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A comparative study on epidural Labour analgesia with 0.1% Ropivacaine and Fentanyl and 0.1% Levobupivacaine and Fentanyl on maternal and fetal outcome

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Abstract
Background: This study is done to assess the efficacy of 0.1% Ropivacaine and 0.1% Levobupivacaine with 2microgram/ml Fentanyl in epidural labour analgesia on maternal and fetal outcome.
Materials and Methods: This comparitive study was conducted at the Department of O&G at RMMCH in 2019-2021 after ethical committee approval. Study was conducted in 60 patients in active phase of labour and they were divided into two equal groups. Group A received 0.1% Levobupivacaine and 2microgram/ml Fentanyl. Group B received 0.1% Ropivacaine and 2microgram/ml Fentanyl as epidural analgesia. The duration of 1st stage, 2nd stage of labour, mode of delivery, neonatal outcome and complications were observed. Statistical analysis is done by Independent't' test and Chi-square test. Probability value less than 0.05 was considered statistically significant.
Results: Both the demographic and the obstetric parameters were comparable in both groups. Groups A & B were comparable with respect to mode of delivery, duration of 1st and 2nd stage, APGAR score at 1st minute. The APGAR score at 5th minute was better in Group B. Both groups provide equal analgesia without any significant maternal or fetal side effects.
Conclusion: The effect of 0.1% Ropivacaine and 0.1% Levobupivacaine with 2microgram/ml fentanyl in epidural Labour analgesia are similar in terms of duration of labour, mode of delivery and neonatal outcome.

Keywords: Epidural Labour analgesia, 0.1% Levobupivacaine, 0.1% Ropivacaine, Fentanyl

Introduction
Attempts to alleviate labour pain started in 18th century. The public consider labour pain as divine so there was a strong public opinion against labour analgesia. But this belief was changed when John Snow administered chloroform to Queen Victoria in 1853 for the delivery of her 8th child Leopold. She later said "Dr Snow administered the blessed chloroform and its effect was calming and relaxing beyond measure" [1]. Painful labour can have negative impact on maternal and fetal physiology. Various type of analgesia have been tried since time to alleviate this pain. The introduction of neuraxial analgesia into obstetrics took place at the end of 19th century. Various studies were done to study the outcomes of epidural labor analgesia in terms of pain relief, maternal and fetal outcome. The study by Debasmita das *et al*. [2]. have compared 0.1% Ropivacaine and 0.1% Levobupivacaine with 2microgram/ml fentanyl and concluded that both provide equivalent labour analgesia without significant maternal and fetal side effect.

Materials and Methods
After approval from Institutional Ethics Committee, the present prospective, study was conducted on 60 parturient with single live full term fetus in vertex presentation, in active labour with 3 cm cervical dilatation without any obstetric complications. A detailed history of the patient was obtained. Baseline investigations done. The procedure was explained to the patient and an informed written consent was taken. Baseline maternal blood pressure, maternal pulse, fetal heart rate was recorded before the onset of procedure. Pervaginal examination was done-when the cervical dilatation of 3 cm or more, drugs were given alternatively to patients.

An 18 G IV cannula was inserted into the forearm and patients were well hydrated with fluids at the rate of 15-20 ml/kg over 30 minutes. The patient was positioned in the left lateral position on the table and the back is prepared with betadine and sterile drapes. A local infiltration of 2 ml of 2% lignocaine was given at L3-L4 intervertebral space. An 18 G Tuohy needle inserted into epidural space with the loss of resistance to air technique. A catheter was threaded into the epidural space for a distance of approximately 3-5 cm. A test dose with 3 ml of 2% lignocaine with 1:200000 Adrenaline was injected to rule out intravascular or subarachnoid placement. The study was conducted from October 2019 to October 2021. Patients were divided into two groups (Group A and Group B, -30 in each group). For labour epidural analgesia, parturient in Group A received 0.1% Levo bupivacaine with Fentanyl 2 mcg/mL and those in Group B received 0.1% Ropivacaine with Fentanyl 2 mcg/mL. Once the contractions begins patient was shown the visual analogue scale. Partogram was marked to assess the progress of labour. The progress of labour was assessed by no of contraction, pervaginal examination every 4th hourly for cervical dilatation, effacement and descent of fetal head. The time interval between the administrations of epidural drug to the full cervical dilatation noted. The duration of second stage of labour that is full dilatation of cervix to delivery of the baby was documented. Mode of delivery, postpartum complications noted. The Baby will be immediately assessed by the pediatrician and the APGAR score of the neonate at 1 and 5 minutes was recorded and analyzed.

Results

Table 1: Mean age between two groups

Age (in years)	Group A (Levobupivacaine and Fentanyl)	Group B (Ropivacaine and Fentanyl)
	Mean age	Mean age
	24.63 years	26.73 years

Table 1 represents age of the study patients. The mean age of the group 'A' was 24.63± 3.38 years whereas it was 26.73±3.08 for group 'B'. The difference in the age was statistically significant between the groups, t = 2.51, p= 0.015, <0.05. Hence, the age of the study population is comparable between two groups

Table 2: Gravidity status of both groups

	Group A (Levobupivacaine and Fentanyl)		Group B (Ropivacaine and Fentanyl)	
	Number of study Subjects	Percentage	Number of study Subjects	Percentage
Primi	13	43.3	11	36.7
Multi	17	56.7	19	63.3
Total	30	100	30	100

Table 2 data regarding gravidity status of the study women is presented. In group A, 43.3% had primigravida and 56.7% had multigravida. In group `B` 36.7% had Primi Gravida and 63.3% had multigravida. There was significant association in the gravidity between groups, x^2 = 10.48, p=0.001 <0.05. Hence, the gravidity selection is equal between groups.

Table 3: Comparison of Mode of delivery between two groups

Mode of Delivery	Group A (Levobupivacaine and Fentanyl)		Group B (Ropivacaine and Fentanyl)	
	Number of study Subjects	Percentage	Number of study Subjects	Percentage
Normal	23	76.7	23	76.7
Operative outlet forceps	4	13.3	5	16.7
LSCS	3	10.0	2	6.7
Total	30	100	30	100

In table 3 mode of delivery is presented. The most of the women had normal mode of delivery, group A (76.7%) and group `B` (76.7%), LSCS was the mode of delivery in 10% of group `A` and 6.7% of group `B`. Outlet forceps was performed in 13.3% of group ‘A` and 16.7% of group `B` It is inferred that there was significant association in mode of delivery between groups,x^2 = 23.47, P=0.001 <0.05 and hence; both groups had similar mode of delivery. The rate of LSCS with both of these drugs are less than the normal LSCS rate in India (17.2% according to National Family Health Survey 2015-16).

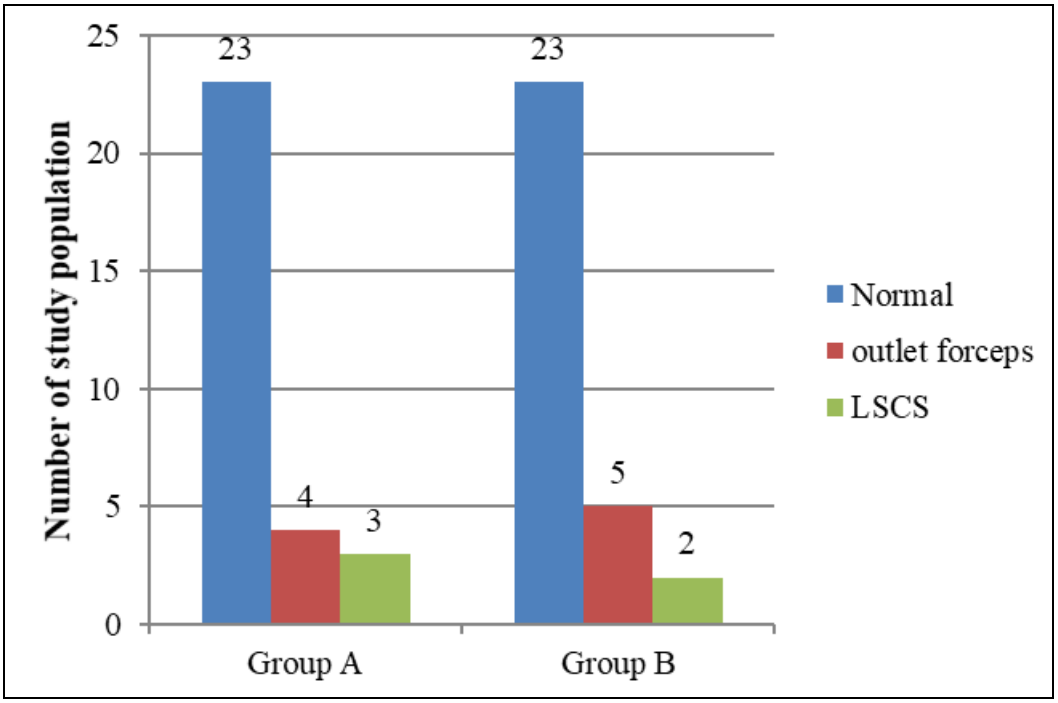

Fig 1: Comparison of Mode of delivery between two groups

Table 4: Pain Assessment-Visual Analogue Scale –Comparison between Groups

Visual analogue scale	Group A (Levobupivacaine and Fentanyl)		Group b (Ropivacaine and Fentanyl)	
	Number of study subjects	Percentage	Number of study subjects	Percentage
2	13	43.3%	11	36.67%
3	8	26.67%	11	36.67%
4	9	30.0%	8	26.67%
Total	30	100	30	100

In both groups maximum patients are having VAS score 2. In group A 43.3% and in group B 36.67% VAS score. Comparison of VAS score between the groups was not statistically significant with p value of 0.403. The pain relief is excellent in both groups.

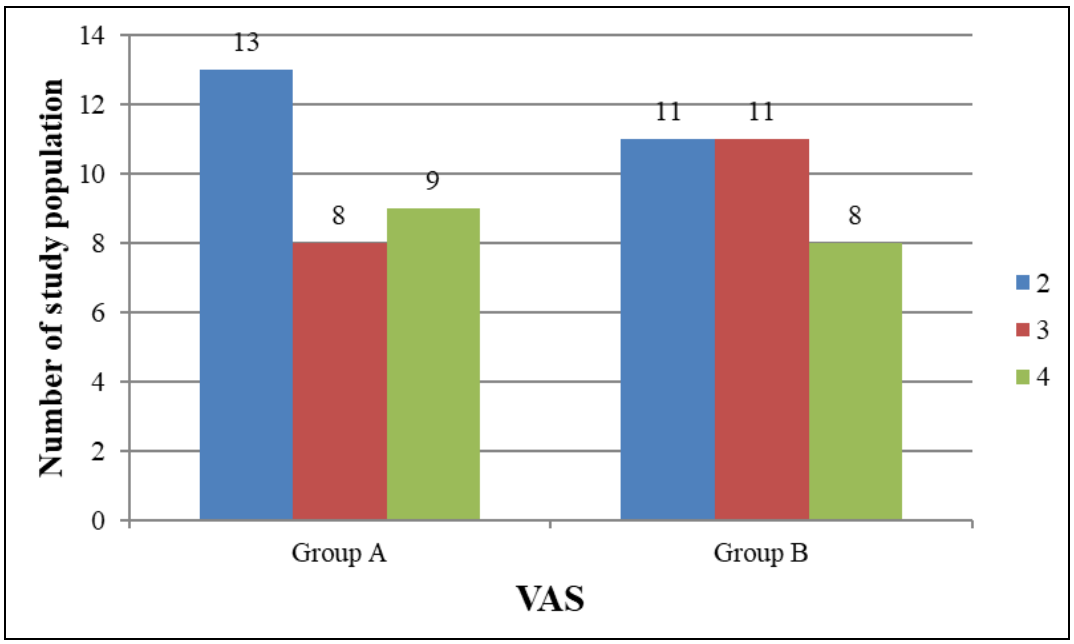

Fig 2: Pain Assessment-Visual Analogue Scale –Comparison between Groups

Comparison of duration labour between two groups

The mean duration of labour and its comparisons between groups is presented. The mean duration of labour in the first stage was 233.17 ±105.18 minutes in group `A` and it was 251.53±116.54 in group `B`. The difference is statistically insignificant, t= 0.64, p=0.514 >0.05. Hence duration was more or less similar between the groups. The progress of labour is faster with epidural analgesia comparing to normal duration of

first stage of labour. Likewise there was insignificant difference in the duration of labour was observed in the second stage between the groups, t=0.61, p=0.540 >0.05.

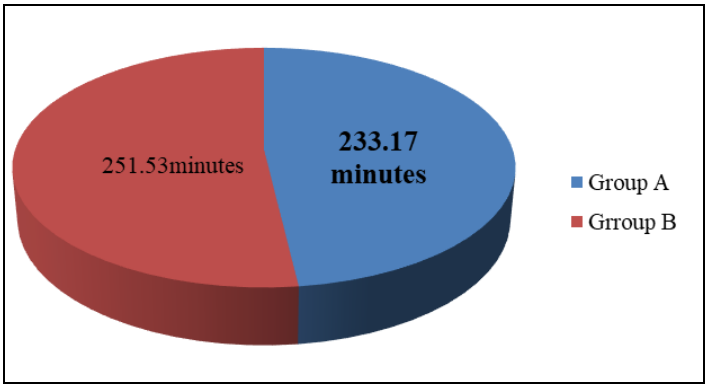

Fig 3: Duration of First Stage

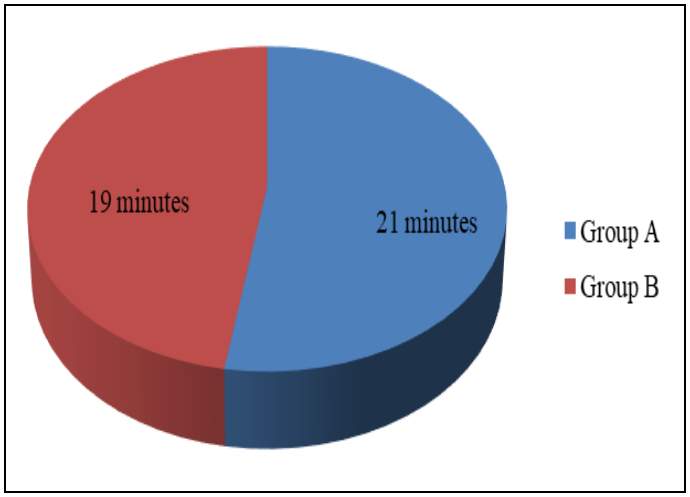

Fig 4: Duration of Second Stage

Table 5: Comparison of APGAR at 1st minute

APGAR (1 Minute)	Group A (Levobupivacaine and Fentanyl)		Group B (Ropivacaine and Fentanyl)	
	Number of study Subjects	Percentage	Number of study Subjects	Percentage
6	3	10	-	-
7	27	90	19	63.3
8	-	-	11	36.7
Total	30	100	30	100

It is inferred from table 5 that 90% of group `A` and 63.3% of group `B` neonates had APGAR score of 7 at 1st minute. Group B has APGAR SCORE more than 6 for all babies. In Group A three babies have APGAR 6. There was significant association of APGAR score between groups, X^2= 5.76, P=0.016 indicating that both groups had similarity in APGAR scores.

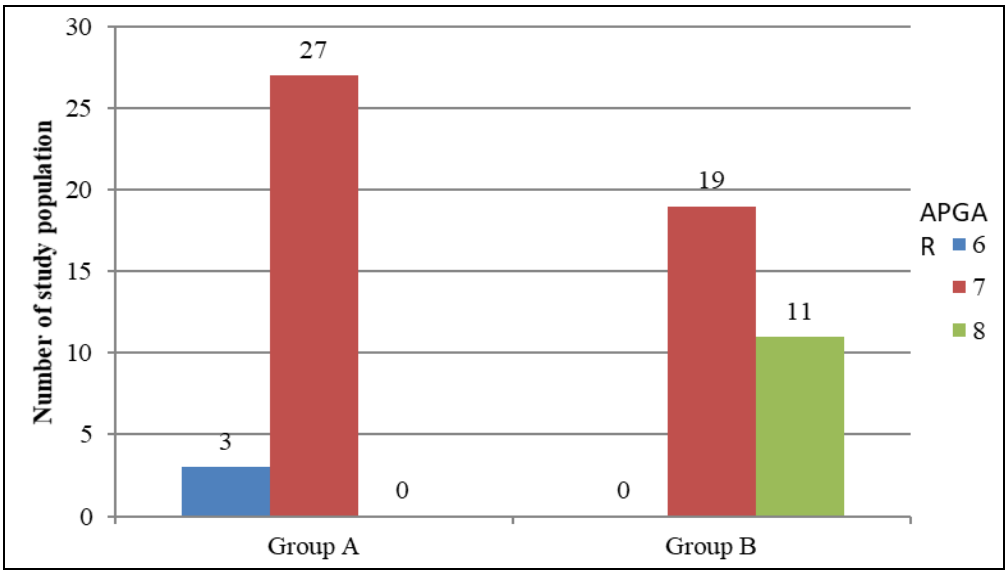

Fig 5: Comparison of APGAR at 1st minute

Table 6: Comparison of APGAR at 5th minute

APGAR (5 Minutes)	Group A (Levobupivacaine and Fentanyl)		Group B (Ropivacaine and Fentanyl)	
	Number of Study Subjects	Percentage	Number of study subjects	Percentage
8	15	50	11	36.7
9	15	50	17	56.7
10	-	-	2	6.7
Total	30	100	30	100

Table 6, APGAR score of neonates at 5th minute is presented. APGAR score was 8 for the 50% of neonates in group `A` and it was 9 for the 50% of neonates in group `A`. In group `B`, 36.7% had APGAR score of 8, 56.7% had the score of 9 and 6.7% had the score of 10. Group B babies have better APGAR score. The association of APGAR score was statistically insignificant between the groups, x^2 =1.35, P=0.510 >0.05.

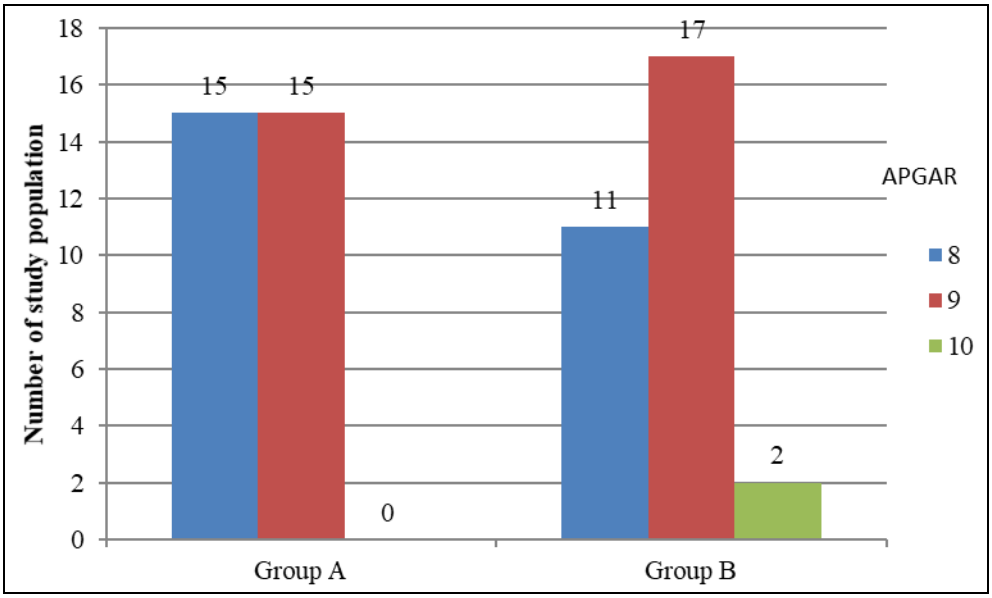

Fig 6: Comparison of APGAR at 5th minute

Table 7: Complication of the women

Complication	Group A (Levobupivacaine and Fentanyl)		Group B (Ropivacaine and Fentanyl)	
	Number of study Subjects	Percentage	Number of study Subjects	Percentage
Hypotension	11	36.7	10	33.3
Post epidural headache	5	16.7	-	-
Total	16		10	

It is inferred from table 7 that 36.7% of group `A` and 33.3% of group `B` had hypotension, whereas 16.7% of group `B` had post epidural headache. Both drugs have good safety profile with less side effects. Among their side effects Hypotension is the common complication with both drugs.

Discussion

Clinical trials comparing Levobupivacaine and Ropivacaine suggest that they are similar in terms of pain scores and side effects. Purdie NL *et al*. [3], concluded that 0.1% Ropivacaine with 0.0002% Fentanyl and 0.1% Levobupivacaine with 0.0002% Fentanyl are clinically equipotent for labour analgesia in terms of onset time, duration and quality of analgesia, mode of delivery, neonatal outcome and maternal satisfaction.

In our study the labour epidural analgesia of 0.1% Levobupivacaine and 2 microgram/ml Fentanyl was compared with 0.1% Ropivacaine and 2 microgram/ml Fentanyl on maternal and fetal outcomes such as duration of first and second stage of labour, pain relief, mode of delivery and APGAR score. The comparison of duration of labour was analysed by independent sample't' test. The comparison of mode of delivery and APGAR score between groups were analysed by the Chi-square test of association. The entire statistical analysis was carried out by the statistical packages of the social sciences (spss-21).

The mean age of the Levobupivacaine group was 24.63± 3.38 years whereas it was 26.73±3.08 for Ropivacaine group. The difference in the age was statistically significant between the groups (t = 2.51, p= 0.015, <0.05). In Levobupivacaine and Fentanyl group, 43.3% patients are primigravida and 56.7% are multigravida. In other group, 36.7% primigravida and 63.3% multigravida received 0.1% Ropivacaine and Fentanyl.

There was significant association in the gravidity status between two groups (x^2 = 10.48, p=0.001 <0.05). There was significant association in the effacement between groups (x^2= 21.62, P= 0.001) indicating that both groups had similar effacement at the onset of labour analgesia. The dilatation at the onset of labour epidural analgesia is also similar in both groups. It is concluded that demographic and obstetric parameters were comparable between two groups.

Mode of Delivery

Chuttani *et al*. [7] in their prospective study, 60 labouring parturient were randomly allocated into two equal groups to receive either of 0.1% Levobupivacaine and Fentanyl or 0.1% Ropivacaine and Fentanyl as epidural solutions. The incidence of instrumental deliveries were found to be 43.3% in the Levobupivacaine group and 30% in the Ropivacaine group. This difference was not statistically significant. It implies the similarity in the outcomes of both groups.

In our study most of the women had normal mode of delivery, Levobupivacaine group (76.7%) and Ropivacaine group (76.7%). LSCS was the mode of delivery in 10% of Levobupivacaine group and 6.7% of Ropivacaine group. Operative outlet forceps was performed in 13.3% of Levobupivacaine group and 16.7% of Ropivacaine group. It is inferred that there was significant association in mode of delivery between groups, (x^2 = 23.47, P=0.001 <0.05) and hence both groups had similar mode of delivery. Indication for forceps in both group is failed maternal efforts. Out of LSCS cases the most common indication is Meconium stained liquor. One case had deep transverse arrest with Levobupivacaine. It is inferred that both Levobupivacaine and Ropivacaine has no effect in the mode of delivery. The rate of LSCS with both of these drugs are less than the normal LSCS rate in India (17.2% according to National Family Health Survey 2015-16).

Duration of Labour

Bofill *et al*. [4] analyzed the duration of of labour in his study on hundred women in active labour with epidural analgesia with

narcotics. Study showed no significant differences in the length of first stage of labour (p value 0.54) or second stage of labour (p value 0.55)

A study conducted by Debasmita Das *et al*. [2] on 0.1% Levobupivacaine and Fentanyl versus 0.1% Ropivacaine and Fentanyl concluded that the duration of first and second stage of labour was comparable between two groups without any statistical significance.

In our study, the mean duration of labour in the 1stage was 233.17 ±105.18 minutes in Levobupivacaine group and it was 251.53±116.54 in Ropivacaine group. The difference was statistically insignificant, (t= 0.64, p=0.514 >0.05). Hence duration was more or less similar between the groups. Likewise there was insignificant difference in the duration of labour was observed in the 2nd stage between the groups (t=0.61, p=0.540>0.05). Ropivacaine and Levobupivacaine have no effect in the duration of labour. The progress of labour is faster with epidural analgesia comparing to normal duration of first stage of labour.

Neonatal Outcome

Benhamou D *et al*., Pu5rdie NL *et al*. [3]., Beilin Y *et al*. [6]. from their studies using low concentration of Levobupivacaine and Ropivacaine with Fentanyl found no adverse effect on baby.

In our study both groups had similarity in APGAR scores at one minute. While analyzing the fifth minute APGAR score; It was 8 for the 50% of neonates, and 9 for 50% of infants in Levobupivacaine group. In Ropivacaine group, 36.7% had APGAR score of 8, 56.7% had the score of 9 and 6.7% had the score of 10. Ropivacaine Group babies have better fifth minute APGAR score.

Pain Relief

All the parturients in both the groups were satisfied with epidural labour analgesia, with comparable results between two groups. The pain relief scale is 3 (a lot pain relief) in all pregnant ladies of both groups. In both groups maximum patients are having VAS score 2. In Levobupivacaine group 43.3% and in Ropivacaine group 36.67% VAS score 2. The pain relief is excellent in both groups. The present findings are similar to Purdie NL *et al*. [3], who found that patient satisfaction were similar between groups.

Safety Profile

The profile of side effects was comparable between both groups. Among their side effects Hypotension is the common complication with both drugs. In Ropivacaine group 16.7% patients had post epidural headache.

Conclusion

The effect of 0.1% Ropivacaine and 0.1% Levobupivacaine with 2microgram/ml fentanyl in epidural labour analgesia are similar in terms of duration of labour, mode of delivery and neonatal outcome.

References

1. Sykes WS. Essays on the first hundred years of anaesthesia. Park Ridge IL, editors. Wood Library-Museum of Anaesthesiology.2 nd ed. Portland: Powell's Books. 1982;3:318-333.
2. Debasmita Das *et al*. labour epidural analgesia: A randomized double blind comparative study of 0.1% levobupivacaine and fentanyl vs 0.1% ropivacaine with fentanyl. Journal of clinical and diagnostic research. 2018;12(7):6-10.
3. Purdie NL, McGrady EM. Comparison of patient-controlled epidural bolus administration of 0.1% ropivacaine and 0.1% levobupivacaine, both with 0.0002% fentanyl, for analgesia during labour. Anaesthesia. 2004;59(2):133-37.
4. Bofill JA, Vincent RD. Nulliparous active labour, epidural analgesia, and cesarean delivery for dystocia. American Journal of obstetrics and gyneacology. 1997;177(16):1465-70.
5. Benhamou D, Ghosh C, Mercier FJ. A randomized sequential allocation study to determine the minimum effective analgesic concentration of levobupivacaine and ropivacaine in patients receiving epidural analgesia for labour. Anaesthesiology. 2003;99(6):1383-86.
6. Beilin Y, Guinn NR, Bernstein HH, Zahn J, Hossain S, Bodian CA. Local anaesthetics and mode of delivery: bupivacaine versus ropivacaine versus levobupivacaine. Anaesth Analg. 2007;105(3):756-63.
7. Singh U, Chuttani P, Grewal A, Katyal S, Kaura A. A comparative study of low concentration of levobupivacaine versus ropivacaine with fentanyl for patient controlled epidural labour analgesia. J Obstet Anaesth Crit Care. 2018;8(1):35.