (bupivacaine 0.125% bolus; bupivacaine 0.1% patient controlled epidural analgesia) to minimize motor blockade and did not differ by neuraxial technique. This practice is consistent with recommendations to use dilute solutions to facilitate unassisted vaginal delivery and has an established safety profile in obstetric anesthesia practice.[11] Notably, the requirement for additional boluses to maintain analgesia, side effects, and patient satisfaction were also similar between groups.

The gauge of the needle utilized for the dural puncture may also play a significant role in medication delivery based on past in vitro and in vivo studies. In a primate model, Bernards et al[7] demonstrated a flux of medication administered by epidural into the subarachnoid space following dural puncture with 18 to 25G needles. Additionally, the extent of intrathecal medication migration was dependent on the size of the dural hole, the diffusion capacity of the drug, and the distance between the puncture site and epidural drug administration.[7,12] Past publications noting the success of DPE utilized a 25 or 26G Whitacre.[4,6] In contrast, a study that did not find advantages with a DPE block relative to LE used a 27G Whitacre.[5] In our study, a 26G Whitacre was utilized to promote success with dural puncture and medication movement while also minimizing the potential risk of postdural puncture headache.

Prior studies have not examined labor analgesia onset in terms of the presence or absence of contractions. The uncertain cyclical nature of labor makes this a difficult parameter to measure. Nonetheless, almost 60% of patients, regardless of neuraxial group allocation, reported adequate labor analgesia within 10 minutes. To accurately capture analgesia onset in laboring women with different contraction patterns, only parturients with pain (VAS > 50 mm) were enrolled, and VAS data were collected frequently (every 2 minutes) while marking the presence of contractions during data collection. Cappiello et al[6] captured the percentage of parturients with VAS < 10 mm 20 minutes after epidural placement with DPE or LE technique. However, the onset of analgesia by either technique was not reported in reference to labor contractions.

Secondary outcomes of maternal hemodynamics, fetal heart rate, motor and sensory quality of the block, nausea, pruritus, incidence of nerve injury, and headache did not differ by neuraxial technique. This low side-effect profile with DPE is consistent with prior reports.[5,6] It is interesting that patients who did not experience adequate pain relief by 10 minutes were equally satisfied with their epidural experience when compared with patients who achieved adequate pain relief by 10 minutes. This suggests that other factors, apart from rapid onset of pain relief, also determine adequate patient satisfaction in the setting of childbirth. However, because we were not adequately powered to examine these side effects, further investigation is warranted.

This study does have some limitations. The onset of adequate labor analgesia remains difficult to measure given the uncertain cyclical nature of labor that differs by each parturient and their progress in childbirth. While we attempted to control for this by recording the presence or absence of contraction on VAS data collection, enrolling only patients with known pain (VAS > 50 mm), and recording factors such as cervical dilation and augmented

labor, it is difficult to precisely define the onset of labor analgesia when comparing numerous parturients in various stages of labor. Consequently, this is an inherent limitation of our study and, therefore, caution may be warranted in interpreting the faster onset of analgesia with the DPE technique as reported in this study. A second limitation is the lack of blinding. Although the study personnel did not perform the regional technique, we did not specifically blind study team members from the randomization. However, all VAS marks were made by the patients and they were blinded to the group assignment. Further, while our study was designed to record physician rescue boluses, the number or frequency of patient-administered boluses by patient controlled epidural analgesia were not captured and were not compared between groups. Finally, we selected a 26G Whitacre. However, future studies looking at different gauges of spinal needles for optimal dural puncture with DPE to facilitate labor analgesia onset are warranted.

In conclusion, although the percentage of parturients of achieving adequate labor analgesia at 10 minutes after epidural bolus did not differ by technique, DPE was associated with shorter median times to VAS ≤ 10 mm compared with LE.

Funding:

Departmental.

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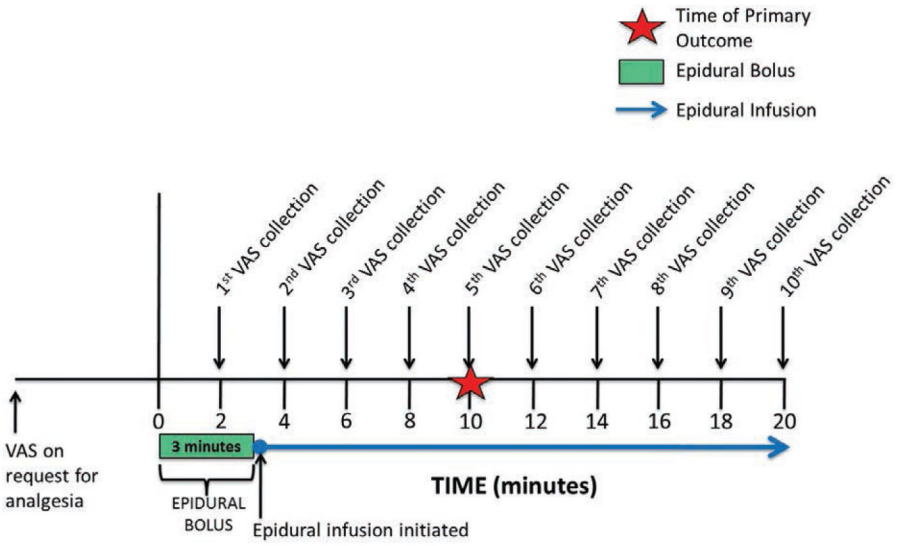

Figure 1.

Schematic of epidural dosing and VAS score data collection. VAS indicates Visual Analog Scale.

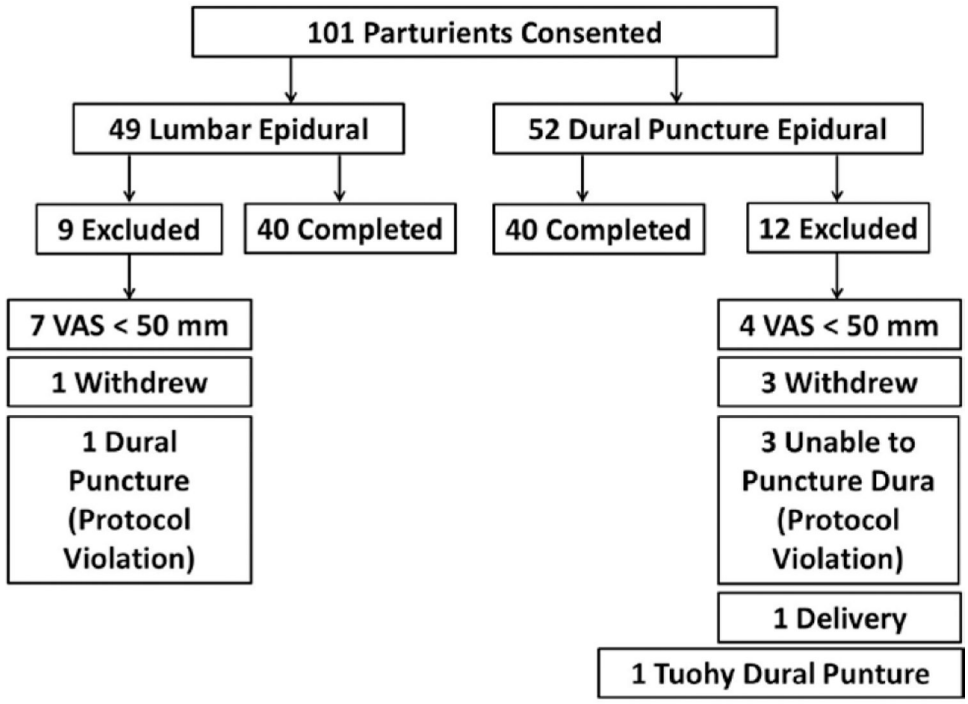

Figure 2.

CONSORT flow diagram of patients enrolled, randomly assigned, and analyzed. Dural puncture was performed with a 26G Whitacre needle through a 17G Tuohy needle in the dural puncture epidural group.

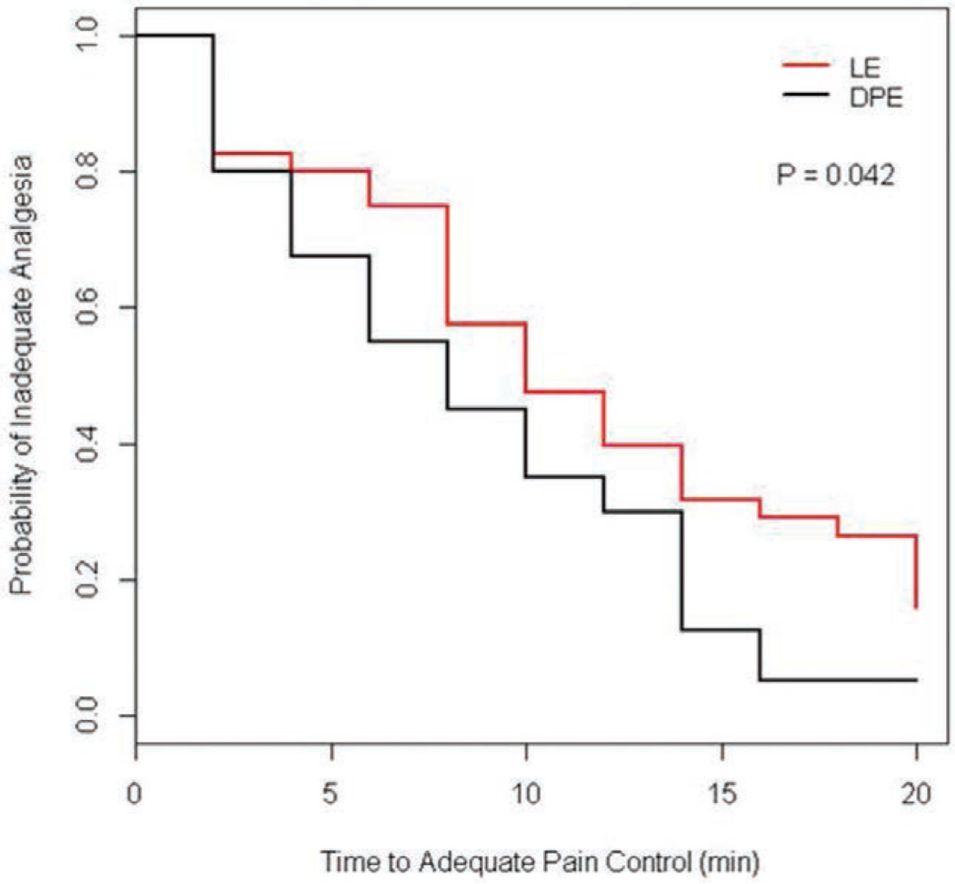

Figure 3.
Kaplan-Meier curves for time to achieving adequate analgesia by neuraxial technique. LE indicates lumbar epidural; DEPE, dural puncture epidural.

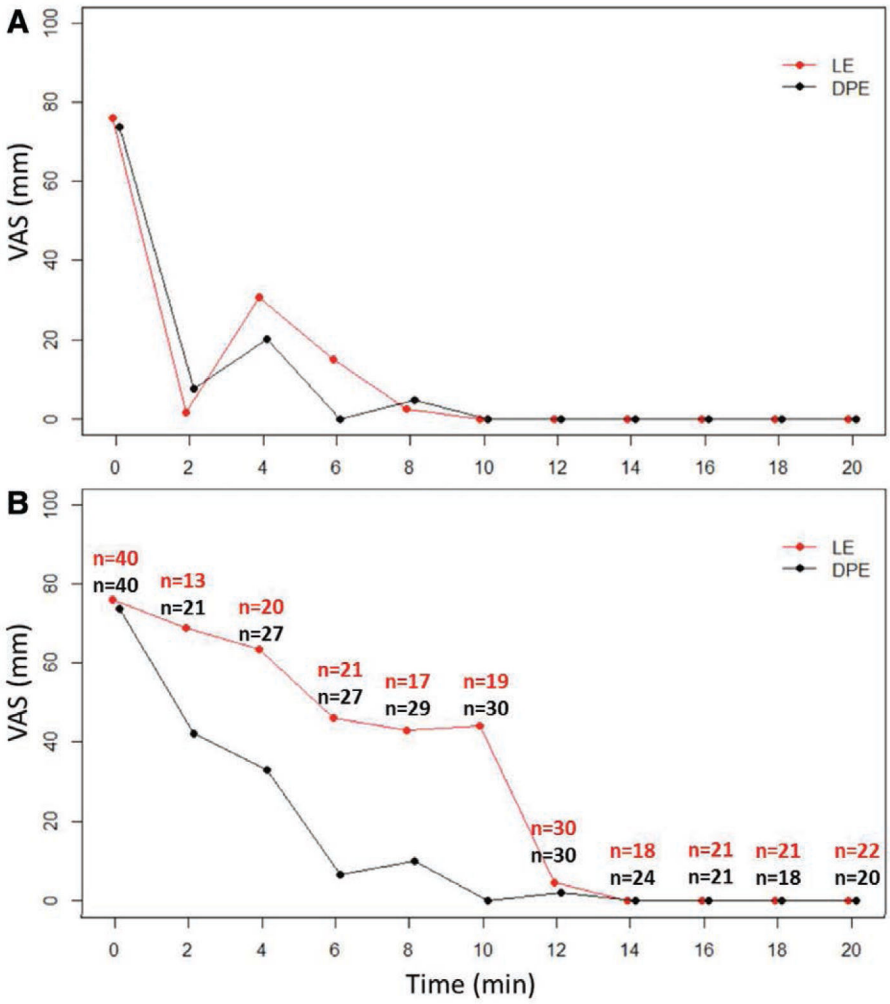

Figure 4.

Median VAS score observed at each time point by neuraxial technique for all parturients (A) and for parturients experiencing an active contraction (B). The number of parturients (n) experiencing a contraction at each data collection point by block type is noted (B). VAS indicates Visual Analog Scale.

Table 1.

Characteristics by Neuraxial Technique

	LE (n = 40)	DPE (n = 40)
VAS before placement (mm)[a]	76.1 (16.4)	78.2 (16.4)
Maternal characteristics		
Maternal age (y)[a]	28.9 (5.24)	27.4 (5.02)
BMI (kg/m^2)[a]	33.1 (8.55)	33.7 (7.86)
Race (Caucasian)[b]	19 (48.7)	18 (46.2)
ASA score 2[b]	38 (95.0)	37 (94.9)
Hemodynamics[a]		
Maternal blood pressure (mm Hg)		
SBP postepidural[c]	123.2 (18.0)	118.2 (24.8)
DBP postepidural[c]	70.5 (4.4)	66.8 (13.0)
FHR (bpm)		
Preepidural	140.0 (12.3)	135.6 (10.7)
Postepidural[c]	138.9 (10.6)	135.9 (11.1)
Labor characteristics		
Gestational age (wk)[a]	39.1 (1.88)	38.9 (1.91)
Nulliparous[b]	18 (36.6)	14 (46.2)
Cervical dilation (cm)[a]	3.8 (1.4)	3.7 (1.5)
Labor augmentation[b]	18 (45.0)	21 (52.5)
Mode of delivery[b]		
Vaginal	31 (77.5)	34 (85)
Assisted (forceps)	1 (2.5)	0 (0)
Cesarean	8 (20)	6 (15)

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; DBP, diastolic blood pressure; DPE, dural puncture epidural; FHR, fetal heart rate; LE, lumbar epidural; SBP, systolic blood pressure; VAS, Visual Analog Scale.

[a]Continuous variables are reported as mean (SD).

[b]Categorical variables are reported as n (%).

[c]Postepidural measurements were acquired 20 min after the initiation of the epidural bolus.

Table 2.

Outcomes by Neuraxial Technique

	LE (n = 40)	DPE (n = 40)	*P*
Primary outcome[a]			
VAS < 10 mm at 10 min	21 (44.7)	26 (55.3)	.256
Secondary outcomes			
Time to adequate analgesia[b] (min)	10 (8–14)	8 (6–10)	.042
Physician bolus during labor	3 (7.50)	7 (17.5)	.176
Patient satisfaction (mm)[a]			
Overall treatment	93 (12)	88 (25)	.547
Time to pain relief	91 (14)	87 (24)	.879
Epidural placement	95 (0.9)	87 (2.6)	.352
Speed of epidural placement	94 (11)	86 (24)	.275

Patient satisfaction data was assessed by subjects marking on a 100 mm scale.

Abbreviations: DPE, dural puncture epidural; LE, lumbar epidural; VAS, Visual Analog Scale.

[a]Data reported as n (%).

[b]Data reported as median (log-log 95% confidence interval).

Table 3.

Block Characteristics and Side Effects by Neuraxial Technique

	LE (n = 40)	DPE (n = 40)
Block characteristics at 20 min		
Sensory block (blunt pinprick)		
Left side achieved T10	32 (91.4)	35 (100.0)
Right side achieved T10	31 (88.6)	34 (97.1)
Block levels unequal bilaterally	5 (14.3)	7 (20.0)
Bromage scale		
1	3 (7.69)	3 (8.11)
2	2 (5.13)	4 (10.8)
3	5 (12.8)	5 (13.5)
4	29 (74.4)	25 (67.6)
Side effects		
Fetal bradycardia within 20 min	3 (7.50)	0 (0.00)
Hypotension within 20 min	3 (7.50)	2 (5.00)
Pruritus within 48 h	5 (12.5)	1 (2.50)
Headache within 48 h	1 (2.50)	0 (0.00)
Nerve damage within 48 h	0 (0.00)	0 (0.00)
Any side effects	8 (20.0)	3 (7.50)

Data reported as n (%).

Abbreviations: DPE, dural puncture epidural; LE, lumbar epidural.