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COMPARATIVE STUDY OF INTRATHECAL PLAIN 0.5 % AND 0.75% ROPIVACAINE FOR LOWER LIMB ORTHOPAEDIC SURGERIES

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ABSTRACT

Aim and objective: In this study we compared the quality of spinal anaesthesia with two different concentrations of plain ropivacaine. **Methods:** 100 ASA I and II patients scheduled for elective lower abdominal and lower limb surgeries under spinal anaesthesia were enrolled. They were divided into two groups, Group A received 3ml of 0.5% plain ropivacaine and group B received 3ml of 0.75% plain ropivacaine. Onset, maximum blockade, time for maximum blockade and total duration of sensory and motor blockade, total duration of surgery, total duration of analgesia and side effects were noted. **Results:** Onset of sensory and motor blockade was similar in both the groups, median upper level of analgesia obtained with 0.5% was T10 and with 0.75% was T8. The median duration of sensory blockade was 180 min in group A and 240 min in group B. Incidence of complete motor blockade was higher and median total duration longer in 0.75% group (180 min in group B and 120 min in group A). Hemodynamic changes were minimal in both groups. No side effects were found. **Conclusion:** We conclude that intrathecal plain ropivacaine 0.75% results in good quality of sensory and motor block than 0.5% for orthopedic surgeries.

KEYWORDS: Ropivacaine, intrathecal, motor blockade, orthopaedic surgeries.

INTRODUCTION

Ropivacaine a new long-acting amide local anaesthetic agent, is a pure S-enantiomer, with a high pKa and relatively low-lipid solubility.[1] Ropivacaine provides effective spinal anesthesia for lower limb and hip surgeries.[2] Plain solutions are less reliable for surgery above a dermatomal level of L1.[3] the objective of the current study is to establish the reliability and efficacy of plain 0.5% and 0.75% intrathecal ropivacaine in patients undergoing lower limb surgeries.

MATERIALS AND METHODS

After approval of Institutional Ethical Committee, a prospective, randomised, double-blind study was conducted on 100 patients undergoing major lower limb orthopaedic surgeries. Written informed consent was obtained from all patients. Inclusion criteria include - patients of American Society of Anaesthesiologists physical Status I or II of either sex, aged between 18 and 60 years, presenting for lower limb orthopaedic surgery. Exclusion criteria were - patients having contraindications to spinal anaesthesia, a resting heart rate of <60 per min, allergy to amide local anaesthetic, a significant history of substance abuse and pregnant women. The study was conducted in 100 patients over a period of 12 months. They were randomly divided into two groups of 50 patients each by using the computer randomization table. Patients were randomly allocated to receive either intrathecal 3.0 ml of 0.5% Ropivacaine (Group A) or 3.0 ml of 0.75% Ropivacaine (Group B).

Following arrival into the operation theatre, intravenous access was established. Electrocardiogram, blood pressure and pulse oximeter readings were recorded. After ensuring sterile conditions, spinal anaesthesia was performed, and the patient received one of the two study drugs.

A decrease of more than 25% from the baseline in the systolic blood pressure was considered hypotension and decrease in the heart rate below 50 beats per min was considered bradycardia and treated with intravenous mephentermine and atropine respectively.

The level of sensory and motor block was evaluated every two minutes for 15 min and thereafter at 15 min interval for 6 hours. The sensory block level was evaluated with the pin prick test. The motor block level was assessed according to the Bromage Scale.

Grade	criteria	Degree of block
III	Unable to move feet and knees	Complete (100%)
II	Only able to move feet	Almost complete block (66%)
I	Unable to flex knees, but with free movement of feet	Partial (33%)
0	Unable to move legs or feet	Null (0%)

The sensory block in patients was assessed by recording maximum sensory block level, time to achieve maximum sensory block, and it's regression to L1 dermatome. The time to achieve maximum motor block and the duration of total motor block was recorded. Patients were observed for other side effects.

SPSS Statistics 20.0 software was used for statistical calculation. Statistical evaluation was performed using paired and unpaired t-test and analysis of variance. Data were presented as mean ± standard deviation and $P < 0.05$ was considered significant. Categorical data were analyzed using the Chi-square test.

RESULTS

The demographic data in both the groups were comparable in terms of age, gender, height, weight and duration of surgery. (Table 1).

Table 1. Demographic data

Parameter	GROUP A (mean± SD)	GROUP B (mean± SD)
Age (years)	40.64 ± 9.22	39 ± 9.73
Weight (kg)	61.26 ± 8.37	61.4 ± 6.8
Height (cm)	164.6 ± 6.72	165.18 ± 6.67
Gender (Male/Female)	31/19	35/15
Duration of Surgery (Min)	93.2 ± 21.98	95.7 ± 17.85

Values are in mean ± SD, both groups were comparable P > 0.05, not significant

Maximum Sensory level achieved: In Group A median level achieved was T_{10} and in Group B it was T_8. The difference obtained between the two groups was statistically significant ($P < 0.05$).

Mean time required to reach maximum sensory level in Group A was 14.7 ± 4.824 min and in Group B was 15.96 ± 5.086 min.

The complete motor blockade was however seen in 96% of patients in Group B, while score was 80% in Group A. In the rest of the patients 20% in Group A and 4% in Group B, Grade II motor was seen. The difference between them was found to be statistically significant ($P< 0.05$).

Mean time of segment regression to L1 of sensory analgesia in Group A was 92.56 ± 11.846 min and in Group B was 137.3 ± 13.06 min was statistically significant (P < 0.05).

Total Duration of Sensory Block was 184.5 ± 18.385 min in Group A and 238.8 ± 19.260 min and the difference were highly statistically significant.

The mean total duration of motor blockade in Group A was 120.3 ± 15.59 min and in Group B was 178.8 ± 16.053 min and difference was statistically significant.

Table 2: Spinal block characteristics

Parameters	Group A	Group B	P value
Highest sensory level (range)	T10 (T8 – T12)	T8 (T6 - T10)	0.032
Time to reach peak sensory Level (min)	14.7 ± 4.824	15.96 ± 5.86	0.2068
Time to reach max motor blockade (min)	17.02 ± 3.711	15.84 ± 3.786	0.095
Time for two segment regression (min)	92.56 ± 11.846	137.3 ± 13.06	< 0.0001
Total duration of motor blockade (min)	120.3 ± 15.59	178.8 ± 16.053	< 0.0001
Total duration of sensory blockade (min)	184.5 ± 18.385	238.8 ± 19.260	< 0.0001

Values are in mean ±SD, P > 0.05 non-significant, P < 0.05 significant, SD - Standard deviation, Group A - 0.5% Ropivacaine ; Group B - 0.75% Ropivacaine.

Nausea and vomiting was less in both groups. Number of patients requiring vasopressors for fall in blood pressure was three in Group A compared to five in Group B. One patient in Group A required Inj. Atropine for bradycardia while three patients in Group B required treatment for bradycardia. The difference was statistically insignificant (P > 0.05). Shivering was seen in both groups but it was insignificant. Headache was not seen in either group.

Table 3: Complications

Parameter	Group A	Group B
Nausea	2 (4%)	3 (6%)
Vomiting	1 (2%)	1 (2%)
Hypotension	3 (6%)	5 (10%)
Bradycardia	1 (2%)	3 (6%)
Shivering	4 (8%)	3 (6%)
Headache	0	0

Group A - 0.5% Ropivacaine; Group B - 0.75% Ropivacaine. Values are presented as number of patients and expressed in percentages.

Hemodynamic variables: Mean basal pulse rate in Group A was 79.44 ± 9.664 per min and in Group B was 77.76 ± 8.598 per min. Mean minimal pulse rate in Group A was 68.30 ± 1.225 per min and in Group B was 65.88 ± 1.123 per min. Mean maximum pulse rate in Group A

was 86.34 ± 9.316 per min and in Group B was 82.8 ± 8.831 per min. Thus mean Basal, Minimal and Maximum pulse rate were comparable in both the groups.

Mean basal systolic arterial pressure was 129.2 ± 8.211 mm Hg in Group A and 127.92 ± 8.609 mm Hg in Group B. However, mean minimal systolic arterial pressure was 115.76 ± 11.39 mm Hg in Group A and 111.48 ± 13.098 mm Hg in Group B. Thus decrease in systolic blood pressure in Group B was more than in Group A, but this difference was found to be statistically not significant.

Mean basal diastolic blood pressure was 78.4 ± 6.033 mm Hg in Group A and 78.88 ± 5.88 mm Hg in Group B. Mean minimal diastolic blood pressure was 67.88 ± 7.28 mm Hg in Group A and 69.36 ± 7.27 mm Hg in Group B. Both groups were comparable with no statistical difference.

Table 4: Hemodynamic variables

Parameters	Group A	Group B	P value
Basal pulse rate	79.44 ± 9.664	77.76 ± 8.598	> 0.05
Minimal pulse rate	68.30 ± 1.225	65.88 ± 1.123	> 0.05
Maximum pulse rate	86.34 ± 9.316	82.8 ± 8.831	> 0.05
Basal systolic Bp	129.2 ± 8.211	127.92 ± 8.609	> 0.05
Minimal systolic Bp	115.76 ± 11.39	111.48 ± 13.098	> 0.05
Basal diastolic Bp	78.4 ± 6.033	78.88 ± 5.88	> 0.05
Minimal diastolic Bp	67.88 ± 7.28	69.36 ± 7.27	> 0.05

Values are in mean ±SD, SD - Standard deviation, P > 0.05 non -significant, Group A - 0.5% Ropivacaine; Group B - 0.75% Ropivacaine, Bp- blood pressure.

DISCUSSION

The present study demonstrated that both group A and B provided satisfactory anaesthetic conditions for lower limb surgeries. Most sub-arachnoid block features being comparable. Eledjam JJ et al also mentioned that the primary benefit of ropivacaine is its lower toxicity, mainly lower cardiotoxicity, following accidental intravascular injection. For that reason, ropivacaine is a good choice for both intraoperative and postoperative regional anaesthesia and analgesia.[4]

McNamee *et al*. studied the efficacy and safety of two concentrations of intrathecal ropivacaine -7.5 mg/ml (18.75 mg) and 10 mg/ml (25 mg) for total hip arthroplasty. Intrathecal ropivacaine, in doses of 18.75 and 25 mg, was well tolerated and provided effective.[5]

A dose response study done by Lee *et al*. provided a useful guide for clinicians to choose optimal dose of the spinal ropivacaine under different clinical situations. They observed that the ED50 and ED95 for the spinal ropivacaine in lower limb surgery of 50 min duration or less were 7.6 mg and 11.4 mg respectively.[6]

Van Kleef et al in 1994 conducted a study on Spinal Anaesthesia with ropivacaine: A Double-Blind Study on the Efficacy and Safety of 0.5% and 0.75% Solutions in patients undergoing minor lower limb surgery study show that ropivacaine has good analgesic properties in the two concentrations used. Spinal anaesthesia with 0.75% ropivacaine provides the most satisfactory conditions for lower limb surgery.[7] Our results are consistent with Van Kleef *et al*. as we observed comparable levels of highest dermatome blocked, the time taken to reach the peak sensory and motor level and the duration of the sensory block. The motor block was significantly shorter with Group A (120.3 ± 15.59 min) as compared to Group B (178.8 ± 16.053 min). The mean time for sensory blockade is significantly prolonged in Group B as compared to Group A.

Malinovsky *et al*. compared intrathecal ropivacaine to bupivacaine in patients scheduled for trans-urethral resection of prostrate. They found that 15 mg of intrathecal ropivacaine provided similar motor and haemodynamic effects but less potent anaesthesia than 10 mg bupivacaine for endoscopic urological surgery.[8] In this study the hemodynamic changes observed in both the groups were minimal and no significant differences were found between the groups.In a comparative study conducted by Dwivedi P et al cardiovascular changes were similar in plain and hyperbaric roipvacaine groups.[9] Apart from hemodynamic changes other side effects observed were nausea, vomiting and shivering and were similar in both the groups.

Luck *et al*. used equal doses of hyperbaric ropivacaine, bupivacaine and levobupivacaine (15 mg) intrathecally for elective surgery and found that ropivacaine provided reliable spinal anaesthesia of shorter duration than bupivacaine and levobupivacaine and concluded that the recovery profile of ropivacaine may be useful where prompt mobilisation is required.[10]

CONCLUSION

This study concludes that plain ropivacaine when used intrathecally in the concentration of 0.5% and 0.75% provides adequate level of analgesia, excellent hemodynamic stability and a reliable muscle relaxation. Plain ropivacaine in concentration of 0.75% was found to be

having higher level of dermatomal blockade, good motor blockade and prolonged sensory and prolonged motor blockade in comparison with 0.5% concentration.

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