

ORIGINAL ARTICLE

Comparison between intrathecal isobaric ropivacaine 0.75% with hyperbaric bupivacaine 0.5%: A double blind randomized controlled study

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ABSTRACT

Background: To compare the sensory and motor loss and duration of analgesia in patients undergoing lower abdominal and lower limb surgeries when isobaric ropivacaine or bupivacaine were used in spinal anesthesia.

Methodology: One hundred ASA grades I & II patients of either sex in the age range of 20-60 years undergoing lower abdominal and lower limb surgery were randomly divided into two equal groups: in Ropivacaine Group, patients received 22.5 mg of inj. ropivacaine for spinal analgesia and in Bupivacaine Group; 15 mg of inj. bupivacaine was used for spinal analgesia. Parameters observed were onset of sensory and motor block, two segments regression and duration of motor blockade.

Results: The sensory onset was significantly delayed in the Ropivacaine Group (42.6 ± 11.39 min) compared to the Bupivacaine Group (18.4 ± 6.53 min), $P < 0.001$. The motor onset was also significantly delayed in Ropivacaine Group (55.54 ± 13.01 min) compared to Bupivacaine Group (27.5 ± 8.03 min), $P < 0.001$. The peak sensory time was significantly delayed in the Ropivacaine Group (10.92 ± 2.60 min) compared to Bupivacaine Group (7.38 ± 1.69 min), $P < 0.001$. The peak motor time was also significantly delayed in the Ropivacaine Group (8.92 ± 2.41 min) compared to the Bupivacaine Group (4.82 ± 1.22 min), $P < 0.001$. The two dermatomal sensory segment regression was significantly prolonged in Ropivacaine Group (117.2 ± 12.5 min) compared to Bupivacaine Group (108.5 ± 10.61 min), $P < 0.001$. The duration of motor blockade was significantly prolonged in the Bupivacaine Group (190.2 ± 28.37 min) compared to the Ropivacaine Group (149.7 ± 8.60 min), $P < 0.001$. The duration of post-operative analgesia was similar in both the groups and was statistically insignificant. There was no significant difference in the comparison of heart rate, blood pressure nor significant respiratory side effects between the groups. The quality of sedation was better in Ropivacaine Group (1.16 ± 0.37) as compared to Bupivacaine Group (0.96 ± 0.49) but statistically insignificant.

Conclusion: Intrathecal plain ropivacaine might be superior to bupivacaine in terms of a longer sensory block, and a shorter motor block duration. Therefore 0.75% isobaric ropivacaine can be safely used in lower limb and lower abdominal surgeries, especially in cases where early ambulation is desired.

Key words: Bupivacaine; Ropivacaine; Intrathecal; Postoperative analgesia

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INTRODUCTION

Spinal anesthesia, also called spinal analgesia or sub-arachnoid block (SAB), is a form of regional anesthesia involving injection of a local anesthetic into the cerebrospinal fluid (CSF) through a fine needle.

Spinal anesthesia is widely used for lower limb and lower

abdominal surgeries. It has been the mainstay for regional anesthesia in developing countries, especially in India. Various local anesthetics have been injected into the intrathecal space to achieve intrathecal blockade, starting with cocaine way back in 1898.

Bupivacaine is being extensively used and produces an

Comparison between intrathecal isobaric ropivacaine 0.75% with hyperbaric bupivacaine 0.5%

adequate sensory and motor blockade.¹ However it has its own disadvantages and side-effects such as cardiac and central nervous system toxicity.²

The acute and most serious adverse effects of local anesthetics involve the cardiovascular and central nervous system.³ They are usually because of accidental intravascular injections or a pronounced overdose. These adverse effects have prompted a search for drugs with lesser toxicity.

Newer long-acting local anesthetics (ropivacaine, levobupivacaine) have recently been introduced for clinical use. The claimed benefits of these are reduced cardiac toxicity on overdose and more specific effects on sensory rather than motor nerve fibres.⁴⁻⁷ Ropivacaine was developed after bupivacaine, ropivacaine was found to have less cardiotoxicity than bupivacaine in animal models. Unlike bupivacaine, ropivacaine has been developed and marketed as the pure S (-) enantiomer of propivacaine. It is less lipophilic than bupivacaine. This property is associated with a decreased potential for CNS toxicity and cardiotoxicity.⁸

Numerous experimental studies were conducted to identify the fine cellular mechanism of the local anesthetic toxicity which refined the understanding of their action. The identification of optically active isomers of the mepivacaine family led to the selection of ropivacaine, a pure S(-) enantiomer, whose toxicology was selectively and extensively studied before its introduction on the market in 1996. During the rapid and extensive use of ropivacaine in the clinic, unwanted side-effects have been found to be very limited.¹³

Besides being well tolerated and safe, ropivacaine has a short time to onset of anesthesia and results in a sensory and motor blockade of duration appropriate for the indication or procedure.

In the present study, we compared the efficacy of 22.5 mg (3ml) of 0.75% isobaric ropivacaine with a control group using 15 mg (3ml) of 0.5% hyperbaric bupivacaine. The parameters that were observed are: duration of motor blockade, two segments regression, and sensory and motor onset.

METHODOLOGY

This randomized double blind study was conducted with 100 patients belonging to ASA grade I & II of either sex in the age range of 20-60 years after permission from institutional ethics committee. The study was done in the period of March 2010 to March 2011. Consent was taken from all patients. All of the patients undergoing surgery of lower abdomen or lower limb, as well as those undergoing gynecological procedures were subjected to a thorough pre-anesthetic evaluation and relevant laboratory investigations.

Inclusion criteria were: age between 20 – 60 years; patients willing to get enrolled in study; patients willing for spinal anesthesia; and those with an ASA physical status I or II. Pregnant patients were excluded. One hundred selected patients were divided into two equal groups of 50 patients each by a lottery method.

Bupivacaine Group: In this group patients were given 0.5% hyperbaric bupivacaine 3 ml (15 mg) intrathecally.

Ropivacaine Group: In this group patients were given 0.75% isobaric ropivacaine 3 ml (21.5 mg) intrathecally.

The syringes were prepared according to the allocated group by a 3rd person (anesthesiologist), and he did not take part in the subsequent conduct of the study.

A detailed history and a thorough general examination were done for all the patients undergoing lower abdominal and lower limb surgeries. Pre-operative explaining of the procedure was done to gain the confidence of the patients and written consent was taken. All the patients were kept fasting overnight prior to the scheduled day of operation. Patients were evaluated for vital parameters like pulse rate, respiratory rate, oxygen saturation (SpO₂), blood pressure and ECG changes in pre-operative room. Patients were preloaded with 0.4% hydroxyethyl starch 6 ml/kg body weight 15 minutes before subarachnoid block.

Under all aseptic precautions, subarachnoid block was given with suitable small bore spinal needle (26G Quinke) in sitting or lateral position through mid-line approach intrathecally. Bupivacaine Group was injected with 3 ml 0.5% of bupivacaine and Ropivacaine Group was injected with 3 ml of 0.75% of ropivacaine. Pulse, blood pressure and SpO₂ were measured every 5 minutes for half an hour and thereafter every 10 minutes.

The sensory block was tested by pinprick test until it reaches T₅-T₆ level and then surgical incision was allowed. The degree of motor blockade was assessed by loss of antigravity movements of the legs by the Bromage scale (Box 1).¹¹

Box 1: Bromage scale

Score	Criteria
1	Complete block (unable to move feet or knee)
2	Almost complete block (able to move feet only)
3	Partial block (just able to move knees)
4	Detectable weakness of hip flexion while supine (full flexion of knees)
5	No detectable weakness of hip flexion while supine
6	Able to perform partial knee bend

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

T0 - Time of Spinal anesthesia

T1 - Time of onset of sensory block (loss of pinprick sensation)

T2 - Time of onset of motor block (inability to lift the extended leg)

T3 – Time of peak sensory block

T4 – Time of peak motor block

In the intra-operative period, patients were closely monitored for pulse rate, respiratory rate, SpO₂, blood pressure and blood loss. Any side effects such as nausea, vomiting, pain, shivering, pruritus, sedation, respiratory discomfort were noted and treated with appropriate drugs.

The following interventions were made (and the same were noted) as needed:

- A. Hypotension; mean NIBP below 20 % of the base line - treated as follows until blood pressure normalized.
 - Head low position
 - Bolus of 100 ml of crystalloid solution
 - Infusion of 100 ml of hydroxyethyl starch solution, followed by 100 ml infusion every 15 min.
 - Sympathomimetics; inj. mephentermine 6 mg IV to begin with and repeated if necessary, to a maximum of 30 mg.
 - Blood transfusion in hypovolemia due to severe bleeding.
 - Bradycardia; pulse rate less than 60/min, treated with inj. atropine 0.5 mg IV, repeated if required.
- B. SpO₂ fall below 95 %
 - O₂ therapy by mask 4-6 L.

Subsequently, patient was transferred to the Post Anesthesia Care Unit (PACU) where residual sensory blockade was monitored and its wearing off time was noted (when sensation to pinprick regressed by two-dermatome segment – T5), residual motor blockade was monitored and its wearing off time was noted (when patient started to lift legs against gravity – T6). Patients were transferred from the PACU after recording the two-segment sensory regression and motor wear-off time.

The patients were also assessed regarding the postoperative pain, after the wearing off of the sensory block with VAS (visual analogue score) and when the VAS reached 5 or more, the patient was immediately given rescue post-operative analgesia with injection diclofenac sodium 75 mg IM.

VAS involves use of a 10 cm long line on a piece of white paper and it represents patient's assessment of the degree of pain. Its use was explained to all the patients pre-

operatively. Patients rated the degree of pain by making a mark on the scale. Thus the pain score was obtained by measuring the distance from the '0' end to the indicated mark. Pain was termed as;

Pain Score: 0-3=mild; 3-7=moderate; >7=severe

At the end of the study, results in the two groups were tabulated and subjected to statistical analysis by applying Statistical Package for Social Sciences (SPSS) version 11. The Z-test was used for comparisons of the components of the total deviation. The results were considered statistically significant when P-value was < 0.05. Finally the results in the two groups were compared to draw the conclusion.

RESULTS

Both groups were comparable with respect to their demographic profile (Table 1). The sensory onset was delayed in the Ropivacaine Group (42.6 ± 11.39 min) compared to Bupivacaine Group (18.4 ± 6.53 min), P-value <0.001. The motor onset was also found to be delayed in the Ropivacaine Group (55.54 ± 13.01 min) compared to Bupivacaine Group (27.5 ± 8.03 min), P-value <0.001 (Table 2). The peak sensory time was delayed in the Ropivacaine Group (10.92 ± 2.60 min) compared to the Bupivacaine Group (7.38 ± 1.69 min), P-value <0.001. The peak motor time was also delayed in the Ropivacaine Group (8.92 ± 2.41 min) compared to the Bupivacaine Group (4.82 ± 1.22 min), P-value <0.001 (Table 2).

Table 1: Comparison of demographic profile in study groups

Parameters	Bupivacaine Group Mean±SD (n=50)	Ropivacaine Group Mean±SD (n=50)	Z Value	P-value
Age (Yrs)	38.52 ± 12.89	40.26 ± 11.25	0.72	>0.05
Height (cm)	160.86 ± 7.24	161.98 ± 7.97	0.74	>0.05
Weight (Kg)	62.28 ± 11.05	59 ± 8.74	1.65	>0.05

Table 2: Comparison of onset of sensory (T1) and motor (T2) block and peak sensory (T3) and Peak motor (T4) in study groups

Time	Bupivacaine Group Mean±SD (n=50)	Ropivacaine Group Mean±SD (n=50)	Z value	P-value
T1- sensory onset (sec)	18.4±6.53	42.6±11.39	13.03	<0.001
T2- motor onset (sec)	27.5±8.03	55.54±13.01	12.97	<0.001
T3- sensory peak (min)	7.38±1.69	10.92±2.60	8.07	<0.001
T4- motor peak (min)	4.82±1.22	8.92±2.41	10.74	<0.001

There was no significant difference in heart rate, systolic and diastolic blood pressure, respiratory rate and SpO₂

Comparison between intrathecal isobaric ropivacaine 0.75% with hyperbaric bupivacaine 0.5%

between two groups, P-value >0.05 (Table 3). The quality of sedation in both the groups was compared at various time intervals and showed statistically significant differences between the two groups (Table 4).

Table- 3 : Comparison Of Vital Parameters (Heart rate, Blood pressure, Respiratory rate, SpO₂)

Vital parameters	Bupivacaine Group Mean ± SD (n=50)	Ropivacaine Group Mean ± SD (n=50)	Z Value	P-value
Heart rate (beats/min)	80.82 ± 11.03	81.78 ± 8.01	0.60	>0.05
Systolic BP (mmHg)	109.78 ± 13.98	111.32 ± 13.61	0.56	>0.05
Diastolic BP (mmHg)	63.4 ± 11.21	64.96 ± 10.28	0.72	>0.05
RR (/mins)	15.74 ± 0.85	15.64 ± 0.78	0.61	>0.05
SpO ₂	98.7 ± 1.14	99.06 ± 0.91	1.74	>0.05

Table 4: Comparison of quality of sedation in control and study groups

Sedation	Bupivacaine Group Mean ± SD (n=50)	Ropivacaine Group Mean ± SD (n=50)	Z value	P-value
Score	0.96 ± 0.49	1.16 ± 0.37	2.29	<0.05

The two-dermatomal segments regression of sensory level was compared and was significantly prolonged in the Ropivacaine Group (117.2 ± 12.5 min) when compared with Bupivacaine Group (108.5 ± 10.61 min) (P-value <0.001) (Table 5). The duration of motor blockade was compared and was significantly prolonged in the Bupivacaine Group (190.2 ± 28.37 min) compared to the Ropivacaine Group (149.7 ± 8.60 min), P-value <0.001 (Table 5). The post-operative analgesia was compared in both the groups and was comparable in both the groups, with no statistically significant difference. In the bupivacaine Group the duration of analgesia was 212.1 ± 42.81 min whereas duration of analgesia in the Ropivacaine Group was 209.9 ± 23.38 min (Table 5).

Table 5: Comparison of T5 (Two dermatomal regression) and T6 (Duration of motor blockade) and T7 (post-operative analgesia) in study groups

Time (in minutes)	Bupivacaine Group Mean ± SD (n=50)	Ropivacaine Group Mean ± SD(n=50)	Z-value	P-value
T5- Two dermatomal regression	108.5 ± 10.61	117.2 ± 12.5	3.75	<0.001
T6- Duration of motor blockade	190.2 ± 28.37	149.7 ± 8.60	9.66	<0.001
T7- Post-operative analgesia	212.1 ± 42.81	209.9 ± 23.38	0.32	>0.05

Bradycardia and hypotension were compared in both the groups. Seven patients in Bupivacaine Group experienced hypotension as compared to two patients in Ropivacaine Group, but this difference was found to be not statistically significant. Six patients in the Bupivacaine Group experienced bradycardia as compared to only one patient in Ropivacaine Group, P-value <0.05 (Table 6).

Table 6: Side effects in study groups

Side effects	Bupivacaine Group n(%)	Ropivacaine Group n(%)	P-value
Bradycardia	6 (12)	1(2)	<0.05
Hypotension	7 (14)	2(4)	>0.05

DISCUSSION

It was demonstrated that the significantly faster onset and regression of sensory block was seen with intrathecal bupivacaine and opioids, however significantly shorter motor block duration with intrathecal plain ropivacaine might be advantageous because it allowed a faster discharge, and/ or early recognition of any neurologic complications.

Ropivacaine is a local anesthetic with lower cardiotoxic potential than racemic bupivacaine. The majority of published data on ropivacaine concerns its use in the epidural space.^{14,15}

Whiteside et al in 2003⁹ compared the clinical efficacy of hyperbaric ropivacaine with that of the commercially available hyperbaric preparation of bupivacaine. They observed that time to peak motor blockade was delayed in the Ropivacaine Group (20 min) as compared to Bupivacaine Group (15 min), P<0.001.

Kallio et al in 2004¹⁰ carried out a study in which they compared intrathecal plain solutions containing ropivacaine 15 and 20 mg versus bupivacaine 10 mg in a prospective, randomized, double-blinded study. This study included 90 ambulatory lower-extremity surgery patients who received 2 ml of ropivacaine 1%, ropivacaine 0.75%, or bupivacaine 0.5%. They observed that the time for two dermatomal regression of sensory level was prolonged in the ropivacaine Group-15mg (90 min) when compared with the Bupivacaine Group-10 mg (70 min). We found the two segment regression of sensory level to be prolonged with 0.75% isobaric ropivacaine (21.5 mg) when compared with 0.5% hyperbaric bupivacaine (15 mg).

Sanchez et al in 2009¹² compared the effects of intrathecal isobaric ropivacaine (IR) versus isobaric bupivacaine (IB) in a dose ratio of 3:2 in non-ambulatory urologic and orthopedic surgery. 117 patients scheduled for surgery

were randomized and assigned in a double-blind fashion to receive either 15 mg of IR (n = 58) or 10 mg of IB (n = 59). They concluded that the motor blockade was longer in the IB Group (266.5+/- 29.5) compared to the IR Groups (226.4 ± 22.3 min), $p < 0.001$. We found the duration of motor blockade to be prolonged with bupivacaine (15 mg) when compared with ropivacaine (21.5 mg).

In 2007, Camorica et al¹⁶ carried out a study to determine the median effective dose (ED50) for motor block of intrathecal ropivacaine, levobupivacaine, and bupivacaine and to define their motor-blocking potency ratios. 104 parturients were enrolled in this study undergoing elective cesarean delivery with combined spinal-epidural anesthesia and were randomized to one of three groups to receive intrathecal 0.5% (wt/vol) ropivacaine, levobupivacaine, or bupivacaine. The initial dose was 4 mg, and the testing interval was set at 1 mg. As assessed using up-down analysis, intrathecal ED50 for motor block was 5.79 mg for ropivacaine (95% CI 4.62–6.96), 4.83 mg for levobupivacaine (95% CI 4.35–5.32) and 3.44 mg for bupivacaine (95% CI 2.55–4.34) ($P < 0.001$). The relative motor blocking potency ratios were ropivacaine/bupivacaine 0.59 (95% CI, 0.42–0.82), ropivacaine/levobupivacaine 0.83 (95% CI 0.64–1.09), and levobupivacaine/bupivacaine 0.71 (95% CI 0.51–0.98). They concluded that there is a clinical profile of potency for motor block for the pipercoloxylylidines when administered spinally: low, intermediate and high for ropivacaine, levobupivacaine and bupivacaine respectively.

In 2008, Mantouvalou et al¹⁷ performed a study to compare the anaesthetic efficacy and safety of three local anesthetic agents: racemic bupivacaine and its two isomers: ropivacaine and levobupivacaine, in patients undergoing lower abdominal surgery. 150 patients, ASA I-III, were randomized to receive an intrathecal injection of one of

three local anesthetic solutions. Group A (n = 40) received 3 ml of isobaric bupivacaine 5 mg/ml (15 mg). Group B (n=40) received 3 ml of isobaric ropivacaine 5 mg/ml (15 mg). Group C (n=40) received 3 ml of isobaric levobupivacaine 5 mg/ml (15 mg). The onset of motor block was significantly faster in the bupivacaine group compared with that in the ropivacaine group and almost the same of that in the levobupivacaine group ($P < 0.05$). Ropivacaine presented a shorter duration of both motor and sensory block than bupivacaine and levobupivacaine ($P < 0.05$). Bupivacaine required more often the use of a vasoactive drug (ephedrine) compared to both ropivacaine and levobupivacaine and of a sympathomimetic drug (atropine) compared to the ropivacaine group.

Hypotension and bradycardia were found to occur more often with the Bupivacaine Group as compared to Ropivacaine Group. Seven patients in Bupivacaine Group experienced hypotension as compared to only two patients in Ropivacaine Group. This difference was not statistically significant but has clinical significance.

Six patients in Bupivacaine Group experienced bradycardia as compared to only one patient in Ropivacaine Group. This difference was statistically significant, $P < 0.05$. Hence, the requirement of intraoperative interventions for hemodynamic stability was increased with the Bupivacaine Group as compared to Ropivacaine Group.

CONCLUSION

We conclude that intrathecal plain ropivacaine is superior to bupivacaine in terms of a longer sensory block, and a shorter motor block duration. Therefore 0.75% isobaric ropivacaine can be used in lower limb and lower abdominal surgery, especially in cases where early ambulation is desired.

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Young Project Against Pain - Call for Entry

It's been 3 years since the law 38/2010 on the treatment of pain and palliative care. Such a law, unique in Europe, recognizes the citizen's right to have access to pain management and palliative care. Law 38/2010 also recognizes the need for adequate post-graduate training through the establishment, in collaboration with the Ministry of University and Research, Master's Degree in Pain Therapy and Palliative Care.

Given the growing interest in the discipline and a view of the interdisciplinary clinical and basic research of the pain it is also necessary to help the growth and the formation of "research network" among young researchers in this discipline that they can become competitive in the international arena.

The project Young Against Pain is proposed, with the help of unconditional Grunenthal, to support the careers of 30 young researchers and medical specialists Italians who are involved in research projects related to the treatment of acute pain and / or chronic. The project aims to promote translational clinical and experimental research in the field of treatment of acute pain and / or chronic. Candidates will be selected based on the research project, and (in a tie) according to their Curriculum Vitae and its publications indexed in therapy of acute and / or chronic.

The 30 selected researchers will be awarded with entry (including travel and accommodation) to SIMPAR to be held in Rome next two days (March 28 to 29 in 2014). In addition, proposers of the best three research projects will be rewarded with entry (including travel and accommodation) to the next IASP World Congress to be held in Buenos Aires (Argentina), 6-11 October 2014. The 3 winners for next year will also participate in the research activities of the University of Parma in the projects currently in place and with their research project.

How to participate: Their CV and research project must be submitted online at yap@simpar.eu by 31/01/2014.

Website: <http://www.simpar.eu/simpar/progettoyap/>