

Original Article

Comparison of Intrathecal 0.5% hyperbaric bupivacaine with 0.5% hyperbaric ropivacaine in lower limb and lower abdominal surgery

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ABSTRACT

Background: Spinal Anesthesia is most preferred technique for Lower Limb and Lower Abdominal surgeries. This study was designed to compare the clinical efficacy of hyperbaric solutions of 0.5% Ropivacaine and Bupivacaine.

Methods: After obtaining ethical committee clearance and informed patient consent 100 ASA grade I and II patients undergoing elective lower-abdominal and lower-limb surgeries under spinal anaesthesia were recruited and randomized to receive 3ml Ropivacaine (with glucose 83 mg/ml) or 3 ml Bupivacaine (with glucose 80 mg/ml). Groups were named as group R and B respectively.

The parameters that were compared were onset (primary outcome) and duration of sensory block, intensity and duration of motor block (secondary outcomes) and recovery profile. $P < 0.05$ was considered to be statistically significant.

Result: Ropivacaine as compared to Bupivacaine showed slower onset of sensory block, shorter time to regression and shorter duration of sensory block. Motor block also was delayed with respect to onset, degree of block and duration for Ropivacaine group compared to Bupivacaine group. Patients receiving ropivacaine recovered faster in terms of mobilization (Group R vs B - mean 253.5 min vs 331 min) and time to micturate (Group R vs B - mean 276 min and 340.5 min). Hemodynamics were stable in Group R as compared to B as More patients in the bupivacaine group required treatment for hypotension. Intraoperative and post operative periods were free of Side effects in the Group R.

Conclusion: Hyperbaric Ropivacaine 0.5% with 83 mg/ml of glucose provides reliable spinal anaesthesia of shorter duration and with less hypotension than bupivacaine and can provide a safe alternative to Bupivacaine in day care setting for infraumbilical surgeries.

Key Words: Hyperbaric, Bupivacaine, Ropivacaine, spinal.

INTRODUCTION

Regional anesthesia has the potential to provide excellent operating conditions and prolonged postoperative analgesia^[1]. Spinal anaesthesia is by and large the technique of choice of anesthesia for lower abdominal surgeries^[2]. The advantage is due to the fact that injection of a small amount of local anesthetic drug is done. But it is very important to control the spread of this local anesthetic through the cerebrospinal fluid so that adequate surgical anesthesia is produced and complications are reduced.^[2] General anesthesia has several complications like post operative delirium, thromboembolism and these can be reduced to a great extent by spinal anesthesia.

Ropivacaine, is a relatively new amino-amide local anaesthetic agent similar in chemical structure to bupivacaine. Recent studies that compared ropivacaine and bupivacaine concluded that ropivacaine is safe for intrathecal use primarily because of a shorter duration of action. Incidence of transient neurological symptoms is also lesser as compared to lignocaine used intrathecally. Due to predictable block characteristics intrathecal use of hyperbaric local anesthetics is indicated. Ropivacaine, which blocks sensory nerve fibers more readily than motor fibers, is now gaining popularity due to its reduced cardiac toxicity with overdose. Recent studies with intrathecal ropivacaine have demonstrated low cardiovascular and neurotoxic effects, good tolerability and efficacy.^[3]

MATERIALS AND METHODS

A randomized prospective double blind study was conducted on 100 patients belonging to ASA grade I & II of either sex and ages between 20-60 years posted for different surgeries on lower abdomen and lower extremity after obtaining Institutional ethical committee clearance. Patients who consented for the procedure were enrolled and included for the study. Patients who were unwilling for the procedure, with uncontrolled hypertension, cardiac problems, psychiatric and neurological disorders, known allergies, hypers-

sensitivity to local anaesthetics, contraindication to spinal anaesthesia, such as infection at the site of lumbar spine, septicemia, coagulopathies were excluded from the study. A detailed pre-anaesthetic evaluation including history, thorough general and systemic examination and all relevant investigations were done for all the patients. 100 selected patients were randomly divided into two equal groups of 50 patients each by computer generated numbers. One group labelled as group R which received 3 ml of 0.5% hyperbaric ropivacaine and another labeled group B who received 3 ml of commercially available 0.5% hyperbaric bupivacaine (Anawin heavy from Neon labs). All patients were kept Nil orally for 4-6 hours before surgery. On the night before operation, all the patients received tablet ranitidine 150 mg and tablet alprazolam 0.5 mg. On arrival at the preoperative room, a suitable peripheral intravenous (IV) access was performed with an 18-gauge cannula. Premedication was done with Injection metoclopramide 10 mg IV and injection ranitidine 50 mg IV 30 min before shift to operation theatre. Preloading was done with 10-15 ml/kg of ringer lactate or normal saline over 15 min. Anesthesiologists observing the patient intra-operatively and in the recovery room were blinded to the drugs administered. In the operation theatre, monitoring was done to record baseline readings of the following parameters like Pulse rate (PR), noninvasive blood pressure (NIBP), respiratory rate (RR) and saturation (SPO₂). All patients were placed in sitting position. The hyperbaric ropivacaine solution was prepared by anesthesiologist who was unaware of the study parameters. Under strict aseptic conditions and supervision of senior anesthetist hyperbaric ropivacaine was prepared using commercially available 0.75 % Isobaric Ropivacaine 4 ml (Ropin from Neon labs) solution and 25% Dextrose 10 ml ampoule which were autoclaved prior to use. 2ml of isobaric 0.75% ropivacaine solution was taken and 1 ml of 25% Dextrose was added to it making a total volume of 3 ml and each ml containing approximately 83.33 mg of

dextrose as each ml of 25% dextrose solution contains 250 mg of dextrose and hence making the solution 0.5%. Under strict asepsis, lumbar puncture was performed using a midline approach at the interspinous spaces L3-L4 or L4-L5 using a 25G Quinke spinal needle with bevel-end facing cephalad. After obtaining clear CSF, the prepared anesthetic drugs were injected over a period of 10 seconds.

Immediately after intrathecal injection of drugs (taken as 0 min), all the patients were kept in a supine horizontal position, and readings of blood pressure (BP), heart rate (HR), and mean arterial pressure (MAP) were taken.

Following parameters were assessed with respect to sensory anesthesia by pinprick at 2 min intervals - Onset of sensory block, time of highest level of sensory block, time to two segment regression, duration of sensory block. Motor block characteristics were assessed in terms of onset of motor block, degree of motor block using a modified Bromage scale (MBS) [Table-1], time to maximum motor block, time to regression and total duration of motor block. Surgery was allowed to start after adequate level of anesthesia obtained. Intraoperative hemodynamic parameters (BP, HR, and MAP) were assessed at 1 min, 2 min, 5 min, 10 min, 15 min, 20 min, 30 min, 45min and 60min.

Side effects of spinal anesthesia were noted and necessary interventions carried out. Hypotension, defined as a fall in systolic blood pressure >20% from the baseline was treated with IV injection of mephentermine 3 mg or IV fluids or both based on requirements. Bradycardia, fall in heart rate <60 beats/min was treated with injection atropine 0.6 mg IV. Adequate administration of IV fluids was carried out. Complications like shivering, nausea and vomiting were treated accordingly. Patients complaining of pain were given rescue analgesics or converted to general anesthesia. Total surgery time was noted.

Upon completion of surgery patients were observed in post operative room for hemodynamic parameters (BP, HR, and MAP) were recorded at

0 min, 30 min intervals and later 4 hourly for 24 hours. Motor block regression in the lower limbs was assessed by using MBS at 0-60 min, 60-120 min, and 120-180 min intervals. Sensory blockade regression time up to S2 was checked by using the pinprick method in the mid clavicular line bilaterally. These assessments were continued until complete regression of motor block in the lower limbs, and sensory block to S2. Time to the first onset of micturition (in minutes) was recorded; bladder catheterization was performed only if surgically indicated.

The patient satisfaction score was assessed by patient comfort score (PCS). It is graded from 1-4 as below:

1. Complete absence of sensation in the operative limb.
2. Sensation of limb movement only but with no discomfort present.
3. Mild discomfort but with the patient declining any offer of further analgesia or with no obvious clinical need for such further intervention.
4. Patient expresses wish for additional analgesia or exhibits an obvious clinical need for such intervention.

Injection midazolam 1.5 mg with injection pentazocine 15 mg were given intravenously in case of patients with complaints of uncomfortable legs and anxiousness. All the operations were performed successfully in both the groups.

Statistical Analysis

Sample size was calculated based on alpha error, beta error, confidence limit and confidence interval and power of the study. On assumption of alpha error as 5%, beta error 0.12, power of the study as 80%, a minimum sample size of 30 was derived to detect a difference of 35%. To increase the power of study the sample size was increased to 50. Results are expressed as mean values \pm standard deviation (SD) or median value if appropriate. Categorical data were compared using chi-square analysis, and for continuous data, *t*-test analysis

was used using SPSS version 21 Software .Results were considered significant if $P < 0.05$.

RESULTS

In the present study, the mean specific gravity of the freshly prepared hyperbaric ropivacaine 0.5% solution (by the addition of 83mg/mL dextrose) observed was 1.148 and hyperbaric bupivacaine 0.5% was 1.160. The two groups were comparable with regard to age, sex, height, weight, ASA status, and types of surgeries [Table-2] and [Figure -1].

The characteristics of spinal block in terms of sensory and motor block patterns is as shown. Onset of sensory block tested with pin prick in group B was 4.5 ± 1.2 min and 3.2 ± 0.75 min in group R ($P=0.000$). Peak onset of sensory block in group B is 9.17 ± 1.51 min while 9.10 ± 1.97 min in group R ($P = 0.88$).

Median maximum sensory block height level with pinprick analgesia was T5 in group B and T6 in group R. The total duration of sensory block regression to S2 was faster with ropivacaine (bupivacaine 180.60 ± 23.06 min; ropivacaine 157.44 ± 17.78 min; $P < 0.001$). The onset of motor block 7.9 ± 2.4 min in group B and 8.4 ± 2.1 min in group R. The duration of motor block was 126.3 ± 38.3 min in group R and 148.7 ± 35.4 min in group B ($P=0.000$) [Table-3]

Patients receiving ropivacaine mobilized sooner (ropivacaine mean 253.5 min; bupivacaine 331 min; $P=0.002$). Time to micturate was sooner in

group R (ropivacaine mean 276 min; bupivacaine 340.5 min; $P=0.01$) .The intraoperative mean arterial blood pressure and heart rate distribution in the two groups fell gradually over 10-15 min, and thereafter increased slowly before reaching less than the baseline value (Fig-2, Fig-3). However, the fall was more in group B but was not statistically significant [$P > 0.05$]. Three patients in the bupivacaine group required injection mephentermine 3 mg IV intraoperatively to correct hypotension while none required it in the ropivacaine group.

In the ropivacaine group, there were less number of patients having legs discomfort and requiring sedations and additional analgesics compared to bupivacaine ($P = 0.002$).

The quality of anaesthesia (intraoperative muscle relaxation) and analgesia was similar in both the groups.

Table-1: Modified Bromage Scale

Score	Criteria
0	Full movement
1	Inability to raise extended leg but can bend knee
2	Inability to bend knee but can flex ankle
3	No movement

Table-2: Demographic data

	Group R(n=50)	Group B(n=50)	P value
Age(Years)	41.9±11.4	43.1±14.6	0.76
Gender(M/F)	32/18	35/15	0.56
ASA Status(I/II)	1.13±0.34	1.16±0.37	0.91
Weight(Kgs)	65±5.27	67.50±5.20	0.21
Height(Cms)	159.22±7.24	161.24±7.49	0.73

Table-3: Comparison of results of spinal anesthesia in both groups

	Group R(n=50)	Group B(n=50)	P value
Time of onset of sensory block(min)	3.2±0.75	4.5±1.2	0.00
Time of peak sensory block(min)	9.10 ± 1.97	9.17± 1.51	0.00
Duration of sensory block(min)	157.44 ± 17.78	180.60 ± 23.06	0.02
Time to onset of motor block(min)	8.4±2.1	7.9±2.4	0.10
Duration of motor block	126.3±38.3	148.7±35.4	0.00
Time to mobilize(min)	253.3±11.1	331±13.5	0.002
Time to micturate(min)	276±5.67	340.5±6.78	0.01
Degree of motor block	1.50 ± 0.82;	2.40 ± 0.4	0.001

Table-4: Side effects of drugs

	Group R(n=50)	Group B(n=50)	P value
Hypotension	2	6	<0.05
Bradycardia	0	0	>0.05
Shivering	1	2	>0.05
Post dural puncture headache	0	0	>0.05
Transient neurological symptoms	0	0	>0.05

Fig-1: Types of surgeries done in the study

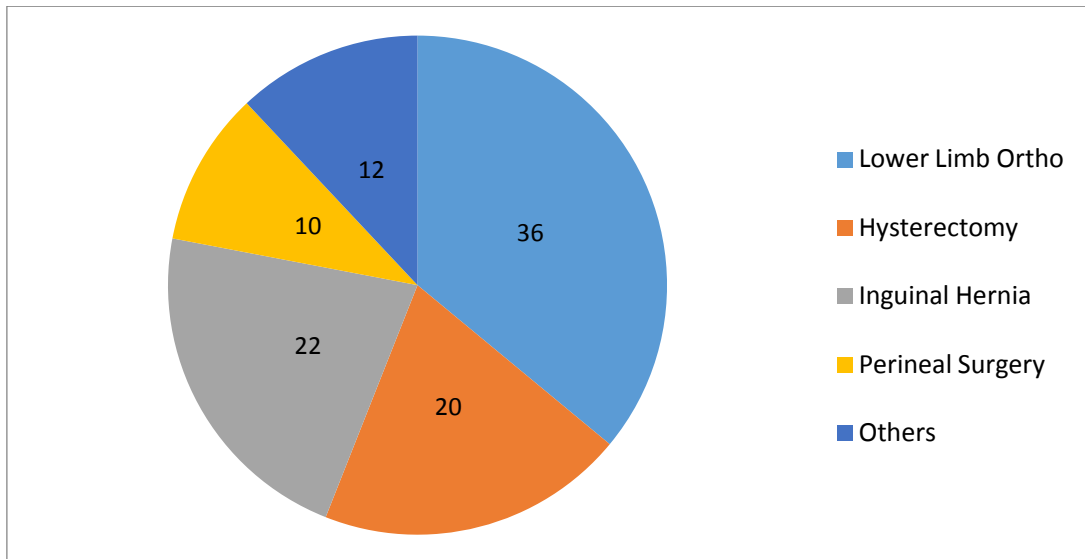


Fig-2: Intra-operative Systolic blood pressure monitoring (On the X-axis is the time in min and on the Y-axis is the Systolic BP value in mm of Hg)

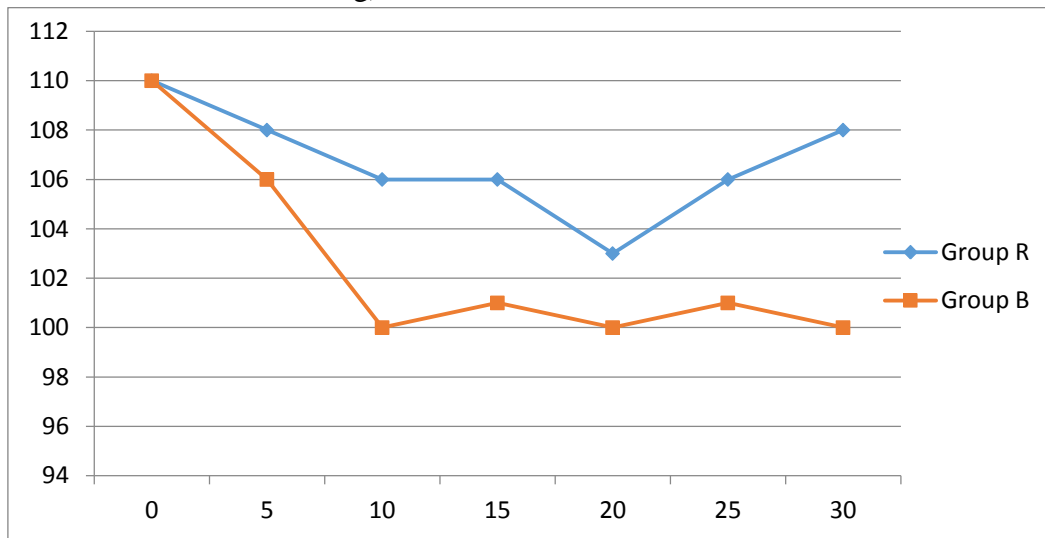
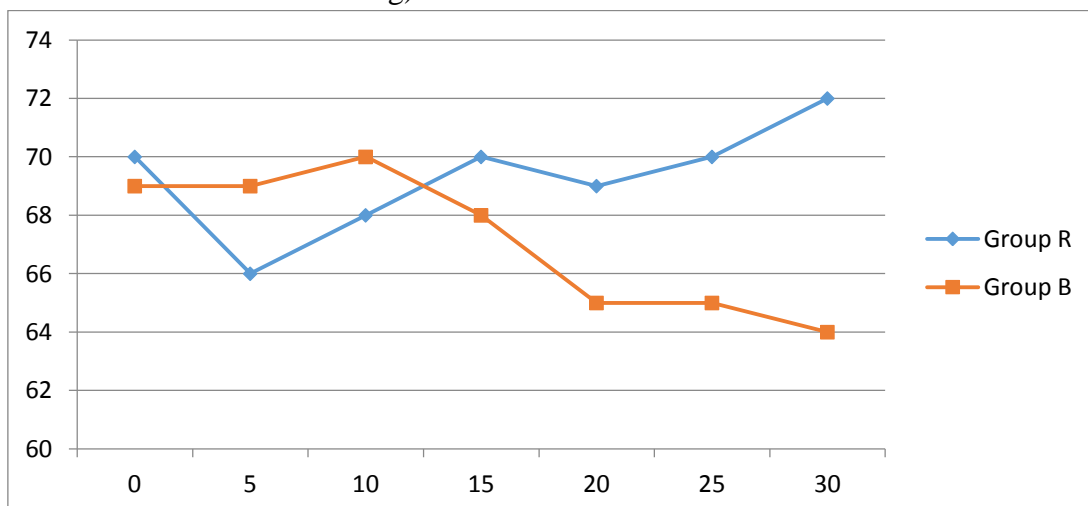


Fig-3: Intra-operative Diastolic blood pressure monitoring (On the X-axis is the time in min and on the Y-axis is the Diastolic BP value in mm of Hg)



DISCUSSION

Ropivacaine is nearly identical to bupivacaine in onset, quality and duration of sensory block. Earlier studies with isobaric Ropivacaine had reports of variable block patterns for surgery and addition of glucose to ropivacaine solution has shown to have better effects for spinal anesthesia. A study done by Wille concluded that addition of glucose in the ranges of 3-8% to isobaric ropivacaine to make the solution hyperbaric is safe for intrathecal use^[4]. But it produces lesser duration of motor blockade and has a better safety profile.^[5] This was very helpful for short duration surgeries as well as for early ambulation. In the present study, spinal anaesthesia was successful in almost 95% of patients in each group & in none of the patients, conversion to general anaesthesia was required. The onset time at T10 was significantly less in ropivacaine group. Kallio *et al.*^[6] while comparing hyperbaric and plain ropivacaine reported that intrathecal hyperbaric ropivacaine 15 mg resulted in a faster onset, greater success rate of analgesia at the level of T10 dermatome, and faster recovery of blocks.^[7] Another study conducted by Ben David *et al.*^[8] found that the addition of fentanyl increases the level and duration of sensory block without altering the motor block characteristics. It resulted in the use of smaller doses of local anesthetic, minimizing the duration of motor block, lower incidence of excessively high block, and hypotension. Successful blocks with ropivacaine 12 mg have been described in arthroscopy and unilateral spinal anesthesia. On the other hand, for operations in which higher block is required even much higher doses have proved insufficient. The time to reach maximal sensory level of T8 was significantly more in ropivacaine group. Wahedi *et al.*^[9] had a failure rate of 20% with intrathecal plain ropivacaine 15 mg (3 mL of 5 mg/mL) in abdominal surgery^[9] and Malinovsky *et al.*^[10] found 16% failure of spinal anesthesia with plain ropivacaine 15 mg (5 mL of 3 mg/mL) for urological surgery. In case of unilateral spinal anesthesia, bilateral sensory block occurred in

85% of the patients in the bupivacaine group versus 40% in the ropivacaine group. The incidence of bilateral block in a study by Bigat *et al.* was 70% in the bupivacaine group and 25% in the ropivacaine group.^[11]

The mean time for two segment regression and duration of sensory block was significantly less in ropivacaine group. Time to attain complete motor block of lower limbs was similar in both groups but the motor block regressed faster in ropivacaine group. The results of our study were similar to conclusion of other studies^[12,13,14]. The lesser lipophilic nature of ropivacaine causes slower penetration the large myelinated A fibers than the more lipid soluble bupivacaine.^[15] It has selective action on the pain-transmitting A β and C nerves rather than A β fibres, which are involved in motor function.

In our study for lower abdominal surgery and lower limb surgery, patients required at least midthoracic block, and we used 15 mg of freshly prepared hyperbaric ropivacaine, which provided reliable anesthesia of shorter duration and minimal hypotension. Main advantage of intrathecal ropivacaine is a shorter duration of action and less motor block than bupivacaine. This is in contrast to some of the early studies, which found that there was no difference in the onset time of motor block.

Regarding motor block regression from grade 3 to grade 0, it was significantly shorter in the ropivacaine group. Patients in the ropivacaine group could move their lower limbs comparatively faster than the bupivacaine group which is in agreement with the conclusions of earlier studies. The present study correlates with those of Osama-Al-Abdulahdi *et al.*^[13] and J.F Luck *et al.*^[7] who also found statistically insignificant difference in quality of anaesthesia between hyperbaric ropivacaine and bupivacaine when given intrathecally.

The time to first onset of micturition was 236.38 ± 90.44 min in the ropivacaine group and 289.85 ± 73.21 min in the bupivacaine group ($P= 0.037$). A similar finding was reported by Kulkarni *et*

al.^[17] and Whiteside *et al.*^[18] The hemodynamic parameters were found to be comparable between the groups.^[18]

In the present study, three patients in the bupivacaine group required injection mephentermine 3 mg IV to correct hypotension while in a study conducted by McNamee *et al.*, injection ephedrine 3 mg was used to correct hypotension in 26% of the patients in the bupivacaine group and 12% patients in the ropivacaine group.^[19]

Ropivacaine is available only as isobaric solution, which has a specific gravity of 0.988 at 37° C. This solution is slightly hypobaric, and therefore has more variable and unpredictable block because gravity has no effect on their spread in the supine position.^[20] Addition of glucose leads to a more rapid cephalad spread with less variation in maximum sensory and motor block. Addition of dextrose improves reliability of block.^[14,18]

The present study shows that glucose-containing solutions of hyperbaric ropivacaine can produce predictable and reliable spinal anesthesia for a wide range of surgical procedures. This is in contrast to the result of some earlier study of intrathecal ropivacaine, which described a variation in the spread of the local anesthetic agents and found it to be frequently inadequate for surgery. In the present study, intrathecal ropivacaine produced excellent intraoperative anaesthesia, indistinguishable from spinal bupivacaine.

Only limitation of this study was the density/baricity of freshly prepared hyperbaric ropivacaine was not checked as standard densitometer was not available in our institution and hyperbaric ropivacaine is not available commercially and so it has to be prepared with proper asepsis immediately before the procedure.

CONCLUSION

It maybe concluded that freshly prepared hyperbaric ropivacaine is a better alternative to hyperbaric bupivacaine for undergoing lower abdominal surgery and lower limb surgery, with faster onset and recovery of motor and sensory

blocks, shorter duration of time to onset of micturition, and better hemodynamic stability than the commercially available hyperbaric bupivacaine. Its use in day care setting where early ambulation is required is preferable. However in order to comply with increased surgical duration and post operative analgesia hyperbaric ropivacaine may be mixed with adjuvants.

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