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Comparison Of Epidural Ropivacaine Versus Combined Spinal Epidural With Intrathecal Fentanyl And Epidural Ropivacaine For Ambulatory Labour Analgesia

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Abstract

Background: Labour is one of the most painful procedures which the females experience in their life. Epidural labour analgesia with or without spinal block has been one of the most effective technique for pain relief during labour.

Materials and methods: 60 ASA 1 or 2 nulliparous parturients with vertex presentation divided into two groups of 30 each and randomly assigned using computer generated randomization table. Group A (epidural) received 0.2% Ropivacaine infusion through epidural route only @ 8ml/hr and group B (CSE) received 25 microgram fentanyl via spinal route followed by 0.2% Ropivacaine infusion via epidural route @ 8 ml /hr. Analgesia onset time, pain relief, incidence of motor blockade, duration of labor and incidence of instrumental and cesarean delivery and various side effects on mother and foetus were evaluated.

Results: The analgesia onset time was significantly low in epidural group 12.0 ± 1.2 min compared to 1.3 ± 0.3 min in CSE group; p-value <0.05. VAS was significantly lower at 5 and 10 min in CSE group (P<0.05). No significant difference in the type of delivery or neonatal APGAR score at 1 min and 5 min was observed (p-value <0.05) and maternal satisfaction was excellent in both cases in the majority of cases in both groups. Side effects were statistically insignificant in the two groups**.**

Conclusion: Onset of analgesia was faster in CSE group although both techniques provided satisfactory labour analgesia. Maternal and foetal outcomes were similar in both groups.

Keywords: epidural, combined spinal epidural, analgesia, ropivacine, labour

Introduction

Labour is considered as one of the most painful conditions ever experienced by a woman. Maternal request is an indication for labour analgesia, if there is no medical contraindication, as recognized by American College of Obstetricians and Gynecologists (ACOG).[1]

Maternal stress response resulting from labour pain can be detrimental for mother as well as foetus.[2]

Maternal physiological responses by labour pain may not be beneficial to foetal well-being. Maternal hyperventilation results in increased oxygen consumption, plasma catecholamine concentrations, tachycardia and hypertension. Additionally, maternal hyperventilation may lead to a reduction in foetal oxygenation, hence abnormal foetal heart rate patterns and may result in an increased operative delivery.[3,4] Good and early pain relief is the primary

requirement of labouring women, Also minimal motor blockade is required for ambulatory labour analgesia and effective participation in labour.

Various pharmacological and non-pharmacological techniques are available for relieving labour pain. Pharmacological methods include central neuraxial blocks like epidural and combined spinal-epidural blockade (CSE), peripheral nerve blocks (paracervical and pudendal), and intravenous analgesia (opioids and non-opioids).[5] Non-pharmacological methods include hydrotherapy, acupuncture, and transcutaneous electrical nerve stimulation.[6]

Among these various methods, neuraxial analgesia (epidural, spinal anaesthesia, and combined spinal-epidural anaesthesia) is considered the most effective.[7] CSE for labour analgesia is a popular technique that allows rapid onset of analgesia with minimal motor block, and various local anaesthetics and opioids either alone or in combination have been used for this purpose.[8,9]

Ropivacaine, an amide local anaesthetic is more selective for sensory fibres when compared to other local anaesthetics, producing lesser motor blockade.[10]

The present study aimed at evaluating the effectiveness of CSE analgesia with intrathecal fentanyl versus epidural analgesia only using low dose epidural Ropivacaine infusion in both groups (in terms of onset and quality of analgesia) and to evaluate the effect of these two techniques on maternal and fetal wellbeing.

Materials and methods:

This prospective randomized double-blind study was conducted at a teaching hospital on 60 parturients after obtaining written informed consent from the patients. Inclusion criteria were set to American society of anesthesiology 1 or 2 nulliparous term parturients with vertex presentation requesting labour analgesia and having regular contractions every 5 minutes (active labour). Parturients with severe medical or obstetrical conditions, multiple pregnancy, premature labour, previous lower segment cesarean section (LSCS), neurological diseases, psychiatric diseases, administration of opioid analgesia by another route in the previous 4 hours and those with contraindication to neuraxial block were excluded from the study. Two groups of 30 parturients each were formed: group A (received epidural) and group B (received CSE) and they were randomly assigned to one of the two groups using a computer-generated randomization table. Epidural and CSE were only given when labour was established with cervical dilatation more than 3 cm with reassuring fetal heart rate (FHR). Group A received 0.2% Ropivacaine infusion through epidural route only @ 8ml/hr and group B received 25 microgram Fentanyl in 1.5 ml sterile water via spinal route followed by 0.2% Ropivacaine infusion via epidural route @ 8 ml/hr. Rescue analgesia was given as epidural bolus dose of 0.2% Ropivacaine 5 ml at VAS (visual analogue score) >3. Hemodynamic parameters were monitored from the time epidural or CSE was administered till the time of delivery, also analgesia onset time, pain relief using the VAS at various time intervals, incidence of motor blockade, type of normal vaginal delivery, duration of labour, incidence of instrumental and cesarean delivery, foetal heart rate, Neonatal APGAR score, other side effects, level of maternal satisfaction and willingness for future labour analgesia were evaluated.

Statistical analysis

The statistical analyses were performed using SPSS (Statistical package for social sciences) version 17 for windows. Descriptive statistics were presented as mean±SD. Two-sided independent student's t-tests were used to analyze continuous data and Chi-square test was used to compare categorical variables between treatment allocations. A P-value of <0.05 was considered as statistically significant.

Results

A total of 60 parturients were randomized in two groups of 30 each during the study period. Parturients in the two groups were comparable to their baseline demographics in terms of weight and Age (p-value >0.05), Duration of labour (p-value 0.894) (Table 1). The analgesia onset time was significantly low in group A (Epidural) 12.0 ± 1.2 min compared to 1.3 ± 0.3 min in group B (CSE); p-value <0.001 (Table 1).

Table 1. Demographic details and other parameters

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Variables		Group A (Epidural)		Group B (CSE)		P value
		Mean	SD	Mean	SD	
Age (Years)		27.1	3.2	25.8	3.6	0.153
Weight (kg)		68.2	7.3	68.1	4.8	0.933
Onset of analgesia (Min)		12.0	1.2	1.3	.3	<0.001
Total Ropivacaine used (mg)		115.1	17.2	115.0	17.7	0.9888
No. of Ropivacaine doses (Rescue analgesia)	0	25 (83.3%)		24 (80%)		0.739
	1	5 (16.7%)		6 (20%)		
Duration of labour (min)		433.4	67.2	431.1	66.5	0.894
APGAR 1min		8.2	.4	8.2	.4	0.744
APGAR 5min		10.0	.0	10.0	.0	NA
Type of delivery	NVD	25 (83.3%)		23 (76.7%)		0.768
	Forceps	4 (13.3%)		5 (16.7%)		
	LSCS	1 (3.3%)		2 (6.7%)		
LOMS	Yes	25 (83.3%)		28 (93.3%)		0.228
	No	5 (16.7%)		2 (6.7%)		

Abbreviations: CSE: combined spinal epidural; kg: kilogram; mg; milligram; min; minute; No.: number; LOMS: level of maternal satisfaction; NA: not applicable

Hemodynamic parameters like heart rate, systolic and diastolic blood pressure remained comparable in two groups throughout labour except for Heart rate at 5 min and 10 min when the difference was statistically significant (p-value <0.05) (Figure 1-3).

Figure 1. Mean heart rate in two groups

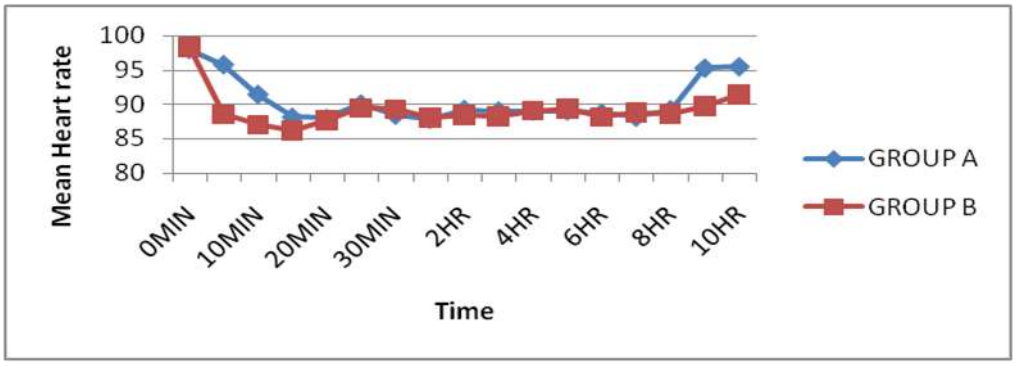

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Figure 2. Mean systolic blood pressure in two groups

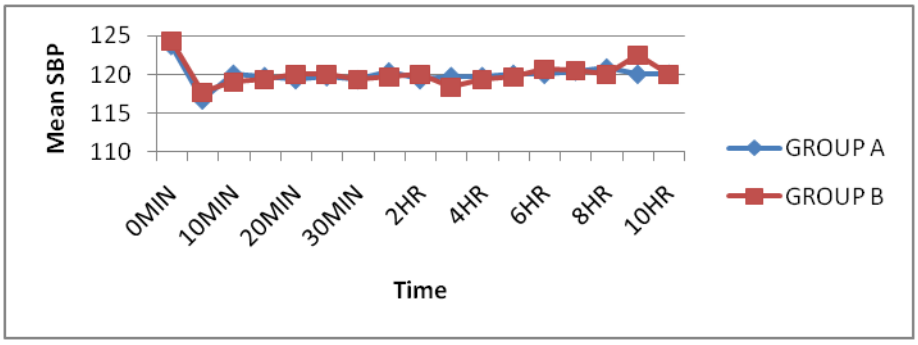


Figure 3. Mean diastolic blood presure in two groups

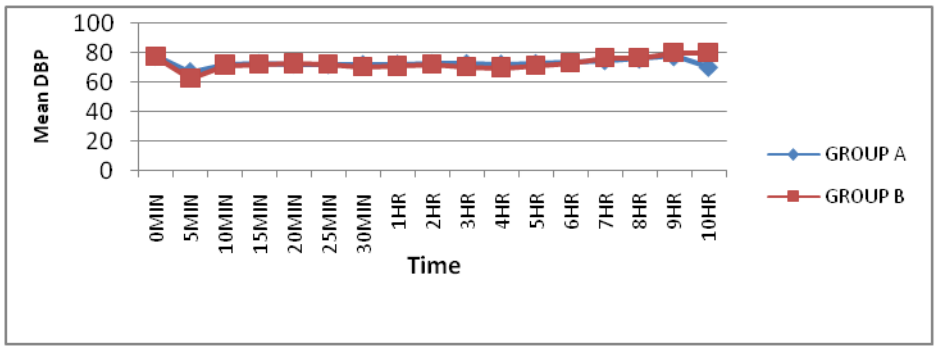
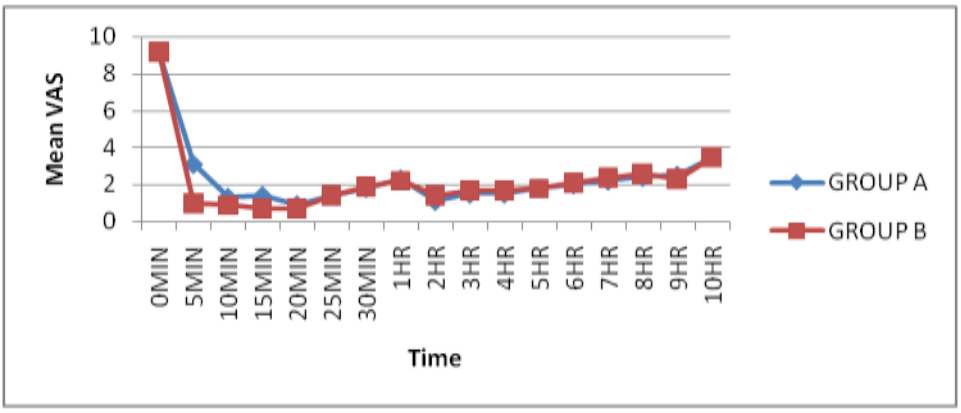


Figure 3. Mean diastolic blood presure in two groups

VAS was significantly lower in the CSE group at 5 and 10 min likely because of the rapid onset of analgesia in CSE Group compared to the epidural group (P<0.05) and thereafter it was statistically insignificant (Figure 4).

Figure 4. Mean VAS in two groups



Total amount of Ropivacaine and total number of Ropivacaine bolus doses as rescue analgesia in two groups was statistically insignificant (p-value 0.739) (Table 1).

Foetal heart rate (Figure 4), type of delivery and neonatal APGAR score at 1 min and 5 min were statistically insignicant (p-value <0.05) (Table 1).

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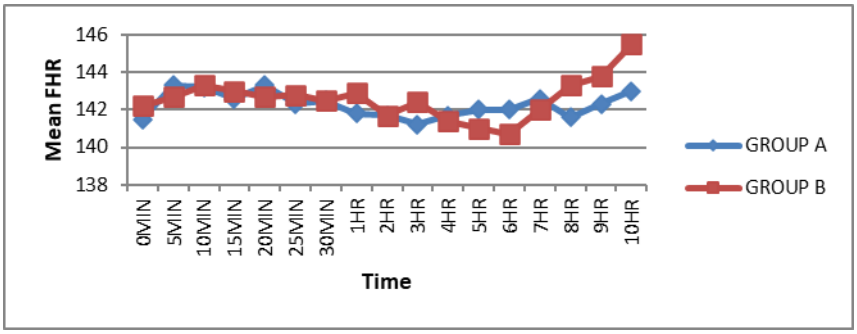
Figure 5. Mean foetal heart rate in two groups



Level of maternal satisfaction was excellent in both cases in the majority of cases in both groups (p-value >0.05), and all the parturients were willing for future use of labour analgesia (Table 1). Incidence of motor blockade was statistically insignificant throughout labour (Table 2).

Table 2. Modified Bromage Score (MBS) in two groups

Time	MBS	Group A		Group B		P Value
		N	%	N	%	
0 Min	0	30	100	30	100	NA
5 Min	0	30	100	30	100	NA
10 Min	0	30	100	30	100	NA
15 Min	0	30	100	30	100	NA
20 Min	0	30	100	30	100	NA
25 Min	0	30	100	30	100	NA
30 Min	0	30	100	30	100	NA
1 Hr	0	30	100	30	100	NA
2 Hr	0	30	100	30	100	NA
3 Hr	0	29	96.7	30	100	0.313
	1	1	3.3	0	0	
4 Hr	0	29	96.7	29	96.7	1.000
	1	1	3.3	1	3.3	
5 Hr	0	30	100	29	96.7	0.313
	1	0	0	1	3.3	
6 Hr	0	29	100	29	96.7	0.321
	1	0	0	1	3.3	
7 Hr	0	23	100	22	100	NA
8 Hr	0	12	100	12	100	NA
9 Hr	0	4	100	4	100	NA

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10 Hr	0	2	100	2	100	NA

Other side effects like sedation, hypotension, nausea, pruritis, urinary retention were statistically insignificant in the two groups (Table 3).

Table 3. Complications observed in two groups

Complications		Group A		Group B		P Value
		N	%	N	%	
Hypotension	Yes	0	0	0	0	NA
	No	30	100	30	100	
Nausea	Yes	0	0	0	0	NA
	No	30	100	30	100	
Pruritis	Yes	0	0	3	10	0.076
	No	30	100	27	90	
Urinary Retention	Yes	1	3.3	0	0	0.313
	No	29	96.7	30	100	

Discussion:

Labour analgesia is a challenging task with subjective end points. Any intervention or drug administered with the purpose of labour analgesia can have varying effects both to mother as well as foetus both desirable and undesirable and has always remained a topic of debates and discussion.

In our study, there was a statistically significant difference with regard to onset of analgesia where CSE group had early onset analgesia because of intrathecally injected opioid up to first 10 minutes after which the other group also had similar VAS values.

Our results were also favoured by Craig M Palmer et al[11] who also observed that intrathecal fentanyl produces rapid onset, profound labour analgesia with little benefit of increasing the dose beyond 25 mcg when it is used as the sole agent for intrathecal labour analgesia.

Our results are supported by Robert D' Angelo et al[12] who observed that in intrathecal sufentanil group there was significant lower VAS at 5, 15 and 30 min hence rapid onset analgesia with the duration of analgesia 123 min (versus 68 min) and motor block less frequently and concluded that intrathecal sufentanil leads to rapid onset analgesia and lacks the motor blockade.

In our study, after 10 minutes the VAS values were quite low in both the groups resulting in an excellent level of analgesia throughout labour duration with statistically insignificant differences with infusion of 0.2% Ropivacaine and requirement of rescue analgesia was minimal in both the groups.

Our results are comparable to study by Sia AT et al[13] in which effectiveness of 0.2% and 0.125% ropivacaine in patient-controlled epidural analgesia for labour analgesia and incidence of motor block was compared; and observed that sufficient analgesia had been obtained in both 0.2% and 0.125% concentrations epidural analgesia for labour analgesia and that hourly rate of ropivacaine consumption, degree of pain relief, maternal-fetal outcomes and overall satisfaction score were similar.

Our results were also comparable to study by Chhetty YK et al[14] who observed that 0.2% ropivacaine was superior with regard to faster onset, prolonged duration and lesser breakthrough pain requiring lesser top-ups. Agarwal A et al[15] also concluded that both ropivacaine & levobupivacaine are highly effective for labour analgesia using the CSE technique with

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comparable VAS scores at all time intervals, comparable hemodynamic profile, minimal adverse maternal or neonatal outcomes.

We found no- minimum motor block in either group when assessed with modified bromage scale with statistically insignificant differences in the incidence or severity of motor block between the groups.

Our results were also comparable to Agarwal A et al[15] who in their study also observed that both 0.125% levobupivacaine and 0.12% ropivacaine are highly effective for labour analgesia using the CSE technique and produce a negligible motor block in the parturients (grade 1 block in 6.7% cases in group ropivacaine versus 13% in Group levobupivacaine). There were no statistically significant differences in the parameters of motor block (incidence or severity) between the groups.

Another study by Asik I et al[16] also favoured our results who compared bupivacaine 0.2% and ropivacaine 0.2% with fentanyl for epidural analgesia during labour in which women were randomly allocated to receive either bupivacaine 0.2% with fentanyl 2 mcg/ml (B/F), or ropivacaine 0.2% with fentanyl 2 mcg/ml (R/F). 8 ml of the study solution was administered via epidural analgesia. Motor block was observed in two patients in the R/F group whereas in 10 patients in the B/F group ($P < 0.05$). The results suggested that ropivacaine 0.2% combined with fentanyl 2 mcg/ml provided effective analgesia with significantly less motor block than a bupivacaine/fentanyl combination at the same concentrations during labour and delivery.

Our results were also consistent with Beilin et al[17] who conducted a randomized study to determine the lowest concentration of ropivacaine for the initiation of labour epidural analgesia in which patients were divided into three groups to receive 13 ml of either ropivacaine 0.20% (Group I), ropivacaine 0.15% (Group II), or ropivacaine 0.10% (Group III). Similar to our study they also noted that no patient developed a motor block greater than Bromage 1.

However, a higher incidence of motor block observed in another study could be attributed to higher concentrations of ropivacaine used (0.25% in Eddleston JM et al).[18]

In our study there was a statistically insignificant difference with regard to the need of instrumental delivery or risk of cesarean delivery, also the duration of labour was unaffected by the type of analgesia given. Our results were similar to Chhetty YK et al[14] who also observed that injection delivery interval was comparable in both groups and that epidural analgesia had no statistically significant impact on the risk of cesarean section,

In our study, there was statistically insignificant difference in both groups with regard to maternal hemodynamics during labour, foetal heart rate throughout labour period, as well as APGAR score at 1 & 5 minutes of delivery and all the newborn had APGAR score of at least 8 or more at 1 min and 10 after 5 min in either group.

Our results were similar to Agarwal A et al[15] who in their study found that both levobupivacaine and ropivacaine are equally effective for labour analgesia using the combined spinal epidural technique with minimal adverse maternal or neonatal outcomes.

In our study, there were minimal side effects with statistically insignificant differences in two groups. Similar results were also seen by Agarwal A et al.[15] Similarly Chhetty YK et al[14] in their study observed no hypotension, hypersensitivity reaction, pruritus, nausea, urinary retention, vomiting, respiratory depression, weakness in the limbs or shivering, though cases of pruritus were observed by Debon et al[19] and hypotension by Bernard JM et al[20] were reported with epidural labour analgesia which were observed in our study also.

In our study level of maternal satisfaction was excellent in maximum patients in either group (86.6% in epidural and 93.3% in CSE group). Our results were in accordance to study by Chhetty YK et al[14] and Beilin et al[17] (92% satisfaction).

Conclusion:

This study concludes that both epidural as well as combined spinal epidural with intrathecal fentanyl and ropivacaine 0.2% infusion in epidural in both are excellent modalities of labour analgesia in parturients who demand labour analgesia with early-onset, better analgesia, no motor block and minimal adverse effects. Combined spinal epidural has the benefit of faster onset of analgesia than epidural although both techniques provide satisfactory labour analgesia. Maternal and foetal outcomes are similar in both

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groups with stable maternal hemodynamics and no adverse fetal outcomes in either group.

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