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A pilot study comparing dural puncture epidural with 27G Whitacre needle and conventional lumbar epidural labor analgesia

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Abstract

Background: The dural puncture epidural (DPE) technique is relatively a new technique of labor analgesia and has been advocated with the advantage of faster onset of pain relief. However, there are differences of opinion regarding the efficacy of the DPE technique and the size of the spinal needle to be used for the DPE. Various studies have suggested that DPE can only be done with a larger gauge of a spinal needle; however, recent studies have variable observations. We have compared the conventional lumbar epidural analgesia and DPE using a 27G pencil-point needle to assess the efficacy of DPE and its possible side effects.

Results: The time to achieve a 50% reduction in VAS was 7.06 ± 0.79 min in group CLE ($n = 15$) and 5.0 ± 1.06 min in group DPE ($n = 15$) (difference of two means was 2.06, 95% CI [1.36, 2.75], $t = 5.99$, $p < 0.0001$). The time to achieve VAS < 3 in group CLE was 14.93 ± 1.98 min, and in the group DPE, it was 10.13 ± 1.45 min (difference of two means was 4.8, 95% CI [3.52, 6.09], $t = 7.55$, $p < 0.0001$). The mode of delivery, APGAR scores, and side effects were comparable ($p > 0.05$).

Conclusions: DPE provided faster relief of labor pain than the conventional labor epidural analgesia. There were no added side effects by DPE in conventional lumbar epidural analgesia for labor. A 27G Whitacre pencil-point needle can be used for DPE.

Trial registration: CTRI, CTRI/2020/08/027060. Registered on 10/08/2020. Trial registered prospectively. CTRI website URL: <http://ctri.nic.in>

Keywords: Epidural, Dural puncture epidural, Labor analgesia, Bupivacaine

Background

Dural puncture epidural (DPE) is a novel modification to improve the speed and quality of epidural analgesia (Chau et al. 2017; Chau and Tsen 2017). In DPE, after localization of the epidural space, a pencil-point spinal needle is passed through the Tuohy needle to puncture

the dura without administering the drugs in the sub-arachnoid space, followed by the conventional epidural technique (Suzuki et al. 1996). However, there is a controversy regarding the effectivity of the DPE technique over conventional epidural analgesia (Gupta et al. 2013) and also regarding the size of the spinal needle used for DPE (Suzuki et al. 1996; Cappiello et al. 2008; Thomas et al. 2005; Yadav et al. 2018; Wilson et al. 2018). We conducted a pilot study to evaluate the efficacy of a 27G Whitacre pencil-point needle in DPE and compare it

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with the conventional epidural analgesic technique. The primary objective was to assess the onset time of analgesia, and the secondary objectives were to assess the maternal and fetal side effects.

Methods

After clearance from the ethical committee and registration in the trial registry (CTRI/2020/08/027060, registered on 10/08/2020, trial registered prospectively), we conducted this comparative prospective open-label study from 15 August 2020 to 20 November 2020 in an industrial hospital. Only the full-term primigravida parturients with singleton pregnancy, vertex presentation, between 20 and 35 years of age, in active labor having moderate to severe labor pains, and requesting for the labor epidural analgesia were selected after written informed consent. Patients with a medical condition like preeclampsia or eclampsia, any contraindication to normal vaginal delivery (pelvic inadequacy or deformity, abnormal placentation), or any contraindication to the spinal or epidural analgesia were excluded. Patients with a history of drug allergy and migraine were also excluded. A written informed consent was taken from each patient willing to participate in the study. All the consented patients were counseled and taught to report their pain on a visual analogue scale of 0–10 (0 = no pain and 10 = excruciating pain) and pre-procedural VAS was recorded. A total of 30 selected subjects were randomly divided into two equal groups: DPE ($n = 15$) and conventional lumbar epidural analgesia (CLE; $n = 15$) by a computer-generated random table, and group allocation was concealed in an opaque envelope. Monitors for continuous electrocardiography (ECG), non-invasive blood pressure (NIBP), and pulse oximetry (SpO₂) were connected, and patients were co-hydrated with 500 ml Ringers' lactate while sterile preparations were on for the epidural. In all the patients, epidural space localization was done at the L3–L4 level in sitting position with an 18G Tuohy needle (PORTEX®, CSEcure® Combined Spinal Epidural System, 18G epidural and 27G spinal needle) with loss of resistance to saline after infiltration of needle entry point with 3 ml 1% lidocaine. Patients who had accidental dural puncture were excluded from the study. The group allocation was revealed only after successful epidural space localization. In group CLE, 3 ml saline was given through an epidural needle and a 19G epidural catheter was inserted in the epidural space in the cranial direction and the epidural needle was removed. The epidural catheter was fixed at the skin keeping 3 cm in the epidural space. In group DPE, after epidural space localization, a 27G Whitacre pencil-point needle was inserted by a needle-through-needle approach and the dura was punctured. The stylet of the needle was withdrawn to see the free flow of cerebrospinal fluid (CSF).

Once confirmed, the spinal needle was removed and the epidural catheter was inserted after injection of 3 ml saline. The catheter was fixed in a similar manner as done in group CLE. After placement, the epidural catheter was aspirated to test the absence of blood or CSF for correct epidural placement. If aspiration test was positive (blood or CSF present), the catheter was re-cited and the patient was excluded from the analysis. For free aspiration and considering it spinal catheter, the analgesic consequences and management are totally different. Therefore, we wanted to exclude them. However, this situation did not arise. When aspiration was negative, 12 ml 0.125% bupivacaine (injection Anawin, Neon laboratories Ltd.) was given slowly through the catheter over 5 min with repeated aspirations. Then, an infusion of 0.08% bupivacaine and fentanyl (injection Fent 50 µg/ml, Neon laboratories Ltd.) 1.66 µg/ml at the rate of (@) 10 ml/h was started. Bupivacaine 0.125% 5 ml was given after 25 min from initial bolus and afterward as rescue analgesia for breakthrough pain whenever VAS was > 5 (every 5 min till the VAS was < 3). The time to initiate the epidural was recorded, and times to achieve 50% reduction in the VAS and time to achieve VAS < 3 were recorded. The total dose of the bupivacaine used, the time and mode of delivery, and APGAR scores at 1 and 5 min were recorded. Side effects like nausea, vomiting, doses of rescue antiemetic (injection ondansetron), and motor weakness in the lower limbs were recorded. Motor block in the lower extremities was assessed by using the Breen Modified Bromage scale as follows: (BMBS: grade 1 as a complete motor block to grade 6 as no motor block):

- Grade 1—complete block (unable to move the feet or knees)
- Grade 2—almost complete block (able to move the feet only)
- Grade 3—partial block (just able to move the knees)
- Grade 4—detectable weakness of hip flexion while supine (full flexion of the knees)
- Grade 5—no detectable weakness of hip flexion while supine (full flexion of the knees)
- Grade 6—able to perform partial knee bend.

Patients were followed up for post-dural puncture headaches during their hospital stay and were suggested to report back if any such complaint occurred. Failure or partial success was defined when VAS was never < 3 after the first dose and even after 2 rescue doses. In such patients, it was decided to give alternate analgesics (injection pethidine (Neon laboratories Ltd.) 25 mg intravenous boluses PRN) and to exclude from the analysis. However, no patient was excluded due to failure or partial effect.

Sample size calculation and choosing the number of subjects 30 were based on the studies suggesting sample size for pilot studies with moderate effect size keeping 95% confidence level, 80% power, and $< 0.05\%$ p value for significance (Whitehead et al. 2016).

Statistical analysis was done using MedCalc version 17.9.4. Continuous data was assessed for normality using the Kolmogorov-Smirnov test of normality. Normally distributed data (represented as mean \pm SD) was assessed using Student's t -test (two tailed) and non-normally distributed data [represented as median (IQR)] was assessed using the Mann-Whitney U -test. Ordinal data like the APGAR score was assessed using the Mann-Whitney U -test. The obstetric outcome and the side effects were analyzed by using the chi-square test. A p -value < 0.05 was considered significant. After the initial analysis, the effect size (Cohen's d) was calculated to assess the impact of clinical significance.

Results

A total of 30 patients were randomized with no exclusions or dropouts. The CONSORT flow diagram is depicted in Fig. 1. The demographic variables were comparable in both groups ($p > 0.05$) (Table 1). The time to achieve a 50% reduction in VAS was 7.06 ± 0.79 min in group CLE and 5.0 ± 1.06 min in group DPE (difference of two means was 2.06, 95% CI [1.36, 2.75], $t = 5.99$, $p < 0.0001$) (Fig. 2). The time to achieve VAS < 3 in group CLE was 14.93 ± 1.98 min, and in group DPE, it was 10.13 ± 1.45 min (difference of two means was 4.8, 95% CI [3.52, 6.09], $t = 7.55$, $p < 0.0001$) (Fig. 3). For the mode of delivery, in group CLE, there was normal vaginal delivery (NVD) in 10 (66.66%), instrumental delivery (ID) in 2 (13.33%), and lower segment cesarean section (LSCS) in 3 (20%) while in group DPE, NVD 11 (73.33%), ID 1 (6.6%), and LSCS 3 (20%), respectively ($p = 0.816$);

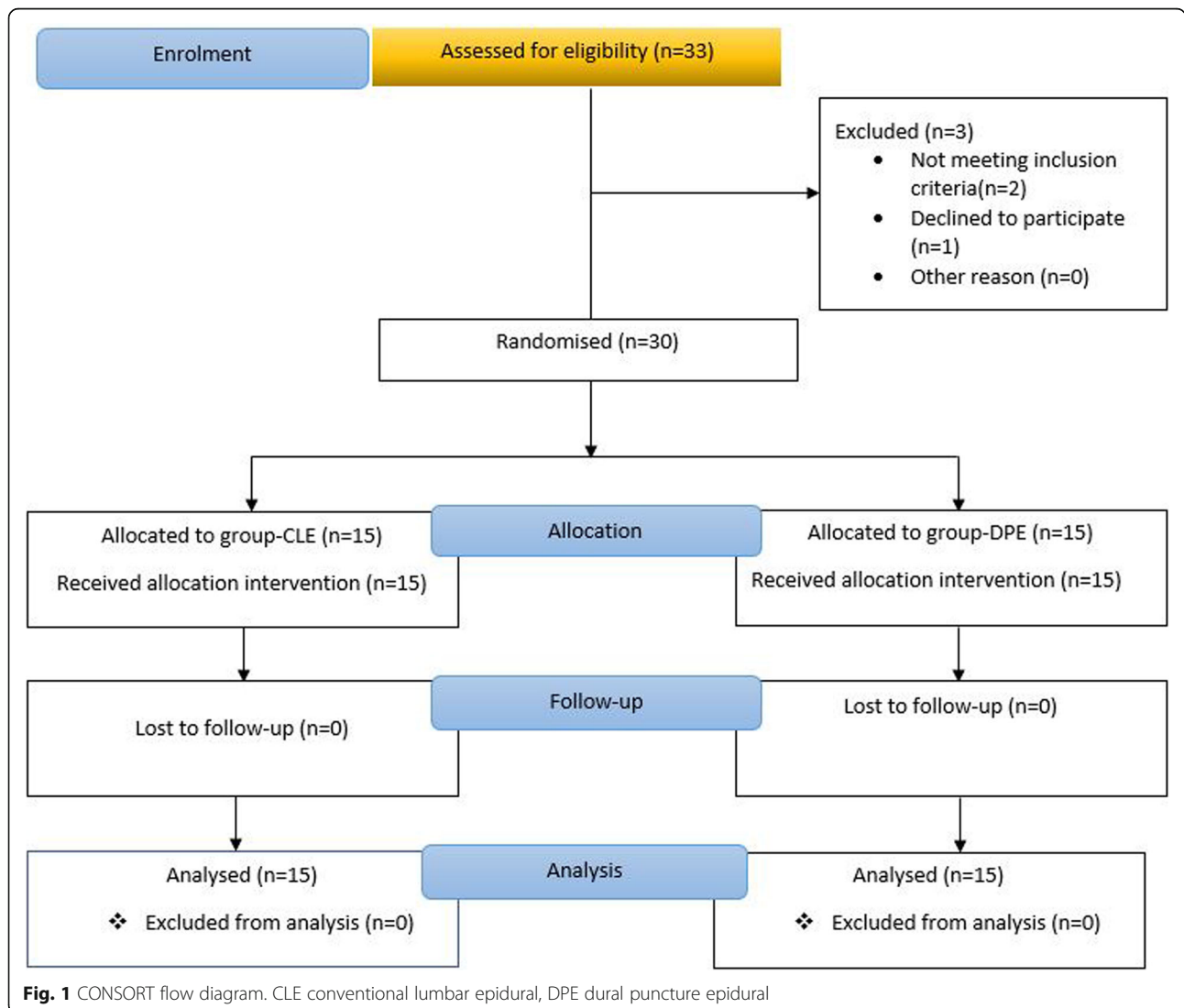


Fig. 1 CONSORT flow diagram. CLE conventional lumbar epidural, DPE dural puncture epidural

Table 1 Comparison of demographic variables between the study groups

Characteristics	DPE group (n = 15)	CLE group (n = 15)	p-value
Age (years) (mean ± SD)	27.7 ± 3.9	24.5 ± 2.9	0.0175
Height (cm) (mean ± SD)	150.5 ± 4	150.6 ± 4.2	0.9422
Weight (kg) (mean ± SD)	59.1 ± 5.5	58.6 ± 5.2	0.706
Gestational age (weeks) (mean ± SD)	37.7 ± 1.9	37.6 ± 1.7	0.740
ASA status (II/III) (number)	15/0	15/0	1

CLE conventional lumbar epidural, DPE dural puncture epidural

the result is not significant (Table 2). In both groups, one patient (6.6%) complained of nausea-vomiting, and one patient (6.66%) complained of pruritus ($p = 1$) (Table 2). The APGAR score at 1 min in group CLE mean (IQR) was 8 (8–9) and in group DPE 8 (8–9) ($z = 1.09, p = 0.271$), and at 5 min, it was 9 (9–10) in group CLE and 9 (9–10) in group DPE ($z = 0.24, p = 0.80$). Differences in APGAR at 1 min and 5 min were not significant ($p > 0.05$) (Table 2). The total bupivacaine used in both groups was comparable; in group DPE, it was 39.18 (5.49) mg and in group CLE it was 38.27 (9.39) mg ($t = 0.32, p = 0.74$) (Table 2). The number of rescue doses was also comparable: in DPE median (IQR) 0 (0–2) and in group CLE it was 0 (0–2) ($z = 0.02, p = 0.98$) (Table 2).

For the independent sample’s t -test (two tailed), Cohen’s d was 2.0 for the time to achieve a reduction in VAS by 50% and it was 2.5 to achieve VAS < 3.

No patient had motor weakness, hypotension, or bradycardia. No patient had complained of post-dural puncture headache.

Discussion

The results of this randomized pilot study showed that the time to achieve the reduction in VAS by 50% as well as to achieve VAS < 3 was significantly less in group DPE. Other parameters like obstetric outcome, APGAR, total dose of bupivacaine, and numbers of rescue doses were comparable. The side effects like nausea-vomiting and pruritus were also comparable. No patient had any

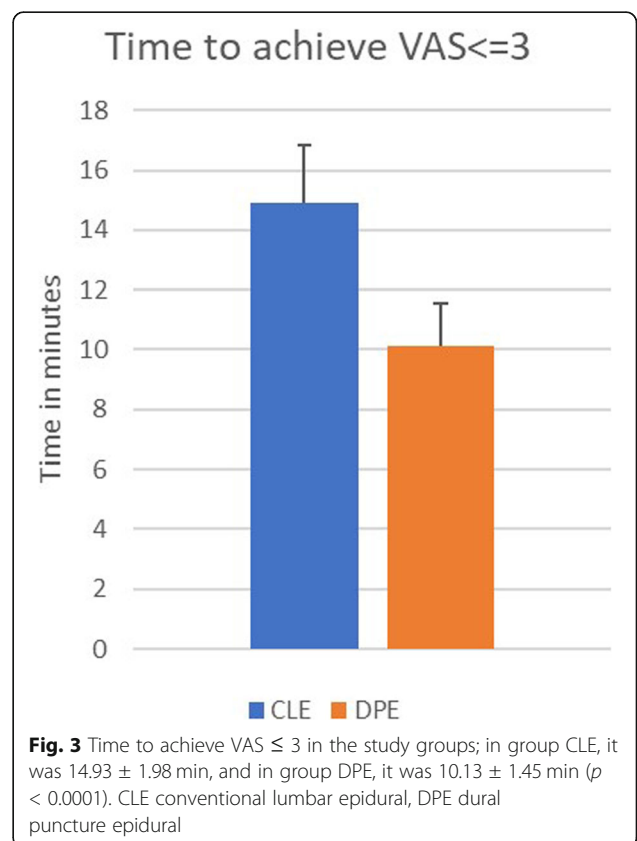
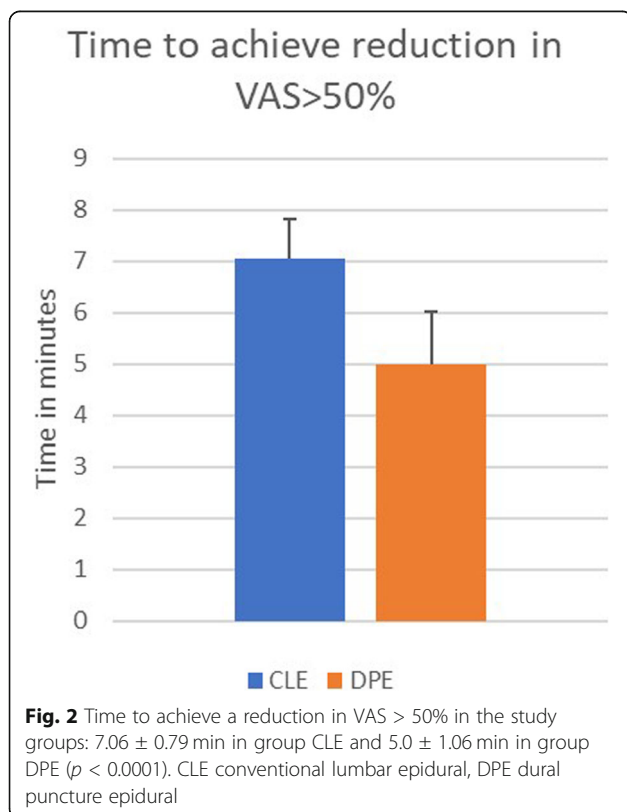


Table 2 Comparison of study groups for total bupivacaine used, rescue drug doses, duration of labor, APGAR scores, side effects, and obstetric outcome

Parameters	DPE group (n = 15)	CLE group (n = 15)	p value
Total dose of bupivacaine (mg)	39.18 ± 5.49	38.27 ± 9.39	0.74
Rescue dose, median (IQR)	0 (0–2)	0 (0–2)	0.98
Duration of labor in minutes	187.93 ± 38.49	179.93 ± 68.97	0.69
APGAR score at 1 min, median (IQR)	8 (8–9)	8 (8–9)	0.27
APGAR score at 5 min, median (IQR)	9 (9–9)	9 (9–9)	0.80
Pruritus	1	1	1
Nausea/vomiting	1	1	1
Mode of delivery			
NVD	11	10	0.816
ID	1	2	
LSCS	3	3	

CLE conventional lumbar epidural, DPE dural puncture epidural, ID instrumental delivery, LSCS lower segment cesarean section, NVD normal vaginal delivery

untoward hemodynamic changes, motor weakness, respiratory depression, or post-dural puncture headache.

Lumbar epidural analgesia is the gold standard technique for pain relief during labor (Hawkins 2010), and the dural puncture epidural (DPE) is a novel modification to improve the speed and quality of epidural analgesia (Chau et al. 2017; Chau and Tsen 2017). There are two important queries raised here. Firstly, is DPE better than conventional epidural? and, secondly, if the 27G Whitacre pencil-point needle can be used for DPE? In a study by Gupta et al., the authors concluded that the DPE technique did not provide superior labor analgesia as compared to the CLE technique but the onset was significantly faster in the DPE group ($p = 0.04$) (Gupta et al. 2013). However, Chau et al. concluded in a randomized controlled trial (RCT) that the DPE technique improves labor analgesia quality compared with epidural (Chau et al. 2017) and have suggested that the DPE technique appears to offer a paradigm shift in obstetric analgesia and anesthesia (Chau and Tsen 2017). Capiello et al. suggested that the DPE technique may benefit parturients by improving sacral spread, onset, and bilateral spread as compared to standard epidural analgesia (Capiello et al. 2008). Although two systematic reviews of RCT comparing DPE with epidural analgesia concluded that there is a lack of clear evidence on either the benefits or the risks of the DPE technique, it was suggested that more studies are required with different sizes of the needles before any conclusion (Heesen et al. 2019; Layera et al. 2019). However, a recent review concluded that despite controversies and concerns, more rapid onset of analgesia, early bilateral sacral analgesia, lower incidence of asymmetric block, and fewer maternal and fetal side effects are provided with DPE when compared to conventional epidural (Gunaydin and Erel 2019).

Regarding the size and type of spinal needle, there is an assumption that the dural hole made during

DPE facilitates the transfer of drug into sub-arachnoid space and causes faster onset (Leach and Smith 1988).

Bernards et al. and Swenson et al. concluded that the passage of epidurally given drugs to sub-arachnoid space via the dural hole was directly proportional to the size of the dural hole (Bernards et al. 1994; Swenson et al. 1996). However, there is a controversy regarding the size of the needle and the effectiveness of the DPE technique. Capiello et al. used a 25G pencil-point needle and found a quicker and better effect (Capiello et al. 2008). Wilson et al. used a 26G spinal needle and found it effective in DPE (Wilson et al. 2018). When two different sizes were compared in DPE, the 25-gauge pencil-point spinal needles provide a 1.6-min shorter onset time than with 27-gauge spinal needles. The authors concluded that, although this difference was statistically significant, such a difference may not be clinically relevant (Contreras et al. 2019). Thomas et al. showed that dural puncture with a 27-gauge Whitacre needle did not improve epidural labor analgesia quality (Thomas et al. 2005). However, Yadav et al. used a 27G Whitacre needle and concluded that DPE has the potential to fasten onset and improve the quality of labor analgesia when compared with the conventional epidural technique (Yadav et al. 2018).

Though it seems logical that a larger hole will allow the passage of a larger amount of drug across the dural puncture, the fundamental basis of larger drug translocation through a larger hole has been questioned (Bernards et al. 1994). The net influx or efflux from spinal space depends upon many factors including the volume and pressure of epidurally injected drugs vis-à-vis pressures of CSF (Paul and Wildsmith 1989). Moreover, with so much heterogeneity in the protocols of various studies regarding the volume used, time for completing the injection, size of the needle, and variability of patient's

demography in these studies, it is difficult to conclude the exact role of needle size in DPE.

As far as the obstetric outcome is concerned, many studies have shown comparable results. We also have observed comparable results in both groups ($p > 0.05$). However, Cappiello et al. observed less numbers of vaginal deliveries in the DPE group when compared to the epidural (Cappiello et al. 2008). The obstetric outcome is difficult to compare amongst the studies. The decision, particularly the LSCS, is often dependent on multiple factors like the local hospital protocol and the experience of the attending obstetrician (Naji et al. 2010).

The present study was a pilot study, and it was aimed to find out the difference in the speed of onset of pain relief. The results showed that the onset of relief was faster with DPE. Our study also supported the view that even a 27G needle can be used for DPE. The parameters like APGAR scores, obstetric outcome, and side effects were comparable. However, for the comparison of other parameters like manipulation of catheters and differences in the quality of block (unilateral block and sacral sparing, etc.) and obstetric outcomes, a RCT with a larger number of subjects is necessary.

We selected 30 subjects for our pilot study because, in a published review of statistical studies for the sample size for pilot trials, it has been suggested to use “12 subjects per treatment arm” or “at least 30 subjects to estimate a parameter” (Whitehead et al. 2016).

However, even with a smaller number of subjects, to establish clinical relevance to our results, we have calculated the effect size (Cohen's d). The statistical significance testing alone is not adequate to evaluate a clinically relevant effect. The effect size estimation facilitates the decision whether a clinically relevant effect is found or not. It also helps in determining the sample size for future studies and facilitates the comparison between scientific studies (Aarts et al. 2014). Cohen's d is an appropriate effect size for the comparison between two means. The results of Cohen's d suggested that $d = 0.2$ be considered a “small” effect size, 0.5 represents a “medium” effect size, and 0.8 represents a “large” effect size (Aarts et al. 2014). In the present study for the independent samples t -test (two tailed), Cohen's d was 2.0 for the time to achieve a reduction in VAS by 50% and it was 2.5 to achieve VAS < 3 .

The novel and positive aspect of our study was to use a drug regimen which we already have been using in our practice for labor epidural for the last 13 years with satisfactory results. This was one of the reasons to conduct a pilot study instead of choosing the data and drug regimens from different protocols and adapt to it. However, the major limitation of the present pilot study was that it was “open label” and this could have led to potential

bias during selection and observation. Few other limitations were also present in our study like detailed sensory mapping including the highest level of sensory block, sacral spread, and segmental sparing was not done. Also, the study was not adequately powered to evaluate common problems of catheter manipulation and other catheter-related issues.

Nonetheless, we aim to include all the necessary but missed points for observation in the next RCT with an adequate number of subjects and adequately powered study.

Conclusions

With the results of the present pilot study, we conclude that DPE provided faster relief of labor pain than the conventional labor epidural. A 27G Whitacre pencil-point needle can be used for DPE. There were no added side effects by DPE in conventional lumbar epidural analgesia for labor.

Abbreviations

APGAR: Appearance, Pulse, Grimace, Activity, and Respiration; @: At the rate of; CLE: Conventional lumbar epidural; CSF: Cerebrospinal fluid; DPE: Dural puncture epidural; ECG: Electrocardiograph; LA: Local anesthetic; BMBS: Breen Modified Bromage scale; NIBP: Non-invasive blood pressure; VAS: Visual analogue score

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Authors' contributions

AJ: concept, intervention, manuscript writing, and final draft. SS: observation and review of the literature. NS: intervention, review of the literature, and editing. SC: editing, review, and final draft. AB: review of the literature and editing. BS: intervention, review of the literature, and editing. All the authors have read and approved the final manuscript.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

Written approval from Tata Motors Hospital Ethical Committee was taken (4 March 2019, Ref. # Anaesth/001-03/2019), and a written consent to participate from patients was taken.

Consent for publication

Written informed consent to present, discuss, and publish the patient's medical information, management details, and pictures was taken.

Competing interests

The authors declare that they have no competing interests.

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