A randomized clinical trial to compare continuous epidural infusion technique with that of intermittent boluses for maintenance of epidural labour analgesia in combined spinal epidural analgesia

Shidhaye R V*, Sukhatankar V C**, Dhulkhed V K*, Divekar D S*, Abhijit S***, Shidhaye R R****

Abstract

A prospective randomized study was designed to compare two commonly practiced techniques continuous epidural infusion (CEI) and intermittent boluses on demand (IB) for maintenance of labour analgesia, in combined spinal epidural analgesia. After hospital ethical committee approval, 60 randomly selected parturients were divided in two groups. Initially all parturients were given intrathecal bolus dose of fentanyl 25 micrograms and Bupivacaine 1.25 mg. Then continuous epidural infusion of Bupivacaine 0.20 % with Fentanyl 0.5 µg/ml, at a rate of 10 ml/hr was given in CEI group and Eight to ten ml of same combinations of Bupivacaine – Fentanyl solution were given as intermittent boluses, in IB group. Quality of analgesia and overall satisfaction was found to be superior in CEI group than IB group. Motor activity and bearing down ability were well preserved in both groups resulting in no difference as regards to duration of labour, mode of delivery and neonatal outcome.

Keywords : *Analgesia, Labour; Analgesic techniques, Walking epidural; Drug delivery; Continuous Epidural Infusion; Intermittent Bolus; Drug delivery; Analgesics opioid.*

Introduction

The goal of maternal labour analgesia is relief of pain without compromising maternal safety, progress of labour and foetal well-being. Traditional epidural techniques have been associated with prolonged labour, oxytocin augmentation, and increased incidence of instrumental vaginal delivery. The combined spinal-epidural (CSE) technique has been introduced in an attempt to reduce these adverse effects. CSE is believed to improve maternal mobility during labour and provide more rapid onset of analgesia than epidural analgesia, which could contribute to increased maternal satisfaction.[1] The aim of this study was to develop a safe dosing regimen to maintain satisfactory labour analgesia and at the same time ensure good motor activity and good bearing down ability, after initiation of the analgesia by intrathecal administration of fentanyl and bupivacaine. It was decided to test two different commonly practiced techniques - continuous epidural infusion technique and intermittent boluses on demand technique from the point of view of safety & efficacy, degree of motor blockade and duration of labour.

* Professor, Dept of Anaesthesia, RMC, Loni
** Assosiate Professor, Dept of Anaesthesia, RMC, Loni
*** Registrar, Dept of Anaesthesia, RMC, Loni
**** Lecturer, Indian Institute of Public Health, Hyderabad

Address for correspondence:
Dr Shidhaye Ramchandra Vinayak , Professor Dept of Anaesthesia, Rural Medical College, PIMS, Loni
Email: rvshidhaye@yahoo.com

Materials and methods

After approval from the hospital ethical committee, this study was carried out in randomly selected sixty uncomplicated full term pregnant patients who were in active labour. Exclusion criteria were multiple-pregnancy or abnormal presentation, systemic disorder like diabetes mellitus, hypertension and heart disease, spine deformity, blood coagulation disorder, bad obstetric history and foetal abnormity. The procedure of epidural labour analgesia was explained to the selected patients and written, informed, valid consent was obtained. Vital parameters – heart rate, blood pressure, respiratory rate, SpO_2 and foetal heart rate (FHR) were recorded. Labour analgesia was then started in the

first stage of labour when cervical dilatation was 3 to 5 cm. Five hundred millilitres of Ringer's lactate was administered intravenously as a preload. Sixteen gauge Tuohy's needle was passed under aseptic measures, in L2 – L3 or L3 – L4 space and gradually advanced till the epidural space reached which was identified by loss of resistance technique. Epidural catheter was threaded through the needle and passed cephaled two spaces (3-4cm) above the point of insertion and was fixed to the skin. Then lumber puncture was done at one space bellow with 27 number spinal needle and all patients were given intrathecal bolus dose of fentanyl 25 micrograms and Bupivacaine 1.25 mg through it. All patients were then allocated randomly in equal numbers for the maintenance of analgesia through one of two techniques:

CEI Group: Continuous epidural infusion of Bupivacaine 0.20 % with Fentanyl (0.5 μg/ml) at a rate of 10 ml/hr.
IB Group: Intermittent bolus epidural injection of Bupivacaine 0.20 % with Fentanyl (0.5 μg/ml) on demand, 6 to 10 ml in volume as per assessment of the progress of labour.

Continuous epidural infusion was started half an hour after initial intrathecal block and intermittent bolus epidural injections were started on patient's demand. All patients were frequently assessed for sensory level and motor activity. Sensory level was assessed with pin prick method and the degree of motor blockade was tested using Modified Bromage scale(Table 1). When the sensory block was higher than T7 or the motor blockade was below score 4 as per the Bromage scale infusion was stopped for 10 minutes. When patients had severe break through pain (VAS pain score > 3) additional top-ups of 3 ml of 0.20 % bupivacaine with fentanyl 0.5 micrograms/ml were administered. Maternal parameters like pulse rate, blood pressure and respiratory rate were monitored frequently. FHR was monitored through tococardiography. The progress of labour was observed in conjunction with an obstetric colleague to record the frequency, duration and intensity of the uterine contractions, cervical dilatation and descent of the presenting part. Bearing-down ability was assessed by asking the patients about the perception of the urge to bear down. Neonates were

Table 1: Modified Bromage score as used by Breen

Score	Criteria
1	Complete block (unable to move feet or knees)
2	Almost complete block (able to move feet only)
3	Partial block (just able to move knees)
4	Detectable weakness of hip flexion while supine (full flexion of knees)
5	No detectable weakness of hip flexion while supine
6	Able to perform partial knee bend

assessed with the Apgar score 1 minute and 5 minutes after birth. The patients were observed for any side effects or complications, such as pruritus, nausea and vomiting, hypotension, a headache, sedation and respiratory depression. The procedure of labour analgesia was stopped after delivery and the duration of labour analgesia was recorded. The total dose of bupivacaine and fentanyl was also calculated. Quality of analgesia was assessed with the help of linear Visual Analogue Pain score (VAS). On this scale '0' cm. indicated no pain at all and 10 cm. indicated worst pain. Highest VAS for more than ten minutes any time during the labour analgesia period was taken on record

Table 2: Quality of analgesia

	VAS
Excellent	Less than 1
Good	Between 1 to 3
Fair	Between 3 to 7
No analgesia at all	More than 7

Table 3: Baseline characteristics

Characteristics	CEI Group	IB Group	p value
	Mean ± SD	Mean ± SD	
Age in years	24.4 ± 2.84	25.33 ± 3.45	> 0.05
Height in cms	152.4 ± 4.91	154.33 ± 4.87	> 0.05
Weight in kgs	50.9 ± 4.29	50.5 ± 2.96	> 0.05
Primipara	16 (53.33 %)	17 (56.67 %)	> 0.05
Secondpara	11 (36.67 %)	9 (30 %)	> 0.05
Multipara	3 (10 %)	4 (13.33 %)	> 0.05
Gestational age at beginning of labour analgesia (Duration of Ammenorrea in)	38.27 ± 0.54	38.4 ± 0.56	> 0.05
Cervical dilatation in cms at the beginning of labour analgesia	4 ± 0.49	4 ± 0.56	> 0.05

CEI = Continuous epidural infusion, IB = Intermittent bolus epidural injection, %= Percentages

for that patient. Quality of analgesia was graded as shown in Table 2.

All women were interviewed again within 24 hours after delivery by an anesthetist colleague, who was unaware of the technique used. The women were asked the level of their satisfaction regarding quality of analgesia. They were graded as Excellent, Good and Bad.

Data analysis was done using STATA 10. For continuous variables descriptive statistics (mean and standard deviations) were computed. Comparison of means in two groups was done using t-test. For categorical variables proportions were computed. Comparison of proportions in two groups was done using chi-square test.

Results

Patients' characteristics are shown in Table 3. There was no significant difference between the two groups. Maximum numbers of cases were in the age group of 21 to 24 and were nulliparous.

There was no significant difference with respect to age, height, weight, parity, Gestational age and Cervical dilatation in the two groups (p-value > 0.05).Twenty nine (96.67 %) parturients from CEI group and 21 (70%) from IB group reported excellent analgesia. This difference is significant. ($P < 0.05$) .

Patients' satisfaction as assessed by independent anesthetic colleague was significantly higher in patients from CEI group (90 %) than from IB group (60%) ($P < 0.05$).

There was no motor blockade throughout the labour in both

Table 4: Quality Of Analgesia

	CEI Group	IB Group
Excellent	29 (96.67 %)	21 (70%) *
Good	1 (3.33 %)	8 (26.67 %)
Fair	0	1 (3.33 %)
Total	30	30

CEI = Continuous epidural infusion IB = Intermittent bolus epidural injection % = Percentages * $p < 0.05$

Table 5 : Maternal satisfaction: Overall impression about quality of analgesia expressed in post delivery interview in all groups

No. of mothers who expressed level of overall satisfaction as	CEI Group	IB Group
Excellent ; Fully satisfied	27 (90 %)	18 (60%) *
Good ; Overall satisfied	3 (10 %)	9 (30%)
Fair ; Partially satisfied	0	3 (10%)
Inadequate Not at all satisfied	0	0
Total no. of delivered mothers	30	30

CEI = Continuous epidural infusion IB = Intermittent bolus epidural injection % = Percentages * $p < 0.05$

Table 6: Degree of motor weakness, bearing down ability and mode of delivery

	CEI Group	IB Group
Degree of motor blockade Modified Bromage scale IV	0	1 (3.33 %)*
Degree of motor blockade Modified Bromage scale above V	30 (100%)	29 (96.67 %)*
Excellent Bearing down ability	27 (90%)	28 (93.33 %)*
Spontaneous vaginal delivery	28 (93.33 %)	28 (93.33 %)*
Total no. of delivered mothers	30	30

CEI = Continuous epidural infusion IB = Intermittent bolus epidural injection % = Percentages * $p > 0.05$

groups. Mild weakness was observed in only one case of IB group. Maximum number of cases in both groups delivered spontaneously vaginally. Only 2 patients from CEI group and one from IB group required cesarean section. One patient from IB group required ventouse delivery. Pruritus was observed in 3 (10%) patients from CEI group and 4 (13.33 %) from IB group. Nausea and vomiting was observed in 1(3.33%) patient from IB group. No patient had headache, urinary retention, severe hypotension, respiratory depression, and any other complications.

Discussion

CSE combines the benefits of spinal anesthesia, in respect of rapid onset and reliable effect, with the benefits of

Table 7: Comparison of other outcome characteristics in both groups under study

Characteristics	CEI Group	IB Group
	Mean ± SD	Mean ± SD
Duration of labour analgesia (hrs.)	5.87 ± 2.12	6.49 ± 1.99 *
Total dose required of Bupivacaine mgs	103.32 ± 45.41	116.28 ± 42.44 *
Total dose required of Fentanyl Micrograms	50.48 ± 11.36	53.69 ± 10.54 *
APGAR score at one minute after birth	8.9 ± 0.84	8.83 ± 0.75 *
No. of occasions FHR <100 / min	0	0
No. of occasions FHR >160/ min	0	0

CEI = Continuous epidural infusion, IB = Intermittent bolus epidural injection, * p > 0.05

continuous epidural anesthesia, in respect of titration of analgesics and flexibility for prolongation.[2] Overall, women seem to prefer the low-dose combined spinal-epidural technique to standard epidurals, perhaps because of the faster onset, lesser motor block, and feeling of greater self-control.[3] Hughes D et al [4] concluded in their systematic review that there is no standard CSE or epidural technique. Compared with epidural, CSE provides faster onset of effective pain relief from the time of injection, and increases the incidence of maternal satisfaction though CSE women experience more itch. Simmons SW et al [5] updating the same systematic review again in 2007 concluded that there appears to be little basis for offering CSE over epidurals in labour with no difference in overall maternal satisfaction despite a slightly faster onset with CSE and less pruritus with epidurals. There is no difference in ability to mobilize, obstetric outcome or neonatal outcome. However, the significantly higher incidence of urinary retention and rescue interventions with traditional techniques would favor the use of low-dose epidurals. We thought that not only the initiation of the block by spinal route ,but the techniques for further maintenance of the block by epidural route are equally important for proper evaluation of efficacy of CSE. So a prospective randomized study was designed to compare two different, commonly practiced techniques- continuous epidural infusion and traditional intermittent top-ups on demand for maintenance of labour analgesia, in combined spinal epidural analgesia after initiation of block by intrathecal administration of bupivacaine – fentanyl solution. While subarachnoid injection of solely opioids provides fast pain relief for nearly 2 hrs in the first stage of labour with an opportunity of ambulation for the parturient ("walking epidural"), the subarachnoid injection of a combination of low doses of opioids and local anesthetics provides profound analgesia with minor motor blocking side effects for 1-2 hrs in the second stage of labour.[2] So we initiated the sensory block by intrathecal bolus dose of fentanyl 25 micrograms and

Bupivacaine 1.25 mg. Many workers recommend test dose before giving epidural bolus, to confirm catheter placement [6] but this lacks sensitivity and specificity.[7] Omitting a lidocaine-epinephrine test dose should permit ambulation in the early post block period for most parturients who elect this option.[8] In this study we have not given any test dose. Analgesic efficacy was assessed with the help of linear Visual Analogue Pain score (VAS). There were 96.67% parturients from CEI group who had an excellent analgesia as compared to 70 % in IB group. This difference is significant indicating continuous infusion techniques are better. Maternal satisfaction was assessed by overall impression about quality of analgesia expressed by mothers in post delivery interview in both groups. There were 60% mothers from IB group and 90% mothers from CEI group who were fully satisfied and expressed the quality of analgesia as excellent. This difference is significant indicating that quality of analgesia in the CEI group is better than IB group. No patient complained of inadequate analgesia. Degree of motor blockade and bearing down ability and their effect on duration of labour, and mode of delivery were observed .Motor activity was well preserved in both groups except in 1 patient from IB group. Bearing down ability was also well preserved in all patients. These findings were similar to the findings of Plunkett BA et al [9] The total duration of labour was found to be ranging from 2 to 10 hours. There was no significant difference among two groups indicating there is no effect of continuous infusion or intermittent top-up technique on duration of labour. Usha Kiran et al[10] showed reduction in motor blockade associated with intermittent top-up epidural regimes compared with CEI did not affect the outcome of labour. Liu EH, Sia AT [11] also showed that Epidural analgesia using low concentration infusions of bupivacaine is unlikely to increase the risk of caesarean section .Our results are consistent with all these study reports. In our study only 2 patients from CEI group and one from IB required cesarean section and one from IB required ventouse delivery. Rest all had spontaneous vaginal delivery. This can be attributed to preservation of motor activity and excellent bearing down ability in both groups. Similarly there was no significant difference in total dose required of bupivacaine and fentanyl in both groups. All patients were observed for side effects. Pruritus was observed in 3 (10%) patients from CEI group and 4 (13.33 %) from IB group due to fentanyl. Only one patient from IB group had nausea and vomiting. There was no incidence of headache, urinary retention, maternal respiratory depression and any other complications. Capogna G and Camorcia M.[12] showed that small doses of epidural or spinal opioids alone or combined with low doses of local anesthetics does not affect the well-being of the neonate at birth. When considering the neonatal outcome, combined spinal epidural analgesia is as well tolerated as low-dose epidural analgesia. Our study also showed no significant difference in neonatal outcome in different groups. Apgar score at five minutes after birth was 9-10 in 90 % of patients in both groups and in 10 % of patients it was 8-9. In conclusion, our study revealed that the continuous epidural infusion technique is superior to the intermittent boluses technique for maintenance of labour analgesia in combined spinal epidural analgesia after initiation of block by intrathecal administration of bupivacaine – fentanyl solution.

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