Original Article

Effect of Obesity on Dural Puncture Epidural Analgesic Onset in Parturients Scheduled for Normal Vaginal Delivery

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Abstract

Background: Obese parturients are at higher risk for epidural analgesic failure, so the dural puncture epidural (DPE) technique may have a particular advantage in this population. DPE has been suggested to improve the efficacy of labor epidural analgesia, potentially by facilitating the translocation of medication from the epidural to the intrathecal space. We designed this prospective interventional study to explore the influence of obesity on DPE technique regarding labor analgesia onset and quality.

Materials and Methods: The study was prospective interventional. A total of 64 parturients consented to receive DPE labor analgesia. Parturients were assigned according to pregestational body mass index groups into normal weight and obese groups. After the successful placement of the epidural catheter and puncturing of the dura, an analgesic regimen was initiated. The primary outcome was the median time to onset of sensory block assessed by Kaplan-Meier analysis.

Results: We found the median time to onset of sensory block to be 6 min in obese parturients compared with 13 min in nonobese. The difference between both groups was statistically significant (Chi-squared = 56.663, df = 1, P < 0.0001). Incidence rate ratio (95% CI) = 21.0 (9.51, 46.5). No asymmetrical block was noticed in both group, but a higher incidence of perineal dose supplementation and postoperative nausea were observed in the obese group.

Conclusion: DPE offers a favorable risk-benefit ratio for the management of neuraxial analgesia in obese parturients. Further studies comparing different volumes, concentrations, and methods of application of DPE local anesthetic are needed.

Keywords: Body mass index (BMI), Combined spinal epidural (CSE), Dural puncture epidural (DPE), Maternal satisfaction, Labor pain, Obesity

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Introduction

Spinal, epidural, or combined anesthesia are widely used for labor analgesia. It is due to the lower morbidity and mortality compared to general anesthesia (1). Current guidelines recommend specifically early epidural analgesia for parturients with a body mass index (BMI)≥40 kg/m^2 (2) as obese

parturients are at more risk of emergency cesarean delivery, instrumental delivery, and macrosomic neonates. Additionally, the insertion and management of labor epidurals in obese women are not always straightforward (2).

The epidural technique is the standard technique for labor analgesia. It offers several advantages, including an easily titratable local anesthetic dose and level of anesthesia, the ability to extend the block for prolonged surgery, slower and more easily controllable hemodynamic changes, and a decreased potential for excess motor blockade (3).

However, it can be associated with slow onset, epidural catheter failure, inadequate sacral spread, and asymmetrical or patchy sensory blockade (4). On the other hand, the combined spinal epidural (CSE) technique provides rapid onset of uniform sensory blockade with excellent sacral coverage, but is adversely associated with maternal pruritus, fetal bradycardia, and delayed functional testing of the epidural catheter (5).

The dural puncture epidural (DPE) technique is a modification of the CSE technique. A spinal needle is inserted, creating a dural puncture. No medication is injected into the subarachnoid space. This small dural hole appears to enhance the effectiveness of administered epidural drugs by acting as a conduit for the translocation of medications from the epidural space to the subarachnoid space. DPE is characterized by rapid onset of analgesia, better sacral spread, and a lower risk of an asymmetrical block (4).

In this study, DPE used for labor analgesia will be explored & compared in obese & non-obese parturients. Acknowledging that the flux between the epidural and dural spaces might be dependent on the pressure gradient between the 2 spaces, we hypothesize that DPE will have a faster onset to adequate analgesia with a better sacral spread in obese parturients when compared to non-obese ones. The reason for this hypothesis may be related to increased intraabdominal pressure and the presence of engorged epidural veins and fat, which forces more epidurally administered medications to reach cerebrospinal fluid (CSF) in obese parturients.

Methods

Ethics: The University Ethics committee provided ethical approval for this study (FMASU R 149 / 2021) on 28/8/2021. The study was prospectively registered at Clinical trial Registry ClinicalTrials.gov Identifier: NCT04963452 by WHO and ICMJE standards. Written informed consent was obtained from all parturients.

Parturients' recruitment: Parturients were divided into two groups according to their pregestational BMI (6) as per the WHO's classification of obesity (7).

Non obese: BMI=20-24.9 kg/m^2

Obese: BMI=30-49.9 kg/m^2

Maternal body mass index (BMI; kg/m^2) was calculated from the parturient's pre-pregnancy self-reported height and weight.

Inclusion criteria: We enrolled 64 parturients scheduled for spontaneous or induced vaginal delivery, with a pre-epidural placement verbal numerical rating pain score ≥ 50 (during an active contraction) and cervical dilatation < 5 cm N.B.

The most easily applied score for labor pain assessment is the verbal numerical rating pain score (VNRS), where the parturient is asked to give a number from 0 to 100 to indicate the severity of the pain, 0 being no pain and 100 being the worst pain ever (8).

Exclusion criteria:

1- > 3 trials of epidural insertion

2- Inadvertent dural puncture using the epidural needle

3- Severe cardiac, respiratory, renal, or hepatic diseases.

Anesthesia and surgical procedure: Baseline vitals were documented after the application of routine basic monitoring, and an 18-G intravenous (IV) cannula was inserted. Due to the unavailability of the CSE set, we used separate epidural and spinal needles. The parturients had epidural block performed under complete aseptic technique, at L3–L4 level via the midline approach, with parturients in the sitting position, using an 18-gauge, 8 cm Tuohy needle and loss of resistance to air technique for identification of the epidural space. After confirmation of epidural space, a 20-gauge, closed-tip, multiport epidural catheter was inserted 4 cm cephalad into the epidural space. Then they received a dural puncture with a 26-

gauge spinal needle, inserted through L4–L5, but no subarachnoid drug was injected.

Epidural regimen: After negative aspiration for blood and CSF, all parturients received the initial dosing regimen per the study protocol. Initial dosing for the DPE technique consisted of 20 mL of 0.25% bupivacaine with fentanyl 2 µg/mL fractionated into four 5-mL boluses, waiting for 2 minutes between each aliquot. Analgesia was considered adequate if the VNRS score was <30. The onset of analgesia was defined as from the time of the first bolus dose to the time of achieving VNRS <30. Upon initial dosing, the continuous epidural infusion was initiated immediately with a fixed infusion at a rate of 10 mL/h of 0.25% bupivacaine. The infusion was prepared in a 50 mL syringe of 25 mL normal saline + 25 mL Bupivacaine 0.5% + 50 µg fentanyl. This dosing regimen was guided by previous research (4, 9).

If the epidural has worked well, but the parturient is now in pain, an additional 10 ml of study medication was administered. If the top-up dose did not provide adequate pain relief, the catheter was withdrawn in 1–2 cm increments. An additional top-up dose of 5 ml of 0.25% bupivacaine was administered. If there is still no effect, consider replacing the epidural at this stage. This suggested protocol was guided by previous research (8). Suppose pain scores have never been less than 30 within 40min after initial epidural placement despite checking the epidural site and connections. In that case, it is considered an epidural failure. The epidural will be replaced at this stage, as the epidural will never be satisfactory

Parturient Reported Outcomes: The primary outcome was the "onset of sensory block," which was analyzed using Kaplan–Meier curves. Other reported outcomes:

1- Maternal satisfaction Numerical Rating Scale (10) for DPE

- Assessed after delivery
- They choose one of four descriptive terms: excellent, satisfactory, poor, or useless

2- Maternal adverse effects

a) Pruritus was evaluated by asking the parturient for presence and severity graded on a scale ranging from 0 = none, 1 = mild, 2 = moderate, and 3 = severe .

b) Nausea was evaluated by asking the parturient for presence and severity graded on a scale ranging from 0 = none, 1 = mild, 2 = moderate, and 3 = severe .

c) Incidence of postdural puncture headache (PDPH) and persistent lumbar back pain (LBP) (assessed after 24 h).

Sample Size: By using the G power program for sample size calculation, setting power at 80%, alpha error at 5%, and assuming medium effect size difference (0.3) in the outcome of dural puncture epidural (VNRS pain score) between parturients undergoing normal vaginal delivery with increased BMI and those with normal BMI. Based on that, a sample size of at least 32 parturients with increased BMI and 32 parturients with normal BMI undergoing normal vaginal delivery will be sufficient to achieve the study objectives.

Statistical Methods: Data were analyzed using IBM© SPSS© Statistics version 23 (IBM© Corp., Armonk, NY). Continuous numerical data are presented as mean, and SD and intergroup differences are compared using the independent-samples t-test. Skewed data are presented as a median and interquartile range, and between-group differences are compared with the Mann-Whitney U-test. Categorical data are presented as counts and percentages, and differences are compared using the chi-squared test or Fisher's exact test. Ordinal data are compared using the chi-squared test for trends. A time-to-event analysis is done using the Kaplan-Meier method. The log-rank test is used to compare Kaplan-Meier curves. Repeated measures analysis of variance (ANOVA) is used to examine the effect of BMI on the change in pain scores and hemodynamic variables. P-value < 0.05 is considered statistically significant.

Results

A total of 64 parturient completed the study. No significant differences were observed regarding demographic and obstetric characteristics between the two groups. Regarding DPE procedural details, obese parturients significantly had longer performance time and a higher number of epidural attempts. Additionally, epidural catheter manipulation and catheter replacement incidences were significantly higher in the obese group (Table 1). No cases of

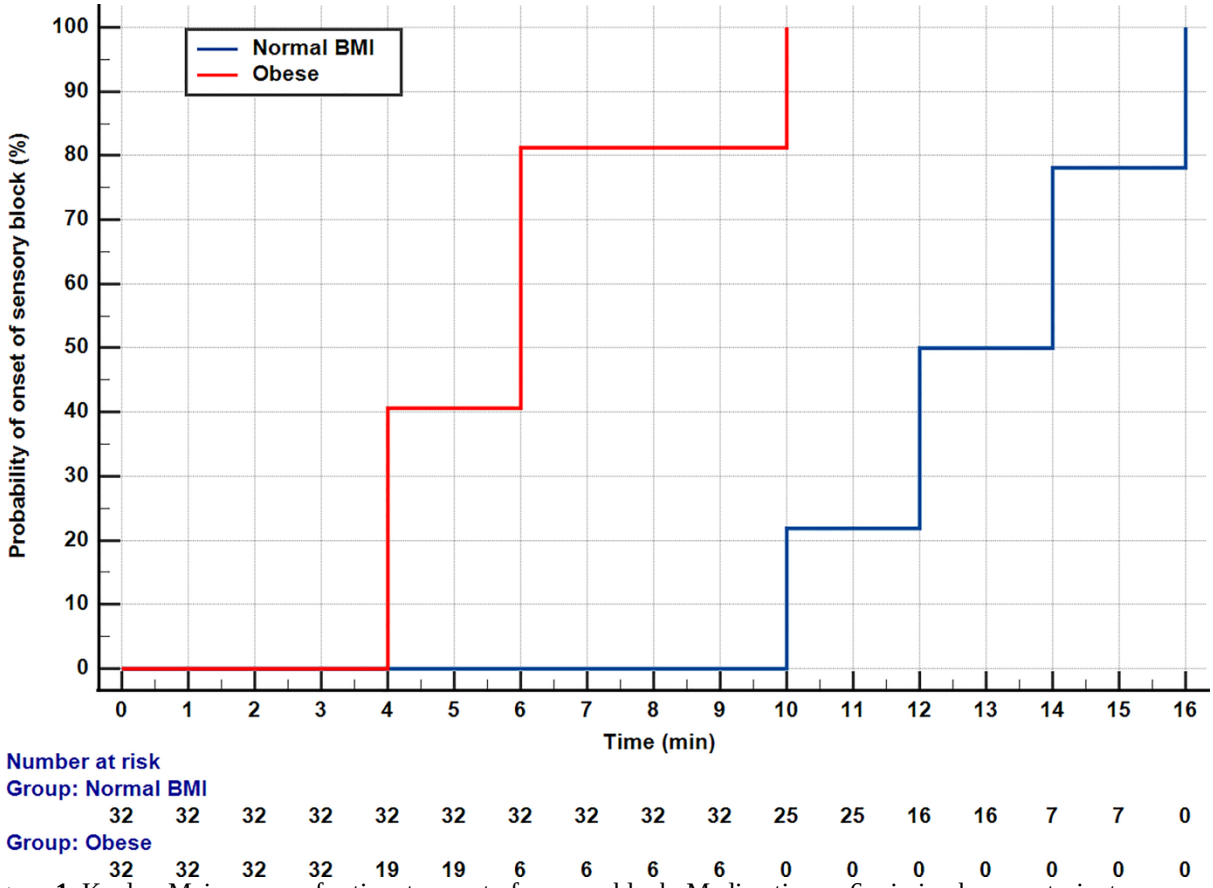

Figure 1. Kaplan-Meier curves for time to onset of sensory block. Median time = 6 min in obese parturients compared with 12 min in parturients with normal BMI. Difference between both groups is statistically significant (Logrank Chi-squared = 56.663, df = 1, p < 0.0001). Incidence rate ratio (95% CI) = 21.0 (9.51, 46.5).

intrathecal or intravascular catheter insertion were encountered in any parturient in any group.

Concerning DPE analgesic onset, Kaplan–Meier curves showed that the obese group had a statistically significant earlier onset of the sensory block with a VNRS score of <30 (median time of 6 minutes in the obese group versus 13 min in the nonobese group) and earlier onset of T7 sensory block (median time of 8 minutes in obese group versus 24 min in the nonobese group) (Table 1 and Figure 1). The obese group experienced an earlier onset of epidural top-up dose (median time of 150 minutes in the obese group versus 180 min in the nonobese group) as detected by Kaplan-Meier curves- but that was statistically insignificant. Finally, we conducted repeated measures ANOVA to examine the effect of obesity on the change in VNRS. The assumption of sphericity was not met (Mauchly's test of sphericity $P < 0.001$, Greenhouse-Geisser $\varepsilon = 0.408$, Huynh-Feldt $\varepsilon = 0.515$). So, the Greenhouse-Geisser was applied to correct the degrees of freedom. There is a statistically significant effect of time ($F(6.12, 195.69) = 61.77$, $P < 0.001$) with a statistically significant Time group interaction ($F(6.12, 195.69) = 3.22$, $P = 0.005$). Between-Subjects effect is statistically significant ($F(1, 32) = 12.30$, $P = 0.001$). Estimated marginal mean VNRS was significantly lower in the Obese group (mean difference = 3.88, SE = 1.1, t = 3.51, df = 32, Tukey-adjusted $P = 0.001$) (Figure 2)

Obese parturients had a higher incidence of perineal dose supplementation (65.6% in the obese group versus 40.6% in the nonobese group). No case of asymmetrical block was encountered in any parturient. (Table 1)

Finally, there was a higher incidence of moderate and severe nausea in the obese group (90% in obese versus 37% in nonobese). A significantly higher number of parturients had experienced LPB

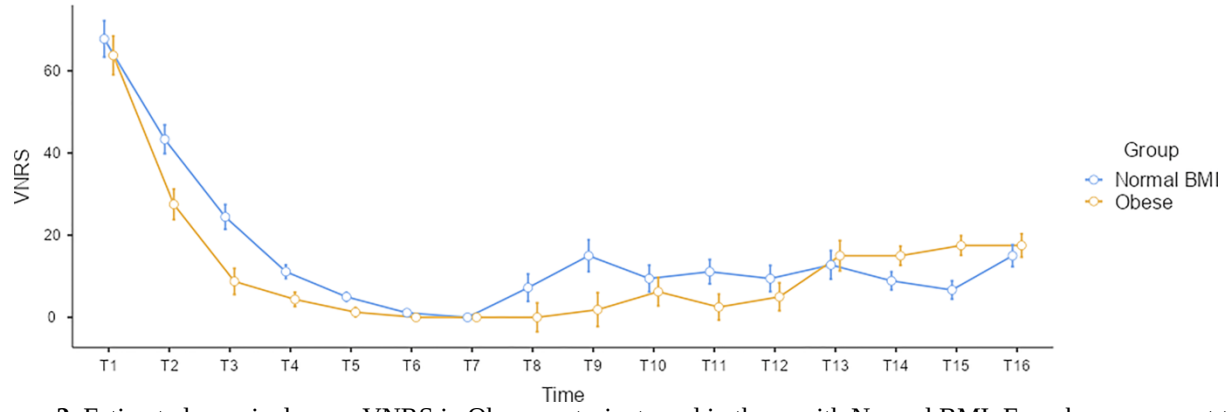

Figure 2. Estimated marginal mean VNRS in Obese parturients and in those with Normal BMI. Error bars represent the standard error (SE). There is a statistically significant effect of time (F [6.12, 195.69] = 61.77, P < .001) with a statistically significant Time * Group interaction (F[6.12, 195.69] = 3.22, P = .005). Between-Subjects effect is statistically significant (F [1, 32] = 12.30, P = .001). Estimated marginal mean VNRS is significantly lower in the Obese group (mean difference = 3.88, SE = 1.1, t = 3.51, df = 32, Tukey-adjusted P = .001).

Table 1: Procedural details of DPE block and course of labor.

Variable	Normal BMI (N=32)	Obese (N=32)	p-value
Performance time (min)	6 (5.0 to 7.0)	11 (9.5 to 13.0)	**<0.0001†**
Number of epidural placement attempts	1 (1 to 2)	2 (2 to 3)	**<0.0001†**
Epidural catheter manipulation	0 (0.0%)	11 (34.4%)	**<0.001§**
Epidural catheter replacement	0 (0.0%)	6 (18.8%)	**0.024‡**
Time to onset of sensory block (min)	13 (12 to 14)	6 (4 to 6)	**<0.0001†**
Time to T7 sensory block (min)	24 (22 to 26)	8 (6 to 10)	**<0.0001†**
Need for perineal dose supplementation	13 (40.6%)	21 (65.6%)	**0.045§**
Time to first epidural top-up dose (min)	180 (120 to 200)	150 (128.8 to 170.0)	0.485†
Total labor epidural time (min)	310 (245 to 595)	340 (270 to 550)	0.809†
Assisted Vaginal Delivery	6 (18.8%)	8 (25.0%)	0.545§
CS	5 (15.6%)	10 (31.3%)	0.140§

Data are median (interquartile range) or count (percentage).
†. Mann-Whitney test.
‡. Fisher's exact test.
§. Pearson chi-squared test.

(66% in obese versus 9% in nonobese). There was no significant difference between the two groups regarding pruritis, PDPH, and maternal satisfaction.

Discussion

DPE and labor analgesia quality: In this study, we chose the DPE technique to be explored for its

proposed advantages. The key finding of our study was that the DPE technique provided significantly earlier analgesic onset in the obese group (median:6 minutes in obese versus 13 minutes in nonobese) with 0% asymmetrical block in both groups. Additionally, a significantly low VNRS pain score was noticed in the obese group all over the labor timeline. Despite these beneficial effects, there was more sacral sparing in 66% of the obese group when compared to only 41% in the non-obese group.

In this research, very rapid onset was noticed in the obese group. We could attribute this to 2 main reasons:

1- we used a high concentration and large volume in the initial epidural dose. It is postulated that the medication transfer through the dural hole is probably facilitated when higher epidural volumes and/or shorter injection times are used (11).

2- the relative decrease in CSF volume in obese parturients may influence transferred medications through the dural hole (6). It is assumed that the gravid uterus and abdominal panniculus cause compression on the inferior vena cava resulting in epidural vein engorgement and increased abdominal pressures displacing soft tissues through the intervertebral foramina. Subsequently, decreased CSF volume and possibly increasing CSF pressure will be followed (6). These previous two causes would explain why obese parturients in our study encountered rapid onset of analgesia and rapid achievement of a high level of T7 sensory block.

In obese parturients, 75–80% of the normal local anesthetic neuraxial dose is suggested to be sufficient (12). Given that we did not reduce local anesthetic dosage in the obese group, this could explain significantly low VNRS pain scores throughout the labor process.

Supporting our results, Panni and their colleagues (13) found that obese parturients had significantly decreased epidural bupivacaine analgesic requirements by a factor of 1.68 when compared to non-obese, with a higher initial level of block. On the other hand, Tan and their colleagues (14) did not find significant differences in the quality of analgesia between DPE and standard epidural technique for labor analgesia in obese parturients using programmed intermittent boluses. They attributed their results to the usage of diluted local anesthetic (0.1% ropivacaine) that had a low diffusion gradient to be transferred through either meninges or dural holes.

Sacral coverage is important, and if not present, it often indicates inadequate analgesia, particularly during the second stage of labor and with instrumented deliveries. The S2-4 nerve roots are covered with thick dura mater, have a large diameter, and are further away from the tip of the epidural catheter than the roots transmitting pain in the first stage of labor (T10-L1). These factors could reduce diffusion to sacral nerve roots leading to sacral sparing and failure of labor analgesia in the second stage. (15) Previous studies observed that DPE improved sacral coverage in nonobese parturients (16). However, in our study, 66% of obese parturients required perineal dose supplementation compared to nonobese ones (41%). In trying to improve sacral spread in obese parturients, we suggest the combination of the DPE technique with programmed intermittent boluses using a higher concentration of local anesthetics. It could offer effective analgesia, as observed by Song and colleagues' study (17) on nonobese parturients. They suggested that the higher injectate pressures used in the intermittent bolus technique might increase drug transfer through the dural puncture, increasing its effectiveness. A higher concentration of local anesthetics should be considered in this approach, as diluted local anesthetic might be ineffective, as assumed by Tan and their colleagues (14).

DPE and procedural difficulties and complications:

Performing neuraxial blockade in obese parturients can be technically challenging because:

1- bony landmarks are more difficult to palpate. Midline anatomical. landmarks are deeper

2- interlaminar, and interspinous spaces are narrowed due to degenerative diseases

3- back flexion is more limited (7).

Moreover, since neuraxial labor analgesia offers several important clinical benefits to obese parturients (18), some tips were postulated to ensure better localization of epidural space, with decreasing incidence of epidural catheter displacement:

1. The sitting position is preferred by the obese (3). The sitting flexed position brings the epidural space closer to the skin. Also, the prominence of the seventh

cervical vertebra and gluteal cleft can be observed in this position allowing for easier identification of the midline compared with the lateral position (12).

2. Ultrasonography can also help identify the midline and estimate the depth of the epidural space, especially if the paramedian sagittal oblique plane is used (19).

3. It is advised to begin using the standard-length needles that are easier to manipulate and only transition to the longer set when assured the length of the needle is the only barrier to reaching the epidural space. Longer needles can cause serious injury and are difficult to control (20).

4. The loss of resistance technique with saline solution is usually recommended for obese parturients. As ligaments are softer due to progesterone leading to false positive results. However, using a loss of resistance technique with saline can hinder the identification of an inadvertent dural puncture (ADP) (21).

5. Securing the catheter with tape in the upright sitting position. Changing position from flexed to sitting causes redistribution of subcutaneous tissue, and the catheter frequently appears to be drawn inwards (20).

In this study, we observed: significant procedural difficulties in obese parturients, which matches the results obtained in previous studies (21-23). We observed: a higher number of epidural placement attempts in the obese group with subsequent longer performance time (a median of 11 minutes in obese versus 6 minutes in nonobese). Additionally, epidural catheter manipulation and replacement were significantly higher in the obese group (34% & 19% versus 0%&0%, respectively).

In a retrospective study (21), the need for three or more attempts was significantly more frequent among obese, 9.1% against 5.3% non-obese. Another study (22) concluded that the risk of difficult epidural placement is 2.6 times higher for obese parturients compared to non-obese pregnant parturients.

Observed adverse effects: The evidence suggests that high BMI may protect against developing PDPH, especially in parturients with BMI >50 kg/m2 (20). It may be related to increased intraabdominal pressure and the presence of engorged epidural veins and fat that may cause tamponade CSF leak (6). Our study found no significant difference between the two groups, especially since all obese patients had BMI <50 kg/m2. Possibly, the dural hole was too small to cause PDPH. Additionally, PDPH usually occurs 72 hours after dural puncture, and PDPH was measured only during the 1st 24 hours after delivery.

Sixty-six % of obese parturients suffered from LBP; this higher incidence in obese parturients could be attributed to 2 main reasons, a higher number of puncture attempts and obesity itself, which might be associated with chronic low back pain (24).

There was a higher incidence of moderate and severe nausea in the obese group (90% in obese versus 37% in non-obese). This higher incidence could be due to the augmented effect of obesity and pregnancy on nausea. Obesity had a higher incidence of diabetes, gastroesophageal reflux disease, and elevated abdominal pressure (25). Due to the physiological changes of pregnancy, the obstetric patient is more prone to nausea and vomiting through impaired motility of the esophagus, stomach, and small bowel as a result of smooth muscle relaxation by increased levels of hormones, particularly progesterone (26). These data highlight the importance of nausea and vomiting prophylaxis in obese parturients.

This study does have some limitations**.** First, there was no imaging facility to directly visualize the intrathecal spread of drugs to assess the dural hole's continuous functioning. Second, we did not document maternal motor or fetal APGAR scores to detect the influence of DPE and obesity on them. Third, further research should consider how “BMI at delivery” might affect these labor analgesia when DPE is used. Forth, the onset of adequate labor analgesia remains challenging to measure given the cyclical nature of labor that differs by each parturient and their progress in childbirth. We tried to control this variable by recording the presence or absence of contraction when the VNRS score was measured and frequent follow-ups every 2 minutes. However, precisely defining the onset of labor analgesia is still challenging.

Consequently, this is an inherent limitation of our study. Therefore, caution may be warranted in interpreting the faster onset of analgesia with the DPE technique. Future studies are needed to confirm our observed data.

Important definitions:

For this study, the following definitions were used (9, 22).

1. The asymmetrical block was defined as a sensory blockade with a difference of greater than three dermatomal levels between the left and right sides of the parturient. Management: 5 mL of bupivacaine 0.25% with parturient lying on the unblocked side for 15 minutes.
2. Sacral sparing was defined as pain perceived by the parturient at delivery. Management: A perineal dose was given if the sacral block was not adequate in the form of 5 mL bupivacaine 0.25% in a sitting position for 15 minutes.
3. Hypotension was defined as a 20% decrease from baseline systolic blood pressure. Management: Hypotension was treated with left uterine tilt positioning, increased intravenous fluid hydration (single fluid bolus of 500 mL), facemask oxygenation, and intravenous ephedrine in incremental doses of 5–10 mg.
4. Epidural difficulty: If >1 attempt to place the epidural catheter was required, it was considered difficult.
5. Epidural failure: failed epidural was defined as unsatisfactory epidural analgesia within 40 minutes of initiation; despite continuous epidural infusion, testing of the epidural catheter connections, and top-up doses administration per study protocol.
6. Manipulation of epidural catheter was defined as any physical adjustment or manipulation of the catheter, such as pulling back the catheter to achieve a better quality of analgesia to parturient satisfaction.
7. Replacement of an epidural catheter was defined as an epidural catheter replaced anytime during labor after initial placement, including those replaced for intravenous or intrathecal catheter placement and inadequate analgesia.

Conclusion

DPE offers a favorable risk-benefit ratio for the management of neuraxial analgesia in obese parturients. Further studies comparing different volumes, concentrations, and methods of application of DPE local anesthetic are needed.

Acknowledgment

None.

Conflicts of Interest

The authors declare that they have no conflict of interest.

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