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Original Research Paper

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"COMPARISON OF ANAESTHETIC EFFECT OF INTRATHECAL ISOBARIC LEVOBUPIVACAINE 0.5% VERSUS ISOBARIC ROPIVACAINE 0.75% FOR LOWER LIMB ORTHOPEDIC SURGERIES"

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ABSTRACT

Background: This study was undertaken to compare anaesthetic effect of intrathecal isobaric levobupivacaine 0.5% and isobaric ropivacaine 0.75% in lower limb orthopedic surgeries with regards to onset, duration of sensory-motor block and side effect profile. **Methods:** We allocated 80 patients into two groups to receive subarachnoid block of 3-ml 0.5% isobaric levobupivacaine (group L) or 3-ml 0.75% isobaric ropivacaine (group R). The onset and duration of sensory and motor block, regression of sensory block, duration of analgesia and side effects were recorded. Haemodynamic parameters observed till 24 hours postoperatively. **Results:** The mean time of onset of sensory block was more in group A (5.50±2.42 min) compared to group B (4.2±1.38 min) (p=0.0042). The mean time to reach maximum level of sensory block was significantly higher in group A (9.7 min) compared to group B (7.28 min) statistically (p=0.0087). The mean time of regression of sensory block up to L1 was significantly more in group B (128.28±37.23 min) compared to group A (108.78±25.46 min) (p=0.0077). The mean time of onset of motor block of Bromage score 2 was significantly more in group A (5.2±1.2 min) compared to group B (4.58±1.20 min) (p=0.023). There was significant difference in the mean VAS score in between the groups A and B at 1 hour, 4hrs,and 8 hrs (P<0.05). No significant difference observed in side effect profiles in between group A and B. **Conclusion:** We conclude that both intrathecal isobaric 0.75% ropivacaine and 0.5% levobupivacaine in lower orthopedic surgeries possess similar block characteristics except difference in their time to onset, attainment of maximum level for sensory block and onset of motor block which was significantly shorter with levobupivacaine compared to ropivacaine. Time to regression of sensory block was prolonged in levobupivacaine than ropivacaine.

KEYWORDS : Ropivacaine, levobupivacaine, analgesia, subarachnoid block, sensory, motor.

INTRODUCTION

Several orthopedic surgeries such as fracture such as lower limb and artheroscopic surgeries are commonly performed under spinal anaesthesia and mostly procedures last for 2 to 3 hour. Required level of surgical anaesthesia is upto T8-T10 level.

Ropivacaine and levobupivacaine are the recently introduced local anaesthetic drugs. Ropivacaine is a long-acting amide and local anaesthetic agent that is less lipophilic than bupivacaine therefore less likely to penetrate large myelinated motor fibers, resulting in a relatively reduced motor blockade. Levobupivacaine, an amide local anaesthetic agent, is the isolated S-enantiomer of racaemic bupivacaine. It is the long acting, lower cardiotoxicity compared to bupivacaine and advantage of lesser motor blockade making it preferable when early mobilization is suggested.

Both the Levobupivacaine and Ropivacaine drugs are available as isobaric solutions in India

The present study was formulated to compare the anaesthetic effect of aintrathecal isobaric 0.5% levobupivacaine with intrathecal isobaric 0.75%ropivacaine for lower limb orthopaedic surgeries.

METHODS

We obtained approval from the institutional ethics committee and written informed consent from the subjects for participation in the study. A total of 80 patients, of either sex (ASA physical status I and II, age 18-60 years), weighing 50 to 80 kgs, height of 150 to 180cm who were scheduled to undergo elective lower limb orthopedic surgeries were analysed for the study. Patient refusing to participate or unwilling to give consent, any bleeding disorder and patient on anticoagulants, neurological and musculoskeletal diseas (history of epilepsy, raised intracranial pressure, intracranial tumor, myopathies, preexixting neuromuscular weakness etc), local infection at the injection site, history of any allergy to local anaesthetic agents, history of drug/alcohol abuse, patients with contraindication for regional anaesthesia and patients with history of cardiac illness (history of MI, heart block, significant arrhythmia or heart failure at the time of surgery) were excluded from the study. All patients were randomly allocated into 2 groups of 40 each; In group A: 22.5 mg (3 mL) of isobaric 0.75% ropivacaine was injected. In group B: 15 mg (3 mL) of isobaric 0.5% levobupivacaine was injected. All patients were examined during the pre-operative visit one day prior to surgery and were advised to remain NPO as per ASA fasting guidelines. In the operating room all the standard ASA monitors was attached to the patient including of pulse oximetry for saturation, non-invasive blood pressure monitoring (NIBP) and electrocardiogram (ECG). The baseline recording of vital parameters i.e. pulse rate, blood pressure and SpO2 were recorded. An 18 G intravenous cannula was inserted and a fluid bolus of 10 ml/kg RL was started. The procedure of SAB was explained to the patient. The subarachnoid puncture was performed at the L3-L4 intervertebral space with a 25G Quincke needle using the midline approach in sitting position after free flow of CSF and negative aspiration of the blood,the drug was injected in the subarachnoid space.

In the postoperative period hemodynamics of the patient and VAS was observed. In the postoperative period, injection paracetamol 1gm IV was given 8 hourly as a part of multimodal analgesia. If VAS exceeded more than 5, rescue analgesia injection tramadol 100mg was given. Side effects such as nausea, vomiting, shivering and pruritus were recorded. The following parameters were studied -: the onset of sensory block: time taken for maximum sensory, the time to regression of block to L1, the onset of motor block blockade ,the time to onset of complete motor bloackage and duration of

analgesia. haemodynamic parameters- pulse rate, SBP , DBP,MAP and arterial oxygen saturation (SpO2) were measured at baseline, intraoperatively and postoperatively.

RESULTS

Total 80 patients included in the study, demographic data in both groups were comparable. In our study, mean heart rate, mean systolic blood pressure, mean diastolic blood pressure, mean MAP (mean arterial blood pressure) were recorded at baseline (pre-operative), intro-operatively and post-operatively at various time intervals upto 24 hours after the surgeries. The heart rate, Mean systolic, mean diastolic and mean arterial blood pressures in both groups no differences statistically at any time intervals recorded (p>0.0 5). All observed parametres are summarized in table no 1 and table no 2.

Table1- Mean onset and duration of motor and sensory block in both groups

Onset	Group A, time in mins, (mean ±SD)	Group B, time in mins, (mean ±SD)	Significance
Mean onset of sensory Block	5.50±2.42	4.2±1.38	(p < 0.05)
Time taken for maximum sensory blockade	9.7±4.42	7.28 ±.3.58	(p < 0.05)
The time to regression of block to L1	108±25.46	128.28±37.23	(p < 0.05)
Onset of motor block	5.2± 1.2	4.58±1.20	(p < 0.05)
The time to onset of complete motor bloackage	8.58 ±5.37	8.4±3.49	(p >0.05)
Duration of analgesia	218. 55±40.65	234.93±54.93	(p >0.05)

Table 2-Mean VAS Score:

Time Interval	Group A		Group B		P value
	Mean	Standard deviation	Mean	Standard deviation	
Post op	0.1	0.44	0.05	031	0.5628
1 hour	2.15	1.00	1.3	1.04	0.0004(S)
4 hours	3.85	0.80	3.2	1.16	0.0046(S)
8 hours	3.2	0.94	2.75	.98	0.0393(S)
12 hours	2.1	0.50	1.9	0.59	0.1060(NS)
18 hours	1.825	0.50	1.725	0.60	0.4205(NS)
24 hours	1	0	1.525	0.60	<0.0001(NS)

Table 3-Side Effects wise Distribution:

Side Effects	Group A	Group B
Bradycardia	3	1
Hypotension	3	3
Nausea	2	2
Shivering	5	4
Hypotension +Bradycardia	2	0
Total	15	10
P value	0.6992 (NS)	
Chi-square value	2.199 with df= 4	

DISCUSSION

The demographic characteristics such as age, height, weight and sex were comparable in the two groups. Of the total 80 patients included in the study, the mean age of patients in group B (38.65±13.02 years) ,group A (35.55±11.33 years) was no statistically significant difference (p>0.05) The patients were distribution among the two groups comparably equally with no statistical significant difference (p>0.05). Previous studies on comparsion of these two drugs also had patients with similar demographic characteristics.

In present study, we observed that the mean time of onset of sensory block was 5.50±2.42 min in group A as compared to 4.2±1.38 min in group B (p=0.0042). Mean time of onset of sensory block was significantly faster in group B. 65% patients of group A and 57.5% of group B achieved T6 level as the maximum level of sensory block which was found to be comparable in both groups statistically (p>0.05). The mean time to reach maximum level of sensory block was observed to significantly higher in group A (9.7± 4.42 min) as compared to group B (7.28±3.58 min)(p=0.0087). The mean time of regression of sensory block up to L1 was found to be significantly more in group B (128.28±37.23 min) as compared to group A (108.78±25.46 min) (p=0.0077). The mean duration of analgesia was recorded and found to be comparable statistically in both groups; i.e., 234.93±54.50 min in group B and 218.55±40.65 min in group A (p>0.05)

Samar et al observed that the mean onset of the sensory block with levobupivacaine (6.97 ±1.82 mins) was significantly faster than with ropivacaine (8.47 ±2.55 mins), p<0.05, and the mean duration of the sensory block with levobupivacaine (147.63 ±27.53 mins) was significantly longer than with ropivacaine (97.40 ±12.38 mins), p<0.05. **Mantouvalou et al** reported that the time to achieve maximum surgical analgesia with 3 ml of 0.5% isobaric levobupivacaine was 11±6 minsand 2-segment regression time of sensory blockade was 65 ±11 min. **Mehta et al** reported faster onset of sensory block with levobupivacaine (4.38± 1.53) compared to ropivacaine (5.45±1.0 min**). D'Souza et al** reported that the onset of the sensory block with 3 ml of 0.5% levobupivacaine was 5.50 ±4.25 mins, and it was 5.25 ±4.00 mins with 3 ml of 0.75% ropivacaine.

Our study findings showed that 15 mg isobaric 0.5% levobupivacaine has faster onset and prolonged duration of sensory block compared to 22.5 mg isobaric 0.75% ropivacaine. Levobupivacaine and ropivacaine are amino-amide local anesthestic drugs and are S-enantiomer of bupivacaine. The pKa of both these drugs is 8.1, so both have almost similar pharmacological characteristics. However the disparity between the two drugs in onset and duration of block may be attributable to liposolubility of these two drugs. Ropivacaine has pipecoloxylidide with 3-carbon chain and levobupivacine has a 4-carbon side chain which explains the different lipid solubility of these drugs which might somewhat explain our study results. Our study results are in accordance with research done on these two drugs previously.

In current study, it was observed that the mean time of onset of motor block (bromage score 2) was significantly more in group A (5.2±1.2 min) as compared to group B (4.58±1.20 min) (p=0.023). The mean time to onset of maximum motor block was observed to be comparable in both groups statistically (p>0.05); in group A, being 8.58±5.37 min and in group B being 8.4±3.49 min. The mean duration of motor block was observed to be comparable in both the groups {(211.23±54.25 min and (199. 4±40.04 min) in group A and B respectively (p>0.05)}.**Samar et al**reported the onset of motor block was quicker with levobupivacaine (10.27 ±1.92 mins) compared to ropivacaine (12.93 ±2.55 mins), p<0.05, and the mean duration of motor block was longer with levobupivacaine (207.33 ±22.27 mins) as compared to ropivacaine (146.60 ±21.22 mins), p<0.05. **D'Souza et al** found that the median onset of Bromage 3 with 0.5% levobupivacaine (isobaric) was five mins compared to 18 mins with 0.75% ropivacaine (isobaric), which was statistically significant. **Mantouvalou et al** and **Fattorini et al** found that the onset of Bromage 3 with

0.5% isobaric levobupivacaine was 11 ±7 mins and 11 ±6 mins respectively**. D'Souza et al** found that the median duration of Bromage 3 motor block with 0.5% levobupivacaine (isobaric) was 240 mins, and it was 195 mins with 0.75% ropivacaine (isobaric). **Fattorini et al**found that regression of motor block from Bromage 3 to 2 in the 0.5% levobupivacaine (isobaric) group was 256 ±6 mins**. Mantouvalouet al** found that regression of motor block from Bromage 3 to 2 with 0.5% levobupivacaine (isobaric) was 79 ±19 mins.

The difference in motor block might be explained due to difference in potency of these two drugs. Literature has reported the potency of the ropivacaine to that of levobupivacaine was approximately 2:3. Our study finding showed that levobupivacine has prolonged motor block compared to ropivacaine.These study results are also in concordance with previous studies.

There was significant difference in the mean VAS score in between the groups A and B at 1 hour, 4hrs,and 8 hrs there after not significant difference .the mean of vas score was significantly higher in group A compare to group B. ($P<0.05$).

Similar results obtained by **suresh kumar et al** vas score was significant in group R at 1 hr and and 4hr compared to group B ($p<0.05$)

In our study, mean heart rate, mean systolic blood pressure, mean diastolic blood pressure, mean MAP (mean arterial blood pressure) were recorded at baseline (pre-operative), intro-operatively and post-operatively at various time intervals upto 24 hours after the surgeries. Fall and subsequent rise inmean heart rate was observed which was observed to be gradual and smooth. The heart rates were observed to be comparable in both the groups statistically ($p>0.05$) at all the intervals. Mean systolic, diastolic and mean arterial blood pressureswere also observed to gradually falling and subsequently rising, similarly in both groups with no differences statistically at any time intervals recorded ($p>0.05$).

Samar et al also stated that both the fall and the subsequent rise in mean pulse rate intraoperatively with levobupivacaine was more gradual as compared to the fall and rise with ropivacaine; however, it was not statistically significant. They noticed a steeper rise in pulse rate with ropivacaine at two hours which suggested early wearing off of the subarachnoid block. They reported that in their study, SBP demonstrated a greater fall from the baseline intraoperatively in group R compared to group L until 90 mins. The SBP in both groups reached the lowest value at approximately the same time around two mins. However, steeper rise in mean SBP in group R at 165 mins suggested early wearing off of subarachnoid block with ropivacaine. Results suggest that the haemodynamic effects of levobupivacaine are relatively more stable than the more labile effects of ropivacaine.

Total 25 cases of side effects were seen in 80 patients in the current study as mentioned in table no 3.

CONCLUSION

We conclude that both intrathecal isobaric 0.75% ropivacaine and 0.5% levobupivacaine in lower orthopedic surgeries possess similar block characteristics except difference in their time to onset, attainment of maximum level for sensory block and onset of motor block which was significantly shorter with levobupivacaine compared to ropivacaine. Time to regression of sensory block was prolonged in levobupivacaine than ropivacaine. Duration of analgesia and motor blockade were comparable.

Limitation

As it is said, no one is perfect, our study also has certain limitations-

1. The main limitation of this study was the heterogeneity of surgical procedures
2. In our study was conducted on healthy subject ASA grade 1and 2 these study results may not be generalized to pregnant patients or patients having systemic illness.
3. We didn't measure the plasma concentration of study drugs, so systemic adverse events attributable to these drugs and their correlation with plasma concentration could not be ascertained.
4. We didn't assessed neurological complaint such as paraesthesia,numbness and focal neurological deficit in lower limb.

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