

Intrathecal ropivacaine vs bupivacaine in endoscopic urological surgeries

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Aims: To compare sensory, motor effects and haemodynamic stability of 2ml intrathecal isobaric ropivacaine (0.75%) with 3ml hyperbaric bupivacaine (0.75%) in patients undergoing endoscopic urological surgery.

Study Design: Randomized controlled trial involving 142 patients undergoing transurethral resection of prostate (TURP) and URS (urethroscopy) in a tertiary care hospital, India.

Methods and materials: Patients were randomly allocated to, Group 1 (3ml of 0.5% (15mg) hyperbaric bupivacaine) and Group 2 (2ml of 0.75% isobaric ropivacaine(15mg)). Onset and highest level of sensory block, onset and duration of motor block, quality of anaesthesia and muscle relaxation, haemodynamic parameters and adverse effects if any were studied. Statistical analysis used: Unpaired t-test was used to test continuous variables and chi square test/Fisher's exact test for categorical variables.

Results: The mean of highest sensory block, 2 segment regression of sensory block and time for sensory level to regress below T10 was significantly more in group 1 compared to group 2 (P<0.05). There was a significant delay of mean time to onset of motor block to Bromage score 1 in group 2(P<0.001). The mean duration of complete motor blockade was significantly more in group 1 (P value <0.001). Hypotension was most commonly seen in group 1.

Conclusion: Ropivacaine provides comparable quality of sensory block but has slower onset and significantly shorter duration of motor block compared to hyperbaric bupivacaine.

Keywords: Subarachnoid anaesthetic techniques; bupivacaine; ropivacaine; intrathecal; postoperative analgesia

Introduction

Subarachnoid block (SAB) is a regionally acting local anaesthetic mainly used for performing transurethral resection of prostate and urethroscopy (URS).¹ Bupivacaine has high potency and minimal neurological symptoms. However in high concentration it is cardiotoxic.^{2,3} Ropivacaine has lesser cardiotoxicity and has shorter motor block duration.⁴ Many studies have compared the two drugs but with varying results especially with regard to duration of sensory and motor block and this could be clinically important

for elderly patients undergoing short duration urological surgery.

Hence, the primary aim of the study was to compare the onset and duration of sensory block and motor block, maximum height of sensory block, haemodynamic parameters and associated complications between isobaric ropivacaine and hyperbaric bupivacaine.

Subjects and Methods

Single blinded randomized controlled trial was conducted on adults undergoing urological procedures and urethroscopy under spinal anaesthesia in the department of anaesthesia of a tertiary care teaching hospital.

Adults above 18 years if age with American Society of Anaesthesiologists (ASA) Physical Status 1 and 2 were included. Patients with coagulopathy, hypovolaemia, body mass index > 35 kg/m², spinal abnormalities, local infection

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over lumbar spine, and history of allergy to amide local anaesthetics were excluded.

Sample size was calculated by assuming the mean duration of sensory block in the ropivacaine group as 155 minutes and in bupivacaine group as 190 minutes, with respective standard deviations of 80 and 60, as per previous study by Kulkarni KR et al.⁵ The other parameters considered for sample size calculation were 80% power of study and 5% alpha error. Based on the above parameters the required sample size was 66 in each group, to account for a non-participant rate of about 10%, it was decided to include 71 subjects in each group. The random allocation of subjects was done into two groups of 71 participants each to the intervention groups by using a computer-generated random number sequence. Subjects belonging to group-1 received 0.5% hyperbaric bupivacaine (15mg) and group-2 received 0.75% isobaric ropivacaine (15mg) through intrathecal route. Allocation concealment was done using Serially Numbered Opaque Sealed Envelope (SNOSE) method, which was kept in the custody of an independent statistician. There were two observers in the study. Observer 1 conducted a thorough preoperative evaluation the day before surgery, reviewed laboratory investigations explained about the procedure, and noted the intraoperative timings and performed the outcome assessment. Observer 2 performed the sub arachnoid block. The person assessing the outcomes was blinded to the intervention.

Study was approved by Institutional ethical committee (IEC). Informed written consent was obtained from all the study participants.

After shifting the patient to operation theatre intravenous access was secured. Baseline clinical characteristics such as heart rate, blood pressure and mean arterial pressure were recorded. Patients were positioned in lateral position and under strict asepsis and local anaesthesia, lumbar puncture was done at L3-L4 space using 26G Quincke needle by single prick midline approach. After confirming flow of clear CSF group specific drug was injected intrathecally. Patients were placed in supine position with pillows under the head immediately and then in lithotomy position after achieving sensory block up to T10 segment.

Parameters studied

Sensory block was assessed by loss of sensation for pin prick every two minutes along the midclavicular line on both sides and the higher of the two sides was taken as end point for this parameter. The time for onset of analgesia at T10 was noted. The highest sensory level was noted as the highest dermatomal level where sensation was lost and remained unchanged for four consecutive readings. Sensory level was checked every five minutes till 1 hour and thereafter at the interval of 15 minutes each till 2-segment regression (defined as recovery of sensory block by two segments from the highest level achieved in that patient) and sensory recovery (around S2-S4 segments).

Motor blockade was assessed by using Modified Bromage Scale (MDS) at similar time intervals as that of assessment of sensory block.⁶ Motor blockade was evaluated at 2-minute intervals till a modified Bromage scale score of 1 was obtained. (score of 1 implied complete motor block) The time was noted at the onset of motor blockade. Duration of complete motor block was defined as “the time from intrathecal injection to regression of block to Bromage score of <3.” The time of recovery from motor blockade was noted when modified Bromage score 6 was obtained. All patients had follow-up visit on the day after the operation to look for full recovery of sensory and motor function and complications like nausea, vomiting, pruritis, headache and any transient neurological symptoms.

Continuous haemodynamic monitoring was done for 8 hours from the time of block. Blood pressure was recorded every 5 minutes for 30 minutes and every 15- minutes till 60 minutes, and every 60 minutes till 480 minutes. Heart rate and rhythm were noted during the same interval. In event of fall of heart rate >30% of baseline or <50 bpm and reduction in SBP >30% from baseline or SBP <100mmHg, it was treated with atropine 0.6mg and mephentermine 3mg intravenously respectively. The requirements of these drugs and duration of surgery was recorded.

Statistical analysis was performed by IBM SPSS statistical software version 21. Independent sample t-test and chi square test/Fisher's exact test was done. P value < 0.05 was considered significant. The study was registered with clinicaltrials.org (CTRI/2018/05/014252)

Results

The mean age was slightly higher in group 2, as compared to group 1, but in both groups, it was less than 60 years. The other baseline demographic and clinical characteristics and ASA status were similar across the study groups (Table 1).

Table 1: Comparison of baseline characteristics of study groups

Baseline characteristics	Study group		P value
	Group 1(n=71)	Group 2(n=71)	
Age (in years)	53.72 ± 13.75	59.83 ± 12.91	0.007
Height(cm)	160 ± 8.72	159.38 ± 8.15	0.662
Weight(kg)	62.92 ± 8.88	62.52 ± 6.62	0.765
ASA status			
I	33 (46.5%)	32 (45.1%)	0.939
II	34 (47.9%)	34 (47.9%)	
III	04 (5.6%)	05 (7%)	

The mean± SD duration of surgery was similar and was completed within 1 hour in all subjects in both groups. The onset time of sensory block was about 6 minutes and similar between the study groups. The mean of highest sensory block, 2 segment regression of sensory block and time for sensory level to regress below T10 was significantly more in group 1 compared to group 2 (p <0.05). This was close to 3 hours in both the groups. There was a significant delay of mean time to onset of motor block to Bromage score 1 in group 2 (<0.001). The mean duration of complete motor blockade was also close to 3 hours and was significantly more in group 1 (P value <0.001). (Table 2)

Table 2: Characteristics of subarachnoid block

Observations (Mean± SD)	Group		P value
	Group 1(n=71)	Group 2(n=71)	
Surgery duration	41.90 ± 7.72	41.82 ± 8.59	0.959
Onset time of sensory block (minutes)	5.80 ± 1.39	5.68 ± 1.57	0.611
Highest sensory block	6.90 ± 1.02	6.58 ± 0.83	0.042
2 segment regression of sensory block (minutes)	129.56 ± 15.80	111.55 ± 22.62	<0.001
Time for sensory level to regress below T10 (minutes)	178.792 ± 16.41	172.14 ± 14.18	0.009

Time to onset of motor block to Bromage score 1 (minutes)	4.63 ± 1.22	6.24 ± 1.52	<0.001
Duration of motor blockade	198.11 ± 18.69	134.82 ± 19.72	<0.001
Duration of complete motor blockade	169.04 ± 17.81	110.08 ± 13.28	<0.001

Hypotension was the most common adverse event, which was significantly more in group 1. (Table 3)

Table 3: Frequency of adverse events

Event	Group 1(n=71)	Group 2(n=71)	Chi square	P value
Hypotension (n%)	30 (42.25%)	13 (18.30%)	9.640	0.001
Bradycardia (n%)	0 (0%)	0 (0%)	**	*
Conversion to GA (n%)	0 (0%)	0 (0%)	**	*

**Chi square test not applicable.

*No statistical test was applied- due to 0 subjects in the cells.

Table 4: Comparison of mean mephetermine in mg with study group

Parameter	Group		P value
	Group 1 (n=71)	Group 2 (n=71)	
Mephetermine (in mg) (Mean± SD)	1.35 ± 1.67	0.56 ± 1.17	0.001

With respect to the heart rate at 5, 120 and 480 minutes there was a statistically significant difference between the 2 groups (P value <0.05) (Figure 1) and similarly in basal systolic blood pressure at 5 and 480 minutes (P value <0.05). (Figure 2)

Figure 1: Trend line diagram comparing heart rate at baseline and at different follow up periods

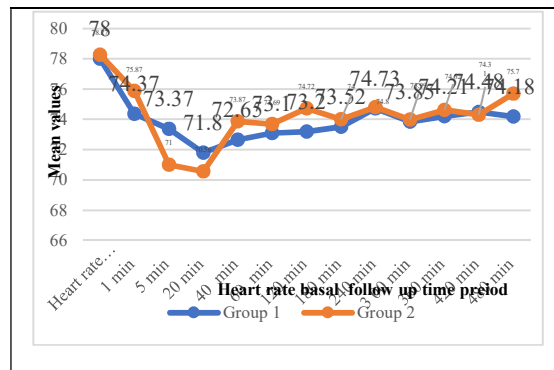
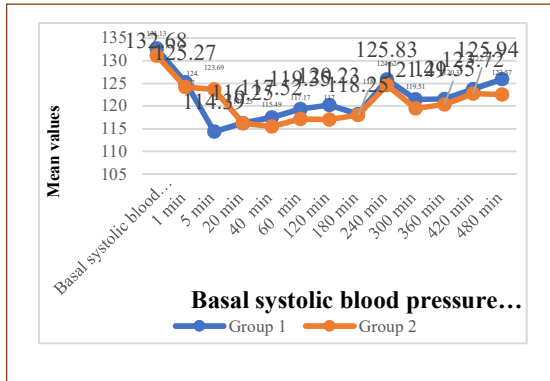


Figure 2: Trend line diagram of comparison of mean basal systolic blood pressure and follow up time period with study group



The difference in the mean value of basal diastolic blood pressure were statistically significant at 5, 20, 360, 420 and 480 minutes (P value <0.05). (Figure 3) The mean blood pressure across study groups were statistically significant at 5, 60, 360, 420 and 480 minutes. (Figure 4).

Figure 3: Trend line diagram of comparison of mean basal diastolic blood pressure and follow up time period with study group

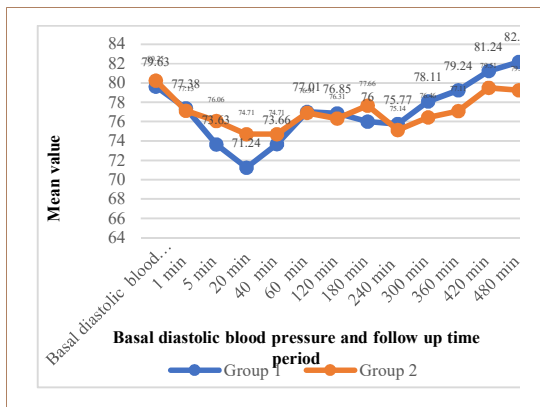
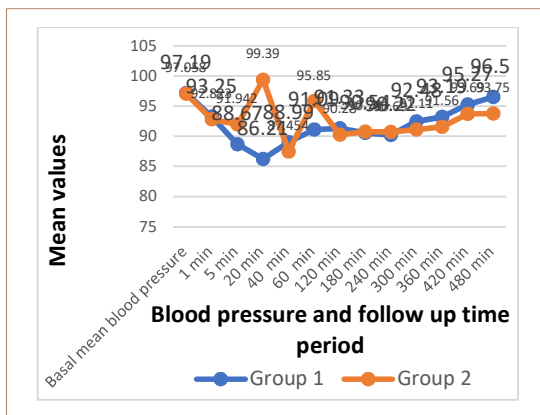
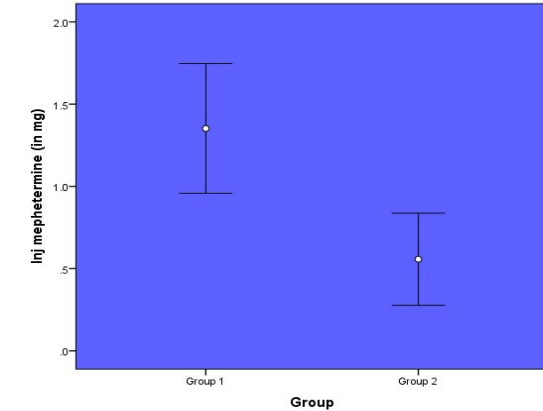


Figure 4: Trend line diagram of comparison of mean basal mean blood pressure and follow up time period with study group



The mephentermine injection was administered significantly more in group 1 compared to group 2. (P value 0.001). (Figure 5)

Figure 5: Error bar diagram of comparison of mean mephentermine (in mg) with study group



Discussion

Many studies in past compared hyperbaric ropivacaine with hyperbaric bupivacaine. But hyperbaric ropivacaine is not sold commercially and the preparation of hyperbaric ropivacaine is difficult as maximum antiseptic environment is required to avoid contamination. So, we conducted our study in patients requiring endoscopic lower urological surgeries using isobaric ropivacaine and hyperbaric bupivacaine as they are commercially available.

In the current study, it was seen that there were similarities in the mean time needed for onset at T10 between the groups. In a comparable study which used hyperbaric ropivacaine anaesthetic mixture was used for assisted delivery, onset time of block to T10 was 3.2 minutes which was shorter than our study probably due to the quantity of drug and the baricity of the drug used.⁷ In another study, comparison was done between 3 hyperbariclocal anaesthetic mixtures and median range of time for analgesia at T10 was 2-5 min for racemic bupivacaine, 2-15 min for levobupivacaine, and 2-15 minutes for ropivacaine respectively.⁸

In this study, the highest level of sensory block achieved and the duration it lasted was shorter for ropivacaine group. This result was in contrast to other studies where the highest level was more in the ropivacaine group.^{9,10} In the present study, it was observed that regression of two dermatomes with ropivacaine mixture was short compared to bupivacaine and this attributes with other

studies.^{8,11} Also in our study, time to regression to below T10 was also shorter in group-2 and was in accordance to another study where 141-211 minutes was seen when administered with ropivacaine mixture and 154-209 minutes with bupivacaine mixture.¹²

In the current study, it was noted that the mean period of motor blockade onset to Bromage score of 1 was 4.63 ± 1.22 minutes with bupivacaine and 6.24 ± 1.52 minutes with ropivacaine which means that the ropivacaine mixture resulted in delayed motor block and this was in agreement with previous studies.^{9,13}

In the present study it was also seen that the duration of complete motor block in group-2 (133.74 ± 18.64) was shorter and statistically significant when compared to group-1. This was in accordance to a study where isobaric ropivacaine 0.75% had shorter complete motor block compared with hyperbaric bupivacaine 0.5%.⁸ In another study it was noted that ropivacaine group took 63-120 min for complete motor block when compared to bupivacaine group (126-183 min).¹² Our study comparable to the other study, ropivacaine group took 93-162 min when compared with bupivacaine group. (157-234 min).^{12,5,9,10}

In our study hypotension was seen in most patients (41.7%) in group 1 compared to 18.6% in group 2. In another study bupivacaine group had 42.5% hypotension than in ropivacaine group 25%.¹³ This was also proven by many studies.^{5,9,14} and easily managed by mephenteramine bolus. Haemodynamic parameters such as heart rate, systolic blood pressure was similar in both groups. This was in accordance to many other studies where similar results were seen with both the mixtures of LA.^{10,11}

It is also evident from the current study findings, the surgical procedure was completed in less than 1-hour in all the study participants, but the duration of sensory and motor block was close to 3 hours. This prolonged duration may interfere with post-operative assessment and may put the elderly subjects at unnecessary risk of haemodynamic instability. Considering the significantly shorter duration of the block ropivacaine may be considered superior in this respect.

We can conclude that 3ml of isobaric ropivacaine when administered intrathecally offers sufficient anaesthesia for endoscopic urological surgeries. There is a delayed onset and shorter duration of motor block with ropivacaine. With the above characteristics and safer haemodynamic and side effect profile ropivacaine may be considered superior to bupivacaine for intrathecal usage in elderly subjects undergoing urological procedures.

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