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Epidural Bupivacaine 0.5% and Ropivacaine 0.75% in Lower Limb Orthopedic Procedures : a comparative study

by

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Abstract

Background Epidural blockade is one of the most useful and versatile procedures in modern anaesthesiology. Bupivacaine a long acting amide local anaesthetic though widely used but associated with side effects like neuro and cardio toxicity. Ropivacaine, developed as a possible alternative to Bupivacaine, has lower lipophilicity hence associated with a decreased potential for neuro and cardiac toxicity .

Aims Study was done to compare the haemodynamic variations , onset time and duration of sensory and motor block and complications if any of epidural anaesthesia produced by bupivacaine 0.5% and ropivacaine 0.75% in patients undergoing lower limb surgery.

Methodology 60 patients, aged between 18-65 years, ASA I and II, undergoing various lower limb surgeries were randomly allocated in 2 groups of 30 each. The time for loss of pinprick at T10, intensity of motor block, duration of sensory and motor block and hemodynamic changes were assessedfor both the groups and compared .

Results The time of onset and duration of sensory block was comparable for both the drugs. Bupivacaine 0.5% produced more intensity and longer duration of motor block than ropivacaine 0.75% Both the drugs were comparable with respect to hemodynamic changes.

Conclusions Epidural ropivacaine 0.75% can be safely used as a possible alternative to bupivacaine 0.5% in lower limb orthopedic procedures.

Keywords : **Epidural Anaesthesia; bupivacaine; Ropivacaine; lower limb surgeries;**

Introduction

Epidural blockade is becoming one of the most useful and versatile procedures in modern anesthesiology. It is more versatile than spinal anesthesia, giving the clinician the opportunity to provide anaesthesia and analgesia, as well as enabling chronic pain management. It provides better postoperative pain control and more rapid recovery from surgery. For orthopaedic surgery, the provision of pain relief enables early post operative mobilization, accelerates rehabilitation and return to normal function**.** . It also decreases intraoperative blood loss, perioperative ischaemic events, postoperative hypoxic episodes & venous thrombosis offering an excellent sensory block. [1] Bupivacaine is commercially available as a racemic mixture containing equal

proportions of the S(-) and R(+) isomers. Despite its popularity, it is associated with a number of side effects like unwanted motor blockade, CNS and cardiotoxicity. There have been many reports of death attributable to bupivacaine induced cardiotoxicity after accidental intravenous injection. These cases resulted in the continued search for new and safer local anaesthetic agents.[2] Ropivacaine, a new long acting amide local anaesthetic was introduced as an answer to bupivacaine induced cardiotoxicity. Ropivacaine is developed as a pure S(-) enantiomer of propivacaine. It is less lipophilic than bupivacaine and is less likely to penetrate large myelinated motor fibres resulting in a relatively reduced motor blockade. This reduced lipophilicity is also associated with decreased potential for neuro and cardiotoxicity. Thus ropivacaine appears to be an important option for regional anaesthesia and for the management of post operative and labour pain.[3] The present study is designed to evaluate the time of onset and duration of sensory and motor blockade of ropivacaine 0.75% and bupivacaine 0.5% when administered epidurally for lower limb surgeries.

Material and method

After approval from ethic committee, 90 patients between the age group 18-65 years of ASA I and II physical status, scheduled to undergo various lower limb orthopedic procedures under epidural anaesthesia with anticipated duration of surgery more than 1hr were included and randomly allocated into two groups of 30 patients each. A prospective double blind study was conducted after taking an informed consent from the patients. Patients with a history of hypertension, diabetes, and liver disease,acute or chronic renal disease, known case of neurological disease, psychiatric disorders with anticipated difficult airway, neurosurgical and cardiovascular surgical cases and patients posted for emergency surgeries ,patients with BMI >28 kg/m^2 , patients shorter than 150 cm , infection at the site of injection , with congenital

anomalies of spine and patients with coagulation abnormalities , history of seizures and patients in shock were all excluded from the study. All patients included in the study were visited on the previous day of surgery and a detailed pre anaesthetic examination was carried out. An informed valid written consent was taken. Premedication with tablet lorezepam 2mg and ranitidine 150mg was given orally the night before surgery. Patients were asked to maintain nil per oral

status for at least 6 hours. In the operation theatre, baseline blood pressure and pulse was recorded. An 18 G IV cannula was inserted and all patients received 20 ml/kg of Ringers lactate solution to increase their circulating fluid volume before the epidural block. Patients were given left lateral position and under aseptic conditions skin was infiltrated with lignocaine 2% and 2 ml was given . Epidural space was located with 18 G Tuohy needle in L3-L4 space using the midline approach with loss of resistance technique and after negative aspiration for blood epidural space was located, 3ml of lignocaine test dose was administered to exclude intrathecal and intravascular placement of the needle. After 5 min period, the study drug was injected incrementally over 2 min and later patients were made supine. All assessments were made by an anaesthetist who did not know the drug used.

Measurement of blood pressure and pulse rate were recorded at 0,5,10,15,20 min and thereafter every 15min. Intraoperatively and postoperatively, complications like fall in blood pressure, variation in heart rate, respiratory rate and SpO2 were noted. Sensory blockade using pinprick sensation was assessed until complete loss of sensation at T10 (taken as onset of sensory block) and then every 2 min to determine the time taken for maximum height of block and there after every 15 min to determine the time for two segment regression and regression of sensory block at T12 taken as duration of sensory block. When sensory block reached T10 motor block was

assessed using a modified bromage score. (Table 1) Thirty was the number in each group, where any results could be statistically significant hence this number was selected. Student T-Test was used to find out significance between samples. Data was reported as mean value ±S.D. A P-value of < 0.05 was considered statistically significant, <0.001 as highly significant and > 0.05 as not significant.

Results

Demographic profile of three groups were similar regarding age , sex , height , duration of surgery (Table2) and ASA status of the patients. The mean time for onset of sensory block at T_{10} was 9.06 ± 3.82 min for group R and 8.7 ±2.95 min for group B (p=0.72). Time for regression of sensory block to T_{12}(duration of sensory block) was 194 ±11.93 min and 190 ± 11.30 min for group R and group B respectively (p=0.37) (table 3). In group R, 13 patients (43.33%) had a maximum height of sensory block up to T_6, 8 patients (26.66%) upto T_7 and 9patients (30%) up to T_8. In group B, 11 patients (36.66%) had a maximum sensory block upto T_6, 6 patients (20%) up to T7 and 12 patients (40%) upto T_8 and one patient (3.33%) upto T_5 (table 4). Statistical analysis by chi squared test shows that the two groups are comparable (p>0.05) Total duration of motor block was 130 ±11.31 min in group R and 157 ± 12.09 min in group B(p < 0.001) When the sensory block reached $T_{10,}$ the mean modified Bromage grade of motor block achieved in group R was 2.1 and in group B was 1.6(p=0.002) Statistical analysis using students unpaired t-test shows that this difference is statistically significant (Table 5). Changes in heart rate, blood pressure and respiration were similar between the groups.

DISCUSSION

Orthopedic surgeries are usually associated with perioperative pain which is a potent trigger for the stress response and autonomic system and is thought to be an indirect cause of various adverse effects like myocardial ischaemia, infarction, thromboembolic phenomena, impaired pulmonary function, ileus, fatigue, muscle catabolism, postoperative infection and postoperative confusional states. Epidural anaesthesia and analgesia is considered by many as the gold standard technique for major surgery. It has the potential to provide complete analgesia for as long as the epidural is continued. Epidural techniques are particularly effective at providing dynamic analgesia, allowing the patient to mobilize and resume normal activities unlimited by pain. It also improves the postoperative outcome and attenuates the physiologic response to surgery, in particular, significant reduction in pulmonary infections, pulmonary embolism, ileus, acute renal failure and blood loss.[4]

Bupivacaine is an excellent drug for epidural anaesthesia, but its major disadvantage is its cardiotoxicity when used in high volumes required for epidural block. Ropivacaine is a long acting regional anaesthetic which has been developed for the purpose of reducing the potential toxicity associated with bupivacaine. It is developed as a pure S(-) enantiomer. R and S enantiomers of local anaesthetics have been demonstrated to have a different affinity for the different ion channels of sodium, potassium and calcium which results in a significant reduction of CNS and cardiac toxicity of the S(-) compared to R(+) enantiomers.[3,5,6] The present study included 60 patients of ASA I and II physical status aged between 18-65 yrs, undergoing various orthopedic procedures on the lower limb under epidural anaesthesia. The mean age incidences and sex distribution between the groups were comparable. The mean height, weight and duration of surgery were similar. We found that the onset of sensory block with ropivacaine and bupivacaine was comparable. Studies have shown that that there was no statistical difference in

the onset of analgesia between the drugs.[8,9] We have used 15ml volume of both the drugs and our study demonstrated that in the ropivacaine group 43% patients had a maximum dermatomal level of sensory block to T6 and 30% to T8. In the bupivacaine group 37% had a maximum height of block to T_6 and 40% to T_8. Thus the maximum height of sensory block between the two groups was comparable when equal volumes were used. Similarly, A P Wolff et al[8] in their study found out that the maximum cephalad spread between the two groups was comparable. They had used 20ml volume of ropivacaine and bupivacaine and the maximum cephalad spread was T_4 with both the drugs.

Time for two segment regression was similar for both the drugs in our study. Wahedi et al[9] in their study also observed that the two segment regression time was 140 ± 60 min for bupivacaine 0.5% and 124 ± 29 min for ropivacaine

0.75% and were comparable. We found that our results are in contrast to the results obtained by Katz et al[7] who observed that the times to two segment regression were 2.7 ± 0.8 hours with bupivacaine 0.5% and 3.4 ± 1.0 hours with

ropivacaine 0.75%, which was significantly longer than bupivacaine.

We have studied the duration of sensory block upto its regression to T_{12} ad sie the duration of surgery was approximately 118minand mean time of regression of sensory block at t12 was 194 min the supplemental analgesia was given with injection tramadol 50 mg intravenously so that the patient doesn't have discomfort with the various orthopaedic positions used. The time for regression of sensory block to T_{12} was similar for both the drugs and we were unable to demonstrate any statistically significant difference between the groups. Studies by D P McGlade et al[10] and Katz et al[7] also have shown that time for regression of sensory block to T_{12} was similar for both the drugs

In our study, the mean modified Bromage grading of motor block was 1.6±0.6 with bupivacaine and 2.1±0.7 with ropivacaine when the sensory block reached T_{10}. As this difference was found to be statistically significant, bupivacaine group is said to have a higher intensity of motor block than ropivacaine. Ropivacaine is less lipophilic than bupivacaine and is less likely to penetrate the large myelinated motor fibres resulting in a relatively reduced motor blockade. Thus it has a greater degree of motor and sensory differentiation which is useful when motor blockade is undesirable.[3,5,6] Similar results have been reported in studies by Andrea Casati et al[11] and L M M Morrison et al.[12] This is in contrast to studies done by D P McGlade et al[10]and David L Brown et al[13]who failed to demonstrate a significant difference in the intensity of motor blockade between the two drugs. We have assessed the motor block when the sensory block reached T_{10} and then evaluated at the end of surgery only because of a possible interference with the surgeon during the procedure. This may explain why some of the patients had an inadequate motor block before the surgery. No problems were reported by the surgeons during the procedure. The total duration of motor block was 130±11.31 min for ropivacaine and 157±12.09 min for bupivacaine. This difference was found to be statistically significant. Hence, ropivacaine has a shorter duration of motor block than bupivacaine. Our results are similar to a study done by David L Brown et al[13] where the duration of motor block with 20 ml of 0.5% ropivacaine was 220 ± 52 min and 0.5% bupivacaine was 276 ± 52 min which was longer. This is in contrast to D P McGlade et al[10] who failed to demonstrate a significant difference in the duration of motor blockade when 0.5% concentration of the drugs were used.

We observed that there was a fall in the systolic and diastolic blood pressure below the baseline after epidural administration at various intervals in both the groups. But this difference was not statistically significant ($p>0.05$). Two patients in group R and three patients in group B had

clinically significant hypotension (SBP<30% baseline) which was corrected with IV mephentermine 6mg bolus. Pulse rate was

assessed at various intervals after the administration of epidural anaesthesia and the change in mean pulse rate between the groups was not statistically significant (p>0.05). one patient in each group had bradycardia (heart rate <60) which was corrected with IV atropine 0.5mg bolus. There was no difference in the respiratory rate between the groups when measured at various intervals after administration of epidural anaesthesia. (p>0.05) Our results correlate with studies done by D P McGlade et al[10] and David L Brown et al[13] who also observed that there was no statistically significant difference between the groups with respect to hemodynamic changes.

CONCLUSIONS

Results of this study demonstrate that there was no statistically significant difference in the onset and duration of sensory blockade between ropivacaine 0.75% and bupivacaine 0.5%. the cardiovascular changes ie the heart rate and blood pressure changes were similar between the groups. Bupivacaine 0.5% produced more intense motor blockade of longer duration compared to ropivacaine 0.75%.

In conclusion, epidural ropivacaine 0.75% can be safely used as a possible alternative to bupivacaine 0.5% in lower limb orthopedic procedures.

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Table 1: Modified Bromage Scale	
Score	Description
1	Complete block (unable to move feet / knees)
2	Almost Complete block (able to move feet only)
3	Partial block (just able to move knees)
4	Detectable weakness of hip flexion while supine (full flexion of knees)
5	No detectable weakness of hip flexion while supine
6	Able to perform partial knee bend

Table 2 : Demographic profile and duration of surgery in the two groups			
	Ropivacaine n=30	Bupivacaine n=30	Significance
Age (yrs)	30.2 ± 9.15	32.9 ± 9.43	ns
Height (cm)	158.9 ± 3.6	160 ± 3.4	ns
Weight (kg)	56.73 ± 7.52	58.93 ± 8.22	ns
Sex (male /female)	18/12	17/13	ns
Duration of surgery (min)	118.8 ± 23.6	114.7 ± 16.2	ns

Table 3: sensory block			
	Ropivacaine n=30	Bupivacaine n=30	P value
Onset of sensory	9.06 ± 3.82	8.76 ± 2.95	0.73 (ns)

block(min)			
Time for maximum height of sensory block (min)	15.76 ± 5.29	15.1 ± 5.43	0.63 (ns)
Time of two segment regression (min)	100 ±13.34	102 ±13.87	0.48 (ns)
Time for regression of sensory blockto T12 (duration of sensory block)(min)	194 ± 17.93	190 ± 11.47	0.37 (ns)

Table 4 : Maximum height of sensory block at segmental level : no o patients

	Ropivacaine n=30	Bupivacaine n =30	P value
T_5	-	1(3.33)	> 0.005
T_6	13 (43.33%)	11 (36.66%)	
T_7	8(26.66 %)	6 (20 %)	
T_8	9(30 %.)	12 (40 %)	

Table 5: motor block

	Ropivacaine n=30	Bupivacaine n=30	P value
Total duration of motor block (min)	130± 11.31	157 ± 12.09	< 0.001 (HS)
Modified Bromage grading of motor block	2.1	1.6	0.002 (s)

Table 6: Incidence of complications- number of patients in each group

	Ropivacaine	Bupivacaine
Hypotension	1	3
Bradycardia	1	1
Nausea Vomiting	3	3