International Journal of Research in Medical Sciences
Gupta HB et al. Int J Res Med Sci. 2016 Aug;4(8):3134-3140
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012
DOI: http://dx.doi.org/10.18203/2320-6012.ijrms20162227

Research Article

A prospective, comparative, observational study of quality of spinal anaesthesia with 0.5% and 0.75% plain isobaric ropivacaine in lower abdomen and lower limb surgeries

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Received: 30 June 2016
Accepted: 12 July 2016

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ABSTRACT

Background: Spinal anaesthesia or subarachnoid block remains one of the basic techniques in the arsenal of modern anaesthesiology. Aim of the study was to evaluate and compare quality of spinal anaesthesia with isobaric 0.5% and 0.75% intrathecal ropivacaine in patients undergoing lower abdominal and lower limb surgeries.
Methods: 100 patients between 18 and 60 years, of either gender belonging to ASA class I or II, posted for elective lower abdominal and lower limb surgeries, planned under spinal anaesthesia using ropivacaine. Patients were grouped as group A: 3 ml (15 mg) of 0.5% plain ropivacaine and Group B: 3ml (22.5mg) of 0.75% plain ropivacaine. Parameters observed were onset and duration of sensory and motor block, maximum sensory level achieved degree of motor blockade, two segment regression, and haemodynamic changes.
Results: No significant differences were noted in Mean time for onset and time to achieve maximum level of sensory and motor blockade in both groups. Maximal dermatomal level was T10 in group A and T8 in group B which was statistically significant. Also, 96% patients had grade III motor blockade in group B as compared to 80% in group A which was statistically significant. Significant differences were noted in Time for two segment regression (92.56±11.846 minutes in group A and 137.3±13.06 min in group B), the duration of sensory blockade (184.5±18.385 min in group A and 238.8±19.260 min in group B) and duration of motor blockade (120.3±15.59 min in group A and 178.8±16.053 min in group B).
Conclusions: Intrathecal isobaric ropivacaine 0.5% and 0.75% are safe and effective with minimal intraoperative and postoperative side effects. Recommended for short duration orthopaedic and lower abdominal surgeries where prolonged motor blockade is undesirable.

Keywords: Isobaric, Ropivacaine, Intrathecal, Motor blockade

INTRODUCTION

Spinal anaesthesia or subarachnoid block remains one of the basic techniques in the arsenal of modern anaesthesiology. The spinal anaesthesia has the potential for being uniquely safe anaesthetic technique due to the combination of profound analgesia, muscle relaxation and less systemic and metabolic disturbances. Preservation of airway, decrease blood loss and ability to provide residual postoperative analgesia are further advantages.[1] Spinal or intrathecal anaesthesia has a long history of success and is more popular, mostly due to an increasing number of ambulatory procedures and interventions, for which the ideal spinal anaesthetic would provide rapid and adequate surgical anaesthesia together with early ambulation to allow early discharge.

Bupivacaine is extensively used and produces an adequate sensory and motor blockade.[2] Although intrathecal bupivacaine has low incidence of

postoperative complications, it has selective cardiac effects which are more pronounced with R-isomer than S-isomer. These adverse effects have prompted a search for drugs with lesser toxicity. Newer long-acting local anaesthetics (ropivacaine, levobupivacaine) have been introduced for clinical use.

Ropivacaine is a long-acting, enantiomerically pure (S-enantiomer) amide local anaesthetic, with a low lipid solubility which blocks sensory nerve fibres (Aδ and C fibres) to a greater degree than those controlling motor function (Aβ fibres).[3]

Due to this property, Ropivacaine has consistently demonstrated an improved safety profile over bupivacaine, with a reduced CNS and cardio toxic potential.[4]

Most common preparations used in practice are hyperbaric in nature which is associated with cephalad spread due to gravity and increase in severity of autonomic blockade and its complications as compared to isobaric preparations whose spread is likely to be more dependent on other factors such as the currents produced by injection and simple diffusion and hence are restricted to the level of injection and less severe autonomic blockade.[5]

In this study, the quality and safety of isobaric preparations of 0.5% and 0.75% ropivacaine in lower abdominal and lower limb surgeries was evaluated.

METHODS

After permission from institutional ethics committee, the prospective comparative observational study was carried out in 100 patients aged between 18 years and 60 years, of either gender, belonging to ASA Class I or Class II, posted for elective lower abdominal and lower limb surgeries which were planned under spinal anaesthesia using ropivacaine. The study was conducted from June 2013 to May 2014.

Inclusion criteria were patients of either gender, aged between 18-60 years, belonging to ASA Class I or II, willing for spinal anaesthesia scheduled for elective lower abdominal and lower limb surgeries. Patients undergoing emergency surgeries and pregnant patients were excluded from the study.

Patients were grouped into two groups of 50 each.

- Group A: received 3ml (15mg) of 0.5% plain Ropivacaine.
- Group B: received 3ml (22.5mg) of 0.75% plain Ropivacaine.

A detailed Preoperative history and general examination was carried out in all patients All baseline investigations were noted and patients were explained about the proposed anaestheia technique and present study and written informed consent was taken. Patients were kept fasting overnight prior to surgery.

Patients were taken in operation theatre and vital parameters were monitored using multi parameter monitor having pulse oximetry, electrocardiogram, and non-invasive blood pressure. Intravenous line was secured with 18-gauge IV cannula and preloading was done with Ringer lactate 7 ml/kg IV.

The position of table was kept horizontal. Under all aseptic precautions, with patient in sitting position, lumbar puncture was performed at the level of $L_3 - L_4$ interspace through a midline approach using 25G quincke spinal needle and study drug ropivacaine 3 ml either 0.5% or 0.75% was injected after confirmation of needle tip in the subarachnoid space by free and clear flow of CSF. Patients were made to lie down in the supine position immediately with the table kept flat horizontally and supplementary oxygen at the rate of 4 lt/min by face mask was started.[5]

Sensory level was determined by pinprick method using sterile 24 gauge hypodermic needle. Sensations of pinprick were tested every minute from time 'Zero', which is injection of drug in subarachnoid space.

Maximum sensory dermatome level was tested by pinprick in midclavicular line every minute until the level stabilized for two consecutive tests. Afterwards sensory level was tested every 15 minutes until two segment regressions and up to complete sensory recovery and recorded.

Quality of motor blockade was assessed by modified Bromage scale.

- Grade 0-No Motor block.
- Grade I-Inability to raise the extended leg.
- Grade II-Inability to flex the knee, able to flex the ankle.
- Grade III-Inability to flex the ankle, complete motor blockade.

The following readings were noted for assessment of onset of blockade:

- Time for Onset of sensory blockade.
- Time for Onset of motor blockade**.**
- Time taken for maximum dermatomal sensory blockade.
- Maximum sensory level achieved.
- Quality of motor blockade.

In the Intra operative period Pulse Rate, Respiratory Rate, Blood Pressure, Oxygen saturation monitoring was done at 1,3,5,10,15 minutes and thereafter every 15 minutes till end of the surgery. In the perioperative period patients

received IV fluids according to the blood loss during surgeries by using standard method of correction. Hypotension was defined as reduction of Systolic Blood Pressure (SBP) more than 30% below baseline and was treated with

- O_2 supplementation via face mask at the rate of 4ltrs/ min
- Pushing IV fluids (200 ml bolus)
- Injection Ephedrine 6 mg IV

Bradycardia was defined as the heart rate less than 50 beats/minute and was treated with injection Atropine 0.6mg IV. Patients were also monitored for any side effects such as nausea, vomiting, shivering, and pruritus.

At the end of the surgery, patients were transferred to post anaesthesia care unit where the residual blockade was monitored. Time taken for two dermatome segment regression was noted for the duration of the sensory blockade. Duration of motor blockade was noted as the time taken for complete motor recovery. Patients were also observed for any adverse effects.

Statistical analysis

Sample size of 50 patients per group was calculated using power and sample size calculation.Parametric Data was expressed as Mean±Standard deviation. Analysis of data was done by using student's unpaired t-test for parametric data and Fischer exact test for categorical data. P value less than 0.05 was considered to be significant.

RESULTS

Both groups were comparable in the demographic characteristics such as age, height, weight, gender, and ASA classification (Table 1).

Table 1: Demographic characteristics.

Characteristics		Group A (0.5% Plain Ropivacaine)	Group B (0.75% Plain Ropivacaine)	p value
Age (years)		40.64±9.22	39±9.73	0.3895
Weight (kgs)		61.26±8.37	61.4±6.8	0.9271
Height (cms)		164.6±6.72	165.18±6.67	0.6662
Gender	Males	31 (62%)	35 (70%)	0.5269
	Females	19 (38%)	15 (30%)	
ASA	Grade 1	40 (80%)	38 (76%)	0.8097
	Grade 2	10 (10%)	12 (24%)	

Table 2: Time required for onset and maximum time for sensory and motor blockade.

Parameter	Group A	Group B	p value
Onset of sensory blockade (minutes)	2.06±0.6824	1.88±0.7182	0.2019
Time required for maximum sensory level (minutes)	14.7±4.8	15.96±5.86	0.2068
Mean time for onset of motor blockade (minutes)	7.84±2.902	6.8±3.057	0.082
Mean time to maximum motor blockade (minutes)	17.02±3.711	15.84±3.786	0.095

Table 3: Maximum dermatomal level of sensory analgesia.

Maximum level achieved (T)	Group A	Group B	P value
T_4	0	3 (6%)	0.0002
T_6	2 (4%)	11 (22%)	
T_8	14 (28%)	22 (44%)	
T_{10}	20 (40%)	12 (24%)	
T_{12}	14 (28%)	2 (4%)	

Time required for onset of sensory blockade was 1.88±0.718 minutes in Group B which was lesser than 2.06±0.68 minutes in Group A (P>0.05). The mean time required to reach maximum sensory level was earlier in Group A (14.7±4.8 minutes) than Group B (15.96±5.86 minutes), but this difference in both the durations was not statistically significant (P>0.05). The onset of motor blockade was clinically earlier in Group B (6.8±3.057 minutes) than Group A (7.84±2.902 minutes) (P>0.05) and the mean time required to achieve maximum motor blockade was greater in Group A (17.02±3.711minutes) than in Group B (15.84±3.786 minutes) and the

difference between the two groups was not statistically significant. (P>0.05) (Table 2). In majority of the patients, maximum dermatomal level of analgesia was between T_8-T_{10}. 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 found to be statistically significant (P < 0.05) (Table 3).

The complete motor blockade was however seen in 96% of patients in group B, as compared to 80% in group A. In the rest of the patients, i.e., 20% in group A and 4% in group B, grade II motor blockade was seen. The difference between the degrees of motor blockade achieved was statistically significant (Table 4).

Table 4: Modified bromage scale achieved.

Modified bromage scale	Number of Patients		P value
	Group A	Group B	
0	0	0	
I	0	0	
II	10 (20%)	2 (4%)	0.0277
III	40 (80%)	48 (96%)	
Total	50	50	

There was no significant difference in the pulse rate in both the groups. The decrease in systolic blood pressure in Group B was more than in Group A, but this difference was not statistically significant. No significant difference was noted in diastolic blood pressure, mean arterial pressure and oxygen saturation in both the groups (Table 5).

There was no significant difference in the pulse rate in both the groups. The decrease in systolic blood pressure in Group B was more than in Group A, but this difference was not statistically significant. No significant difference was noted in diastolic blood pressure, mean arterial pressure and oxygen saturation in both the groups (Table 5). Mean time for the two segment regression of sensory analgesia was greater in Group B (137.3±13.06 minutes) than Group A (92.56±11.846 minutes), and the difference between them was statistically significant (P<0.05). The mean total duration of sensory blockade was also greater in Group B (238.8±19.260 minutes**)** than group A (184.5±18.385 minutes), this difference being highly statistically significant. Also, the mean total duration of motor blockade was greater in Group B (178.8±16.053 minutes) than the Group A (120.3±15.59 minutes) and the difference between them was statistically significant (Table 6).

Table 5: Haemodynamic parameters.

Parameter	Group A	Group B	p value
Mean pulse rate (beats/min)	86.34±9.316	82.8±8.831	0.0540
Systolic blood pressure (mm hg)	115.76±11.39	111.48±13.098	0.0845
Diastolic BP (mm hg)	67.88±7.28	69.36±7.27	0.3121
Mean arterial pressure (mm hg)	83.92±7.922	83.38±8.436	0.52
Oxygen saturation	98.42±0.641	98.24 ± 0.591	0.1478

Table 6: Total duration of sensory and motor blockade.

Parameter	Group A	Group B	P value
Mean time for two segment regression (minutes)	92.56 ± 11.846	137.3 ± 13.06	< 0.0001
Mean total duration of sensory blockade (minutes)	184.5 ± 18.385	238.8 ± 19.260	< 0.0001
Mean total duration of motor blockade (minutes)	120.3 ± 15.59	178.8 ± 16.053	< 0.0001

Patients in whom level of analgesia was not adequate for the proposed surgery were given supplementation with opioids to make them comfortable. In our study, 7 patients in group A (14%) and 3 patients in group B (6%) required additional analgesia, but the difference was statistically insignificant. There were no significant differences in the incidence of nausea, vomiting, hypotension, bradycardia, shivering and headache between both the groups (Table 7).

Table 7: Adverse effects.

Adverse effects	Number Of patients (%)	
	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

DISCUSSION

Various local anaesthetics commonly used for spinal anaesthesia are lignocaine, bupivacaine, levobupivacaine, and ropivacaine. Nowadays, ropivacaine has been used successfully for spinal anaesthesia.

Ropivacaine is well tolerated after intrathecal use, and was found to have a shorter duration of action than bupivacaine. This property makes it a possible alternative to lignocaine for ambulatory surgery because of the low incidence of transient neurological symptoms (TNS).[6]

The reduced lipophilicity of ropivacaine is also associated with decreased potential for central nervous system toxicity and cardiotoxicity and when compared to bupivacaine, the lower lipid solubility of ropivacaine would predict that it is likely to produce a greater differential block of sensory and motor function than bupivacaine.[3,7]

Ropivacaine can be used in both isobaric and hyperbaric forms, though commercially only isobaric forms are available. When compared with the isobaric solutions, the hyperbaric preparations produced a higher, more consistent block with faster onset and recovery.[5,8]

Van Kleef et al conducted a study using 0.5% and 0.75% isobaric ropivacaine in patients undergoing lower limb surgery. They concluded that the duration of motor block and analgesia are dependent on concentration, where 0.75% ropivacaine provides satisfactory conditions for lower limb surgeries and 0.5% ropivacaine is suitable for transurethral or minor orthopaedic surgeries.[9] Gautier et al evaluated intrathecal ropivacaine for ambulatory surgery using 8mg of bupivacaine and 8,10,12,14mg of ropivacaine. They found that ropivacaine 12mg produced sensory and motor blockade comparable to bupivacaine 8 mg.[10]

Mc Namee et al studied two different concentrations, 18.75 and 25mg of isobaric ropivacaine in patients undergoing total hip arthroplasty. They observed that the mean time for onset of sensory block was similar in both groups, but the duration of sensory and motor block was significantly prolonged in the second group.[11]

In present study the onset of sensory blockade and motor blockade was similar in both the groups and the results were statistically insignificant. Similar findings were noted by Van Kleef et al, Wahedi et al.[9,12] Also, the time taken to achieve maximum sensory and motor blockade was similar in both groups. Rajani Gupta et al and Radhika rani et al had noted similar findings in their study.[7,13]

Maximum level of sensory blockade was found to be T10 in group A and T8 in group B and this difference was found to be statistically significant. Because isobaric solutions were used for the study the level remained restricted to lower segments and these findings were consistent with findings of Van Kleef et al, Wahedi et al.[9,12]

Complete motor blockade was obtained in 80% patients in group A as compared to 96% in group B in our study. Gautier et al had similar results and concluded that the degree of motor blockade increases with the increase in the dose of ropivacaine.[10]

These findings are also consistent with various other studies conducted by Van Kleef et al, Gautier et al, Mc Namee et al, which state that ropivacaine has got lesser motor blockade due to its low lipid solubility resulting in lesser penetration of thick motor fibres.[9-11]

The time taken for two segment regression of sensory blockade, total duration of sensory blockade and motor blockade were significantly prolonged in group B as compared to group A. This suggests that the duration of analgesia increases with increase in concentration of the drug. The same findings have been corroborated by Wahedi et al, Rajni Gupta et al.[9,13] There were no significant differences with respect to heart rate, respiratory rate and oxygen saturation in both the groups. Three patients in group A and five Patients in group B developed hypotension which was treated with fluid bolus and injection ephedrine.

Scott et al reported that ropivacaine caused less cardiovascular symptoms and was at least 25% less toxic than bupivacaine, with regard to the dose tolerated and cardiac depression that appeared at lower dosage on lower plasma concentration with bupivacaine compared to ropivacaine.[14]

Wahedi et al in their study had also observed similar findings on bradycardia, hypotension and headache in both the groups. Mac Namee et al observed that bradycardia was higher in the 1% ropivacaine group, suggesting an increase in side effects with increasing concentration of the drug.[9,11]

Mantouvalou M et al in 2008 noted that hypotension and bradycardia was found to occur more often with Bupivacaine group than with ropivacaine group, requiring higher use of sympathomimetic and vasopressor drugs.[15]

Bozkirly et al, in their study comparing equieffective doses of bupivacaine and ropivacaine in patients undergoing TURP, also noted lower incidence of bradycardia in ropivacaine group as compared to bupivacaine group.[16]

In our study with the use of 0.5% Plain Ropivacaine total seven (14%) patients required supplementation with opioids while with the use of 0.75% Plain Ropivacaine only three (6%) patients required supplementation. This requirement was mainly noted in lower abdominal surgeries and femur fracture repairs which required a greater degree of manipulation.

Van kleef et al also noted that spinal anaesthesia with 0.75% ropivacaine provides the most satisfactory conditions for lower limb surgery of intermediate duration, whereas 0.5% ropivacaine could be suitable for transurethral procedures or minor orthopaedic surgery. Similar findings were noted in other studies.[8,9,15,16,17]

CONCLUSION

Present study demonstrated that intrathecal isobaric ropivacaine 0.5% and0.75% are safe and effective with minimal intraoperative and postoperative side effects. The significantly shorter motor block duration with intrathecal plain ropivacaine might be advantageous because it allowed a faster discharge, and early recognition of neurological complications. It is recommended for short duration orthopaedic and lower abdominal surgeries where prolonged motor blockade is undesirable. This maybe particularly advantageous in day care surgeries.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Gupta HB, Amilkanthwar SN. A prospective, comparative, observational study of quality of spinal anaesthesia with 0.5% and 0.75% plain isobaric ropivacaine in lower abdomen and lower limb surgeries. Int J Res Med Sci 2016;4:3134-40.