e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2022; 14(6); 372-377

Original Research Article

Prospective Comparative Study of Epidural Ropivacaine Vs Epidural Levobupivacaine on the Duration of Analgesia in Adult Patients Undergoing Subumbilical Surgeries

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Received: 15-04-2022 / Revised: 23-05-2022 / Accepted: 05-06-2022
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Conflict of interest: Nil

Abstract

Background: Epidural anesthesia can be used as a sole anesthetic technique for surgical procedures, and it can also be used for post operative pain management.
The aim of this study was to compare the efficacy of Ropivacaine and Levobupivacaine in epidural neuraxial blockade regarding duration of analgesia and adverse effects.
Materials and Methods: This study was done among two group of patients belonging to ASA 1 and 2, who underwent subumbilical surgeries. Both the groups of patients were comparable with regard to age, height and weight. They were allocated into two groups using computer generated randomization. Group A received 12 ml of 0.5 % Ropivacaine and Group B received 12 ml of 0.5 % Levobupivacaine.
Results: The mean duration of analgesia in group A was 195 minutes and in group B was 200 minutes. Since the p value was > 0.05, there was no statistically significant difference in the duration of analgesia between the two drugs. Incidence of adverse effects like hypotension, nausea, vomiting was comparable in both the groups and found to be statistically insignificant. There were no incidence of bradycardia, headache or dizziness in both the groups.
Conclusion: Since the duration of analgesia and adverse effects were comparable in both the drugs, it was concluded that they can be used with equal efficacy in subumbilical surgeries.
Keywords: Epidural, Ropivacaine, Levobupivacaine.

Introduction

Epidural analgesia can reduce cardiovascular and pulmonary morbidity and mortality in high-risk patients undergoing major thoracic and abdominal surgery [1]. The goals of epidural analgesia have shifted from reduction of morbidity and mortality in high-risk patients to facilitation of fast-track recovery in otherwise healthy patients undergoing various types of elective inpatient surgical procedures.

For many years Bupivacaine, an amide local anaesthetic has been used because of its longer duration of action. Compared

with older local anaesthetics, Bupivacaine provides better analgesia without significant motor blockade. In addition, there is less tachyphylaxis with its prolonged administration. However, Bupivacaine is more cardiotoxic than other local anaesthetics. [2,3]

Levobupivacaine and Ropivacaine, two new long-acting local anaesthetics, have been developed as an alternative to Bupivacaine, after the evidence of its severe toxicity [2,3]. Both of these agents are pure left-isomers and due to their three-dimensional structure, seem to have less toxic effects on the central nervous system and on the cardiovascular system. [3,4]

As Levobupivacaine and Ropivacaine have been recently introduced in India, not many studies have been done in India evaluating the use of isobaric Levobupivacaine 0.5% and isobaric Ropivacaine 0.5% for epidural anaesthesia in subumbilical surgeries. Hence there was a need to undertake a study to compare the effectiveness of these two drugs with regard to duration of sensory blockade, haemodynamic effects and any other adverse effects when given epidurally for elective subumbilical procedures.

Aims of Study

To compare the efficacy of Ropivacaine and Levobupivacaine in Epidural neuraxial blockade regarding.

1. Duration of analgesia
2. Adverse effects

Materials and Methods

This was a prospective comparative study conducted among fifty patients who underwent subumbilical surgeries in Govt. T.D.M.C Alappuzha during the period from February 2014 to February 2015. Clearance was obtained from Institutional Study Committee.

Patients were allocated into two study groups, named A and B using Computer generated Randomisation

Group A – Received Epidural Inj. Ropivacaine 0.5% (isobaric) 12 ml.

Group B – Received Epidural Inj.Levobupivacaine 0.5% (isobaric) 12 ml.

Inclusion Criteria

- American Society of Anaesthesiologists (ASA) physical status 1 and 2.
- Age Group: 18 - 55 years
- Body weight: 55 – 75 kg
- Height: 155 - 170 cm
- Either sex

Exclusion Criteria

- Patient refusal for regional anaesthesia.
- Infection at the site of injection.
- History of bleeding diathesis and patients on anticoagulant therapy.
- Hypovolemic patient
- History of allergy to drugs including local anaesthetics.
- History of spinal deformities, spine surgery and preexisting neurological disease.
- Psychologically ill or mentally retarded patients.
- Pregnancy.
- History of convulsions.
- Patients on β blockers and Calcium channel blockers.

Analgesia was assessed by Visual Analogue Scale which was marked from 0 to 100 [5]. Break through pain of >50 in the VAS was be managed with Inj. Tramadol 50 mg iv and the time was noted. Adverse effects (hypotension, bradycardia, nausea, vomiting, headache, dizziness), if any were noted.

Statistical Analysis

Baseline data were entered in Microsoft Excel sheet. Data were analyzed using

SPSS. Data were expressed in its frequency and percentage as well as mean, median and SD. Qualitative variables were summarized using proportions with 95% C.I. Quantitative variables were summarized using mean with standard deviation. Test of significance such as t test for quanitative variables and chi square test for qualitative variables were done. For all statistical evaluations, a two tailed probability of value < 0.05 was considered significant.

Results

When the age distribution of two study groups is compared, mean age in Ropivacaine group was 43.44 years with SD of 7.55 and mean age of Levobupivacaine was 43.28 with SD of 7.27. Statistical analysis using independent t test revealed a p value of >0.05, which was not significant. So, there was no statistical difference between the two groups with respect to age distribution and the two groups were age matched or comparable.

Sex distribution of both study groups when compared, mean value of sex distribution of Ropivacaine was 1.08 with SD of 0.27 and Levobupivacaine was 1.12 with SD of 0.33. Statistical analysis using independent t test revealed a p value of >0.05, which was not significant. So, there was no statistical difference between the two groups with respect to sex distribution and the two groups were sex matched or comparable.

While comparing the weight distribution of the two study groups, mean value of weight of Ropivacaine group was 65.16 with SD of 3.1 and Levobupivacaine was 65.48 with SD of 2.87. As p >0.05, there were no statistical difference between two groups, the two groups were comparable or weight matched.

When mean distribution of height of two study groups are compared, mean value of weight of Ropivacaine group was 165.72 with SD of 1.72 and Levobupivacaine was 165.76 with SD of 1.88. Statistical analysis using independent t test revealed a p value of >0.05, which was not significant. So, there was no statistical difference between the two groups with respect to height distribution and the two groups were height matched or comparable

Table 1: Comparison of Duration of analgesia in minutes based on group

Group	Mean	SD	N	t	P
Ropivacaine	16.44	1.15	25	0.349	0.729
Levobupivacaine	16.56	1.15	25		
Comparison of onset of analgesia					
Group	**Mean**	**SD**	**N**	**t**	**p**
Ropivacaine	195	18.2	25	1.37	0.183
Levobupivacaine	200.6	15.5	25		

Mean value of time of onset of analgesia of two study groups are given above. Mean time of onset of analgesia of Ropivacaine was 16.44 minute with SD of 1.15 and Levobupivacaine was 16.56 minute with SD of 1.15. Statistical analysis using independent t test revealed a p value of >0.05, which was not significant. So, there was no statistical difference between the two groups with respect to the time of onset of analgesia.

Mean value of duration of analgesia of two study groups are given above. Mean duration of analgesia in Ropivacaine was 195 minutes with SD of 18.2 and Levobupivacaine was 200.6 minutes with SD of 15.5. Statistical analysis using independent t test revealed a p value of >0.05, which was not significant. So, there

was no statistical difference between the two groups with respect to the duration of analgesia.

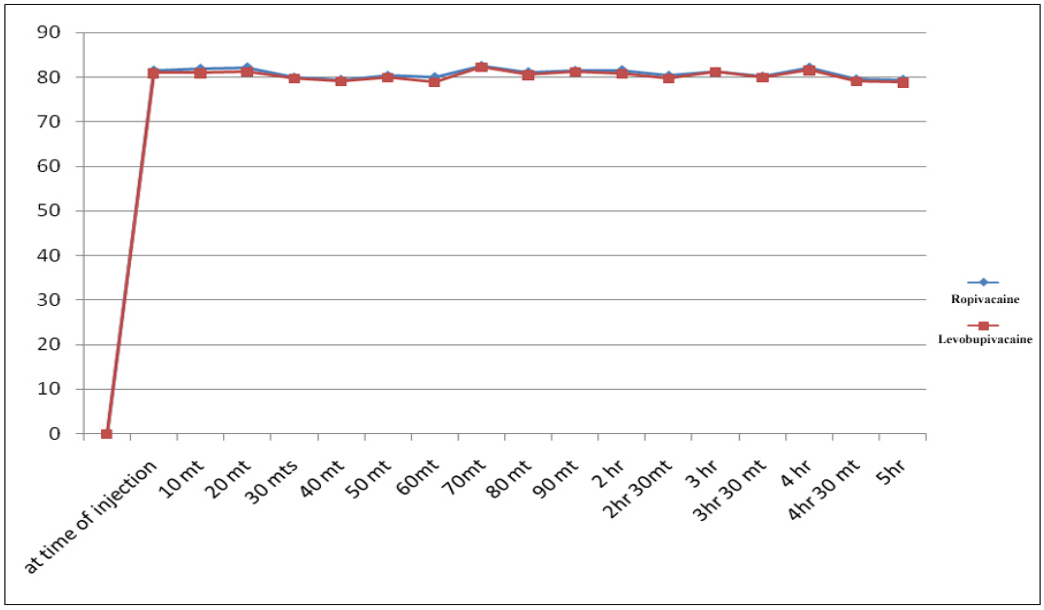

Figure 1: Timeline graph showing the distribution of mean pulse rates for the two groups

Mean pulse rate at various time interval is analysed using independent t test. It shows no significant difference between the two groups, since the p value was >0.05 at all-time intervals.

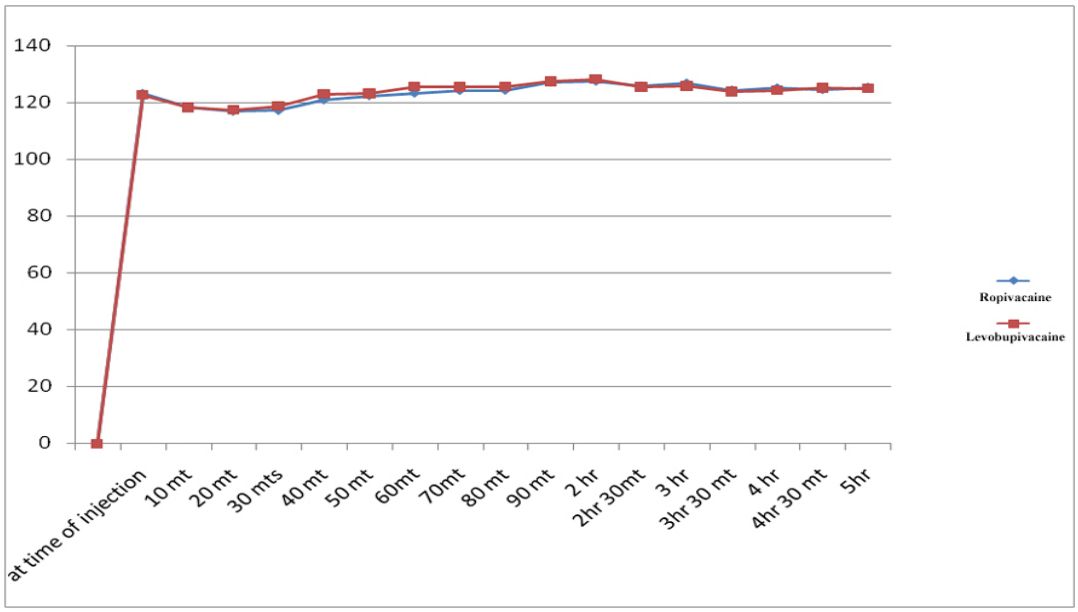

Figure 2: Timeline graph showing the distribution of mean systolic blood pressure of the two groups

Mean systolic blood pressure at various time interval were analysed using independent t test. It shows no significant difference between the two groups since p value was >0.05 at all-time intervals.

Adverse Drug Reactions

There was no significant difference between the two groups when comparing the incidence of hypotension, bradycardia,

nausea, vomiting, headache or dizziness in the two groups.

Discussion

The recognition of acute life-threatening cardiotoxicity of Bupivacaine led to the search for a local anaesthetic agent comparable with Bupivacaine but with lower cardiotoxicity[6]. This resulted in the development of a relatively new amide, Ropivacaine, registered for use in 1996 but introduced in India only in 2009. Ropivacaine is developed as pure 'S' enantiomer with lower lipid solubility, easier reversibility after inadvertent intravascular injection, significant reduction in central nervous system and cardiovascular toxicity, lesser motor blockade and greater differentiation of sensory and motor blockade [7].

Levobupivacaine (S-1-butyl-2-piperidylformo-2', 6'-xylidide hydrochloride), the pure S (-) enantiomer of racemic Bupivacaine, is a new long-acting local anaesthetic that has recently been introduced in India. Because of its significantly decreased cardiovascular and central nervous system toxicity, Levobupivacaine also seems to be an attractive alternative to Bupivacaine. [8,9]

Andrea Casati et al made a study on comparing intraoperative epidural anaesthesia and postoperative analgesia with Levobupivacaine, Bupivacaine and Ropivacaine in 45 patients undergoing total hip replacement [10]. Patients were received epidural block with 0.5% Levobupivacaine 15 ml or 0.5% Bupivacaine 14 ml or 0.5% Ropivacaine 15 ml. Recovery of pinprick sensation at T10 occurred after 214 ± 61 minutes with Levobupivacaine, 213 ± 53 minutes with Bupivacaine, and 233 ± 34 minutes with Ropivacaine ($p = 0.26$). They found that Levobupivacaine 0.5% produced an epidural block of similar onset, quality, and duration as of 0.5% Ropivacaine, A similar degree of pain relief was observed in the groups without differences in local anaesthetic consumption and need for rescue analgesia. [11]

In my study the mean duration of analgesia for Ropivacaine is 195 minutes and Levobupivacaine is 200.3 minutes. Though the mean duration of analgesia is longer for Levobupivacaine when compared to Ropivacaine, the difference is not statistically significant since the p value is 0.183 ie > 0.05.

When comparing the adverse effects between Ropivacaine and Levobupivacaine, among the 25 patients in the first group, only 2 developed hypotension that is the incidence was 8%, in the latter group the incidence was 12 %. But the result is not statistically significant since p value is > 0.05. There was no incidence of bradycardia among the two groups.

On comparing incidence of nausea, it was 12% in the Ropivacaine group and in the levobupivacaine group, it was 8%. That was also found to be statistically insignificant since p value is > 0.05 Vomiting incidence was similar in Ropivacaine and Levobupivacaine groups that is 8%. In this study, none of the patients in the two-group developed headache or dizziness.

Conclusion

Epidural 0.5 % Ropivacaine and 0.5 % Levobupivacaine are effective in providing adequate intraoperative and postoperative analgesia in subumbilical surgeries. There is no significant difference in the duration of analgesia and adverse effects between the two drugs. So, they can be used with equal efficacy in subumbilical surgeries.

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