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A comparison of intrathecal 0.5% hyperbaric ropivacaine with 0.5% hyperbaric bupivacaine for elective surgery: a prospective, randomized, double-blind, controlled study

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ABSTRACT

Background: To compare the onset of action, intensity and duration of motor block of 0.5% hyperbaric ropivacaine with 0.5% hyperbaric bupivacaine for elective lower abdominal, perineal and lower-limb surgeries.

Methods: 70 patients undergoing elective lower abdominal, perineal and lower limb surgery receiving spinal anesthesia were divided randomly into two groups, Group B, (bupivacaine 5 mg/ml with glucose 80 mg/ml;4 ml, and Group R, (ropivacaine 5 mg/ml with glucose 80 mg/ml; 4 ml).

Results: The results were analyzed and compared using Chi-square test, student 's t-test and Fisher's exact tests. The onset of sensory block was more rapid with bupivacaine (p<0.05). The maximum cephalad spread was similar in both groups. However, the time required to maximum extent of cephalic spread was less in Group B (p<0.05). Motor block 3 according to modified bromage scale was obtained in both groups and the time to achieve the same was not significant. The duration of motor blockade i.e., time to complete regression of motor block was significantly greater with Group B than with Group R (0.0001). We found that there was no significant difference in the time taken to achieve grade 3 motor block but ropivacaine gave a lesser degree of motor block which regressed faster than bupivacaine (118 min versus 156 min; p<0.0001). There was no significant difference in hemodynamic parameters except that diastolic and mean pressures remained on lower side in group B (p<0.05).

Conclusions: We conclude that 0.5% hyperbaric ropivacaine provides a sensory block of similar onset and extent, shorter duration of action and less frequency of hypotension as compared to 0.5% hyperbaric bupivacaine.

Keywords: Prospective, Randomized, Hyperbaric, Intrathecal

INTRODUCTION

A total 5% Hyperbaric lignocaine was a drug of choice for intrathecal anesthesia but it has been associated with transient radicular irritation. ¹⁻⁵

Since then, 0.5% hyperbaric bupivacaine has been extensively used for spinal anesthesia. It provides an intense motor block, of longer duration which is usually

not needed for perineal and lower-limb surgeries. Its longer duration of action and urinary retention make it unsuitable for ambulatory anesthesia. This led to a quest for a newer local anesthetic agent which could be used for spinal anesthesia for day-care cases and could sidetrack the cardiotoxic potential of bupivacaine.

Ropivacaine is a relatively new amino-amide local anesthetic which came into market in 1996. It is the first S

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(-) enantiomer of bupivacaine. It appears to be less potent and gives less intense motor block of shorter duration as compared to bupivacaine.⁶⁻⁹ Ropivacaine also has less cardiovascular and central nervous system toxicity than bupivacaine.¹⁰

Large number of studies has been performed using ropivacaine for local infiltration, epidural and peripheral nerve blocks. There is very limited data on the characteristics of intrathecal use of ropivacaine. Amongst which the studies done on hyperbaric ropivacaine are much less as compared to isobaric ropivacaine. ¹¹⁻¹⁵

It is well established that addition of dextrose to local anesthetic increases the specific gravity thereby providing more reliable block as compared to isobaric solutions. ¹⁶⁻¹⁹ This improves their anesthetic profile by giving higher cephalad spread and good muscle relaxation. ¹⁷ Hyperbaric solutions give more predictable block with greater spread in the direction of gravity. It helps to achieve block height as per the requirement of surgery.

In our study, we compared the onset of action, intensity and duration of motor block of 0.5% hyperbaric ropivacaine with 0.5% hyperbaric bupivacaine for elective lower abdominal, perineal and lower-limb surgeries. Ropivacaine is not commercially marketed as hyperbaric solution because of less number of studies done on it and the concern of neurotoxicity. However, it has received an official indication for intrathecal use. We prepared hyperbaric solution by adding 25% dextrose to 0.75% solution of isobaric ropivacaine (Naropin®).

METHODS

Patients undergoing elective lower abdominal, perineal and lower limb surgery under spinal anesthesia were recruited and written informed consent was taken from all patients before operation.

Study design

Prospective, randomized double-blind controlled study.

Study population

A total 70 patients undergoing elective lower abdominal, perineal and lower limb surgery receiving spinal anesthesia were divided into two groups of 35 each.

Group B: Patients who received bupivacaine 5 mg/ml (with glucose 80 mg/ml) 4 ml, intrathecally.

Group R: Patients who received ropivacaine 5 mg/ml (with glucose 80 mg/ml) 4 ml, intrathecally.

Method of randomization

Randomization was done by sealed envelope technique.

Sampling

Inclusion criteria

ASA Grade I and II. Age 18 to 65 year. BMI <35 kg/m². Elective lower abdominal, perineal or lower-limb surgeries.

Exclusion criteria

Patient refusal. ASA Grade III and IV. Emergency surgery. Patients with spine deformity. Pregnant patients. Coagulation disorders. Sensitivity to drugs used. All contraindications to subarachnoid block.

Methodology

All patients were assessed pre-operatively in detail. Investigations were performed as per the requirement of the procedure. Patients were kept nil by mouth for six hours prior to surgery.

All patients were continuously monitored with a pulse oximeter and ECG. Non-invasive blood pressure monitoring was done by automatic brachial oscillometry.

After checking consent and nil by mouth status, patient was brought in the operation room. Monitors were attached, intravenous access was taken with 18 G intravenous cannula and intravenous ringer lactate was started.

Patient was given sitting position with legs extended and local anaesthesia of the skin was given with 2 ml of 2% lignocaine solution at L2-3 or L3-4 intervertebral space. Lumbar puncture was performed using midline technique at the second or third lumbar interspace. A 25 guage Quinke spinal needle was inserted with the bevel facing laterally, and the local anesthetic was injected over 10-15 seconds. The ropivacaine solution was prepared aseptically immediately before injection using 4 ml of 0.75% ropivacaine (4 ml of 7.5 mg. ml-1 that is 30 mg) and 2 ml of glucose 25% (total volume of 6 ml). Out of which 4 ml (20 mg) was injected intrathecally. The bupivacaine solution was (Sensarcaine 0.5% Heavy®) commercially available in the market. The patient was made supine immediately after injection.

The development of the spinal block in onset of action, the extent of sensory block (analgesia to ether gauze) and the time taken for degree of lower limb motor block 3 (modified Bromage scale: 0=full movement; 1=inability to raise extended legs, can bend knee; 2=inability to bend knee, can flex ankle; 3=no movement) was noted. Blood pressure and heart rate were recorded 0, 5, 10, 15, 20, 25, 30 min and at 30 min thereafter until complete regression of the block. Hypotension, defined as decrease in systolic blood pressure >20% from baseline or if <80 mmHg, was treated with injection mephentermine IV 3 mg, and bradycardia, that is heart rate <50 bpm was treated with

inj. atropine 0.6 mg IV fluids were administered to replace the intraoperative losses. Since majority of cases belonged to urology, bladder was catheterized and so time of first micturition could not be assessed. After the surgery, patients were observed in recovery room for return of sensation and regression (ability to move both legs) of motor block.

Constituents of solutions used and densities of solutions at 37°C measured manually.

Table 1: Solution.

Solution	Ropivacaine 7.5mg. ml ⁻¹ (ml)	Glucose 25% (ml)	Bupivacaine Heavy®	Solution injected (ml)	Density (g. ml ⁻¹)
Bupivacaine	0	0	4	4	1.0788
Ropivacaine	4	2	0	4	1.3080

All patients were given oxygen supplementation through nasal cannulae at 3 liter.min¹ Sedation (intravenous midazolam 0.03 mg. kg-1) was given only if the patient was anxious. Failure to achieve spinal block was converted into general anesthesia and those cases were exempted from the study.

The results were analyzed and compared using Chi-square test, student's t-test and Fisher's exact tests. A probability value of <0.05 was considered statistically significant.

All the statistical analysis done using SAS 9.1.3.

RESULTS

The onset of sensory block was more rapid with bupivacaine (p<0.05). The maximum cephalad spread was similar in both groups. However, the time required to maximum extent of cephalic spread was less in Group B (p<0.05). Motor block 3 according to modified bromage scale was obtained in both groups and the time to achieve the same was not significant. There was no significant difference in the duration of surgery in both groups. The duration of motor blockade i.e time to complete regression of motor block was significantly greater with Group B than with Group R (0.0001).

Table 2: Block characteristics.

Parameters	Group B (n= 35)	Group R (n= 35)	P value
Time sensory onset (min)	5.00±0.00	5.57±1.61	0.0399
Max cephalad spread (dermatome)	T6 (T4-T8)	T6 (T4-T8)	
Time max level T6 (min)	10.00±0.00	12.00±4.41	0.0091
Time to motor block Grade 3 (min)	10.00±0.00	10.43±1.42	0.0787
Motor block duration (min)	156.71±34.17	118.86±31.18	<.0001
Surgery duration (min)	81.71±41.43	75.00±25.32	0.4161

Heart rate

Heart rate was comparable in both groups in baseline readings. At all study intervals, there was no significant change in heart rate from the baseline. The heart rate was low in group R as compared to group B (p<0.05) on regression of block. But the change in heart rate from baseline was not significant (p>0.05).

Systolic blood pressure

At all study intervals, the fall in SBP was relatively similar in both groups except at 25 min (p<0.05) from baseline. At all study intervals there was not much difference in SBP in

both groups. There was no significant difference in SBP in both groups with respect to change from baseline (p>0.05).

Diastolic blood pressure

At all study intervals DBP was significantly low in group B (p<0.05) as compared to group R. But the change in DBP from baseline was not significant (p>0.05).

Mean blood pressure

At all study intervals MAP was significantly low in group B (p<0.05) than in group R. But there was no significant difference in the change in MAP with respect to baseline (p>0.05).

Sedation

Eight patients in Group B required sedation as compared to 13 patients in Group R.

Adverse effects

Total 7 out of 35 patients (20%) in group B got hypotension as compared to 2 (5%) in group R which is significant. Bradycardia was found to be of equal significance in both groups. There were two patients in group B who developed post-operative shivering and were treated with injection pentazocine (fortwin) 0.5 mg kg-1.

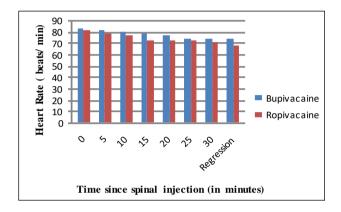


Figure 1: Heart rate.

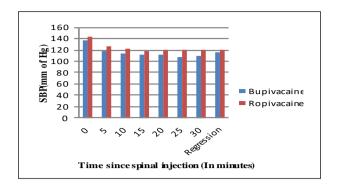


Figure 2: Systolic blood pressure.

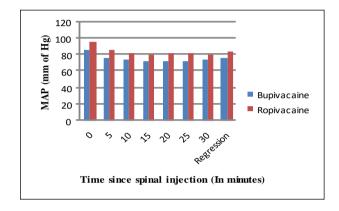


Figure 3: Mean blood pressure.

Table	3:	Heart	rate.
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Heart rate (beats/min) (Mean ≠ SD)	Bupivacaine (At various intervals)	Ropivacaine (At various intervals)	P value	Bupivacaine (Change from baseline)	Ropivacaine (Change from baseline)	P value
Baseline	83.06 ± 14.61	81.74± 15.62	0.7174			
After 5 min	81.89±16.07	78.54 ± 15.40	0.3773	-1.17± 5.37	-3.20± 7.84	0.2108
After 10 min	79.57± 15.59	76.03± 15.37	0.3418	-3.49± 6.88	-5.71± 9.83	0.2756
After 15 min	78.37 ± 15.89	72.74±15.44	0.1375	-4.69 ± 9.32	-9.00± 13.57	0.3310
After 20 min	76.77 ± 15.72	72.66 ± 16.34	0.2869	-6.29± 10.11	-9.09± 13.57	0.2869
After 25 min	74.34± 14.03	72.00 ± 15.50	0.5095	-8.71± 10.09	-9.74± 13.16	0.7149
After 30 min	74.34± 13.62	71.63± 15.66	0.4417	-8.71± 11.04	-10.11± 13.42	0.6351
OnRegression	73.91± 13.30	67.40± 13.10	0.0428	-9.14± 13.65	-14.34± 11.71	0.0917

Table 4: Systolic blood pressure.

SBP (mm Hg) (Mean ± SD)	Bupivacaine (At various intervals)	Ropivacaine (At various intervals)	P value	Bupivacaine (Change from baseline)	Ropivacaine (Change from baseline)	P value
Baseline	136.83 ± 15.28	144.97 ± 23.61	0.0912			
After 5 min	118.69± 19.12	127.63 ± 21.41	0.0697	-18.14 ± 21.01	-17.34± 17.17	0.8620
After 10 min	113.26± 16.91	122.57 ± 22.81	0.0565	-23.57 ± 19.58	-22.40 ± 17.55	0.7929
After 15 min	111.06 ± 17.24	118.89 ± 25.19	0.1338	-25.77 ± 21.24	-26.09± 19.49	0.9488
After 20 min	111.43± 15.31	119.63± 20.90	0.0654	-25.40± 18.84	-25.34± 18.37	0.9898
After 25 min	107.69 ± 15.29	120.57 ± 22.67	0.0069	-29.14± 19.68	-24.40± 21.05	0.3336
After 30 min	110.83 ± 18.15	119.66± 22.73	0.0770	-26.00 ± 23.22	-25.31 ± 20.31	0.8958
On Regression	116.29 ± 16.02	120.80 ± 20.91	0.3143	-20.54 ± 18.99	-20.54 ± 18.99	0.4419

Table 5: Diastolic blood pressure.

DBP (mmHg) (Mean±SD)	Bupivacaine (At various intervals)	Ropivacaine (At various intervals)	P value	Bupivacaine (Change from baseline)	Ropivacaine (Change from baseline)	P value
Baseline	70.89 ± 15.03	77.54 ± 14.04	0.0597			
After 5 min	58.86 ± 14.08	66.09± 12.09	0.0243	-12.03 ± 15.62	-11.46± 13.65	0.8710
After 10 min	56.89 ± 11.99	64.06 ± 10.72	0.0103	-14.00± 17.96	-13.49± 12.24	0.8891
After 15 min	55.00 ± 11.10	62.51 ± 9.58	0.0034	-15.89± 16.86	-15.03± 13.77	0.8165
After 20 min	54.46± 12.34	63.37 ± 10.56	0.0018	-16.43± 18.72	-14.17± 16.51	0.5944
After 25 min	55.14 ± 12.30	63.80 ± 10.73	0.0025	-15.74± 17.25	-13.74± 16.75	0.6242
After 30 min	56.86 ± 13.52	63.20± 10.25	0.0304	-14.03± 16.99	-14.34± 16.33	0.9374
On Regression	65.37 ± 15.48	69.34± 14.45	0.2710	-5.51 ± 20.86	-8.20 ± 16.86	0.5556

Table 6: Mean blood pressure.

MAP (mmHg) (Mean ± SD)	Bupivacaine (At various intervals)	Ropivacaine (At various intervals)	P value	Bupivacaine (Change from baseline)	Ropivacaine (Change from baseline)	P value
Baseline	86.66± 15.71	96.69±17.27	0.0133			
After 5 min	77.54 ± 14.78	86.60±14.06	0.0106	-9.11± 16.09	10.09±14.08	0.7890
After 10 min	75.86 ± 12.45	83.54±13.27	0.0149	-10.80± 16.61	13.14±12.38	0.5058
After 15 min	72.66 ± 10.73	81.34±14.35	0.0055	-14.00± 17.01	15.34±14.72	0.7251
After 20 min	72.51 ± 11.87	82.23±13.63	0.0022	-14.14± 16.30	14.46±16.08	0.9355
After 25 min	72.60 ± 11.63	82.29±13.87	0.0023	-14.06± 15.63	14.40±16.45	0.9290
After 30 min	74.06± 12.69	81.89±14.42	0.0186	-12.60± 17.00	14.80±16.25	0.5818
OnRegression	77.94 ± 13.20	84.66±16.49	0.0642	-8.71 ± 17.05	12.03±17.85	0.4298

Table 7: Sedation.

	Bupivacaine	Ropivacaine
Sedation	8	13

Table 8: Adverse effects.

Adverse event	Bupivacaine	Ropivacaine
Hypotension	7 (20%)	2 (5%)
Bradycardia	5 (14%)	6 (17%)
Vasovagal	0 (0%)	0 (0%)
Shivering	2(5%)	0 (0%)

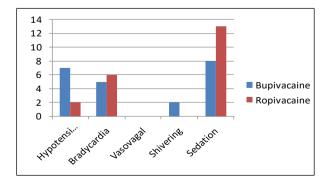


Figure 4: Adverse effect.

DISCUSSION

Lower abdominal, perineal and lower limb surgeries can be done under general anesthesia, spinal or epidural anaesthesia. These surgeries mostly include gynecological, urological and orthopedic cases which can efficaciously be done under spinal anesthesia. Also, most of these cases are of short duration (<3 hours) for which the intense motor block and urinary retention caused by commonly used intrathecal bupivacaine is not necessary. Thus, bupivacaine does not suffice the need of growing number of day-care surgeries.

5% hyperbaric lignocaine which was previously used for short acting spinal anesthesia was reported to cause neurotoxicity and was taken out from clinical use. ¹⁻⁵ These neurological problems made anesthetists to seek for a newer local anesthetic agent with a spinal block effective enough to meet the surgical demands with minimum toxic potential and of shorter duration of action. Its shorter duration of action would be beneficial for day-care cases by allowing to meet the discharge criteria earlier.

Ropivacaine, a newly introduced local anesthetic agent may be a useful alternative to low dose bupivacaine spinal anaesthesia.⁸ Ropivacaine is a pure (-S-) enantiomer of bupivacaine. It is structurally similar to bupivacaine except it has a propyl side chain replacing the butyl group in bupivacaine. This smaller side chain contributes to less lipid solubility, less toxicity and increased separation of sensory and motor blockade as compared to bupivacaine.^{26,27}

We decided to use spinal hyperbaric ropivacaine for lower abdominal and perineal surgeries. We compared the clinical efficacy of 0.5% hyperbaric bupivacaine and 0.5% hyperbaric ropivacaine at equal doses.

When ropivacaine was introduced in market, it was used extensively for labour and postoperative analgesia. It was found to be less potent with less intense motor blockade than bupivacaine. 28 At that time, ropivacaine was not licensed for intrathecal use in due concern of its neurotoxicity. It was confirmed that infusion of ropivacaine in larger doses are required to produce early features of neurotoxicity and cardiotoxicity than bupivacaine.²⁹ Yamashita, et al studied the comparative neurotoxic effects of intrathecal tetracaine, lignocaine, bupivacaine and ropivacaine on spinal cord of rabbits.³⁰ They demonstrated that neurotoxicity of lignocaine was greatest and ropivacaine showed least neurotoxic potential amongst the four drugs. The neurotoxic potential of a drug is known by a reduction in spinal cord blood flow when given intrathecally. Kristensen et al found that high provocative concentration of ropivacaine cause a definite reduction in spinal cord blood flow when given intrathecally in rats but clinically relevant concentration cause only minor changes. This suggests that ropivacaine may be used for spinal anaesthesia without significant effects on spinal cord blood flow.³¹ Earlier studies on ropivacaine included the use of glucose free isobaric solutions.

Sensory block

Time of sensory onset

In our study, onset of sensory block (p<0.05) and the time to reach maximum level of T6 (Group B 10 min and Group R 12 min; p<0.05) was earlier in Group B than in Group Kallio et al 14 who compared intrathecal plain ropivacaine 15 and 20 mg versus bupivacaine 10 mg found that the median onset of analgesia to T10 was 10 min in all groups.

Fettes et al confirmed hyperbaric solution of ropivacaine produces a more consistent block than a plain one and addition of glucose led to a more rapid onset of spread (5 min and 10 min respectively).³² However, the results of our study are in accordance with the study done by Whiteside et al in 2003 who found that the ropivacaine produced a somewhat slower onset at T10 (5 min versus 2 min).⁶

Maximum cephalad spread

Our study showed that equal doses of hyperbaric bupivacaine and hyperbaric ropivacaine showed no significant difference as regards mean height of sensory block (T6) in both the groups. That is in accordance with the studies done by Gautier et al who compared equal doses of ropivacaine 8 mg (4 ml of 0.2%) with bupivacaine 8 mg (4 ml of 0.2%) in which the extent of sensory block was similar in both groups (T8).11 McDonald et al compared hyperbaric preparations of bupivacaine and ropivacaine (0.25% in glucose 5%) in 18 volunteers and they found that equal doses have similar extent of sensory spread (T3 with bupivacaine 12 mg and T4 with ropivacaine 12 mg).8 The result coincides with the study done by Whiteside et al in 2001 who compared intrathecal 3 ml of ropivacaine 0.5% with glucose 10 mg ml^{-1 or} 50 mg ml⁻¹.⁷ There were no significant differences between the extent of maximum block height in both groups (T6). Chung et al compared 12 mg of intrathecal hyperbaric ropivacaine 0.5% and 18 mg of hyperbaric bupivacaine 0.5% in 60 cesarean section patients. They found that the median (range) peak level of anesthesia was T3 (T1-5) in the bupivacaine group and T3 (T1-4) in the ropivacaine group which coincides with our study.

Whiteside et al in 2003 who compared 3ml of hyperbaric bupivacaine 0.5% in glucose 8% and 3 ml of hyperbaric ropivacaine 0.5% in glucose 5% for elective surgery, found that ropivacaine produced a somewhat less maximum cephalad spread (T7 versus T5) than bupivacaine.⁶

Motor block

In our study we found that there was no significant difference in the time taken to achieve grade 3 motor block but ropivacaine gave a lesser degree of motor block which regressed faster than bupivacaine (118 min versus 156 min; p<0.0001). The results of our study are in accordance with Gautier et al who compared intrathecal bupivacaine and intrathecal ropivacaine for knee arthroscopy and found that ropivacaine has a shorter duration of action than bupivacaine (107 min versus169 min).¹¹ Also McDonald et al found that, the degree of motor block produced was less with ropivacaine (p<0.05).8 The study done by Whiteside et al in 2003 confirmed our results that ropivacaine 5 mg ml⁻¹ with glucose 50 mg ml⁻¹ had a less potent effect on motor nerves with both degree and duration in comparison to hyperbaric bupivacaine (90 min versus 180 min; p<0.0001).6 Also, the result coincides with Chung et al 9 who found that the duration of motor block was shorter in ropivacaine group (113 min versus 158 min; p< 0.000.).

Hemodynamic parameters

Heart rate

In our study (Table 6) there was no significant difference in heart rate at various intervals in both groups except on regression of block. There was no obvious difference in bradycardia in group B (14%) and Group R (17%). However, another study done by Kallio et al compared intrathecal plain solutions of ropivacaine 20 or 15 mg with bupivacaine 10 mg. ¹⁴ They found bradycardia in 18%, 14% and 11% respectively.

Blood pressure

In our study (Table 7, 8, 9) there was no significant difference in the fall of systolic pressure from the baseline in both groups (p>0.05) but diastolic and mean pressures were on lower side in Group B than in Group R (p<0.05). But there was no significant difference in SBP, DBP and MBP with respect to change from baseline.⁷ patients in Group B (20%) developed hypotension (Systolic blood pressure <80 mm Hg) as compared to 2 patients in Group R (5%). Those patients were given inj. mephentermine in 3 mg bolus dose. McDonald et al and Gautier et al found no difference in hemodynamic stability of both bupivacaine and ropivacaine.^{8,11} The study done by Whiteside et al in 2003 is in accordance with our study.⁶ They noticed marked difference in cardiovascular changes in both groups. 14 (70%) patients in bupivacaine had fall in systolic pressure as compared to only 3 (15%) in ropivacaine group. Kallio et al found hypotension in 40%, 43% and 20% of patients of plain ropivacaine 20 mg, 15 mg and bupivacaine 10 mg and the need of sympathomimetic for hypotension was 17%, 17% and 7% respectively.¹⁴ While in post-operative room hypotension occurred in 10%, 13% and 7% patients respectively with no need of sympathomimetic in all the groups.

Sedation

Thirteen patients in Group R and eight in Group B were given sedation for anxiety purpose. Verbal contact was maintained at all times and the block was found to be suitable for surgery in all patients. This finding is in accordance to Whiteside et al.⁶

Adverse effects

Shivering occurred in 2 patients of Group B and vasovagal syncope in 1 of the patient of Group R.

Limitations

One of the limitations of our study was that we could not comment on the status of passing urine since most of our patients needed catheterization for surgery. We thereby conclude that hyperbaric ropivacaine provides a comparable block to hyperbaric bupivacaine with shorter duration of action and minimal hypotension.

CONCLUSION

We concluded that 0.5% hyperbaric ropivacaine provides a sensory block of similar onset and extent, shorter duration of action and less frequency of hypotension as compared to 0.5% hyperbaric bupivacaine.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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