e-ISSN: 0976-822X, p-ISSN:2961-6042

Available online on http://www.ijcpr.com/

International Journal of Current Pharmaceutical Review and Research 2025; 17(10); 137-143

Original Research Article

A Comparative Study between Levobupivacaine and Ropivacaine for Epidural Labour Analgesia

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Received: 05-08-2025 / Revised: 04-09-2025 / Accepted: 05-10-2025

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Conflict of interest: Nil

Abstract:

Background: Labor is amongst the most intense pains a childbearing woman may endure. In order to alleviate this, ACOG has been quoted recommending the performance of caesarean sections only at the mother's request for labor analgesia when medically indicated. Neuraxial methods for labor pain, especially combined spinal-epidural and epidural analgesia, include some of the deepest and the longest-lasting pain relief measures. This is a comparative study of the efficacy of 0.1% levobupivacaine and 0.1% ropivacaine with fentanyl as adjuvants for epidural labor analgesia.

Methods: A prospective, randomized, controlled trial was conducted at the Department of Anesthesiology, JNMC & AVBRH, Sawangi, Wardha, over two years. Seventy-eight full-term primigravidae females with uncomplicated singleton pregnancies were included. Participants were randomly divided into two groups: Group L received 12 ml of 0.1% ropivacaine with 2 µg/ml fentanyl. The primary outcomes measured included the onset and duration of analgesia. Secondary outcomes included labour hemodynamics, maternal and fetal outcomes, complications, and need for rescue analgesics.

Results: Duration of analgesia in group L was 66.8 ± 1.52 min, which was considerably longer when compared with group R, where it was 60.2 ± 2.61 minutes with a P<0.0000001. Sensory block onset was earlier in group R at 21.22 ± 1.07 minutes than in group L at 22.8 ± 1.05 minutes, and this was statistically significant but clinically insignificant. Group R required absolutely more doses of rescue analgesia compared to Group L, 5.22 ± 0.65 versus 3.47 ± 0.55, with p < 0.0000001. There were no significant differences in maternal satisfaction, neonatal outcomes, and post-procedural hemodynamics among groups.

Conclusion: Both levobupivacaine and ropivacaine provide effective and safe epidural labour analgesia. However, the longer length of analgesia and the fewer number of rescue doses required with levobupivacaine make it a better option, though the onset time of sensory block was earlier with ropivacaine. Maternal satisfaction and neonatal outcomes of both drugs were similar.

Introduction

The most excruciating suffering a woman can go through while giving birth is labour pains [1]. Therefore, in the absence of a medical contraindication, the American College of Obstetricians and Gynaecologists (ACOG) has recognised caesarean sections performed at the desire of the mother as an indication sufficient for labour analgesia [2]. The best modalities for treating labour pain currently available for labour analgesia are neuraxial methods like combined spinal-epidural (CSE) and epidural analgesia. For the entirety of labour, these methods offer total analgesia [3]. The benefits of epidural anaesthesia include the ability to produce profound analgesia with a quick onset through the injection into the epidural space and the capacity to extend the duration of analgesia with epidural local anaesthetic administration [4].

Similar to the majority of surgical treatments, labour is painful both during and after the operation. This is thought to be a significant barrier to successful rehabilitation. Labour pain is underappreciated as a complication, although it is a relatively common complaint [5]. Ineffective pain management can also result in other physiological issues such as tachycardia, hypertension, cardiac dysrhythmias, and even myocardial ischemia episodes if it is not properly managed. Consequently, it is thought that

using epidural anaesthetic to manage pain in individuals going through either induced or spontaneous labour is a suitable strategy [6].

Levobupivacaine is a new amide local anaesthetic that appears to be almost as effective as racemic bupivacaine, although it has less neurotoxic and cardio-depressant effects [7]. Later research led to the development of ropivacaine, a local anaesthetic with amino amide qualities similar to racemic bupivacaine. Compared to bupivacaine, it offers a broader range of safety because of its decreased hazardous potential [8].

In this prospective randomised trial, the efficacy of 0.1% levobupivacaine and 0.1% ropivacaine with fentanyl as an adjuvant for epidural labour analgesia is examined with respect to the quality of analgesia during labour and the duration and onset of the block. The principal aim was to evaluate the onset and duration of labour analgesia induced by levobupivacaine and ropivacaine. The secondary goals were the assessment of labour hemodynamics, evaluation of mother and foetal outcomes, assessment of complications, and evaluation of the request for rescue analgesics. The study's main hypothesis is that, for epidural labour analgesia, levobupivacine acts more quickly and for a more extended period than ropivacaine.

Material and Methods

Over two years, the Department of Anesthesiology at JNMC & AVBRH, Sawangi, Wardha, conducted this prospective, randomised, controlled trial. After Institutional Ethics Committee clearance, 78 Full-term primigravidae females with singleton uncomplicated pregnancies aged 18–32 who were scheduled for a normal delivery were included in the study. Every patient provided written, informed consent before the trial. Patients with ASA Class III or higher, those who declined to participate in the study, high-risk, complicated pregnancies, pregnancies involving foetal abnormalities, pregnancies contraindicated for neuraxial block, patients with bleeding disorders, mental health conditions, patients with cardiovascular, respiratory, renal, and hepatic diseases, patients with drug allergies, and patients with wounds or infections at the site of epidural insertion were all excluded from the research.

Sample Size Calculation: Based on the difference between the mean duration of labour analgesia in ropivacaine (60 ± 14 minutes) and levobupivacaine (68 ± 11 minutes) (P = 0.027), the sample size was determined from a study by Kumar et al [9]. Considerations included a power of 80%, a double-sided confidence interval of 95%, and a sample size ratio of group L/group R = 1. The sample size of 78 individuals, or 39 in each group, was determined. Two groups of 39 participants each were randomly assigned to receive 12 ml of 0.1% levobupivacaine with 2 µg/ml fentanyl as an adjuvant for Group L and 39 subjects for Group R, which got 12 ml of 0.1% ropivacaine with 2 µg/ml fentanyl as an adjuvant.

The patients scheduled for normal delivery admitted to the gynaecology wards were screened, and the eligible patients who consented to study participation were recruited. After being enrolled in the trial, 78 ASA class II patients between the ages of 18 and 32 who had normal delivery scheduled were divided into two groups at random by computer randomisation.

A comprehensive review of the patient's medical history, an electrocardiogram, a systemic examination, a general physical examination, and an assessment of routine blood testing were all part of the preoperative evaluation. The labour analgesia technique and the prescribed medications were thoroughly explained to the patients.

Parturients were taken to the operating room in the early stages of labour. Every baseline parameter was recorded. Medication and emergency supplies were prepared ahead of time. Intravenous access was established to administer medication and fluids. The patient was positioned sitting with their back arched to improve exposure to intervertebral interspaces. The epidural placement was carried out with an aseptic procedure, and field preparation was maintained. After sterile drapes were placed, anatomic landmarks were used to determine the correct intervertebral space L2-L3. After the needle was inserted, a successful epidural entry was detected by a loss of resistance technique. Following this, the insertion of an epidural catheter was done. The catheter placement was confirmed by the injection of lignocaine and adrenaline, following which the patients were moved to the labour ward. The baseline pain score was determined using a visual analogue scale (VAS) consisting of a 10-cm line ranging from 0 to 10, and epidural analgesia was delivered when the parturient entered the active phase of labour (cervical dilation >4 cm) [10]. The parturient in Group L received 12 ml of 0.1% levobupivacaine containing 2 µg/ml fentanyl, whereas the parturient in Group R received 12 ml of 0.1% ropivacaine containing 2 µg/ml fentanyl.

The main outcomes that were measured were the degree of motor blockade and the onset, duration, and quality of analgesia. The neonatal outcome, maternal satisfaction score, birth mode, and proportion of instrumental delivery were the secondary outcomes. The effectiveness of analgesia was evaluated every five minutes. The period from the first dosage until a VAS of less than three was recorded was the onset of analgesia. A repeat dose of 12 millilitres of the same medication solution would be administered if analgesia was not achieved

in 30 minutes, and the VAS score was measured every 5 minutes. In cases where analgesia proved insufficient, the parturient was eliminated from the research.

The degree of motor blockage was measured fifteen minutes after obtaining a sufficient level of analgesia (VAS <3). A modified Bromage score was used to determine whether there was any motor blockade [11]. A score of 0 indicated no weakness and the ability to raise a straight leg against resistance, a score of 1 indicated the inability to raise the leg straight, a score of 2 indicated the inability to flex the knee and ankle, and a score of 3 indicated the inability to move the lower limb.

The obstetrician determined whether to induce artificial membrane rupture or induce oxytocin infusion to augment labour. Twelve millilitres of the same study medication solution were administered as an epidural top-up if the parturient reported pain (VAS >4). A top-up of 12 millilitres of the same medication solution was administered while the patient was seated during the second stage of labour. The study recorded blood pressure, heart rate, and fetal heart rate every 15 minutes. If noted, side symptoms such as bradycardia, hypotension, pruritus, and nausea were appropriately handled. The trial came to an end when the mother needed a caesarean section or after the baby was delivered. The Apgar score was used to evaluate the neonatal outcome at one and five minutes [12].

When the parturients were comfortable on the second postnatal day, maternal satisfaction was assessed. Three points were awarded for exceptional pain relief, two for decent pain relief, one for fair pain relief, and zero for terrible pain relief. A decrease in SBP or DBP of more than 20% from the baseline value was referred to as hypotension. A twenty percent difference in heart rate from the baseline was considered bradycardia or tachycardia. Every adverse reaction was recorded, including bradycardia, vomiting, nausea, hypotension, respiratory depression, and pruritus. Notable was also the overall amount of time spent in labour and analgesia.

Statistics: After the data was imported into Microsoft Excel, it was expressed using standard deviations, means, and percentages. To compare the groups, the t-test for unpaired students was utilised. For nonparametric data analysis, the chi-square test was utilised. P-values were considered statistically significant if they were less than 0.05. SPSS version 9 was used for the statistical analysis (SPSS Inc., Chicago).

Results

The participants' average age was 23.47 years in group L, with a standard deviation (SD) of 2.95 years, and 23.02 years in group R, with an SD of 2.98 years. There was no difference in the age distribution of the cases between the two groups (p=0.5300). In group R, the mean weight was 73.8 kg with an SD of 4.6 kg, while in group L, it was 74.6 kg with a SD of 5.2 kg. In terms of weight distribution, the groups were comparable (p= 0.9683). Group L's mean height was measured at 154.2 cm with a 3.1 cm SD, whereas Group R's was measured at 152.4 cm with a 2.9 cm SD. The two groups' heights did not differ in a statistically significant way.

The independent t-test was used to evaluate the baseline hemodynamic parameters between the groups, and the results showed that heart rate, blood pressure, respiratory rate, and oxygen saturation did not differ statistically significantly between them. Between the two groups, there was no statistically significant difference in the post-procedural hemodynamic measures. Table 1 demonstrates a statistically significant difference between group R and group L in the onset of sensory block, with group R reporting an earlier onset of the block (p<0.0001). The difference in sensory blocking onset had little therapeutic significance while being statistically significant.

Table 1: Distribution of cases according to onset of sensory block (n=80)

Onset of sensory block	Group L (Mean ± SD)	Group R (Mean ± SD)	p-value
	22.8 ± 1.05	21.22 ± 1.07	<0.0000001

Table 2 shows a statistically significant difference in the length of analgesia, with group L experiencing analgesia for a more extended period than group R (p<0.0000001). Therefore, compared to ropivacaine, levobupivacaine produced analgesia for a more extended period.

Table 2: Distribution of cases from both the groups according to the mean duration of analgesia (n=80)

Mean duration of analgesia (in min)	Group L	Group R	p-value
	66.8 ± 1.52	**60.2 ± 2.61**	**<0.0000001**

With the exception of 60 and 105 minutes, when group R had significantly higher mean VAS values than group L (p=0.0027 and 0.003, respectively), there was no statistically significant difference in the mean VAS ratings between the two groups at the post-operative follow-up time intervals. When the

participant distribution was analysed for the pain grade, Table 3 demonstrates that there was a statistically significant difference in the pain grade at 15 minutes. Compared to Group L, Group R's pain grade was higher (p=0.0444).

Table 3: Distribution of participants according to the pain grade at 15 min (n=80)

Pain grade at 15 min	Group L (Mean ± SD)	Group R (Mean ± SD)	p-value
	0.67 ± 0.47	0.95 ± 0.38	0.00444

Table 4 shows a statistically significant difference in the number of rescue analgesia doses required when the participant distribution was examined concerning the mean number of doses needed. Group R required significantly more rescue analgesia than group L (p<0.0000001).

Table 4: Distribution of participants according to the doses of rescue analgesia needed (n=80)

Mean no of doses of rescue analgesia	Group L (Mean ± SD)	Group R (Mean ± SD)	p-value
	3.47 ± 0.55	5.22 ± 0.65	<0.0000001

Cervical dilatation was found to be uniform in both groups when labour features were compared between them. In terms of labour duration, it was found that group R had much longer labour than group L, with a statistically significant correlation between the overall duration of labour and labour duration (p<0.0001). Table 5 shows no statistically significant difference (p>0.05) in the two groups I and II phases of labour.

Table 5: Labor Characteristics

Labor Characteristics	Group L (Mean ± SD)	Group R (Mean ± SD)	p-value
Duration of I stage (min)	400 ± 26.07	409.16 ± 17.81	0.07493
Duration of II stage (min)	78.33 ± 22.28	75.83 ± 9.96	0.5190
Total duration of labour (min)	455 ± 35.35	485 ± 24.03	0.00002937

The post-delivery hemodynamic parameters, the rate of complications, and the APGAR scores at 1 and 5 minutes were comparable between both groups. The independent t-test was used to assess the post-delivery hemodynamic parameters, and the results showed that heart rate, blood pressure, respiratory rate, and oxygen saturation did not differ statistically significantly between the groups (p>0.05). Maternal satisfaction with the analgesic effects of both medications is displayed in the table below. Table 6 illustrates that nearly two-thirds of individuals from both groups expressed high satisfaction.

Table 6: Distribution of cases from both the groups according to maternal satisfaction score (n=80)

Maternal satisfaction score	Group L [No (%)]	Group R [No (%)]	p-value
Excellent	25 (62.5)	29 (72.5)	0.338
Good	11 (27.5)	5 (12.5)	
Fair	3 (7.5)	4 (10.0)	
Poor	1 (2.5)	2 (5.0)	
Total	40 (100.0)	40 (100.0)	

Discussion

The present study assessed the effectiveness of Levobupivacaine and Ropivacaine used for labour analgesia concerning the analgesic efficacy, effect on the hemodynamic parameters, maternal satisfaction and neonatal outcomes, chiefly the APGAR at 1 and 5 mins. The study revealed that the participants had similar baseline parameters like age, weight and height (p>0.05). Similar results were reported by the studies conducted earlier, which showed no difference in the baseline characteristics of the study participants [9,13–15]. The baseline similarity of the participants ensures that the differences in the effects of the drugs are not due to any of the demographic parameters. No statistical significance between the groups was found in the baseline hemodynamic measures when the independent t-test was used for comparison. Previous studies have shown that baseline hemodynamics were similar, suggesting that the parameters monitored following epidural analgesia do not significantly differ due to unknown intrinsic factors but rather reflect variability that may be related to the effects of the medication [9,13–15].

A substantial difference in the early onset of sensory block was observed between groups R and L (p<0.0001). The difference in sensory blocking onset had little therapeutic significance, while being statistically significant. Levobupicaine's observed delayed onset of action may be caused by the drug's lipid solubility and pharmacodynamics, which can influence the onset of action. In Kumar et al.'s

research, analgesia took longer to start in the levobupivacaine (23.57 ± 1.71 min) and ropivacaine (21.43 ± 2 min) groups than it did in the Gautier et al., and Purdie et al., studies [9,13,16].

The duration of analgesia also showed a statistically significant difference, with group L reporting analgesia for a longer time than group R ($p<0.0000001$). Therefore, compared to ropivacaine, levobupivacaine produced analgesia for a more extended period. The findings of the current investigation were similar to Purdie et al [13]. The difference found in this study is regarded as negligible and has little bearing on therapeutic practice. Our study showed a difference, which can be related to the lipophilic characteristics of levobupivacaine as opposed to ropivacaine. Because of its ability to bind to lipids, this causes a concentration to be higher and acts longer than ropivacaine [17].

At the followup periods, there was no discernible change in the heart rate, SBP, DBP, MAP, RR, or SpO2. Analogously, investigations by Sharma et al., Patel et al., and Chuttani et al. have likewise documented no noteworthy alterations in the hemodynamic parameters [18–20]. At the post-operative followup time intervals, there was no statistical significance in the mean VAS scores, except for 60 and 105 minutes, when group R showed substantially higher mean VAS values than group L ($p=0.0027$ and 0.003, respectively). This was also observed in a few instances where levobupivacaine was found to provide superior analgesia.

There was a statistically significant difference in the pain grade at 15 minutes when the participant distribution was examined in connection to the pain grade ($p=0.0444$), with group R having a more excellent pain grade than group L. Similar findings were documented by Turkmen et al., who found that levobupivacaine prolonged analgesia [21].

A statistically significant difference in the number of doses of rescue analgesia required was found when the distribution of the participants was examined concerning the mean number of analgesic doses required; group R required significantly more rescue analgesia than group L ($p<0.0000001$). Research by El-Shaarawy et al. that looked at levobupivacaine-graded doses found that less rescue analgesia was needed [22].

Most individuals in groups L 23 (57.5%) and R 31 (77.5%) gave birth normally. In group L, there were 11 (27.5%) more instrumental deliveries than in group R (3.5%). The rates for the Caesarean section were the same for both groups. There was no statistically significant variation in the delivery method between the groups. Other studies that documented a comparable incidence of vaginal deliveries were in agreement with this. However, some studies indicated greater rates of caesarean sections in both groups. For example, Purdie et al.'s study showed a rate of 17% in both groups, which was similar to the findings of Lee et al., Agrawal et al., and Patkar et al [13,14,23,24]. The groups' instrumental delivery rates did not differ from one another.

When labour characteristics were examined between the two groups, cervical dilatation was found to be identical. Group R was found to have significantly longer labour than group L in terms of labour duration, with a statistically significant link ($p<0.0001$) between the overall duration of labour and labour duration. When comparing the two groups in the I and II stages of labour, there was no statistically significant difference ($p>0.05$). In the study by Kumar et al., there was no difference in the mean labour duration between the levobupivacaine and ropivacaine groups ($p = 0.830$) [9]. Our results were consistent with research by Lee et al. and Ohel et al., which discovered that the mean labour time was shorter when epidural analgesia was started early as opposed to later [23,25]. The reason for this discrepancy in the outcomes reported by several studies is that their measurements of the commencement of labour varied.

Maternal satisfaction with both medications' analgesic effects was comparable in the current trial ($p=0.338$). About two-thirds of the individuals in both groups expressed very high satisfaction levels. More than 90% of women in both groups reported having great maternal satisfaction in earlier research by Kumar et al. and Purdie et al [9,13].

The birth weight and the APGAR ratings at one and five minutes did not differ between the two groups. At one minute, the maximum APGAR was 8, and at five minutes, it was 10. This was also noted in the study by Kumar et al., which found that the maximum Apgar scores were 8 and 9, respectively, at 1 minute and 5 minutes [9]. Because a lesser concentration of local anaesthetic was used, there was hemodynamic stability, which is responsible for the positive foetal outcome [26]. The rate of complications did not differ statistically significantly between the two groups.

Therefore, the analgesic efficacy and safety profile of levobupivacaine and ropivacaine are similar. Based on the pain grade and the need for rescue analgesia, which was higher for ropivacaine, levobupivacaine has a better analgesic effect [27]. Levobupivacaine produces analgesia for a more extended period, even though ropivacaine causes a sensory block earlier. The foetal outcomes and post-delivery hemodynamics are the same in both groups. Thus, for labour analgesia, both ropivacaine and levobupivacaine can be used successfully [15].

Conclusion

According to our study, levobupivacaine and ropivacaine have similar analgesic efficaciousness and safety profiles for labour analgesia. Based on the pain grade and the need for rescue analgesia, which was higher for ropivacaine, levobupivacaine has a better analgesic effect. Levobupivacaine produces analgesia for a more extended period, even though ropivacaine causes a sensory block earlier. The foetal outcomes and post-delivery hemodynamics were the same in both groups. Thus, for labour analgesia, both ropivacaine and levofloxacin can be used successfully. The study's shortcomings included its limited sample size and single-centre design. It is not possible to generalise the study's findings to other populations. The analysis of the mode of delivery did not account for the experience of the obstetrician and anesthesiologist.

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