

Epidural 0.5% Bupivacaine and 0.5% Levobupivacaine in Lower Limb Surgeries with respect to Block characteristics

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Abstract

Introduction: With the introduction of epidural anaesthesia, it is being widely used for abdominal surgeries and lower limb surgeries and mainstay for providing postoperative analgesia. With the development of enantiomers of Bupivacaine (Levobupivacaine and Ropivacaine), epidural anaesthesia is being used widely with less complications.

Purpose: To compare the block characteristics and duration of analgesia of Bupivacaine 0.5% and Levobupivacaine 0.5% in lower limb surgeries.

Materials and Method: After obtaining ethical committee approval and informed written consent from patients, the study was carried out on 70 patients of either sex, between 18 to 65 years of age. Patients were divided in two groups Group B (Bupivacaine) and Group L (Levobupivacaine) and 20 ml of study drug given in each group.

Result: The Sensory block onset time between group B & L was highly significant. P value ≤ 0.001 . Whereas the Motor block onset time between B & L was not significant (P value = 0.305). The duration of motor (P value = 0.892) and sensory block (P value = 0.659) between both group was not significant. The difference in the time of regression among the group B & L was highly significant in respect of motor and sensory the parameters $P < 0.001$. There was marked difference in the duration of analgesia between the patients of Group B & L. $P = 0.026$

Conclusion: Thus from our study we can conclude that Onset of Sensory & motor block for Levobupivacaine was longer as compared with Bupivacaine. The highest sensory level of T7 segment was found to be with Group B then Group L.

Keywords: Bupivacaine, Epidural, Levobupivacaine

Introduction

Anesthesiologist play a main role in providing comfort to patient, monitor the patient and maintain normal physiological levels.⁽¹⁾

With the advancement of anaesthesia different techniques are being used in combination with different drugs for providing pain relief.⁽²⁾ With introduction of ether and nitrous oxide, a new era of pain relief had begun.

With the introduction of central neuraxial blockade, providing relief to patient from pain intraoperatively and postoperatively is in common practice now-a-days. Epidural anaesthesia provides effective anaesthesia and analgesia intraoperatively and also postoperative pain relief and lead to early mobilization with decreased side effects. Thus it has been used routinely in orthopedic surgeries considering all its advantages.⁽³⁾

In 1957 Bupivacaine was introduced leading a major evolution in development of anaesthesia. An amide with properties of local anesthetic is now being used for more than 60 years. Bupivacaine available in market is a racemic mixture of S(-) and R(+) enantiomers. Due to enantiomeric compound it has various side effects including cardiotoxicity and central nervous system toxicity. Due to side effects there was need for a new local anaesthetic with less side effects and thus enantiomers were developed.⁽⁴⁾

Levobupivacaine, is S (-) enantiomer of Bupivacaine, is less cardiotoxic than Bupivacaine. It is due to lower affinity of enantiomer {S(-)} to the sodium

channels in the heart as compared to the R(+) isomer and has minimum cardiac side effects.⁽⁵⁾

Hence, in this study we compared Levobupivacaine 0.5% and Bupivacaine 0.5% in epidural anaesthesia in elective lower limb surgeries.

Aim and Objectives

To compare Bupivacaine 0.5% and Levobupivacaine 0.5% in epidural anaesthesia in lower limb surgeries, with respect to -

1. Onset and duration of sensory blockade
2. Onset and duration of motor blockade
3. Maximum dermatomal level of analgesia and time taken to achieve that.

Materials and Method

After obtaining ethical committee approval and informed consent from patient, they were randomly divided into 2 groups with 35 patients in each group with a computer generated randomization list before anaesthesia.

1. Group L - 20ml of 0.5% Levobupivacaine
2. Group B - 20 ml of 0.5% Bupivacaine

Inclusion criteria for the study are Adult patients aged between 18 to 65 years of either sex, Patients belonging to ASA class I and II, Weight – 45-70 kgs, Height 150-180cms. Patient posted for below knee orthopedic surgery was selected for the study groups including tibial and ankle surgeries. Patient with the history of uncontrolled labile hypertension, heart block,

dysrhythmia, on therapy with adrenergic receptor antagonist, calcium channel blocker or ACE inhibitor, addiction to narcotic, sedation and contraindication to epidural anaesthesia was not be included in the study. All the patients were thoroughly examined and investigated before the surgery. Tourniquet was applied. Patient requiring additional anesthesia and analgesia was excluded from group.

A peripheral intravenous line with 18 gauge cannula was secured in one of the upper limbs. All the patients was preloaded with 10-20 ml/kg of Ringer lactate 30 minutes prior to the epidural procedure. Multiparameter monitor was connected which records heart rate, non-invasive measurement of systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure(MAP), continuous electrocardiogram (ECG) monitoring and oxygen saturation (SPO2). With the patients in sitting position under aseptic precautions, epidural space was identified by loss of resistance technique to air using 18G Tuohy needle via the midline approach at either L2-3 or L3-4 inter spinous space. An epidural catheter was threaded and fixed. A test dose of 3 ml of 2% lignocaine with 1:200000 adrenaline was injected through the catheter after aspiration. After ruling out intrathecal and intravascular placement of the tip of the catheter, study drug was injected in increments of 5 ml. The patients was turned to supine position after 1 min. Assessment of sensory and motor blockade was done at the end of each minute with the patient in supine position after completion of the injection of 20 ml of the study drug, which is taken as the starting time. The onset time for sensory and motor block, the maximum level of sensory block and duration of sensory and motor block was measured, and the time when patient demands the first rescue analgesia in the postoperative period was noted.

Onset of sensory blockade: was taken as the time from the completion of the injection of the study drug till loss of sensation by pin prick. **Duration of sensory block:** was taken as the time to reach highest dermatomal level of sensory blockade from the time of injection to time for 2 segment sensory regressions.

Motor blockade in the lower limbs was assessed using modified Bromage scale.⁽⁶⁾

0-Pt was able to move hip, knee, & ankle.

1-Pt was not able to move hip, but able to move knee & ankle.

2-Pt was not able to move hip, knee but able to move ankle.

3-Pt was not able to move hip, knee, ankle.

Hypotension is defined as reduction of systolic blood pressure more than 30% from basal systolic blood pressure or SBP less than 90 mmHg and was treated with increased rate of intravenous fluids and if needed injection mephentermine 3 mg (I.V) given in increments. Bradycardia (<60 beats/min, <20%) was treated with injection Atropine 0.6 mg (I.V).

Onset of motor blockade: was taken from the completion of the injection of study drug till the patient develops modified Bromage scale grade 1 motor blockade.

Duration of motor block: was taken from the time of injection till the patient attains complete motor recovery (Bromage 0). Duration of analgesia was taken when the first rescue analgesia given.

Method of randomization: A statistician was consulted and method of randomization, adequacy of sample size and power of test were confirmed.

Study Design	Cross Sectional
Study Period	November 2014 – May 2016
Study Area	Patients posted for Lower limb Orthopedic Surgeries
Sample Size	70 Patients, 35 in each group

Statistical analysis: Results were expressed by standard methods in the form of mean ± standard deviation. Unpaired t- test was used for analysis in numerical data while for frequency fisher exact test was applied. Statistical analysis was performed by SPSS (version 20.0). P-value was considered significant if <0.05 and highly significant if <0.001.

Observations and Results

The objective of the present study was to compare Levobupivacaine 0.5% and Bupivacaine 0.5% in epidural anaesthesia in lower limb surgeries, with respect to Onset and duration of motor blockade and sensory blockade, maximum dermatomal level of analgesia and time taken to achieve maximum level.

Table 1: Group wise distribution of demographic data

Demographic Data	Groups		Significance (B*L)
	Group B	Group L	
	Mean±SD	Mean±SD	
Age* (year)	36.51±10.32	42.77±14.70	P value= 0.43
Height* (cm)	164.03±5.19	163.66±5.64	P value =0.77
Weight* (kg)	64.74±5.08	64.46±5.36	P value =0.82
BMI	23.96±1.45	24.04±1.27	P value = 0.80
Sex	Male	27(77.14%)	X ² = 0.897 P value = 0.638
	Female	8(22.86)	

As shown in Table 1: Group wise distribution of demographic data, like age, height, weight, BMI and sex were tabulated. On perusal of the same we observe no significant deviation in any of these data among

different groups of the cases. P value range was 0.067 to 0.982.

Table 2: Shows onset of Sensory block & Motor block among the groups

Onset Time of Block(min)	Groups		
	Group B	Group L	Significance (B*L)
	Mean±SD	Mean±SD	
Sensory block	9.7±1.88	11.31±1.5	P value=<0.001 T value = -3.7
Motor block	28.6±4.2	29.8±5.3	P value= 0.305 T value = -1.03

As shown in Table 2: The mean Onset time of Sensory block as well as Motor block was mentioned. While, the mean Sensory block time for the two groups B & L was 9.7±1.88 & 11.31±1.5 minutes, respectively. The corresponding time figures for the Motor block were 28.6±4.2 & 29.8±5.3 minutes respectively. The variation in the Sensory block time between group B & L was highly significant. P value = <0.001. The variation in the Motor block time between B & L was not significant.

Table 3: Shows Duration of motor block & duration of sensory block among the groups

Duration (in mins)	Groups		
	Group B	Group L	Significance (B*L)
	Mean±SD	Mean±SD	
Duration of motor block	280±70.9	278±74	P value = 0.892
Duration of sensory block	393±73.6	385±72	P value = 0.659

As shown in Table 3: the duration of motor as well as sensory blocks for the groups of patients B & L were tabulated. While the duration of motor block for the patients of group B & L was 280±70.9 & 278±74 minutes, the time duration for sensory block was 393±73.6 & 385±72 minutes respectively. The variations in the time duration of motor (P value = 0.892) and sensory block (P value = 0.659) between both group was not significant.

Table 4: Shows Highest sensory level among the groups

Highest level	Groups			
	Group B	Group L	Significance (B*L)	
	Mean±SD	Mean±SD		
Highest sensory level (N)	T6	4(11.43%)	5(14.29%)	X ² = 7 P value = 0.53
	T7	15(42.86%)	10(28.57%)	
	T8	6(17.14%)	8(22.86%)	
	T9	5(14.29%)	5(14.29%)	
	T10	5(14.29%)	7(20.00%)	

As shown in Table 4: Consequent upon the administration of different anesthetics to the patients of

both groups, B & L each consisting of 35 members, highest sensory levels for T6 to T10 segments was recorded in the table. The highest sensory level of T7 segment was found to be 15(42.86%) & 10(28.57%) respectively, among the members of each of the group. The variation in the sensory level among the members of both groups, in respect of each of these segments was however not significant. P= 0.53

Table 5: Shows Duration of analgesia among the groups

Duration (in mins)	Groups (B*L)		
	Group B	Group L	Significance
	Mean±SD	Mean±SD	
Duration of analgesia(in mins)	224±18.6	213±20	P value = 0.026

As shown in Table 5: Duration of analgesia was recorded in the table being 224±18.6 & 213±20 minutes for members of Group B & L. There was marked difference in the duration of analgesia between the patients of Group B & L (P= 0.026).

Discussion

Since it was founded that cardiotoxicity of the bupivacaine is because of its enantiomer^(7,8) the S(±) enantiomer (Levobupivacaine) was isolated from the racemic mixture to use as long acting LA as an alternative to its parent compound (Bupivacaine). It was further demonstrated that S(±) Bupivacaine is cardiostable than racemic Bupivacaine.⁹ Levobupivacaine as an long acting LA has been studied extensively.⁽¹⁰⁾ So we decided to compare both Bupicavaine and Levobupivacaine in epidural in lower limb surgeries comparing their block characteristics.

In our study 70 patients of 18 to 65 years of either sex of ASA 1 and 2 undergoing for lower limb surgeries, they were further divided into two groups B(20 ml of 0.5% Bupivacaine) and L (20ml of 0.5% Levobupivacaine). Distribution of demographic data, like age, height, weight, BMI and sex were observed, on perusal of the same we observe no significant deviation in any of these data among different groups of the cases. An Indian study by S. J. V. Kameshwara Rao et al⁽¹¹⁾ reported that patients studied in the groups were comparable with respect to age, sex or weight.

In our study, the mean time for onset of sensory block in Bupivacaine group was 9.7±1.88 minutes, and 11.31±1.5 minutes in Levobupivacaine group. The mean time for onset of motor block in Bupivacaine group was 28.6±4.2 minutes and 29.8±5.3 minutes in Levobupivacaine group. The variation in the Sensory block time between group Bupivacaine & Levobupivacaine was highly significant (P = <0.001). The variation in the Motor block time between two groups was not significant. The onset of motor block is

delayed in case of Levobupivacaine than Bupivacaine, same reported by Kopacz DJ et al.⁽¹²⁾

Andrea Casati et al⁽¹³⁾ studied 45 ASA I-III patients undergoing THR surgery and compared the neuraxial block with 10ml of 0.5% Levobupivacaine, 0.5% Bupivacaine or 0.5% Ropivacaine and found comparable time of onset of sensory and motor block. V A Peduto, et al⁽¹⁴⁾ studied 65 adult patients grading ASA I-III posted for elective lower limb procedures, all given 15ml of 0.5% epidural Levobupivacaine or 0.75% epidural Ropivacaine and founded that onset of sensory block was comparable in both the groups. Various studies shows that no statistical difference was found in onset of analgesia between the drugs as reported by Katz, Jeffrey A et al and A P Wolff et al.⁽¹⁵⁾

Duration of motor blockade was assessed from the time of administration of drug to complete motor recovery. In our study, the mean duration of motor block in Bupivacaine group was 280±70.9 minutes and in Levobupivacaine group was 278±74 minutes. There was no significant variation in duration of motor block between two groups. It was concluded that Levobupivacaine 0.5% produces an-epidural block of similar duration of motor block as the one produced by the same volume of 0.5% Bupivacaine.

The mean duration of sensory analgesia in Bupivacaine group was 393±73.6 minutes and in Levobupivacaine group was 385±72 minutes. conducted A study on 45 ASA I-III patients undergoing elective hip replacement surgery was conducted by Andrea Casati et al⁽¹³⁾ and compared epidural anesthesia with 10ml of 0.5% Levobupivacaine, 0.5% Bupivacaine or 0.5% Ropivacaine. There was no significant difference was found in duration of sensory analgesia comparing the groups. V A Peduto et al⁽¹⁴⁾ studied block characteristics on 65 patients of grade ASA 1-3 undergoing lower limb procedures. Patients were given Levobupivacaine 0.5% 15 ml or Ropivacaine 0.75% 15ml epidurally. Results (duration of sensory blockade) was comparable in both groups. Levobupivacaine has been used in higher concentrations that's is 0.75%and found that it provides a longer duration of blockade for both sensory and motor with decreased side effects.⁽¹³⁾

The highest sensory level of T7-T8 segment was found to be 60% & 51.4% respectively, among the members of each of the groups (as named B & L) respectively. The variation in the sensory level among the members of both groups, in respect of each of these segments was however not significant. Chandran S et al⁽¹⁶⁾ also reported that the mean maximum sensory level reached was T8 in Ropivacaine and Bupivacaine groups.⁽¹¹⁾ Few studies reported, Equal doses of Levobupivacaine and Bupivacaine (15 mL of 0.5%) provide maximum cephalic spread (T7-T8) and duration of analgesia (4-6 h).^(13,17)

Patients were hemodynamically stable peri-operatively.

Conclusion

Thus, from our study we can conclude that Onset of Sensory block for Levobupivacaine was longer as compared with Bupivacaine. Duration of analgesia was more in Bupivacaine. The highest sensory level of T7 segment was found to be with Bupivacaine then Levobupivacaine.

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