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Original Research Article

COMPARISION OF 0.75% HYPERBARIC ROPIVACAINE WITH 0.5% HYPERBARIC BUPIVACAINE FOR SPINAL ANAESTHESIA

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Corresponding Author:
Dr. Virothi Navajyothi,
Email: navajyothivirothi@gmail.com

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Penmetsa Usha Rani[1], Balleda Sandhya[2], Srilakshmi Kothakoona[3], Virothi Navajyothi[4], Mummidi Akhila[5], Vantakula Gnaneswari[6]

[1,2,4]Assistant Professor, Department of Anesthesiology, Andhra Medical College, Visakhapatnam, Andhra Pradesh, India.
[3]Professor, Department of Anesthesiology, Andhra Medical College, Visakhapatnam, Andhra Pradesh, India.
[5,6]Postgraduate, Department of Anesthesiology, Andhra Medical College, Visakhapatnam, Andhra Pradesh, India.

Abstract

Background: To compare the onset of action, intensity and duration of sensory and motor block of 0.75% hyperbaric ropivacaine with 0.5% hyperbaric bupivacaine for elective lower abdominal, perineal and lower limb surgeries. **Material & Methods:** 60 patients undergoing elective lower abdominal, perineal and lower limb surgery receiving spinal anesthesia were divided randomly into two groups. Group B (bupivacaine 5mg/ml with glucose 80mg/ml 3ml) and Group R (ropivacaine 5mg/ml with glucose 80mg/ml 3ml). **Results:** The results were analysed and compared using Students Unpaired T-Test. The onset of sensory block was more rapid with bupivacaine ($p< 0.05$). The time to maximum extent of cephalad spread and the level achieved are similar in both groups. The degree and duration of motor blockade were significantly greater with bupivacaine than with ropivacaine. Hemodynamic changes were insignificant between the two groups. **Conclusion:** We conclude that 0.75% hyperbaric ropivacaine provides sensory block of similar extent and short duration than 0.5% hyperbaric bupivacaine. Motor block degree and duration was also less with 0.75% hyperbaric ropivacaine.

INTRODUCTION

Intrathecal use of Hyperbaric local anesthetic agents has been in practice since decades in Anesthesia as they produce precictable block characteristics and reliable spinal anesthesia.[3,4] Ropivacaine amino amide local anesthetic (LA) agent similar to bupivacaine in chemical structure (S [–] enantiomer but 30 – 40% less potent than bupivacaine.[1,4] Earlier studies have evaluated the efficacy and safety of isobaric ropivacaine for spinal anesthesia.[5,6]

Intrathecal ropivacaine was found to be safe, having shorter duration of action than bupivacaine and less incidence of transient neurological symptoms (TNS) as compared to intrathecal lignocaine. Hyperbaric solutions give more predictable block with greater spread in the direction of gravity. It helps to achieve block height as per requirements of surgery.

The aim of this study is to compare the efficacy of 0.75% hyperbaric bupivacaine with 0.5% hyperbaric bupivaine using equal volume of 3ml.

MATERIALS AND METHODS

After obtaining clearance from institutional ethics committee , Department of Anaesthesiology , Andhra Medical College , Visakhapatnam , Andhra Pradesh , India we conducted the trial.

Study Design

Prospective, randomized double blind controlled study.

Study population

A total of 60 patients undergoing elective lower abdominal, perineal and lower limb surgeries under spinal anesthesia were divided into two groups of 30 each.

Group B: Patients received 0.5% hyperbaric bupivacaine 3ml intrathecally.

Group R: Patients received 0.75% hyperbaric ropivacaine 3ml intrathecally.

Method of randomization

Randomization was done by sealed envelope technique.

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Sampling Inclusion Criteria

ASA grade I and II ages between 18 and 60yrs undergoing lower abdominal, perineal and lower limb surgeries.

Exclusion Criteria

Patients who have refused spinal anesthesia, patients who have infection at injection site, history of drug sensitivity. Patients with spine deformity, pregnant patients and patients with coagulation disorders and patients with all other contraindications to subarachnoid block.

Methodology

All patients were assessed in detail pre operatively. Investigations were performed as per requirement of surgery. Patients were kept nil by mouth for 6hrs prior to surgery.

For anxiolysis oral alprazolam 0.25 to 0.5 mg was given night before surgery. On arrival in the operating room continuous monitoring was done with electrocardiogram, non invasive blood pressure and pulse oximetry. A suitable peripheral vein was cannulated. Intravenous infusion was started with Ringers Lactate @ 10ml/kg 20 min before spinal anesthesia.

Patients were placed in left lateral position for spinal anesthesia (SA) and SA was given using midline approach at L3 – L4 or L4 – L5 intervertebral space. A 25G Quincke needle was used to perform SA with distal port facing laterally and appropriate local anesthetic injected over 10-15seconds. Patients were placed supine immediately after injection.

The development of block was recorded by an investigator who did not know which solution was injected.

The extent of sensory block (analgesia to pin prick with 27swg short bevel needle) ,degree of lower limb motor block (modified bromage scale. 0 = full movements , 1 = inability to raise extended leg, can bend knee 2 = inability to bend knee , can flex ankle 3 = no movement) arterial pressure and heart rate were recorded at 2,5,10,15,20,25 and 30 min and at 30min intervals thereafter until complete regression of block (sensory level at S2 and motor blockade grade 0 on bromage scale) was observed.

Hypotension defined as a decrease in systolic pressure >30% from baseline, was treated with iv bolus of 5ml/kg ringers lactate and if needed mephenteramine in dilutions of 6mg/ml was given. Fluids were administered to replace intra operative losses.

Bladder catheterization was performed only if surgically indicated. After surgery patients were encouraged to mobilize under

Supervision only when sensory block had regressed beyond L1 and the time of first micturition was noted.

Statistical Analysis

Sample size of 60 was taken on basis of pilot study conducted.

Numericals were presented as mean and standard deviation for patient characteristics such as age, weight, height, hemodynamic changes, block parameters such as onset duration and recoverytime of sensory block, time to maximum motor blockade, duration of motor blockade and the time to first micturition.

Categorical values were presented as frequency and percent for patient characteristics such as sex, distribution, ASA status and type of surgery, bromage grade of motor block and incidence of adverse events such as hypotension, bradycardia, backache, PDPH (post dural puncture headache). Students “Unpaired T-Test” for comparisions of mean and proportion were used wherever appropriate $P< 0.05$ was considered to be statistically significant.

RESULTS

In this study both the Groups R and B were comparable with regard to age, sex, height weight, ASA status and type of surgery. [Table 1]

The onset of pinprick analgesia at T10 was rapid in Group B than in Group R, $P = 0.041$ $P<0.05$ (Table 3). The time to maximum extent of cephalad spread and the level achieved are similar in both groups. The mean duration of sensory was shorter in Group R than in Group B ($P=0.012$, $P < 0.05$) . The degree and duration of motor block were significantly greater with bupivacaine than with ropivacaine. The mean time to complete regression of motor blockade was 180 + 35 min with intrathecal bupivacaine as compared to 90 + with hyperbaric bupivacaine ($P= 0.01$, $P < 0.05$). Hemodynamic changes were insignificant between the two groups ($P>0.05$). 6 patients in ropivcaine group and 4 patients in bupivacaine group requested for intraoperative sedation, but verbal contact was maintained at all times and block was suitable for surgery in all patients.

Patients in ropivacaine group were able to mobilize ($P=0.003$) and pass urine ($P=0.001$) sooner than those in bupivacaine group. 3 patients in ropivacine group and 2 patients in bupivacaine group had mild, localized self-limiting tenderness at the site of lumbar puncture at 24hrs, but there were no neurological symptoms in any patients. 2 patients in Group R and 1 patient in Group B developed a mild PDPH treated with bed rest, fluids and analgesic. Neither patient needed an epidural blood patch. [Table 2]

Table 1: Patient characteristics and types of surgery. Data are mean (SD or Range) or frequencies

	Group R (Ropivacaine)	Group B (Bupivacaine)
Number of patients	30	30

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Female/ male	14/15	15/14
ASA status I/II	15/14	13/17
Age (yrs)	55(00 – 00)	56(00 – 00)
Weight(kg)	83 (20)	77(16)
Height (cm)	171(13)	169(12)
Type of Surgery Lower limb Perineal Inguinal hernia	18 7 6	17 13 0

Table 2: Characteristics of neural block and frequency of adverse events. Data are median (range). NS, not significant

	Bupivacaine (n=30)	Ropivacaine (n=30)	P-value
Sensory block			
Onset at T_{10} (min)	2 (2-10)	6 (3-25)	0.041
Maximum cephalad			
spread (dermatome)	T_6	T_6	NS
Time to maximum			
cephalad spread(min) Block height at 90	18 (8 – 25)	18 (10-27)	NS
min(dermatome)	$T_{7/8}$($T_6 – L_1$)	T10/11 (T6 – S2)	0.001
Total duration (min)	225(160–420)	170(110 -250)	0.0001
Motor block			
Grade 3 block , n%	30 (100)	18(60)	0.03
Time to maximum			
Degree (min)	12 (4-15)	18 (10 – 26)	<0.0001
Total duration (min)	180(125 -215)	90(60 – 180)	<0.0001
Adverse events , n% Hypotension Mild back tenderness	8 (26)	7 (23)	NS
	2 (6)	3(10)	NS
Post dural puncture Headache	1(3)	2(6)	NS
Transient neurological Symptoms	0	0	NS
Other factors Time to mobilization (min) Time to first micturition (min)	 328(220 – 450) 335(278 – 470)	 220(170-350) 246(168-412)	 0.003 0.001

DISCUSSION

This study has confirmed that hyperbaric ropivacaine, which is commercially available now, produces reliable sensory and motor blockade like hyperbaric bupivacaine but of shorter duration. These results are in accordance with the studies done by kalpana R Kulkarni,[13] and others and also by J.B Whiteside and others. This is in contrast to the results two early clinical studies which described that blocks varied widely and were inadequate for surgery, in these studies isobaric raopivacaine was used.[5,6]

It is known that ropivacaine is 30 – 40% less potent and effects are short lived than bupivacaine, making it useful for short to intermediate duration of surgeries and ambulatory surgeries.[7,8] We observed that ropivacaine has less potent effect on motor nerves and the degree of sensory motor separation is more compared to bupivacaine but can produce reliable SA , which is supported by similar observations of other studies.[9,10]

The findings are similar to the study carried out by Whiteside and others,[2] who observed mean onset time of motor blockade of 15 minutes and 10 minutes and total duration of around 90 minutes and 180 minutes with similar dose of hyperbaric ropivacaine and bupivacaine respectively. Kalpana R Kulkarni and others also studied and had similar results, they observed time to sensory block of 13.5 min and 15 min and duration of sensory block 155 and 190.5 min with hyperbaric ropivacaine and bupivacaine respectively. Time to complete motor blockade is 14.5 min and 11 min and duration of motor blockade 120 min and 190min with hyperbaric ropivacaine and bupivacaine respectively.

Luck et al,[11] also observed that less degree and duration of motor blockade in 63% with hyperbaric 0.5% ropivacaine as compared to 90% with 0.5% bupivacaine with similar doses.

Lee et al studied intrathecal isobaric ropivacine in different concentrations (2,4,7,10 and 14 mg) for lower limb surgeries and found 100% successful anesthesia with dose of 14mg of ropivacaine.[12] Mc Donald and colleagues 4 compared hyperbaric ropivacaine and bupivacaine in volunteers not undergoing surgery. The solutions used were less concentrated and total doses injected were less. Equal doses of ropivacaine and bupivacaine produced sensory blocks of similar onset and extent but motor block was less which was also of shorter duration with ropivacaine. Based on their results, the authors concluded that ropivacaine is less potent than bupivacaine. Their also found a higher incidence of backache after ropivacaine and concluded that the incidence of side effects was higher in contrast to our study.

Ropivacaine is a long acting amide local anesthetic agent. It produces effects similar to other local anesthetics via reversible inhibition of sodium ion influx in nerve fibres. Ropivacaine is less lipophilic than bupivacaine and less likely to penetrate large myelinated motor fibres, resulting in a relatively

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reduced motor blockade. Thus, ropivacaine has greater degree of motor sensory differentiation. The reduced lipophilicity is also associated with decreased potential for CNS toxicity and cardiotoxicity. It is metabolized extensively in the liver and excreted in urine. Both preparations of 0.5% hyperbaric bupivacaine (sensorcaine) and 0.75% hyperbaric ropivacaine (ropin heavy) were commercially available and both solutions had dextrose 80mg/ml. The difference in onset of sensory block could be due to differences in drug itself. The difference in motor blockade degree and duration is due to the less lipophilic nature of ropivacaine.

Good sensory blocks were associated with a highly favourable recovery profile compared with bupivacaine, with more rapid regression of sensory and motor block earlier mobilization and shorter time to first micturition. With current trends of ambulatory surgery, such a recovery profile is likely to be useful.

CONCLUSION

A solution of hyperbaric ropivacaine can be used to provide reliable spinal anaesthesia comparable to that with hyperbaric bupivacaine in terms of quality of block, but with a shorter recovery profile. The main concern is the difference in the clinical profile of the block (onset, extent, suitability for surgery, duration) produced not the relative potencies of the two drugs. However, further work is required to evaluate the role of hyperbaric ropivacaine for surgical procedures of short– to- intermediate duration, particularly in the ambulatory setting.

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