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Comparative Study of Efficacy of 0.5% and 0.75% Isobaric Ropivacaine for Spinal Anaesthesia in Patients Undergoing Elective Lower Limb Orthopaedic Surgeries

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ABSTRACT

Background: The present study was conducted in 100 patients randomly divided into 2 groups with 50 patients in each group (n=50). Group [R- 0.5]: will receive 3ml (15mg) of 0.5% isobaric Ropivacaine. Group [R- 0.75]: will receive 3ml (22.5mg) of 0.75% isobaric Ropivacaine.

Results: There was a statistically significant difference in the onset of sensory block with Ropivacaine 0.75% compared to Ropivacaine 0.5%. Faster onset were achieved with 0.75% compared to 0.5% Ropivacaine. There was no statistically significant difference in the time for maximum sensory block between the 2 groups. There was no statistically significant difference in the onset of motor block between the groups. Duration of analgesia is prolonged with Ropivacaine 0.75% compared to Ropivacaine 0.5% which was statistically significant. Duration of motor blockade is also prolonged with 0.75% compared to 0.5% Ropivacaine which was statistically significant.

Conclusion: 0.75% Ropivacaine produced better and prolonged sensory blockade with complete motor blockade compared to 0.5% Ropivacaine. Thus 0.75% Ropivacaine will be ideal for prolonged and extensive orthopaedic surgeries of the lower limb.

KEYWORDS

INTRODUCTION

Intrathecal anaesthesia and epidural anaesthesia are the most popular regional anaesthesia techniques used for lower limb orthopaedic surgeries. With spinal anaesthesia, the onset of anaesthesia is more rapid; allowing the surgical incision to be made sooner and also provides post operative analgesia. For decades Lignocaine had been the local anaesthetic of choice for spinal anaesthesia. Its advantages are rapid onset of action and good motor block, manifested as good muscle relaxation. Its use was limited by its short duration of action and has been implicated in transient neurologic symptoms and cauda equina syndrome following intrathecal injection.[2,3]In 2009, Ropivacaine, an aminoamide local anaesthetic, was introduced in India, though it was being used in other parts of the world since early 1990s. The advantage of Ropivacaine is that it produces less motor blockade, when used in lower doses and can be very useful for ambulatory surgeries.[6] As Ropivacaine has been recently introduced in India and not many studies have been done (India) regarding use of Ropivacaine for spinal anaesthesia. Ropivacaine is available as isobaric drug, in two concentrations of 0.5% and 0.75%. A study is required to know the effectiveness of these concentrations for spinal anaesthesia and if a lower dose of 15mg (3ml of 0.5%) intrathecally is also effective for spinal anaesthesia for lower limb orthopaedic surgeries. Hence, a study is needed to compare 0.5% and 0.75% isobaric Ropivacaine for spinal anaesthesia, keeping the volume of both the solutions constant at 3ml.

MATERIAL AND METHODS

One hundred patients aged between 18 years and 60 years of either sex belonging to ASA Class I and Class II posted for elective lower limb orthopaedic surgeries at National Institute of Medical Science and Research, Jaipur, were selected for the study after taking an informed consent. The study population was randomly divided by sealed envelope method into 2 groups with 50 patients in each group (n=50). Group [R- 0.5]: will receive 3ml (15mg) of 0.5% isobaric Ropivacaine. (Ropin0 .5%, Neon Laboratories India Ltd). Group [R- 0.75]: will receive 3ml (22.5mg) of 0.75% isobaric Ropivacaine. (Ropin 0.75%, Neon Laboratories India Ltd). The patients were premedicated with tablet alprazolam 0.5 mg and tablet ranitidine 150 mg orally at bed time on the previous night before surgery. They were kept nil orally from 10 pm onwards on the previous night. Intravenous line was obtained with a 18-gauge cannula and patients were preloaded with Ringer lactate 500 ml half an hour before anaesthesia. Monitoring was done using multiparameter monitor having pulse oximetry, ECG, NIBP and SPO_2. Patients were placed in sitting position. Under aseptic precautions lumbar puncture were performed at the level of L3-L4 through a midline approach using 25 G Quincke spinal needle and study drug was injected after confirmation of needle tip in the subarachnoid space by free flow of CSF and bevel of the needle facing cephalad. The study drug was injected. Patients were made to lie down in the supine posture immediately after the subarachnoid injection of the study drug, keeping the table flat. All patients were given supplementary oxygen through a venti mask.

The following parameters were noted.

- Onset of sensory blockade and motor blockade.
- Maximum level of motor blockade attained and the time taken for the same.
- Total duration of sensory blockade and motor blockade.
- Quality of motor blockade was assessed by modified Bromage scale.
- Total duration of surgery, total duration of analgesia and motor blockade and any adverse effects were noted.

All patients were monitored during the surgery and peri-operative period till complete sensory and motor recovery, employing multi parameter monitor which displays heart rate, systolic blood pressure (SBP) diastolic blood pressure (DBP), mean arterial pressure (MAP), ECG and SPO_2. The results of the study were statistically analyzed between the two groups.

OBSERVATION AND RESULTS

There was no statistical significant difference in the age wise distribution, sex distribution, height of the patients, types of orthopaedic surgical procedures in both the groups. The mean time of onset of sensory blockade at T 10 in Ropivacaine 0.75% group is 5.49±1.27 mins and in Ropivacaine 0.5% group is 8.02±0.6 mins. There is a statistical significant difference between the two groups regarding the onset of sensory blockade

(p=0.000), with the sensory onset being faster in Ropivacaine 0.75% group. (Table 1) The mean time taken for attaining the maximum sensory blockade is 15.73±4.34 mins in Ropivacaine 0.75% group and 15.37±4.54 mins in Ropivacaine 0.5% group. There is no statistical significant difference between the two groups (p=0.69). (Table 2) The mean duration of analgesia is 289.44±31.07 mins in Ropivacaine 0.75% group and 212.35±28.41 mins in Ropivacaine 0.5% group. There is a statistically highly significant difference between the groups (p=0.000). (Table 3) The mean time taken for the onset of motor blockade is 4.73±1.03 mins in Ropivacaine 0.75% group and 4.95±1.20 mins in Ropivacaine 0.5% group. There is no statistical significant difference between the groups (p=0.32). (Table 4) The Bromage scale attained by the patients in both the groups.(Table 5) Complete motor block (Bromage 4) was attained in 47 patients [out of 49 patients] in Ropivacaine 0.75% group whereas it was attained only in 37 patients [out of 48 patients] in Ropivacaine 0.5% group which was statistically significant (p=0.004). Three patients in Ropivacaine 0.5% group achieved Bromage scale of 2 only. The mean duration of motor blockade is 193.28±26.1 mins in Ropivacaine 0.75% group and 150.62±28.68 mins in Ropivacaine 0.5% group. There is statistically highly significant difference between the groups (p=0.000). Recovery from maximum motor block was faster in Ropivacaine 0.5% group compared to Ropivacaine 0.75%. (Table 6)

Table 1: Mean time for onset of sensory block (minutes)

	Mean	SD	p-value
Ropivacaine 0.75%	5.49	1.27	0.000
Ropivacaine 0.5%	8.02	0.6	

Table 2: Time for maximum sensory blockade (minutes)

	Mean	SD	p-value
Ropivacaine 0.75%	15.73	4.34	0.69
Ropivacaine 0.5%	15.37	4.34	

Table 3: Duration of analgesia [in minutes]

	Mean	SD	p-value
Ropivacaine 0.75%	289	31.07	0.000
Ropivacaine 0.5%	212.35	28.41	

Table 4: Motor onset (minutes)

	Mean	SD	p-value
Ropivacaine 0.75%	4.73	1.03	0.32
Ropivacaine 0.5%	4.95	1.20	

Table 5: Grade of motor blockade

	Ropivacaine 0.75% (Number of patients)	Ropivacaine 0.5% (Number of patients)	p-value
Bromage 2	0	3	0.004
Bromage 3	2	7	
Bromage 4	47	38	

Table 6: Duration of motor blockade (minutes)

	Mean	SD	p-value
Ropivacaine 0.75%	193	26.10	0.000
Ropivacaine 0.5%	150.62	28.68	

DISCUSSION

A study entitled "A Double Blind Comparative Study of Efficacy of 0.5% and 0.75% Isobaric Ropivacaine for Spinal Anaesthesia in Patients Undergoing Elective Lower Limb Orthopaedic Surgeries" to evaluate the sensory and motor blocking properties of Ropivacaine 0.5% (15 mg) and 0.75% (22.5 mg) both being isobaric solutions. In our study onset of sensory block is considered as loss of sensation at T10. The mean time for sensory block onset is 5.49 $\pm$1.27 mins in R 0.75 group vs. 8.02$\pm$1.6 mins in R 0.5 group. This is statistically significant (p=0.000) Our study does not correlate with the studies conducted by van Kleef et al.[2] and Wahedi et al.[3] where there was no statistically significant difference in the time taken for onset of sensory blockade between 0.5% and 0.75% Ropivacaine. This is probably due to in both studies the onset of sensory block has not been properly defined. Onset of sensory block is 5.49$\pm$1.27 mins in Ropivacaine 0.75% group, in our study which compares with the study done by Gupta R et al.[7] (4.7$\pm$1.1 mins). In the study conducted by Gupta K et al.[8] it was found to be less than our study (3.5 ± 1.2 mins) because the dose used was higher [3.5 ml]. In our study the mean time for maximum sensory level is 15.73$\pm$4.34 mins in R 0.75 group vs. 15.37$\pm$4.54 min R 0.5 group. There is no statistically significant difference between the groups in the time taken for maximum sensory level. Our study agrees with the studies conducted by van Kleef et al.[2] and Wahedi et al.[3] where there was no statistically significant difference in the time taken for maximum sensory blockade between 0.5% and 0.75% Ropivacaine. Our results regarding 0.75% Ropivacaine (15.73$\pm$4.34 mins) are comparable with the studies conducted by van Kleef et al.[2] (18 mins) and Gupta R et al.[6](12.1$\pm$1.6 mins) regarding 0.75% Ropivacaine. Regarding 0.5% Ropivacaine our results [15.37$\pm$4.54 mins] are also comparable with the studies conducted by van Kleef et al.[2] (15 mins) and Mantouvalou M et al.[5] [12$\pm$9 mins]. In our study the duration of analgesia was 289.44+31.07 mins in R 0.75 compared to 212.35+28.41 mins in R 0.5 group which was statistically highly significant (p=0.000). Our study agrees with the studies conducted by van Kleef et al.[2] and Wahedi et al.[3] where duration of analgesia was statistically significant between 0.5% and 0.75% Ropivacaine. The mean time taken for the onset of motor blockade is 4.73±1.03 mins in Ropivacaine 0.75% group and 4.95±1.20 mins in Ropivacaine 0.5% group. There is no statistical significant difference between the groups (p=0.32). Our results agree with the results of Wahedi et al.[3] where they have found no statistical difference in the mean duration of motor onset. The onset of motor block in the study conducted by Atabeko lu et al.[4] where they have used 3 ml of 0.75% Ropivacaine, was found to be 4.57$\pm$2.57 mins which also compares with our study. In our study it was found that Ropivacaine 0.75% produced more intense motor blockade than Ropivacaine 0.5%. In Ropivacaine 0.75% group number of patients with grade 4 motor blockade[absence of movement in the toes- complete motor blockade] were 47 compared with only 38 patients in Ropivacaine 0.5% group. This is statistically significant (p=0.004) In the study conducted by Wahedi et al.[3] complete motor block was attained in all 20 cases of 0.75% Ropivacaine compared to 14 cases in 0.5% Ropivacaine group. This was statistically significant similar to our study. Similar findings were also found by van Kleef et al.[2] The duration of motor blockade in Ropivacaine 0.75% group is 193.28±26.10 mins compared to 150.62±28.68 mins in Ropivacaine 0.5% group. The duration of motor blockade with Ropivacaine 0.75% is more prolonged than with Ropivacaine 0.5% which is statistically highly significant (p=0.000). Duration of motor blockade was considered once the patient was able to lift his leg against gravity with flexing his knee (Modified Bromage score 0).[1] In studies conducted by van Kleef et al.[2] and Wahedi et al.[3] duration of motor block was 268 (145-415) mins [R-0.75] vs 178 (65-290) mins [R-0.5] and 230 mins [R-0.75] vs 160 mins [R-0.5] respectively in both studies, which was statistically significant which is comparable to our study. Our study of 0.75% Ropivacaine compares with the study conducted by Atabeko lu et al.[4] where the duration of motor blockade was 253.73$\pm$92.81mins

CONCLUSION

From the present study it can be concluded that

1. There was a statistically significant difference in the onset of sensory block with Ropivacaine 0.75% compared to Ropivacaine 0.5%. Faster onset were achieved with 0.75% compared to 0.5% Ropivacaine.
2. There was no statistically significant difference in the time for maximum sensory block between the 2 groups.
3. There was no statistically significant difference in the onset of motor block between the groups.
4. Duration of analgesia is prolonged with Ropivacaine 0.75% compared to Ropivacaine 0.5% which was statistically significant.
5. Duration of motor blockade is also prolonged with 0.75% compared to 0.5% Ropivacaine which was statistically significant.

Hence we can conclude that 0.75% Ropivacaine produced better and prolonged sensory blockade with complete motor blockade

compared to 0.5% Ropivacaine. Thus 0.75% Ropivacaine will be ideal for prolonged and extensive orthopaedic surgeries of the lower limb. However Ropivacaine 0.5% can be used for surgical procedures where complete motor blockade is not needed, e.g. knee arthroscopic surgeries where the surgeon needs movements of legs to identify the ligaments and in ambulatory orthopaedic lower limb surgeries.

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