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A Comparative Analysis of Combined Spinal and Epidural Infusion of Fentanyl and Ropivaciane with Continous Epidural Infusion for Labour Analgesia

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Abstract

Childbirth is an apogee event in a family full of beliefs and traditions which can be either scientific or cultural and personal. Labour (the process of childbirth) is the most excruciating event for the majority of women. The pain experienced during labour puts stress on the maternal body in terms of an increase in mechanical workload, increasing the demand for oxygen and the resulting hyperventilation leads to catecholamine surge with resultant greater uterine contractility and uterine vasoconstriction, thereby hypoperfusion of fetoplacental unit produces foetal hypoxia leading to acidosis. All these consequences due to labour pain can be blunt by providing adequate labour analgesia[1].

In modern labour room practice, neuraxial analgesia is the most reliable, safer and effective method. Therefore, considered to be the gold standard technique in providing better pain relief during labour when compared to other pain relief approaches. Epidural analgesia (EA) is very extensively used due to its well-recognised pain relieving property[2]. It provides significantly effective analgesia. It helps in counteracting the untoward effects of catecholamine increase by blunting the hemodynamic changes and maintaining the maternal cardiac output, heart rate and blood pressure throughout the labour. Combined-spinal epidural analgesia (CSEA) technique combines the advantages of subarachnoid analgesia also, such as speed of onset and reliability of block with the flexibility of extending analgesia, provided by the presence of an epidural catheter and avoids their particular disadvantages[3].The addition of lipophilic opioids to local anaesthetic for neuraxial analgesia increases the duration of sensory block[4]. It doesn't depress neonatal respiration or adversely affect neuro-behavioural scores and other indices of neonatal welfare[5]. Labour analgesia with both techniques are considered to be safe and very effective[6].

Pregnant patients are more prone to harmful effects of local anaesthetics due to ascent at higher level. Hence techniques which can decrease the dose are very beneficial, so in this study we avoided local anaesthetic in spinal, used only opioid and in epidural we used low dose local anaesthetic in form of 0.1% ropivacaine. So, this study was designed to compare the efficacy and

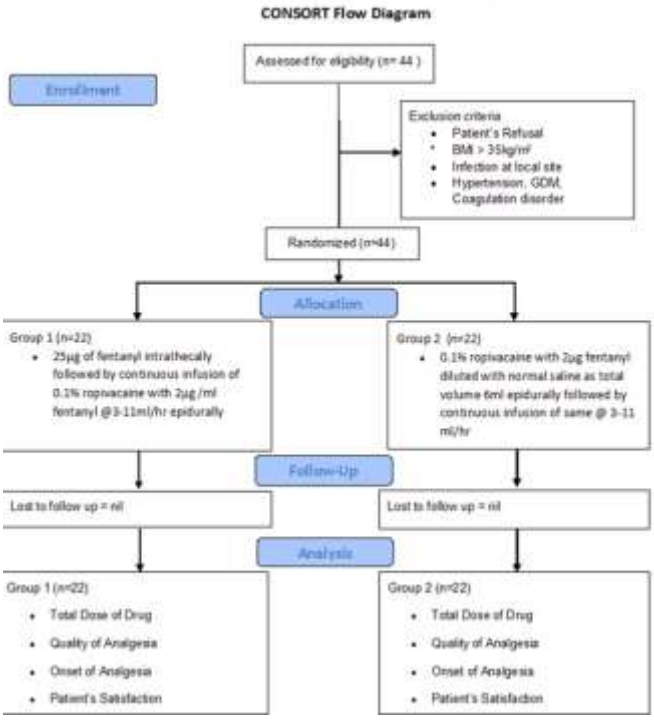
safety of these two techniques with primary aim of onset of analgesia, while secondary aims were to observe amount of local anaesthetic consumption, the quality of analgesia, any potential side effects and maternal satisfaction.

Keywords: Urine Albumin, Maternal Age, Ropivacaine, Intrathecal Injection

Materials & Methods

This prospective randomized hospital-based study was conducted in the Department of Anaesthesiology, PBM hospital, S.P. Medical College after institutional ethical committee approval (No: F.29(Acad)SPMC/2021/4313) and CTRI registration (CTRI/2022/10/046613).Written informed consent was procured from the parturient and her relative. Sample size was calculated by open epi version 3.0 using a comparative study between combined spinal epidural and epidural labour analgesia by joel et al. A total of 44 parturients with the American Society of Anaesthesiologists (ASA) physical status 2, aged 18 to 40yrs with a singleton foetus in a cephalic presentation at term, cervical dilatation of 3-5cm who requested labour analgesia with no contraindication to epidural catheterization were included in this study.

Exclusion criteria included patient refusal, BMI>35kg/m^2, infection at the site of an epidural prick, coagulation disorder, gestation diabetes, hypertensive disorder and raised intracranial tension.



The pre-anaesthetic evaluation was done and all the routine investigations (Hb, BT, CT, Platelet count, urine albumin and sugar) were carried out. The visual analogue scale was explained to the patients. Patients were kept NBM for 6-8 hours before labour analgesia. The study population was divided into 2 groups with 22 patients in each group.

Patients were divided according to the drug received:

Group1	25 µg of fentanyl intrathecally followed by continuous infusion of 0.1% ropivacaine with 2µg/ml fentanyl @ 3-11 ml/hr epidurally.
Group2	0.1% ropivacaine with 2µg/ml fentanyl diluted with normal saline as a total volume of 6 ml epidurally followed by continuous infusion of same @ 3-11ml/hr.

Following parameters like maternal age, height, weight, gestational age, cervical dilatation and parity were recorded. Before placement of the epidural catheter, the VAS score was explained and noted with VAS 0 = no pain and 10 = the worst imaginable pain along with baseline vitals.

Two peripheral lines were secured by using an18G intravenous cannula to preload the patient with 10ml/kg Ringer's lactate solution, and then parturients in both groups were placed in the left lateral position. Following strict aseptic precautions, epidural space was sought with the help of an 18-gauge Tuohy's needle using the loss of resistance technique and then an epidural catheter was inserted 5 cm into the epidural space. Group 1 patients received CSE analgesia where initial analgesia was initiated by an intrathecal injection of 25microgram fentanyl through 25G Quincke's needle in L3-L4 space after placing an epidural catheter by above technique where a continuous infusion of 0.1% ropivacaine with fentanyl 2µg/ml was started at the rate 3-11 ml/hr just after intrathecal injection. Group 2 parturients received 6 ml of 0.1% ropivacaine with 2µg/ml fentanyl via epidural catheter followed by continuous infusion of the same drug at the rate of 3-11ml/hr. After this procedure parturients were turned supine and a wedge was placed under the right buttock to prevent aortocaval compression.

Maternal heart rate, blood pressure, oxygen saturation and respiratory rate were recorded noninvasively every 2 min for 10 mins, then every 5 min for 30 mins, every 20 min for 120-300 min or delivery of the foetus which was earlier. Throughout the study foetal heart rate was recorded with the use of continuous cardiotocography. Ambulation was considered possible after three unassisted steps but always advised by an assistant. Time of onset was taken as the time between drug injection until the time when the parturient becomes pain-free. The highest dermatome, degree of the motor block using a modified Bromage scale and side effects were assessed and recorded. The highest dermatome sensory block was tested in each dermatome bilaterally for the loss of pinprick sensation using a 26G needle. Assessment of cervical dilatation, effacement, station of head and uterine contractions was done by attending obstetrician according to their protocol. FHR was recorded continuously. Duration of 1st and 2nd stage of labour was noted. The mode of delivery was noted. APGAR score of neonates was assessed at 1 and 5 minutes. Occurrences of any side effects like shivering, pruritus, nausea, vomiting, respiratory depression and urinary retention were noted and treated accordingly. Total drug consumption was assessed in both groups. Any adverse events were recorded. Maternal satisfaction with analgesia was assessed after delivery using an arbitrary satisfaction scale (excellent & good).

Results

In our study, all 44 parturients were equally divided into two groups. Both groups were comparable in terms of age, height, weight, and BMI (table 1). Time to VAS less than 3 min (onset of analgesia) was lower in group 1(3.77±0.97) as compared to group 2(9.41±0.59), which was statistically significant (table 2). The total dose of ropivacaine in mg was lesser in Group 1 (11.67±2.5mg) than in Group 2(18.14±3.54) with a p-value of 0.001, so it was statistically significant (table 3). The quality of analgesia was better in group 1 as compared to group 2 upto 150min with a significant p-value of 0.011(table 4). Pruritus was only seen in a few parturients in group 1 and the difference was statistically significant with p value less than 0.001. (graph 1). Patient satisfaction was greater in group 1 as compared to group 2 with a significant p-value of 0.021(graph 2)

Table 1: Comparison of mean age and anthropometric data between the two groups

Age(years)	Mean (SD)		p-value
	Group 1 (N = 22)	Group 2(N = 22)	
	23.5 (2.7)	22.95 (2.99)	0.530
Anthropometric measurements	Mean (SD)		p-value
	Group 1(N = 22)	Group 2(N = 22)	
Height (cm)	157.63 (3.77)	157.45 (4.27)	0.882
Weight (Kg)	61.36 (6.6)	59.68 (5.28)	0.356
BMI (Kg/m^2)	24.65 (2.32)	24.05 (2.3)	0.397

Table 2: Comparison of Time to VAS < 3 between the two groups

Time to VAS < 3	Mean (SD)		p-value
	Group 1(N = 22)	Group 2(N = 22)	
	3.77 (0.97)	9.41 (0.59)	0.001

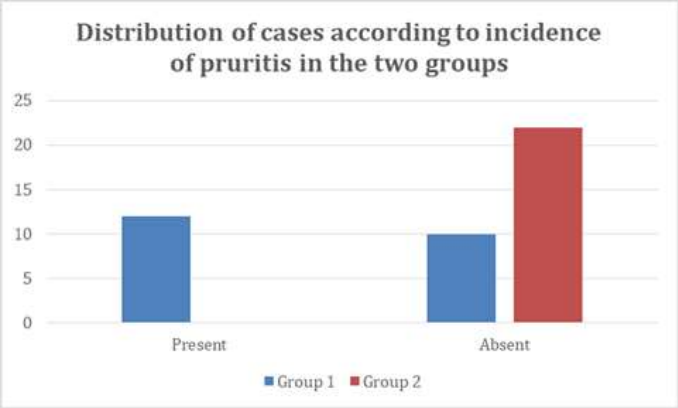
Table 3: Comparison of analgesic requirements between the two groups

	Mean (SD)		p-value
	Group 1(N = 22)	Group 2(N = 22)	
Volume of Ropivacaine (ml)	11.67 (2.5)	18.14 (3.54)	0.001
Total doses of Ropivacaine (mg)	11.67 (2.5)	18.14 (3.54)	0.001
Total Fentanyl (mcg)	48.35 (5.00)	36.29 (7.08)	0.001

Table 4: Comparison of VAS scores between the two groups

VAS	Median (IQR)		p-value
	Group 1 (N = 22)	Group 2 (N = 22)	
Baseline	9.5 (9 - 10)	9 (9 - 10)	0.658
5 min	3 (2 - 3)	8 (7 - 8)	0.001
10 min	2 (2 - 3)	6 (5 - 7)	0.001
15 min	2 (1 - 2)	3.5 (3 - 4)	0.001
20 min	1 (1 - 2)	3 (2 - 3)	0.001
30 min	1 (1 - 1)	2 (2 - 3)	0.001
60 Min	1 (1 - 1)	2 (2 - 3)	0.001
90 min	2 (1 - 2)	2 (2 - 2.25)	0.001
120 min	2 (2 - 2)	2 (2 - 3)	0.015
150 min	2 (2 - 2)	3 (2 - 3)	0.010

180 min	2 (2 - 2)	2.5 (2 - 3)	0.083
210 min	2 (2 - 3)	3 (2 - 3)	0.115
240 min	3 (2 - 3)	3 (2 - 3)	1.000
270 min	2.5 (2 – 2.50)	3 (3 - 3)	1.000
p-value (Inter-group) = 0.011			



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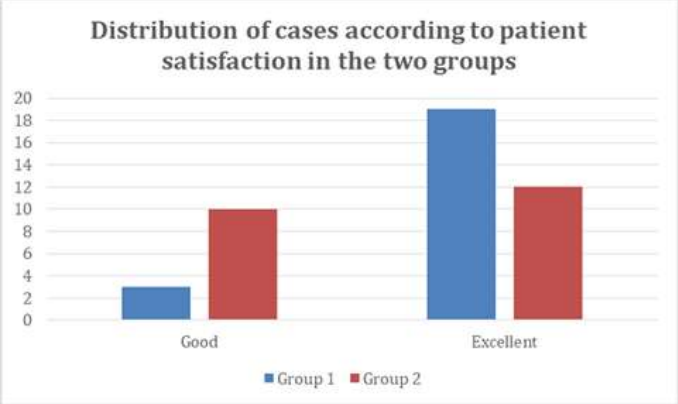

Graph: 2

Discussion

In our study, the mean age (years) in group 1 was 23.5±2.7 and in group 2 was 22.95±2.99. There was no significant difference between the groups in terms of age, weight, height, BMI and parity. In our study, the demographic features had no impact on the outcome of the study which was in congruence with the study conducted by Joel et al(2019)[7] who compared the effectiveness of CSE with low-dose epidural analgesia. In terms of onset of anlagesia, there was a significantly faster onset in group1 than in group 2 with a p-value of 0.001. Both Joel et al (2019)[7] and Hughes D et al (2003)[8] also found that CSE shows a reduced time from first injection to effective maternal analgesia(5.50min) as compared with the epidural group($p<0.001$). The mean total dose (mg) of 0.1% ropivacaine was lower in group 1 (11.67±2.5) as compared to group 2 (18.14±3.54) with a significant p value of 0.001. Our study was comparable with Joel et al (2019)[7]who found that the dose requirement was lower in the CSE group ($P = 0.001$). On comparing VAS score it was observed that in both groups the VAS score significantly decreased from baseline but decrease was much more in group 1 as compared to group 2 with a statistically significant p value <0.01. In the CSE group, after an intrathecal injection of 25µg of fentanyl, an immediate epidural infusion dose was started which did not allow the opioid effect to wean off, resulting in no breakthrough pain. It was also observed that patients became very comfortable after intrathecal opioids and psychologically were much more relaxed and comfortable which might also be an additional factor of low VAS scores in group 1. Joel et al (2019)[7] observed a significantly lower VAS score at 5 & 10min in the CSE group due to the quick onset of the intrathecal component, whereas from 15 min onwards, VAS was significantly lower in the epidural group probably due to weaning off of the spinal opioid and peak action of initial epidural bolus in the epidural group because in CSE group they activated epidural catheter on maternal request not immediately. This variation in outcome in different studies also can be attributed to different pain thresholds and inter-observer variations and differences

in the technique used. In terms of side effects, Pruritus was present in 12 parturients of group 1(CSE) whereas no such complaint was found in group 2(epidural) parturients with a statistically significant p-value of <0.001. No other side effects such as hypotension, bradycardia, motor block, the incidence of c-section and instrumental delivery, vomiting and respiratory depression were noted in both groups. Pruritus occurred only in the CSE group, maybe because of intrathecal administration of fentanyl but none of the parturients required any aggressive treatment for this. Symptoms were mild and resolved on their own without the need for any treatment. This was similar to the study done by Simmons SW et al (2012)[9]who compared combined spinal epidural with low-dose epidural labour analgesia and found more pruritus with CSE. Patient satisfaction level in group 1 was excellent in 19 and good in 3 out of 22 parturients while in group 2 satisfaction level was excellent in 12 and good in 10 parturients out of 22. The p-value was 0.021 which was statistically significant it shows parturients who underwent the CSE group for delivery were more satisfied as compared with epidural group parturients. These findings were similar to the study conducted by Hughes D et al (2003)[8]. It is possibly due to the early onset of analgesia in the CSE group as compared with the epidural group. As both groups were receiving 0.1% ropivacaine with fentanyl 2 µg/ml via infusions so there was no breakthrough pain seen in both groups.

Conclusion

Combined spinal epidural when compared to epidural alone, was found to be better in terms of faster onset, maternal satisfaction and quality of analgesia with less total local anaesthetic consumption and minimal side effects. But as our sample size was small, a larger study is needed to establish above said findings.

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