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Effect of dural puncture epidural technique combined with programmed intermittent epidural bolus on labor analgesia

A randomized, double-blind, parallel-group, controlled clinical trial

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Abstract

Background: Labor analgesia can be achieved by different approaches. The efficacy and safety of combined dural puncture epidural (DPE) with program intermittent epidural bolus (PIEB) are not well characterized. This study aimed to compare the efficacy and safety of DPE combined with PIEB vs epidural (EP) combined with PIEB for labor analgesia.

Methods: We performed a prospective, randomized, double-blind, parallel-group, controlled clinical trial. Eligible pregnant nulliparous women received either DPE combined with PIEB (group D) or epidural combined with PIEB (group E) for labor analgesia. Analgesia was initiated with 0.1% ropivacaine + 0.3 μg/mL sufentanil and maintained with PIEB at 12 mL/h. Primary outcome was the proportion of women with adequate analgesia within 10 minutes after the initiation of analgesics. Secondary outcomes (time to achieve analgesia, time to first request for additional analgesic, proportion of women required additional analgesic or epidural catheter adjustment and resetting, total labor duration, total analgesic consumption, level of anesthesia, and motor block), side effects, and patient satisfaction were also documented.

Results: Out of 174 enrolled women, 160 were included in the analysis. Baseline characteristics were comparable. The proportion of women who achieved adequate analgesia in group D was significantly greater than that in group E (38.8% vs 20.0%, $P < .05$). Compared with group E, group D also showed advantages in faster adequate analgesic achievement, more likely to reach adequate analgesia, a longer time to maintain analgesia, lesser requirements for additional analgesic, and better sensory blocks. There were no significant inter-group differences in other outcome measures.

Conclusions: Compared with epidural and PIEB mode, DPE and PIEB mode achieved better analgesia without increasing maternal or neonatal side-effects during labor.

Abbreviations: BMI = body mass index, DPE = dural puncture epidural, EA = epidural analgesia, EP = epidural, NPRS = numeric pain rating scale, PDPH = post-dural puncture headache, PIEB = program intermittent epidural bolus.

Keywords: clinical trial, dural puncture epidural, epidural analgesia, labor analgesia, program intermittent epidural bolus

1. Introduction

Labor pain is an extremely unpleasant experience for women during delivery.[1] Various analgesic strategies have been proposed to provide adequate pain relief during labor. Most of these strategies involve an initiation step to induce analgesia and a maintenance step to continue the analgesia.[2] Traditionally, patient-controlled epidural analgesia is a commonly used maintenance method during labor. Recent years have witnessed the introduction of the program intermittent epidural bolus (PIEB) technique in clinical settings.[3] Several studies have reported the application of PIEB in labor analgesia. PIEB entails repeated rapid release of a fixed dose of anesthetic into the epidural space. Compared with the continuous slow infusion, PIEB offers the advantages of more rapid and adequate anesthesia with less analgesic consumption and fewer side effects. In previous studies, PIEB was shown

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to reduce the incidence of maternal motor block, instrument-assisted delivery, and cesarean section, as well as to improve patient satisfaction.[4–8]

Compared with the maintenance step, there is no clear consensus about the optimal initiation step for labor analgesia. Epidural (EP) analgesia is the conventional popular method. It has the advantage of few side effects, but carries the disadvantages of slow-onset, incomplete sacrococcygeal block, unilateral analgesia, and a high risk of requirement for catheter replacement during labor.[9,10] Although the combined spinal-epidural analgesia provides rapid and reliable analgesia, it is associated with an increased risk of high uterine tone, less placental perfusion, hypotension, pruritus, and fetal bradycardia, as well as lack of timely assessment of the effects of epidural catheter.[11–14] More recently, an increasing number of hospitals have adopted the use of dural puncture epidural (DPE) analgesia. Studies have shown that DPE is a safe and effective technique for labor analgesia. It provides faster and more adequate analgesia than EP. Although the onset of analgesia with DPE may not be as rapid as that with combined spinal-epidural analgesia, it can reduce the incidence of maternal and fetal side-effects since it avoids direct subarachnoid injections. Therefore, DPE may offer a better benefit-risk ratio in labor analgesia when compared with the 2 classical methods of EP and combined spinal-epidural analgesia.[15–18] However, there is a paucity of studies that have investigated the efficacy and safety of the combined use of DPE and PIEB for labor analgesia. Further research is required to provide more definitive evidence of the efficacy of DPE before its wide application in clinic practice. Therefore, we performed a single-center, prospective clinical trial to compare the efficacy and safety of DPE combined with PIEB vs EP combined with PIEB for labor analgesia.

2. Materials and methods

2.1. Study design and participant selection

This was a prospective, randomized, double-blind, parallel-group, controlled clinical trial conducted at the Shenzhen Maternity and Child Health Hospital, between June 2020 and march 2021. The study protocol was approved by the Medical Ethics Committee of Shenzhen Maternity and Child Healthcare Hospital (SFYLS (2019) NO.134) and prospectively registered at Chinese Clinical Trial Registry (ChiCTR1900024205). Written informed consent was obtained from all subjects prior to their enrollment. The study protocol complied with the guidelines as listed in CONSORT.

The inclusion criteria were: pregnant nulliparous women (gestational age: 37–42 weeks) scheduled for vaginal delivery; American Society of Anesthesiology score of II; body mass index (BMI) < 30 kg/m^2; singleton pregnancy with cephalic presentation; cervical dilation 3 to 4 cm at the time of request for epidural analgesia; no opioid medication in the previous 3 months; no analgesics before the delivery.

The exclusion criteria were: women with contraindication to neuraxial blocks; pregnancy complications, such as hypertension in pregnancy, preeclampsia, or gestational diabetes; known fetal abnormality; conditions associated with increased risk of cesarean section, such as uterine scar; numeric pain rating scale (NPRS) score < 5 during contractions; allergy to analgesics used in the trial; sepsis; history of drug abuse; and history of migraine.

2.2. Study protocol

A random number list was generated by the Excel software (Microsoft, Washington, USA) and sealed in sequentially-coded opaque envelopes. After obtaining written informed consent, participants were randomly assigned to 1 of the 2 groups, based on the random number in the selected envelope. Patients in group D received DPE + PIEB and patients in group E received EP + PIEB.

All neuraxial blocks were performed by the same anesthesiologist who was not involved in the outcome evaluation. The enrolled women also did not know their group assignments. Before the anesthesia, intravenous access (18G cannula) was established and Ringer's lactate solution was infused at the rate of 5 mL/kg/h. The NPRS score before the analgesia (T0) was recorded. Maternal vital signs (including blood pressure, heart rate, pulse, blood oxygen, and temperature) were monitored. Participants were placed in the left lateral decubitus position. After local infiltration anesthesia with 2 to 3mL 1% lidocaine, a 16G Tuohy needle was used to perform epidural puncture through the L2-3 or L3-4 interspace. The certification of epidural space was performed using the loss of resistance to air. After successful epidural puncture in patients in the group D, a needle-through-needle technique was performed using a 25G Whitacre needle for dural puncture. The needle was withdrawn without pushing any drug after cerebrospinal fluid reflux was seen. Patients in group E received the conventional epidural technique. After successful epidural puncture in patients in both groups, a 19G multiport epidural catheter was placed at a depth of 3 to 4 cm. After confirming the lack of any blood or cerebrospinal fluid reflux, the epidural catheter was properly fixed. The women were placed in the supine position. A test dose of 3 mL of 1.5% lidocaine (with 1:200,000 epinephrine) was administered through the epidural catheter. If there was no symptom of total spinal anesthesia or local anesthetic intoxication for 3 minutes, the ZZB-IV pulsatile analgesic pump was connected and the first dose (0.1% ropivacaine + 0.3 μg/mL sufentanil, 12 mL in total, pulse rate 360 mL/h, completed within 2 minutes) was administered through the pump. Then, the anesthesiologist left the room and another anesthesiologist entered the room to assess the patient outcomes. Analgesia was maintained by the PIEB method (pulse frequency 1 bolus/h, 12 mL each dose, injection rate: 360 mL/h). When the maintenance dose could not control the breakthrough pain (NPRS score > 5), additional analgesics (0.1% ropivacaine + 0.3 μg/mL sufentanil 6 mL) were administered as a single dose through patient-controlled epidural analgesia (lock time 25 minutes).

2.3. Outcome measures

Pain intensity was measured using NPRS scores at 2 (T1), 4 (T2), 6 (T3), 8 (T4), and 10 (T5) min after administration of the first dose of analgesic (Fig. 1). NPRS score 0 was indicative of no pain and 10 was indicative of worst pain. The primary outcome was the proportion of women with adequate analgesia, which was defined as: NPRS score ≤ 1 during the contractions; or NPRS score ≤ 1 without the contractions and ≤ 1 during the subsequent contraction.

Secondary outcomes were: time required to achieve analgesia [NPRS scores at each time-point T6, T7, T8, T9, and T10 were recorded (Fig. 1)]; time to first request for additional analgesic; proportion of women who required additional analgesic; proportion of women who required epidural catheter adjustment and resetting; total duration of labor; total analgesic consumption; level of anesthesia at each observation time-point of T5, T10, T11, T12, T13, T14, and T15, respectively, until 5 hours after anesthesia or delivery (whichever occurred first). Sensory block: the blunt needle was started from the S2 dermatomes and moved cephalad. The level of sensory block was observed. The levels of sensory block in the dermatomes in response to the pinprick were recorded. In the lower extremities, the level of dermatome was assessed by stimulating the inguinal crease (L1), anterior thigh (L2), medial knee (L3), medial ankle (L4), dorsal web between the

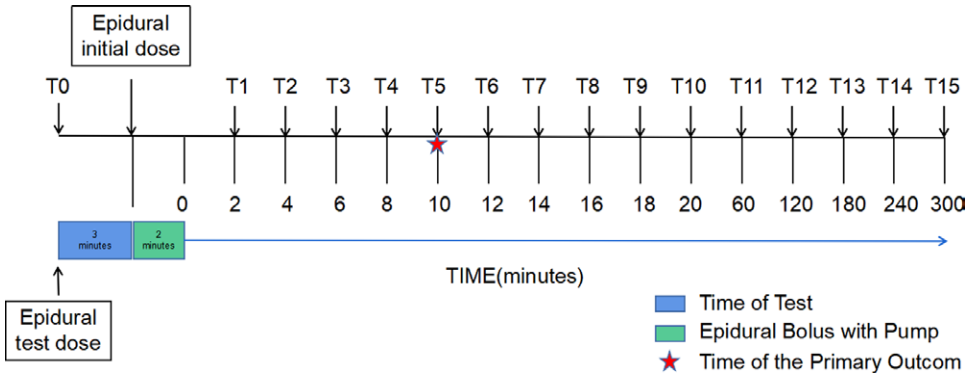

Figure 1. Schematic of epidural dosing and all kind of data collection.

great toe and second toe (L5), lateral heel (S1), and medial popliteal fossa (S2). In the trunk, the level of the dermatomes was assessed along the midclavicular line. The right and left sides were assessed separately. Unilateral block was defined as a difference of 2 dermatomes in the level of sensory block between the right and left sides at any time during the labor. Motor block was assessed using the modified Bromage scale at the time-points of T5, T10, T11, T12, T13, T14, and T15, respectively, until 5 hours after anesthesia or until delivery (whichever occurred first). Modified Bromage scale score was defined as: 0, no motor block; 1, unable to lift the straightened leg but able to flex the knee and move the foot; 2, unable to lift the straightened leg or flex the knee but able to move the foot; 3, unable to bend the ankle, foot or knee (complete block). Incidence of fetal bradycardia (fetal heart rate < 110 beats/min and duration ≥ 10 minutes) within 20 minutes after anesthesia; incidence of maternal hypotension, pruritus, nausea, vomiting, and shivering. Maternal hypotension was defined as systolic blood pressure < 90 mm Hg or decrease in systolic blood pressure by >20% from baseline, or requirement for intravenous fluid resuscitation, left or right lateral decubitus position, or intravenous phenylephrine 40 μg. Pruritus and nausea were scored as: 0, none; 1, mild; 2, moderate; and 3, severe. Mode of delivery: spontaneous or instrumental vaginal delivery, or cesarean; Neonatal Apgar score at 1 and 5 minutes after delivery; maternal symptoms 24 hours after delivery (including headache, back pain, difficult ambulation, sensory abnormalities, and maternal satisfaction scored as failure; incomplete; satisfactory; and very satisfactory).

2.4. Statistical analysis

Before formal enrollment, we included 10 women in each group for a pilot study and found that 60% women in group E and 80% women in group D would achieve adequate analgesia within 10 minutes of the first dose of analgesic. On the basis of pilot study, a power of 80%, and $\alpha = 0.05$, a 2-tailed test required 79 women in each group to demonstrate statistical significance (PASS 15.0, USA). After considering 10% attrition rate, 87 women were included in each group (a total of 174 women).

Inter-group differences with respect to normally-distributed continuous variables were assessed using *t* test; those with respect to non-normally-distributed continuous variables were assessed using Mann–Whitney *U* test. Categorical variables are presented as frequency (percentages) and inter-group differences were assessed using Chi-squared test. Kaplan–Meier curve and univariate Cox regression model were used to evaluate the main outcomes and calculate the 95% confidence intervals. All statistical analyses were performed using SPSS (version 25.0, IBM, New York, USA). Two-tailed *P* values <.05 were considered indicative of statistical significance.

3. Results

A total of 174 pregnant women were enrolled. After exclusion of 14 women (cervical dilation during intervention, puncture failure, withdrawal, or NPRS score > 5 during delivery), 160 women were included in the final analysis (Fig. 2). There were no significant between-group differences with respect to age, height, weight, BMI, gestational age, degree of cervical dilation at the time of epidural insertion, or the initial NPRS score (Table 1).

3.1. Primary outcome analysis

Within 10 minutes after the initiation of analgesia, group D had significantly more women with adequate analgesia than group E ($P < .05$) (Table 2).

3.2. Secondary outcome analyses

Women in group D (11.8 ± 0.5 minutes) required significantly less amount of time to achieve adequate analgesia than women in group E (15.9 ± 0.5 minutes) ($P < .05$) (Table 2, Fig. 3).

Cox proportional hazard model showed that the patients in group D were 2.5 times (hazard ratio 2.5, 95% confidence interval 1.8–3.6, $P < .05$) more likely to achieve adequate analgesia within 20 minutes after analgesic initiation compared with patients in group E. The time to request additional analgesics after the first dose in group D (335.9 ± 161.7 minutes) was significantly greater than that in group E (114.9 ± 108.9 minutes) ($P < .05$). The percentage of women who required additional analgesic in group D (12 women, 15.0%) was significantly lower than that in group E (29 women, 36.8%) ($P < .05$). In group D, the numbers (percentages) of women with sensory block reaching S2 at T5, T10, T11, T12, and T13 time-points [32 (40.0%), 78 (97.5%), 80 (100.0%), 80 (100.0%), and 77 (100.0%), respectively] were significantly greater than those in group E [10 (12.5%), 52 (65.0%), 66 (82.5%), 70 (89.7%), and 74 (94.9%), respectively] ($P < .05$, Table 2).

There were no significant between-group differences with respect to epidural catheter adjustment and resetting rates, duration of labor, total analgesic consumption, proportion of bilateral sensory block levels up to S2 at the 4th and 5th hour after anesthesia, highest sensory block level and motor block assessment at each observed time-point, fetal bradycardia, hypotension, pruritus, nausea, vomiting, shivering, mode of delivery, or neonatal Apgar scores at 1 and 5 minutes (Table 2). None of the patients in either group developed headache, back pain, dyskinesia, or sensory abnormalities 24 hours after delivery. There was no significant between-group difference with respect to maternal satisfaction (Table 3).

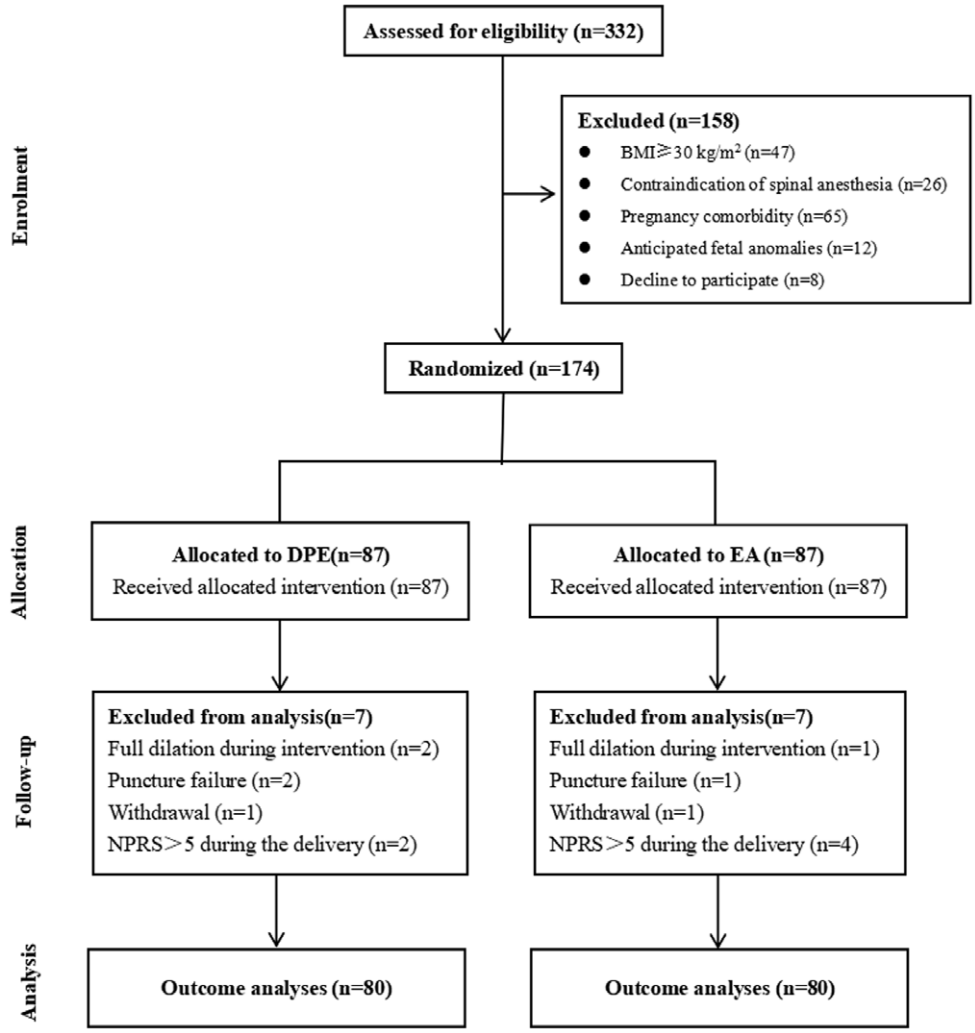

Figure 2. CONSORT diagram of patient flow through the study. BMI = body mass index, CONSORT = Consolidated Standards of Reporting Trials, DPE = dural puncture epidural, EA = epidural analgesia, NPRS = numeric pain rating scale.

Table 1

Subject baseline characteristics.

	D Group (n = 80)	E Group (n = 80)	*P*
Age (yr)	29.7 (4.0)	29.5 (3.8)	.794
Height (cm)	160.3 (4.9)	160.9 (5.7)	.477
Weight (kg)	67.5 (7.7)	67.4 (7.7)	.979
BMI (kg/m^2)	26.3 (2.6)	26.0 (2.4)	.586
Gestational age (d)	276.5 (7.2)	276.8 (7.5)	.805
Cervical dilation at time of epidural insertion (cm)	3.1 (0.3)	3.0 (0.2)	.306
Initial NPRS score	8 (6–10)	8.5 (6–10)	.376

Continuous variables (i.e., age, height, weight, BMI and cervical dilation) are presented as mean (SD), ordinal variables (i.e., NPRS) are presented as median [range]. BMI = body mass index, NPRS = numeric pain rating scale.

4. Discussion

In the present clinical trial, more pregnant nulliparous women achieved adequate analgesia during labor with combined use of DPE and PIEB than EP and PIEB. In addition, pregnant nulliparous women who received DPE and PIEB rapidly achieved adequate analgesia with fewer side effects. Our results suggest that combined use of DPE and PIEB is a viable option for labor analgesia.

In a study by Beilin et al, women with NPRS score ≤ 1 and under EP for labor pain rarely requested additional analgesics compared to women with NPRS score > 1.[19] Therefore, we defined adequate analgesia as an NPRS score ≤ 1 at the time of contraction or an NPRS score ≤ 1 in the absence of contraction but with NPRS score ≤ 1 at the immediately subsequent contraction. Then, we used the proportion of pregnant women achieving adequate analgesia within 10 minutes after analgesia initiation as the primary outcome in the present study. We found that the proportion of pregnant women achieving adequate analgesia within 10 minutes in group D was significantly higher than that in group E. Our result was different from that reported by Wilson et al[17] In their study, patients received DPE through a 26G needle for dural puncture. The first dose of analgesics of 0.125% bupivacaine and 50 μg fentanyl was administered within 3 minutes. They found no significant difference between the DPE group and EP group with respect to the proportion of pregnant women who achieved adequate analgesia within 10 minutes. These inconsistent results may be attributable to different techniques used in the trials. We used a 25 G needle for dural puncture, rather than a 26G needle in their study. A 25 G needle can create a bigger opening in the dura mater, allowing more rapid spread of anesthetics. In addition, we used a pulse rate of 360 mL/h which allows rapid analgesic infusion.

In our study, the mean analgesia onset time in group D (11.8 ± 0.4 minutes) was significantly shorter than that in

group E. This result was similar to that in the study by Chau et al.[18] In their study, patients received 0.125% bupivacaine and 2 μg/mL fentanyl in a total of 20 mL over 5 minutes as the first analgesic; the median time to reach NPRS score ≤ 1 in the DPE group was 11 (interquartile range 4–120) min. This further suggested that the analgesic effect achieved with combined use of intermediate analgesic doses during DPE and PIEB is similar to that achieved with high analgesic doses.

Table 2

Analgesia characteristics and labor outcomes.

	D Group (n = 80)	E Group (n = 80)	*P*
NPRS ≤ 1 at 10 min	31 (38.8)	16 (20.0)	.009*
Time to NPRS ≤ 1 (min)	11.8 (0.5)	15.9 (0.5)	<.001*
Number of epidural top-ups	12 (15.0)	29 (36.3)	.002*
Time to first bolus (min)	335.9 (161.7)	114.9 (108.9)	<.001*
Epidural catheter adjustment	4 (5.0)	7 (8.8)	.349
Epidural catheter replacement	0	0	NS
Duration of labor analgesia (min)	573.0 (340.1)	581.0 (328.0)	.880
Total drugs used (ml)	112.0 (69.7)	119.1 (69.7)	.523
Depth of insertion (cm)	3.5 (3.0–4.0)	3.5 (3.0–4.0)	.537
Block characteristics at 10 min			
Height of sensory block	T10 (T8–T12)	T10 (T8–T12)	.055
Bilateral S2 block	32 (40.0)	10 (12.5)	<.001*
Bromage score ≥ 1	22 (27.5)	15 (18.8)	.189
Block characteristics at 20 min			
Height of sensory block	T10 (T8–T10)	T10 (T8-T10)	1.000
Bilateral S2 block	78 (97.5)	52 (65.0)	<.001*
Bromage score ≥ 1	21 (26.3)	25 (31.3)	.485
Block characteristics at 60 min			
Height of sensory block	T10 (T8–T10)	T10 (T8–T10)	.313
Bilateral S2 block	80 (100.0)	66 (82.5)	<.001*
Bromage score ≥ 1	25 (31.3)	28 (35.0)	.614
Block characteristics at 120 min			
Height of sensory block	T10 (T8–T10)	T10 (T8–T10)	.325
Bilateral S2 block	80 (100.0)	70 (89.74)	.003*
Bromage score ≥ 1	18 (22.5)	15 (19.2)	.613
Block characteristics at 180 min			
Height of sensory block	T10 (T8–T10)	T10 (T8–T10)	.306
Bilateral S2 block	77 (100.0)	74 (94.9)	.045*
Bromage score ≥ 1	12 (15.6)	10 (12.8)	.622
Block characteristics at 240 min			
Height of sensory block	T10 (T8–T10)	T10 (T8–T10)	.561
Bilateral S2 block	71 (100.0)	68 (95.8)	.081
Bromage score ≥ 1	8 (11.3)	7 (9.9)	.785
Block characteristics at 300 min			
Height of sensory block	T10 (T8–T10)	T10 (T10–T10)	.156
Bilateral S2 block	63 (100.0)	60 (95.2)	.081
Bromage score ≥ 1	2 (3.2)	1 (1.6)	.561
Fetal bradycardia within 20 min after analgesia	6 (7.5)	5 (6.3)	.755
Hypotension	8 (10.0)	9 (11.3)	.798
Pruritus	0	0	NS
Nausea	0	0	NS
Vomiting	0	0	NS
Shiver	13 (16.3)	18 (22.5)	.317
Mode of delivery	–	–	.697
Vaginal	67 (83.8)	63 (78.8)	–
Instrumented	4 (5.0)	6 (7.5)	–
Cesarean	9 (11.3)	11 (13.8)	–
Apgar score at 1 min	10 (6–10)	10 (7–10)	.528
Apgar score at 5 min	10 (8–10)	10 (10–10)	.317

NPRS = numeric pain rating scale, NS = non significant.

Continuous variables (i.e., Time to NPRS ≤ 1) are presented as mean (SD). Ordinal variables (i.e., height of sensory block, Apgar score at 1 min and Apgar score at 5 min) are presented as median [range]. Categorical variables (i.e., Number of epidural top-ups, Epidural catheter adjustment, Bilateral S2 block, bromage score ≥ 1, fetal bradycardia after analgesia, hypotension, shiver and mode of delivery) are presented as count (%).

* Statistically significant.

The onset time in DPE has been shown to correlate with the size of the puncture needle. A study by Thomas et al[20] found no significant difference in the analgesic effects between the DPE and EP techniques. This may be attributable to the small puncture needle (27 G) used in their study, which may result in less effective analgesia due to the smaller puncture hole. In other studies, the onset of analgesia in DPE was shown to correlate with the analgesic volume and/or injection duration. A high analgesic volume or short injection duration may facilitate the infusion of analgesics through the dura mater.

In our study, patients in group D had fewer requests for additional analgesics throughout the labor. This result was similar to the findings of Chau et al[18] They reported a > 50% decrease in the additional analgesic requests in the DPE group. In addition, we also found that the time for the first additional analgesic request in group D was longer than that in group E. The above results may be attributable to the better analgesic effect produced by the combined treatment with DPE and PIEB, especially the sacral nerve block. In contrast, there was no significant between-group differences with respect to the total analgesic consumption. This is consistent with previous studies that showed no difference between DPE and EP in terms of total local anesthetic consumption when local analgesic concentrations (0.125% bupivacaine or 0.2% ropivacaine) were used to maintain labor analgesia.[21] It was proposed that there might be an optimal dose range for a drug, in which its volume could maximize its passage through the dura mater while minimizing spontaneous diffusion through the meningeal membrane.[22] Therefore, further studies should be performed to identify this optimal dose and the optimal size of needle for the DPE technique.

In the present study, combined use of DPE and PIEB achieved bilateral sensory block levels up to S2 in more pregnant women within 3 hours after anesthesia. This was consistent with previous studies.[16,18] In another recent study, during DPE combined with PIEB, a bolus dose of 10 mL of 0.1% ropivacaine with 0.3 μg/mL sufentanil, that was followed by the maintenance dose of the same solution at 8 mL/h, was shown to achieve bilateral sensory block levels at S2 at 30 minutes in a greater proportion of pregnant women. More patients achieved complete sacral block, probably due to faster diffusion of local anesthetic to the sacral area.[23] However, we also found no significant between-group difference in the proportion of women with bilateral sensory block levels up to S2 at the 4th and 5th hours after anesthesia. This was probably attributable to the limited spatial volume in the epidural space. Epidural injection has been shown to increase the intracranial pressure in a porcine model. Both epidural elasticity and resistance can increase with the rising intracranial pressure.[24] Another study showed that a net outflow of cerebrospinal fluid into the epidural space may occur immediately after the dural puncture because the resting pressure of cerebrospinal fluid is higher than the pressure in the epidural space. A small hole in the dura mater can limit the amount of analgesics transferred from the epidural space into the subarachnoid space.[25] Therefore, the holes created by the DPE technique can slowly lose their effectiveness after persistent drug infusions. Even if we combined it with the PIEB technique in the present study, the early analgesic effects could not be maintained.

Table 3

Postpartum characteristics (until 24h).

	D Group (n = 80)	E Group (n = 80)	*P*
Postpartum headache	0	0	NS
Back pain	0	0	NS
Motor deficit	0	0	NS
Paresthesia	0	0	NS
Satisfaction score of analgesia (mm)	4 (3–4)	3 (3–4)	.430

Ordinal variables (i.e., Satisfaction score of analgesia) are presented as median [range].

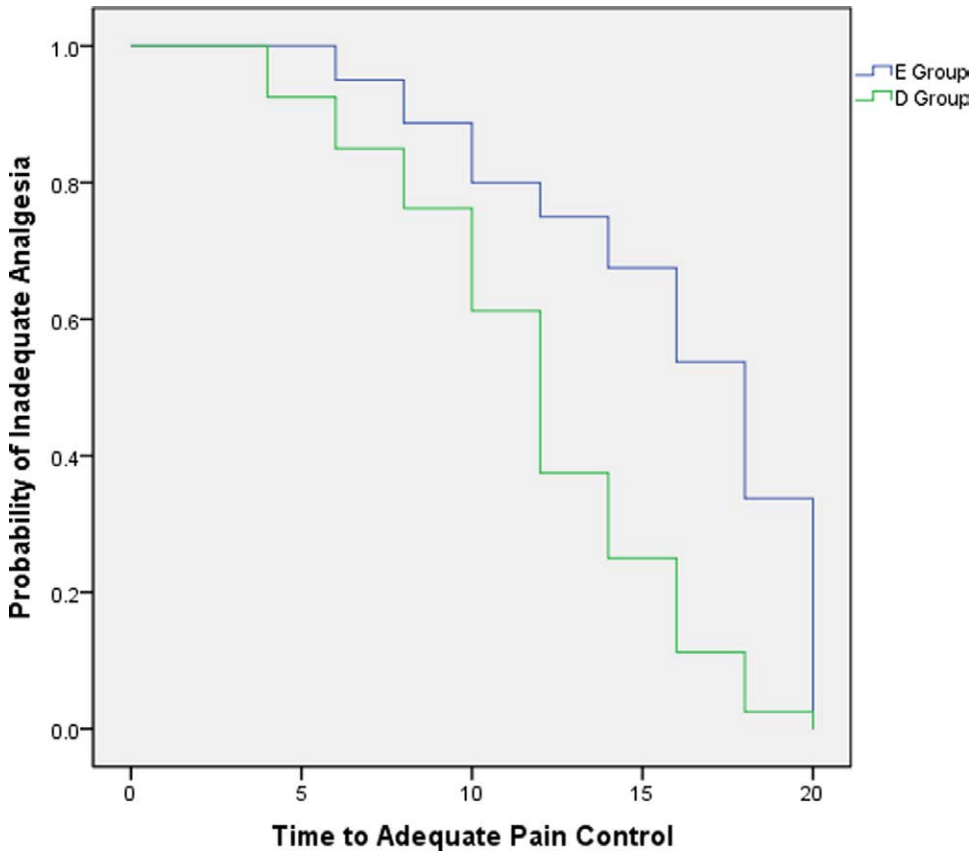

Figure 3. Kaplan–Meier curves for time to achieving adequate analgesia by neuraxial technique. E Group indicates lumbar epidural; D Group indicates dural puncture epidural.

In our study, we found no significant between-group difference with respect to epidural catheter adjustment and resetting rates. This may be attributable to the low frequency of difficult epidural punctures due to the low rate of obese pregnant women in China, which resulted in few requirements for epidural catheter adjustment and resetting. However, the study by Yan et al found the incidence of asymmetric block in DPE is obviously lower than that in EP technique.[26] This may be due to the depth of the epidural catheter in their study was 3 to 5cm, which is deeper than we did.

We found no significant between-group differences in the highest sensory block level and motor block assessments at each observation time-point, which was similar to the previous studies.[17,18] The incidence of side effects (including fetal bradycardia, hypotension, pruritus, nausea, vomiting, and shivering) as well as the total duration of labor, mode of delivery, neonatal Apgar scores at 1 and 5 minutes, and maternal satisfaction were not significantly different between the 2 groups.

The previous view was that atraumatic needles and smaller caliber needles produce a lower incidence of PDPH.[27] In the meta-analysis by Maranhao, they also suggested that the atraumatic needles generally reduce probability of PDPH compared to cutting needles, but there may be a threshold of needle caliber beyond which tip design has little effect on PDPH. In addition, they found that needle caliber was not linearly correlated with the incidence of PDPH. It is possible that due to the slow flow of cerebrospinal fluid and the easy blockage of the lumen, smaller needles may increase the chance of multiple, unrecognized dural punctures.[28] So we can't use simple rules to choose needles. In this trial, we use 25G Whitacre needle for dural puncture. None of the women in either groups developed headache, back pain, dyskinesia, or sensory abnormalities within 24 hours after delivery. This also indicated that the combined use of DPE + PIEB technique for labor analgesia might not result in significant motor block and increase the incidence of side effects.

Some limitations of our study should be acknowledged. This was a single-center study with a relatively small sample size. The results might have been biased by the short-term follow-up period (outcomes were measured up to 5 hours after administration of analgesics), dose of analgesics (different dose of analgesics may result in different analgesia outcomes), and the influence of other medications (such as oxytocin) used during delivery. Further studies with a large sample size, different analgesic doses, and a longer follow-up period should be performed. More outcome measures (such as fetal heart rate variation) should also be closely investigated during labor analgesia.

5. Conclusion

In conclusion, the combined use of DPE and PIEB techniques for labor analgesia may allow more pregnant women to achieve adequate analgesia within 10 minutes after analgesic initiation. It may also shorten the onset of analgesia and improve the bilateral sacral analgesia without increasing the incidence of maternal or neonatal side effects. More studies are warranted on this technique prior to its wider clinical application.

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