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Original Article

Intrathecal isobaric ropivacaine - fentanyl versus intrathecal isobaric levobupivacaine - fentanyl for labor analgesia using single shot spinal technique: Controlled comparative double blinded study.

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ABSTRACT

Background and Aims: The study was designed to compare the efficacy of intrathecal isobaric ropivacaine-fentanyl and intrathecal isobaric Levo-bupivacaine-fentanyl for labor analgesia using single-shot spinal technique, with respect to duration of analgesia, progress of labor and its outcome, block characteristics, hemodynamic changes in mother and various side effects in mother and fetus.

Methods: Sixty multipara parturients in active labor were divided into two groups. Group R received isobaric ropivacaine 0.25% 2.5 mg with fentanyl 25mcg and Group L received isobaric levobupivacaine 0.25%2.5 mg with fentanyl 25mcg. Pulse, blood pressure and oxygen saturation, fetal heart rate, and progress of labor were monitored.

Results: We observed effective labour analgesia which lasted up to 90 minutes in the levobupivacaine- fentanyl group and up to the 75minutes in the ropivacaine-fentanyl group. The time to achieve as <3 was also significantly lower in Group L. Hemodynamic parameters and the APGAR scores were comparable in both the groups and no fetal respiratory depression was observed. No motor blockade and no delay in progress of labor was observed with any of the groups, with minimal and comparable side effects.

Conclusion: To conclude, we found that intrathecal levobupivacaine 2.5mg when used with 25µg of fentanyl, provides excellent and longer pain relief as compared to intrathecal ropivacaine 2.5mg with 25µg fentanyl, for labor analgesia.

Keywords: Labor analgesia, Single-shot spinal, Ropivacaine, Levobupivacaine, Fentanyl, Normal labor.

INTRODUCTION:

Neuraxial anaesthesia is the most effective and least depressant form of intrapartum labor analgesia[1]. Although among all the neuraxial techniques, epidural analgesia[2] and combined spinal epidural (CSE) are more commonly used, the use of single shot spinal labor analgesia has been demonstrated and found effective[3]. This is one of the easiest techniques in parturients with severe restlessness due to pain during the later stages of labor, especially in resource limited situations[4]. We conducted this randomised controlled trial to compare the efficacy of intrathecal isobaric ropivacaine- fentanyl and intrathecal isobaric levobupivacaine - fentanyl for labor analgesia using single shot spinal technique.

METHODS:

The study was conducted after ethical clearance from Institutional Ethical Committee, JLN Medical College and Hospitals, RUHS, India in January 2021 (order no. 49/ Acad-III/MCA/2021) under Anaesthesia Department. The study was registered at ctri.nic.in (CTRI/2021/03/042385).This was a randomized controlled trial, conducted in a double blinded manner. Prior to enrolment, informed written consent was obtained from each parturient. In the present trial, we included multiparous women, 18 to 35 years of age, who had undergone routine antenatal checkups, scheduled for normal vaginal delivery, with single ton fetus, vertex presentation, not with fetal distress, cervical dilatation of more than 4 cm and requesting analgesia. Parturients with contraindication for neuraxial block, primipara females, age below 18 years or above 35 years,with contracted pelvis,cephalo- pelvic disproportion, having coexisting diseases like diabetes, pregnancy induced hypertension, bronchial asthma, epilepsy, systemic or valvular heart disease, spine deformity, or having previous caesarean section, were excluded from the study. Sixty multipara parturients consenting for labor analgesia with singleton pregnancy, vertex presentation, in labor with VAS ≥ 3 or demanding analgesia were selected. Group R (n=30) received injection ropivacaine hydrochloride0.25% isobaric, 2.5 mg (1ml)+ injection fentanyl citrate 25 mcg (0.5ml). It was compared with Group L (n=30) which received injection levobupivacaine hydrochloride 0.25% 2.5 mg (1 ml) + injection fentanyl citrate 25mcg (0.5 ml). In both the groups, total volume was made 1.5 ml. All these drugs were preservative free and were prepared by qualified anaesthetist who was not involved in the study. A written and informed consent was taken when the parturient presented in labor room and explained about the procedure. The parturient was examined and baseline pulse rate, noninvasive blood pressure, oxygen saturation and VAS score were recorded. An

intravenous line was secured with a 20G cannula on non- dominant hand and parturient was pre-loaded with 500ml of RL solution.

The parturient was placed in sitting position. The block was performed at L3- L4 intervertebral space using a 25G Quinke's spinal needle. Time of intrathecal injection was noted. The parturient was then repositioned supinewithleftuterinedisplacement.Cardiotocographpositionedtoassessfetalheart.Aninvestigatorblinded to the intrathecal injection recorded all the observations. The parameters were noted at the time of block over every 3 minutes up to 15 minutes and then every 15 minutes. The observations that were recorded include partogram, sensory blockade, pain relief, motor blockade, sedation, progress of labor, hemodynamic status, neonatal outcome, complications and post-delivery patient satisfaction.

The primary objective of this study was to analyse the duration of analgesia. The secondary objectives included progress of labor and its outcome, block characteristics, hemodynamic changes in mother and various side effects in mother and fetus. The standard partogram chart used in labor room was used to plot progress of labor, maternal and fetal hemodynamic parameters and intrapartum drugs given. Maternal hypotension was defined as fall in blood pressure >20% of baseline or a systolic blood pressure < 90 mm Hg, maternal bradycardia was defined as heart rate<60 beats per minute and desaturation was defined as oxygen saturation measured by pulse oximeter <90%. Onset of sensory blockade was the time from intrathecal injection to the time when VAS began to decrease from its initial value. Time to achieve the sensory blockade was the time from intrathecal injection to the time when a desired sensory level of T10 was achieved. Onset of analgesia was defined as time from intrathecal injection to the time when the VAS score <3 was achieved. Duration of analgesia was the time from intrathecal injection to the time when the VAS score was again recorded >3. Motor blockade was assessed by using modified Bromage score, onset was defined when a score of 1 was achieved. Assessment of sedation was done using Ramsay's sedation scale. Neonatal outcome was assessed in terms of mode of delivery, APGAR score at 1 and 5 minutes and any need for resuscitation. Complications of the drugs used and post-delivery satisfaction were also noted.

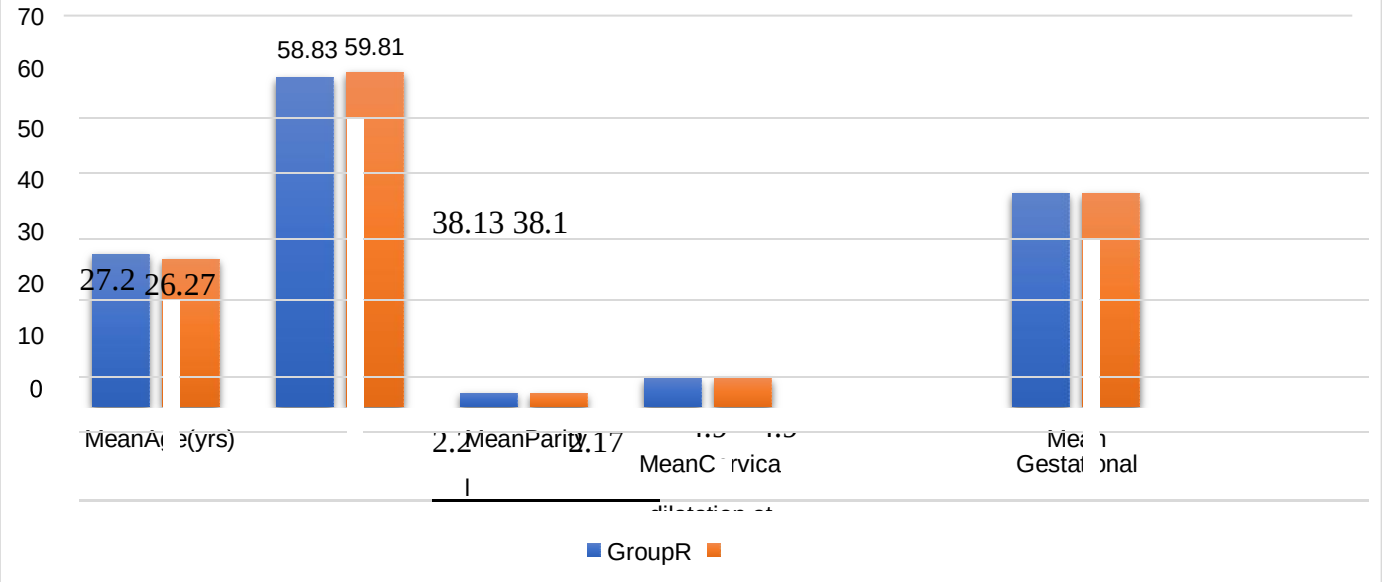
Rescue Analgesia:

A repeat dose of study solution was to be administered if labor prolonged and anaesthesia wore off before delivery [9]. Spinal anaesthesia to be given if caesarean section is required, unless contraindicated or patient is hemodynamically unstable. A loading dose of Injection ketamine (0.2mg/kg), followed by an infusion (0.2mg/kg/h)[10] was to be given to parturient not willing for a repeat spinal anaesthesia. Such patients were excluded from the study. Statistical analysis was performed with the SPSS, version 21 for Windows statistical software package (SPSS inc., Chicago, IL, USA). The Categorical data was presented as numbers (percent) and were compared among groups using Chi square test or Fischer exact test when one of the cells in 2x2 contingency table had expected value <5. The quantitative data was presented as mean and standard deviation and were compared by students t-test. Probability was considered to be significant if less than 0.05.

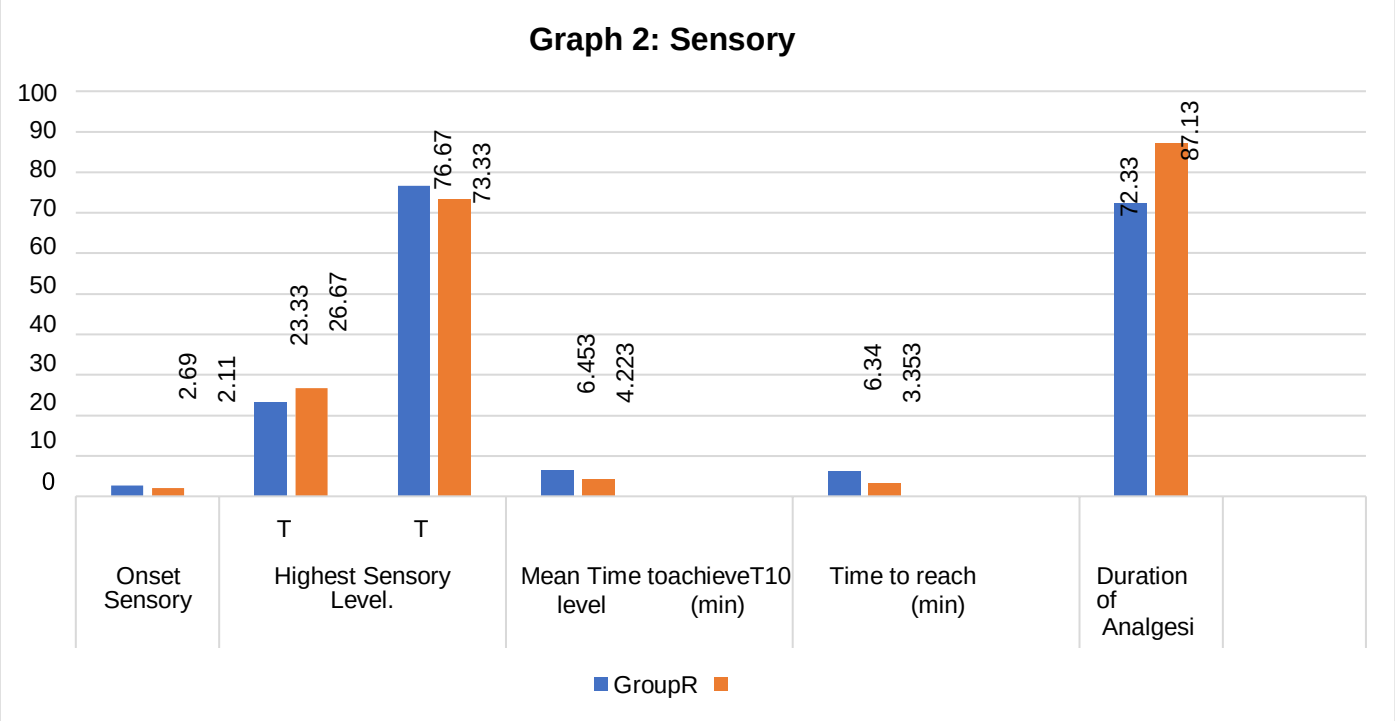
RESULTS

Both the groups were demographically comparable with respect to age, weight, parity, gestational age and cervical dilatation at the beginning of study (Geaph 1).

Graph 1:



The mean onset time for sensory block was 2.11 ± 0.38 in Group L as compared to 2.69 ± 0.24 in Group R. The meantime of sensory block to reach T10 dermatome was 4.22±0.14 in Group Land 6.45±0.21in Group R. The highest level attained in Group R was T8 in 23.33% and T10 in 76.67%, while in Group L T8 level was achieved by 26.67% and T10 by 73.33% parturients (Chart 2). Motor blockade was not observed in any parturient (modified Bromage score of 0). The mean duration of analgesia in Group R was 72.33 ± 3.52 with a median (range) of 72 (66-79), while in Group L the duration was 87.13 ± 5.11 with a median (range) of 86 (78-96).The duration of analgesia was significantly more in Group Las compared to Group R (Chart2). The mean time to reach VAS score <3 was 6.34 ± 0.16 in Group R and 3.35 ± 0.13 in Group L.

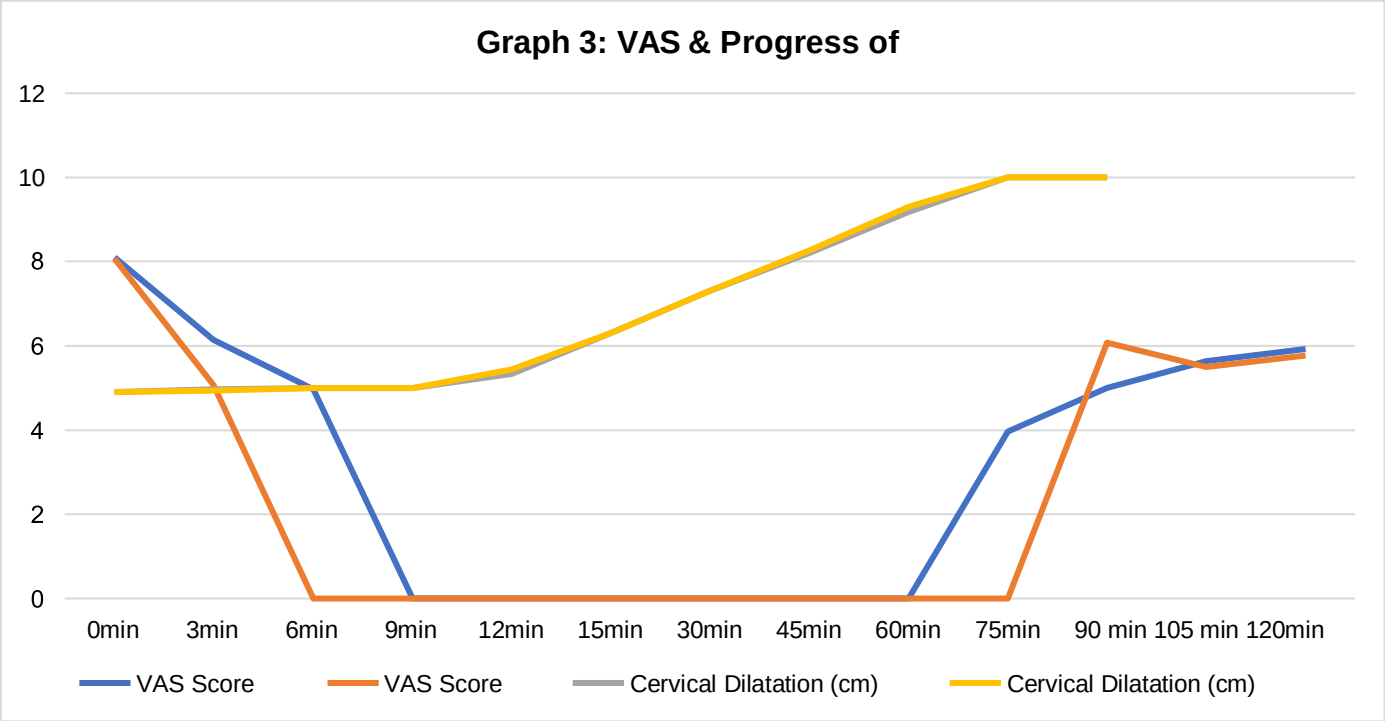


The mean duration of the active phase of first stage and the second stage of labor was comparable in both the groups. The mean duration of active phase of first stage of labor was 54.62 ± 1.77 minutes in Group R, while in Group L it was 55.05±1.55 minutes. The mean duration of second stage of labor was 19.96±1.00 minutes in Group R and 19.99 ± 0.91 minutes in Group L (Table1).

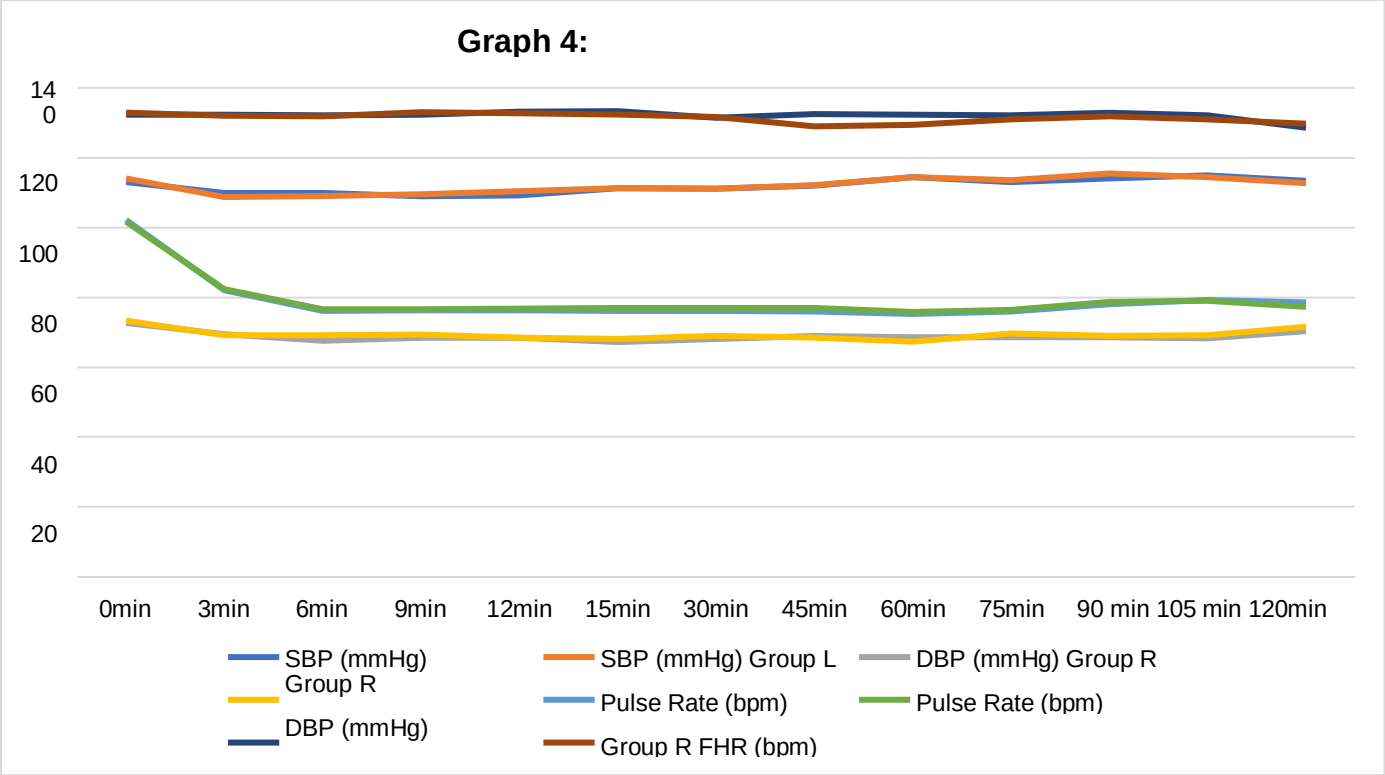
	Group R		Group L		Result (*P* value)
	Mean	SD	Mean	SD	
Stage (after analgesia)	54.62	1.772	55.05	1.55	0.32 (NS)
2 Stage	19.96	1.00	19.99	0.91	0.89 (NS)

Table 1: Duration of labor

The progress of labor was comparable in both the groups with cervical dilatation reaching 10cm in about 60 minutes in both the groups. Cervical dilatation at which intrathecal drug was administered was similar in both the groups with a mean value of 4.9 ± 0.3 (Graph 3).



The mean maternal pulse rate, systolic and diastolic blood pressures and fetal heart rate were comparable from baseline value in both groups and the difference between the two groups was not significant (Graph4).



APGAR Score at 1 minute was either 7 or 8 and at 5 minutes was 9 or 10 in both the groups. There was no event of fetal respiratory depression. The mean APGAR score at 1 min was 7.77 ± 0.42 in Group R and 7.73 ± 0.44 in Group L (Table 2). The mean APGAR score at 5 min was 9.07 ± 0.25 in Group R and 9.03 ± 0.18 in Group L (Table 3).

Table 2: APGAR score at 1 min post-delivery(%)

	Group R		Group L	
	No.	%	No.	%
Score 7	7	23.33	8	26.67
Score 8	23	76.67	22	73.33
Total	30	100.00	30	100.00
Mean ± SD	7.77 ± 0.42		7.73 ± 0.44	
Result (*P* value)	0.76 (NS)			

Table 3: APGAR score at 5 min post-delivery(%)

	Group R		Group L	
	No.	%	No.	%
Score 9	28	93.33	29	96.66
Score 10	2	6.67	1	3.33
Total	30	100.00	30	100.00
Mean ± SD	9.07 ± 0.25		9.03 ± 0.18	
Result (*P* value)	0.55 (NS)			

2 parturients (6.67%) in Group R and 3 parturients (10%) in Group L had nausea;1 parturient (3.33%) in both the groups complained of vomiting; 3 parturients (10%) in Group R and 4 parturients (13.33%) in Group L complained of pruritis; 1 parturient (3.33%) in both the groups complained of PDPH (Table 4).

Table 4: Side effects among parturients (%)

		Group R	Group L
Side Effects	Hypotension	0	0
	Bradycardia	0	0
	Nausea	2	3
	Vomiting	1	1
	Respiratory Depression	0	0
	Urine retention	0	0
	Pruritis	0	0
	PDPH	1	1

Post-delivery satisfaction score was 1 (excellent) in 16 (53.33%) parturients in Group R and 18 (60%) parturients in Group L. Score was 2 (good) in 14 (46.67%) parturients in Group R and 12 (40%) parturients in Group L.

DISCUSSION:

Labor Analgesia has been evolving over years. Advances in this field have tread along journey from the days of ether and chloroform in 1847[12] to the present-day practice of comprehensive programme of labor management. Although among all the neuraxial techniques, epidural analgesia and combined spinal epidural (CSE)[11] are the most commonly used, the use of single shot spinal labor analgesia has been demonstrated and found effective. The advantages of single shot spinal labor analgesia include:

Rapidity of onset of analgesia
Reliability of the technique
Minimal hemodynamic changes
Minimal motor blockade
Feasible in resource limited situations.

The study population was divided into two groups with 30 patients in each group using computer generated tables of random numbers:- Group R, the ropivacaine with fentanyl group and Group L, the levobupivacaine with fentanyl group. Both the groups were demographically comparable with respect to age, weight, parity, gestational age and cervical dilatation at the beginning of study.

The mean onset time for sensory block was 2.11 ± 0.38 in Group L as compared to 2.69 ± 0.244 in Group R. The mean time of sensory block to reach T10d ermatome was 4.22±0.14 in Group Land 6.45±0.21in Group R. This observation was similar to the findings in the study conducted by JP Attri, et al,[5] who reported that mean time of sensory block toreachT10levelwasrapidin Group A (4.72±0.54 min) as compared to Group B (5.58 ± 0.49min). The highest level attained in Group R was T8 in 23.33% and T10 in 76.67%, while in Group L T8 level was achievedby26.67%andT10by73.33%parturients.JPAttri ,etal,[5]intheirstudyfoundthatthepeaksensory block levels in Group A was T5 and T6 in Group B ($P < 0.05$). This was higher than observed in our study. The reason for this disparity can be attributed to the use of higher intrathecal doses of both levobupivacaine (3mg) and ropivacaine (4mg) by JP Attri, etal. Motor blockade was not observed in any parturient (modified Bromage score of 0). The maternal expulsive forces were well preserved in both the groups. In the study done by JPAttri,etal,[5] six parturients in group A and five parturients in Group B developed Grade 1 motor block as pr modified Bromage score (*P* value is 0.74).The reason for this can be due to the use of higher intra the caldoses of both levobupivacaine (3mg) and ropivacaine (4mg) by JP Attri, et al.

The mean duration of analgesia in Group R was 72.33 ± 3.52 with a median (range) of 72 (66-79), while in Group L the duration was 87.13 ± 5.11 with a median (range) of 86 (78-96). The duration of analgesia was significantly more in Group L as compared to Group R. The study done by JP Attri, et al[5] similarly showed levobupivacaine to have more duration of analgesia as compared to ropivacaine, after single intrathecal injection.Theyfoundthatthedurationofanalgesiaingroup AandBis117.00±11.86and90.17±8.85mins respectively. The longer duration in their study can be due to use of higher doses of both the anaesthetics, levobupivacaine 3mg and ropivacaine4mg.

ThemeantimetoreachVASscore<3was6.34±0.16inGrou pRand3.35±0.13inGroupL.TheVASscore remained less than 3 for about 80 minutes in Group R and for about 90 minutes in Group L, after which the VAS started rising. This is in contrast to study done by Kim et al. [6] who found that there was no significant difference between the two study groups and also with Marc V Velde et al. [7] who demonstrated that intrathecalbupivacaineprovidedmostfastonsetofanalgesi aandintrathecallevobupivacaineandropivacaine offer comparable onset time of analgesia during labor analgesia with fixed doses ofsufentanyl.

The mean duration of the active phase of first stage and the second stage of labor was comparable in both the groups. The mean duration of active phase of first stage of labor was 54.62 ± 1.77 minutes in Group R, while inGroupLitwas55.05±1.55minutes.Themeandurationof secondstageoflaborwas19.96±1.00minutes in Group R and 19.99 ± 0.91 minutes in GroupL.

The progress of labor was comparable in both the groups with cervical dilatation reaching 10cm in about 60 minutes in both the groups. Cervical dilatation at which intrathecal drug was administered was similar in both the groups with a mean value of 4.9 ± 0.3. Wong et al.[8] and Ohel et al.[13] studied that the duration of the first stage of labor was significantly shortened in women receiving early labor neuraxial analgesia when compared with systemic opioid analgesia.

The mean maternal pulse rate, systolic and diastolic blood pressures were comparable from baseline value in both groups and the difference between the two groups was not significant.

APGAR Score at 1 minute was either 7 or 8 and at 5 minutes was 9 or 10 in both the groups. There was no event of fetal respiratory depression. The mean APGAR score at 1 min was 7.77 ± 0.42 in Group R and 7.73 ±0.44 in GroupL.The mean APGAR score at 5 min was 9.07±0.25 in GroupR and 9.03±0.18 in Group L. In the study done by J.P Attri et al. [5]APGAR score was noted at 1, 5, and 10 min. One baby in Group A and two babies in Group B in our study had Apgar score 7 at 1 min, and no baby had APGAR score <8 at 5 min and 10 min in both groups. $P > 0.05$ was statistically insignificant.

The mean value of Ramsay sedation score was comparable from baseline value in both groups and there was no significant variation in sedation score in

either group.

2 parturients (6.67%) in Group R and 3 parturients (10%) in Group L had nausea;1 parturient (3.33%) in both the groups complained of vomiting; 1 parturient (3.33%) in both the groups complained of PDPH. In the study done by JP Attriet al.[5], differences in the incidence of side effects and complication between the two groups did not reach statistical significance (*P* >0.05).

Post-delivery satisfaction score was 1 (excellent) in 16 (53.33%) parturients in Group R and 18 (60%) parturients in Group L. Score was 2 (good) in 14 (46.67%) parturients in Group R and 12 (40%) parturients in Group L. Overall satisfaction score was better in Group L as compared to Group R.

CONCLUSION:

To conclude, we found that intrathecal levobupivacaine 2.5mg when used with 25μg of fentanyl, provides excellent and longer pain relief as compared to intrathecal ropivacaine 2.5mg with 25 μg fentanyl, for labor analgesia. No motor blockade and no delay in progress of labor was observed with any of the groups, with minimal and comparable side effects.

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