Original Research Article

Comparative study on 0.1% ropivacaine with 2mcg/ml fentanyl versus 0.1% levobupivacaine with 2 mcg/ml fentanyl for epidural labour analgesia

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Abstract

Background: Analgesic adequacy during labour along with the avoidance of adverse effects is vital for obstetric conditions. Painful labour can have negative impacts on maternal and fetal physiology. In neuraxial analgesia, the analgesics are injected or infused near the spinal cord by using a catheter, usually either intrathecally into the cerebrospinal fluid or epidurally into the fatty tissues around the dura, to block nerves that transmit pain signals to the brain. Much lower pain scores with the least adverse effects on maternal cardiovascular or pulmonary functions and fetal physiology with higher maternal satisfaction are reported with the use of neuraxial analgesia techniques during labour and delivery. **Aim And Objective:** To compare epidural Ropivacaine and levobupivacaine combined with fentanyl concerning, efficacy of pain relief in labour. Level of motor blockade, Effect of fetal and maternal outcomes. **Materials And Methods:** This study of epidural labour analgesia was conducted on 60 full-term labouring women of Rajah Muthiah Medical College and Hospital, Chidambaram. The study population was divided into two groups of 30 each randomly. Group 1 received 0.1% Levobupivacaine with 2mcgs/ml fentanyl. Group 2 received 0.1% Ropivacaine with 2mcgs/ml fentanyl. Epidural analgesia is started with an initial bolus of 10ml of the test drug. After 1hr of the initial dose, intermittent boluses of 5ml are given every 30mins. **Results:** Comparison of the maximum level of the sensory block between the groups was not statically significant with the p-value of 0.732. The maximum number of patients had block at T7 in group-II and T6 in group-I. Comparison of mean MP BR scale between the groups was statically insignificant with a p value of 0.06. The mean MP BR scale of group-I is 0.56 and group-II is 0.73. 13 patients belong to scale 0 in group-I and 22 belong to scale 1 in group-II. Comparison of the VAS scale between the groups was not statically significant with a p value of 0.403. The maximum number of patients belongs to score 2 in group-I. **Conclusion:** This is a randomized controlled study conducted in Rajah Muthiah Medical College and Hospital, Chidambaram. It was conducted to compare the effectiveness of 0.1% Levobupivacaine and 2mcg/ml fentanyl with 0.1% Ropivacaine and 2mcg/ml fentanyl for intermittent epidural labour analgesia. In our study Ropivacaine group shows shorter duration of labour compared to Levobupivacaine group.

Keywords: Levo- Bupivacaine, Epidural, Fentanyl, Labor, Ropivacaine.

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The labor is reported to be one of the most painful experiences in women's life. The pain of labour results in a maternal stress response, which is neither beneficial for the fetus nor the mother. Evidence is suggestive that labour disorder's including maternal hypertension, dystocia, meconium staining, and fetal distress are stress-related.[1] Various methods have been made to alleviate pain. It is now well recognized that a nearly consistent effective method to alleviate pain in labor is lumbar epidural analgesia. Labour epidurals are popular and safe, they provide effective analgesia for labouring parturients.[2]

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Lower dose epidural regimes limit motor block, do not affect the progress of labour, and have minimal side effects on mother and fetus. Labour epidurals can also be used to provide anesthesia for assisted vaginal delivery or cesarean section. Labour epidurals improve maternal pain and satisfaction scores in comparison to systemic analgesics and are the most effective analgesic option for labour.[3] Local anesthetics used in labour epidural produces labour analgesia through reversible inhibition of sodium ion influx in nerve fibers. Amide local anesthetic agents like ropivacaine and levobupivacaine are virtually identical in terms of onset, quality, and duration of sensory block, but ropivacaine and levobupivacaine seems to produce less motor block than bupivacaine.[4] Various local anesthetics can be used either alone or in combination with opioids in this technique. Bupivacaine was most commonly used but concerns about its cardiac toxicity and intensity of its motor block have led to the development of newer drugs such as levobupivacaine and ropivacaine.[5] Levobupivacaine is the S(-) enantiomer of bupivacaine and may have reduced cardiac and central nervous toxicity. Ropivacaine is an amide local anesthetic released in 1996.[6] Several studies suggest that Ropivacaine produced less motor blockade and fewer cardiac side effects than bupivacaine. Epidural administration of local anesthetics with opioids is now commonly used in labour, because of dose minimizing and side effects reducing benefits.[7] Fentanyl a highly potent opioid is a suitable analgesic drug combined with local anesthetics and used in labour for many decades. In our study, we compared 0.1% Ropivacaine with 2mcg/ml fentanyl versus 0.1% levobupivacaine with 2 mcg/ml fentanyl for epidural labour analgesia.[8]

MATERIALS AND METHODS

This study of epidural labour analgesia was conducted on 60 full-term labouring women of Rajah Muthiah Medical College and Hospital, Chidambaram. The study population was divided into two groups of 30 each randomly. Group 1 received 0.1% Levobupivacaine with 2mcgs/ml fentanyl. Group 2 received 0.1% Ropivacaine with 2mcgs/ml fentanyl. Epidural analgesia is started with an initial bolus of 10ml of the test drug. After 1hr of the initial dose, intermittent boluses of 5ml are given every 30mins.

Inclusion Criteria: ASA I and ASA II parturients in active labour. Cervical dilatation > 3cm.Full-term live fetus without any obstetric complication.

Exclusion Criteria: BMI> 30, Height < 150cm, Age < 18yrs, Anticipated difficult intubation, Contraindicated for epidural catheter placement, Sensitivity to study drug.

Placing the patient in the left lateral position, under aseptic precaution, L_2-L_3 interspace was identified and skin infiltration was done with 1ml of 2% lignocaine. Using an 18 G Tuohy needle and 'loss of resistance to air technique' the epidural space was identified. After confirmation by negative aspiration test, 18G epidural catheter was inserted and 5cms kept inside the epidural space. The catheter was taped firmly to the back. The patient was turned to a supine position. After negative aspiration of blood and CSF, the initial dose of 10ml of LA solution was given in divided doses. Intermittent epidural boluses started after 1 hr. 5min of drug solution every 30 min.

STATISTICAL ANALYSIS: The data was expressed in number, percentage, mean and standard deviation. Statistical Package for Social Sciences (SPSS 20.0) version used for analysis. Un paired t-test and Chi-square test used for analysis. A P-value less than 0.05 is considered statistically significant at a 95% confidence interval.

TABLE 1: COMPARISON OF PATIENTS BASED ON THE AGE BETWEEN THE GROUP-I AND II

Age (Years)	Group-I (Levobupivacaine) (n=30)		Group-II (Ropivacaine) (n=30)		p-value
	Number	Percentage (%)	Number	Percentage (%)	
20-25 y	10	33.33	5	16.67	
26-30 y	20	66.67	25	83.33	0.861
MEAN±SD	26.20±1.58		27.00±1.61		

TABLE :1 The data in both groups was normally distributed the parametric test unpaired t-test applied to find the statistical significance between the groups. Comparison of age between the groups was not statically significant with a p-value of 0.861. The mean age of group-I is 2.20 and group-II is 27 years. The data in both groups were normally distributed the parametric test unpaired t-test applied to find the statistical significance between the groups. Comparison of weight between the groups was not statically significant with a p-value of 0.590. A maximum number of patients belongs to weigh less than 60 kg in both groups. Comparison of height between the groups was not statically significant with a p-value of 0.680. The maximum number of patients belong to a height less than 150cm in groupII and 151-160cm in group-II less than 60 kg in both groups

TABLE 2: COMPARISON OF PATIENTS BASED ON THE GRAVIDA BETWEEN THE GROUP-I AND II

Gravida	Group-I (Levobupivacaine) (n=30)	Group-II (Ropivacaine) (n=30)	p-value

	Number	Percentage (%)	Number	Percentage (%)	
First	11	36.67	11	36.67	
Second	12	40.00	13	43.33	**0.763**
Third	7	23.33	6	20.00	

TABLE:2 The data in both groups were normally distributed the parametric test unpaired t-test applied to find the statistical significance between the groups. Comparison of gravida between the groups was not statically significant with a p-value of 0.763. A maximum number of patients belongs to secondary gravid in both groups.

TABLE 3: COMPARISON OF PATIENTS BASED ON THE ONSET OF SENSORY BLOCK BETWEEN THE GROUP-I AND II

Groups	The onset of sensory block (MEAN±SD)	P-value
Group-I (Levobupivacaine)	13.70±3.70	**0.547**
Group-II (Ropivacaine)	13.76±3.27	

TABLE :3 The data in both groups was normally distributed the parametric test unpaired t-test applied to find the statistical significance between the groups. Comparison of onset of the sensory block between the groups was not statically significant with a p-value of 0.547. Both groups showed a similar mean of onset of sensory block.

TABLE 4: COMPARISON OF PATIENTS BASED ON THE SENSORY BLOCK MAX LEVEL BETWEEN THE GROUP-I AND II

The maximum level of sensory block	Group-I (Levobupivacaine) (n=30)		Group-II (Ropivacaine) (n=30)		p-value
	Number	Percentage (%)	Number	Percentage (%)	
T6	10	33.33	11	36.67	
T7	10	33.33	12	40.00	**0.732**
T8	6	20.00	5	16.67	
T10	4	13.34	4	13.33	

TABLE:6 The data in both groups were normally distributed the parametric test unpaired t-test applied to find the statistical significance between the groups. Comparison of the maximum level of the sensory block between the groups was not statically significant with a p-value of 0732. A maximum number of patients had block atT7 in groupII and T6 in group-I.

TABLE 7: COMPARISON OF PATIENTS BASED ON THE LEVEL OF MOTOR BLOCKADE SCALE BETWEEN THE GROUP-I AND II

MP BR scale	Group-I (Levobupivacaine) (n=30)		Group-II (Ropivacaine) (n=30)		p-value
	Number	Percentage (%)	Number	Percentage (%)	
0	13	43.33	8	26.67	
1	17	56.67	22	73.33	**0.06**
MEAN±SD	0.56±0.50		0.73±0.44*		

TABLE:7 The data in both groups were normally distributed the parametric test unpaired t-test applied to find the statistical significance between the groups. Comparison of mean level of motor blockade between the groups was not statically significant with the p-value of 0.06. The mean level of motor blockade of group-I is 0.56 and group-II is 0.73. 13 patients belong to scale 0 in group-I and 22 belong to scale 1 in group-II.

TABLE 8: COMPARISON OF PATIENTS BASED ON THE VAS SCALE BETWEEN THE GROUP-I AND II

VAS scale	Group-I (Levobupivacaine) (n=30)		Group-II (Ropivacaine) (n=30)		p-value
	Number	Percentage (%)	Number	Percentage (%)	
2	13	43.33	11	36.67	
3	8	26.67	11	36.67	**0.403**
4	9	30.00	8	26.67	
MEAN±SD	2.86±0.86		2.90±0.80		

TABLE:8 Comparison of the VAS scale between the groups was not statically significant with the p-value of 0.403. A maximum number of patients belongs to score 2 in group-I.

TABLE 9: COMPARISON OF PATIENTS BASED ON THE SEDATION SCORE BETWEEN THE GROUP-I AND II

Sedation score	Group-I	Group-II

	(Levobupivacaine) (n=30)		(Ropivacaine) (n=30)	
0	30	100.00	30	100.00
1	0	0.00	0	0.00
MEAN±SD	0.00±0.00		0.00±0.00	

TABLE:9 Comparison of sedation score between the groups was not statically significant.

TABLE-11: COMPARISON OF PATIENTS BASED ON THE DURATION OF LABOR BETWEEN THE GROUP-I AND II

Groups	Duration of labor (MEAN±SD)	P-value
Group-I (Levobupivacaine)	159.10±15.72	**0.019**
Group-II (Ropivacaine)	158.73±15.20*	

TABLE:11The data in both groups were normally distributed the parametric test unpaired t-test applied to find the statistical significance between the groups. Comparison of mean duration of labor between the groups was statically significant with the p-value of 0.019.

TABLE 12: COMPARISON OF PATIENTS BASED ON THE COMPLICATIONS BETWEEN THE GROUP-I AND II

Complications	Group-I (Levobupivacaine) (n=30)		Group-II (Ropivacaine) (n=30)		p-value
	Number	Percentage (%)	Number	Percentage (%)	
No	24	80.00	22	73.33	**0.562**
Hypotension	6	20.00	8	26.67	

TABLE:12 The data in both groups was normally distributed the parametric test unpaired t-test applied to find the statistical significance between the groups. Comparison of complications between the groups was not statically significant with the p-value of 0.562. Maximum patients in both groups do not have complications. Hypotension was the complication in both groups was not statistically significant.

TABLE 13: COMPARISON OF PATIENTS BASED ON THE APGAR 1 SCORE BETWEEN THE GROUP-I AND II

APGAR score 1	Group-I (Levobupivacaine) (n=30)		Group-II (Ropivacaine) (n=30)		p-value
	Number	Percentage (%)	Number	Percentage (%)	
6	9	30.00	12	40.00	
7	11	36.67	10	33.33	
8	10	33.33	8	26.67	**0.399**
MEAN±SD	4.43±1.27		4.90±1.21		

TABLE:13 The data in both groups was normally distributed the parametric test unpaired t-test applied to find the statistical significance between the groups. Comparison of APGAR scores 1 between the groups was not statically significant with the p-value of 0.399. Maximum patients belong to score in group-II and group-I 7 and 8.

TABLE 14: COMPARISON OF PATIENTS BASED ON THE APGAR 5 SCORE BETWEEN THE GROUP-I AND II

APGAR score 5	Group-I (Levobupivacaine) (n=30)		Group-II (Ropivacaine) (n=30)		p-value
	Number	Percentage (%)	Number	Percentage (%)	
6	15	50.00	13	43.33	
7	9	30.00	9	30.00	
8	6	20.00	7	23.34	**1.000**
9	0	0.00	1	3.33	
MEAN±SD	6.56±0.89		6.96±0.96		

TABLE:14 The data in both groups was normally distributed the parametric test unpaired t-test applied to find the statistical significance between the groups. Comparison of APGAR scores 5 between the groups was not statically significant with the p-value of 1.000. The maximum number of patients belongs to score and 7 in group-II. The data in both groups were normally distributed the parametric test unpaired t-test applied to find the statistical significance between the groups. Comparison of mean systolic blood pressure between the groups was not statically significant at 2, 5, 10, 15, 30, 60, 90, 120, 150, 180, 240, and 300 min. 0 min showed a significant difference between the groups with the p-value of 0.021. Comparison of mean diastolic blood pressure between the groups was not statically significant at 0, 2, 5, 10, 15, 30, 60,

90, 120, 150, 180, 240, and 300 min between the group-I and II. The data in both groups were normally distributed the parametric test unpaired t-test applied to find the statistical significance between the groups. Comparison of mean pulse rate between the groups was not statically significant at 0, 2, 5, 10, 15, 30, 60, 90, 120, 150, 180, 240, and 300 min between the group-I and II.

DISCUSSION

Epidural bupivacaine provides an excellent sensory block and has been used for labour analgesia for many years.However, concern about its cardiac toxicity and the intensity of motor block has led to the investigation of other agents.[9] Ropivacaine has been associated with reduced incidence of operative vaginal delivery and less motor block when compared to bupivacaine. Recently, it has been shown that ropivacaine appears equipotent to bupivacaine, less cardiotoxic and neurotoxic, and seems to be a more suitable agent for pain relief in labouring women. Lee *et al.*[6] found no significant differences in the mode of delivery, duration of labor, and fetal outcomes in the study comparing the low concentration of ropivacaine 0.08% and levobupivacaine 0.06% with fentanyl (2mcg/ml) for labor epidural analgesia.[10] The present study compared 0.1% levobupivacaine with 2mcg/ml fentanyl vs 0.1% ropivacaine with 2mcg/ml fentanyl in labor epidural analgesia. In the present study, group I patients received 0.1% levobupivacaine with 2µg/ml fentanyl and group II patients received 0.1% ropivacaine with 2µg/ml fentanyl. Purdie *et al.*[36]compared the relative potencies and clinical characteristics of epidural ropivacaine and levobupivacaine in labour using patient-controlled epidural analgesia (PCEA).[11] In a randomized double-blinded study, 60 ASA I or II parturients requesting epidural analgesia in early labour were allocated to receive either 0.1% ropivacaine with fentanyl 2µg/ml or 0.1% levobupivacaine with 2µg/ml. Analgesia was established with 10ml of study solution and maintained using 5ml boluses of study solution with a 5-min lockout interval. There were no significant differences in onset time, duration and quality of analgesia, motor and sensory blockade, local anesthetic consumption, mode of delivery, neonatal outcome, or maternal satisfaction between the groups.[12] They concluded that 0.1% ropivacaine with 2µg/ml fentanyl and 0.1% levobupivacaine with 2µg/ml fentanyl are clinically indistinguishable for labour analgesia and appear pharmacologically equipotent.[13] We found that mode of delivery found was instrument-assisted vaginal delivery seen in 4 in group I and 4 in group II and normal vaginal delivery saw 21 in group I and 19 in group II.[14].Both drugs were equally effective clinically. Maternal demographic characteristics were comparable. There were no statistically significant differences in visual analog pain score, highest sensory block, maternal satisfaction, mode of delivery, total doses of LAs during labor, and motor block at delivery between the groups.[15] The maternal parameters recorded in our study show no statistical difference in values between the two groups. There were minor episodes of hypotension that responded to IV ephedrine. Thus we infer that there is no effect of the above drugs on maternal hemodynamic status.[16] The APGAR values observed at 1st and 5th minutes in both groups showed no significant neonatal depression. Thus we infer that there is no effect on fetal outcome by epidural analgesia. Several other studies are confirming the same.[17,18,19,20]

CONCLUSION

It was conducted to compare the effectiveness of 0.1% Levobupivacaine and 2 mcg/ml fentanyl with 0.1% Ropivacaine and 2mcg/ml fentanyl for intermittent epidural labour analgesia.In our study Ropivacaine group shows a shorter duration of labour compared to the Levobupivacaine group.No statistical differences were seen between the two groups with regards to the motor blockade, level of analgesia, pain scores, maternal parameters, labour, and fetal outcome.We conclude that at equianalgesic concentrations Ropivacaine is superior to levobupivacaine with regards to the duration of labour, with no significant differences in the motor blockade.

REFERENCES

1. Aberg G. Toxicological and local aesthetic effects of optically active isomers of two local anesthetic compounds. ActaPharmacolToxicol Scan. 1972;31:273-86.
2. AbouleishE Rawal N , Shaw J , Lorenz T , Rashad MN. Intrathecal morphine 0.2 mg versus epidural bupivacaine 0.125% or their combination: effects on parturients. Anesthesiology 1991; 74:711-6.
3. Anim-Somuah M, Smyth RM, Cyna AM, Cuthbert A. Epidural versus non-epidural or no analgesia for pain management in labor. Cochrane Database Syst Rev 2018.
4. Beth Glosten. Anesthesia for Obstetrics. Chapter No: 58. In "Textbook of Anesthesia" Ronald D. Miller, 6th edition. Churchill Livingston: P. No. 2024 -2068.
5. Birnbach DJ. Advances in labour analgesia. CJA 2004;51(6):R1-R3.
6. Buggy DJ, MacDowell C. Extradural analgesia with clonidine and fentanyl compared with 0.25% bupivacaine in the first stage of labour. BJA 1996;76:319-217.
7. David C. Campbell. Labour analgesia: what's new and PCEA too? CJA 2003;50(6)R1-R7.
8. Eltzschig HK, Lieberman ES, Camann WR. Regional anesthesia and analgesia for labor and delivery. NEJM 2003;348(4):319-32.
9. Gambling DR, Cole PYC, McMorland GH, Palmer L. Comparative study of patient-controlled epidural analgesia

(PCEA) and continuous infusion epidural analgesia (CEA) during labor. Can J Anaesth. 1988;35(3):249-254.
10. Gross H N, Posner NA. An evaluation of hypnosis for obstetric delivery. Am J ObstetGynecol1963;87:912-20.
11. Hansen TG. Ropivacaine: A pharmacological review. Expert Rev Neurother,2004;4:781-9.
12. Lee A, Fagan D, Lamont M, Tucker GT, Halldin M, Scott DB. Disposition kinetics of ropivacaine in humans. AnesthAnalg. 1989; 69:736-8.
13. Lee HL, Lo LM, Chou CC, Chuah EC. Comparison between 0.08% ropivacaine and 0.06% levobupivacaine for epidural analgesia during nulliparous labour. Chang Gung Med J 2011;34:286-91.
14. Loughnan BA, Carli F, Romney M, Dore CJ, Gordon H.Randomised controlledcomparison of epidural bupivacaine versus pethidine for analgesia in labour. BJA 2000;84(6): 715-19.
15. Obstetrical Anesthesia. In"Williams Obstetrics."F. GaryCunningham, 22nd edition, 2005; McGraw - Hill Companies, Inc: P.No. 473 - 494.
16. Opiod analgesics and anatagonists, mark A Schumacer, Allen I Bashum, Walter IWay. In "Basic and clinical pharmacology" Bertram G Katzung, 10th edition, McGraw-Hill.
17. Rayburn W ,Rathke A , Leuschen MP , et al. Fentanyl citrate analgesia during labor. Am J Obstet Gynecol. 1989; 161:202-206.
18. Robinson AP, Lyons GR, Wilson RC, Gorton HJ, Columb MO. Levobupivacaine for Epidural Analgesia in Labor: The Sparing Effect of Epidural Fentanyl. Anesth Analog2001 ;92:410-4
19. Van Zundert A, Osthiemer SW. Pain relief and anesthesia in obstretics. 1st ed;1996.
20. Vincent J. Collins (1978) *Physiologic and Pharmacologic basis of anesthesia'. 2nd Ed. William and Wilkins: 573-657.

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