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A PROSPECTIVE RANDOMIZED DOUBLE-BLIND STUDY TO COMPARE THE EFFICACY OF INTRATHECAL 0.5% HYPERBARIC BUPIVACAINE AND INTRATHECAL 0.75% HYPERBARIC ROPIVACAINE IN LOWER ABDOMINAL AND LOWER LIMB SURGERIES.

Anaesthesiology

Dr Rochana Girish Bakshi MBBS, DA,DNB (Anaesthesia), Professor, Department Of Anaesthesia, D.Y.Patil hospital, Nerul, Navi Mumbai.

Dr Mona Sanjeevkumar Jadhav MBBS, DA,DNB (Anaesthesia) Associate Professor, Department Of Anaesthesia, D.Y.Patil hospital ,Nerul, Navi Mumbai.

Dr Kirtibala Dhande MBBS, DA,DNB (Anaesthesia) Assistant Professor, Department Of Anaesthesia, D.Y.Patil hospital ,Nerul, Navi Mumbai.

Dr Anuradha Malliwal MBBS,MD(Anaesthesia) Professor, Department Of Anaesthesia, D.Y.Patil hospital, Nerul, Navi Mumbai.

Dr Kaushik Raghu MBBS Resident, Department Of Anaesthesia, D.Y.Patil hospital, Nerul, Navi Mumbai.

Dr Deepak Langade MBBS, MD, PGDASS(Applied Statistics) Professor and Head ,Department of Pharmacology, D.Y.Patil hospital ,Nerul, Navi Mumbai.

ABSTRACT

Introduction: Subarachnoid block (SAB) is the anesthesia of choice for lower abdominal and lower limb surgeries. Bupivacaine, an amino-amide compound, has proved to be a very effective long-acting local anesthetic agent but with a propensity for cardiac toxicity. Ropivacaine, a new amino-amide local anesthetic agent, is similar in chemical structure to bupivacaine, but with a better safety profile and good surgical anesthesia. There is a paucity of literature on 0.75% heavy Ropivacaine, as it has been recently launched. **Material & Methods:** Aim: To compare the efficacy of intrathecal hyperbaric Ropivacaine 0.75% and hyperbaric Bupivacaine 0.5% in lower abdominal and lower limb surgeries. A prospective double-blind randomized study was conducted after institutional ethics committee clearance. 86 patients of either sex were randomized to either ropivacaine (Group 1SR) or bupivacaine (group 2, SB) group.SR group received intrathecal 3.2 ml of 0.75% Ropivacaine and SB group received intrathecal 3.2 ml of 0.5% Bupivacaine. The onset of sensory and motor block, highest sensory level and time to achieve it, regression of motor and sensory block, and hemodynamic parameters were noted by consultants who were not involved in giving drugs. **Results:** The time required for a sensory block to recede was faster in the ropivacaine than bupivacaine group (164.77 ± 43.66min and 188.79 ± 30.65 min respectively), p value< 0.05, p:0.004. The median highest sensory level was T6. Motor block receded much faster in the ropivacaine group (158.49 ± 43.25mim) as compared to the bupivacaine group (206.83 ± 29.13 min), statistically significant, p< 0.0001 **Conclusion:** Hyperbaric Ropivacaine 0.75% has a predictable response and provides optimum surgical anesthesia without any significant effects on hemodynamic parameters. It produces a quick onset of the motor and sensory block with a quick offset as well.

KEYWORDS

Hyperbaric, Ropivacaine, Bupivacaine, Spinal Anesthesia.

INTRODUCTION:

Subarachnoid block (SAB) is the anesthesia of choice and gold standard for lower abdominal and lower limb surgeries, practiced worldwide. It is safe, inexpensive, and easy to perform the technique, offers the advantage of post-surgical pain relief, and avoids the various physiological and psychological phenomena which are vital for early mobilization and postoperative discharge. It has a quick onset and provides satisfactory sensory and motor blockades.

Bupivacaine, an amino-amide compound, was synthesized and introduced into clinical practice in 1963 and proved to be a very effective long-acting local anesthetic agent. In case of accidental intravascular access, bupivacaine may result in re-entrant arrhythmias and cardiac depression, sometimes culminating in cardiac arrest. These shortcomings, of this otherwise novel local anesthetic, resulted in the development of a newer anesthetic agent "ropivacaine.[1]"

Ropivacaine, a new amino-amide local anesthetic agent, is similar in chemical structure to bupivacaine. Extensive clinical data has shown that ropivacaine is effective and safe for regional anesthetic techniques such as epidural and brachial plexus block[2]. However, hyperbaric ropivacaine has been little studied in intrathecal anesthesia. The purpose of this study was to evaluate the efficiency and safety of hyperbaric 0.75% ropivacaine in spinal anesthesia and to compare it with hyperbaric bupivacaine in the lower limb and lower abdominal surgeries.

Aim: To compare the efficacy of intrathecal hyperbaric Ropivacaine 0.75% and hyperbaric Bupivacaine 0.5% in lower abdominal and lower limb surgeries

Primary Objective: To determine the onset and duration of motor and sensory block.

Secondary Objectives: To assess hemodynamic parameters and side effects such as shivering, nausea, vomiting

METHODS:

This prospective randomized study was conducted in a tertiary care hospital, by Department of Anaesthesiology, after institutional ethics committee clearance. Patients of either sex,20 to 60 years of age, undergoing lower limb and lower abdominal surgeries, ASA I & II were included in the study .85 patients of either sex were randomized to either ropivacaine (Group 1 SR) or bupivacaine (group 2, SB) group using the computerized random table. Patients were subjected to a preoperative anesthesia check. Written informed consent was taken and proper fasting guidelines were explained a day prior to surgery.
Exclusion criteria included severe back deformities, raised intracranial pressure, bleeding disorders, neurological disease, local skin infections, morbid obesity, pregnant females etc. The pre-anesthetic evaluation was done at least 24 h prior.

On the day of surgery, an intravenous cannula 18 gauge was inserted into the upper extremity and ringer lactate started. Monitors such as pulse oximeter (SpO2), electrocardiogram (ECG), non -invasive blood pressure (NIBP was attached.

The study population was randomly divided into two groups. Computer-generated codes and closed envelope techniques were used for randomization and double blinding.

Patients received spinal anesthesia in a sitting position, under aseptic precautions with 25G, Quincke tip, and spinal needle, in L3-L4 space by

a qualified anaesthesiologist. The SR group received intrathecal 3.2 ml of 0.75% Ropivacaine and SB g up received intrathecal 3.2 ml of 0.5% Bupivacaine. Patients were positioned supine immediately. The sensory block and level were checked using a 25 G hypodermic needle. The motor block was assessed using the modified Bromage scale. Heart rate (HR), systolic (SBP), diastolic (DBP), and mean arterial pressure(MAP) were measured every 2 mins from the onset of block for the first 20 mins, thereafter every 10 minutes till the end of the procedure.

The following block characteristics were noted:

1. Highest sensory level achieved.
2. Time for highest sensory level to be achieved.
3. Time taken for sensory regression to L1.
4. Onset of complete motor block
5. Time taken for complete motor regression.

Hypotension (20% decrease in MAP), if any, was treated with intermittent boluses of intravenous ephedrine (6 mg). Bradycardia (HR < 50/ minute) was treated with intravenous atropine 0.6 milligram (mg) or Glycopyrrolate 0.2mg.

Modified Bromage Scale

Score	criteria
0	Able to lift legs against gravity
1	Able to flex knee but unable to flex legs
2	Able to move feet bit unable to flex knees
3	Unable to move any joints

The anaesthesiologist recording the observations was blinded to the study drug. The patient was observed in the postoperative recovery area for complete regression of motor and sensory blocks. A Diclofenac injection 75mg in 100ml normal saline (NS) was given as rescue analgesia.

Sample size calculation-Sample size was calculated based on study parameter motor block, alpha error, beta error, confidence limit, confidence interval, and power of the study. On the assumption of alpha error as 5%, beta error as 0.12, and power of the study as 80%, a sample size of 43 was derived for each group.

Statistical Analysis:

The data were subjected to statistical analysis as per the social science system version SPSS 21.0. Students' t-test was used for continuous variables and nominal categorical data were analyzed using chi-square test or Fischer exact test. A p-value of less than 0.05 was considered significant.

RESULTS:

The demographic data of the two groups were comparable in terms of age, weight, gender, and ASA classification. Both groups enrolled 43 patients, however, in 1 patient of bupivacaine adequate level of anesthesia was not achieved, hence converted to general anesthesia. This resulted in 42 patients in the bupivacaine group for final analysis

The time to achieve the highest sensory level was not significantly different in both groups,10.74 min for the Ropivacaine group vs 10 min for bupivacaine, the p-value was not significant, but the time required for the sensory block to recede was significantly faster than bupivacaine,164.77 ± 43.66min in ropivacaine and 188.79 ± 30.65 min in bupivacaine, p value< 0.05, p:0.004.

The median highest sensory level was T6 and the time to achieve this was comparable in both groups and there was no statistical significance.

Time for the onset of motor block was faster in the ropivacaine group (4.2 ± 2.46min) as compared to the bupivacaine group (6.12 ± 3.51min), which was statistically significant, p< 0.05p=0.006(table 2)

Motor block receded much faster in the ropivacaine group (158.49 ± 43.25mim) as compared to the bupivacaine group (206.83 ± 29.13 min), highly significant statistically, p< 0.0001. (Graph 1)

The motor block of ropivacaine regressed faster than its sensory block whereas the motor block of bupivacaine regressed slower than its sensory block. (table2)

Fall in systolic, diastolic, and mean arterial blood pressure were comparable in both groups with respect to values as well as the timing of fall, although insignificant statistically but clinically significant. The Ropivacaine group had stable mean arterial pressure and heart rate. (table1, Figure 1).

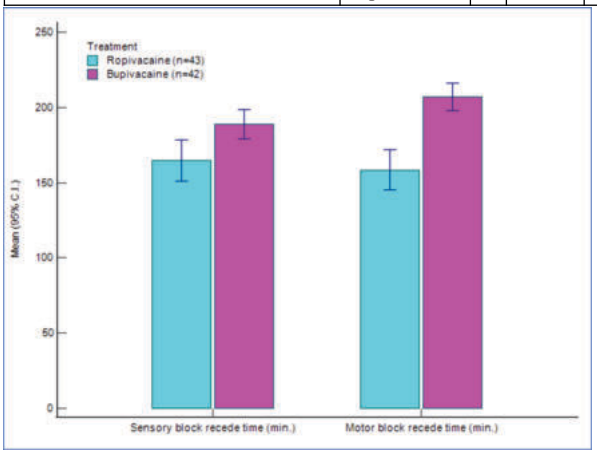
Table 1: Demography and baseline data of patients

						95% C.I.		t-test	
	Group	N	Mean	SD	Mean difference	Lower	Upper	t	p
Age (yrs.)	Ropivacaine	43	43.44	15.16	5.132	-1.085	11.35	1.642	0.104
	Bupivacaine	42	38.31	13.60					
Pulse (Baseline)	Ropivacaine	43	81.53	14.78	-5.037	-11.058	0.985	-1.664	0.100
	Bupivacaine	42	86.57	13.06					
SBP (mm Hg)	Ropivacaine	43	135.91	17.83	1.455	-6.007	8.916	0.388	0.699
	Bupivacaine	42	134.45	16.72					
DBP (mm Hg)	Ropivacaine	43	80.26	10.35	-1.078	-5.457	3.302	-0.489	0.626
	Bupivacaine	42	81.33	9.94					
MAP (mm Hg)	Ropivacaine	43	96.74	12.09	2.578	-2.098	7.253	1.096	0.276
	Bupivacaine	42	94.17	9.39					

Table 2: Block and changes in BP of patients

						95% C.I.		t-test	
	Group	N	Mean	SD	Mean difference	Lower	Upper	t	p
Highest Sensory Level achieved	Ropivacaine	43	6.09	1.64	-0.24	-0.898	0.418	-0.726	0.47
	Bupivacaine	42	6.33	1.39					
Time for highest sensory level (min.)	Ropivacaine	43	10.74	3.63	0.744	-1.072	2.56	0.815	0.417
	Bupivacaine	42	10.00	4.73					
Time for sensory to recede(min.)	Ropivacaine	43	164.77	43.66	-24.018	-40.327	-7.709	-2.929	0.004
	Bupivacaine	42	188.79	30.65					
Time for motor block achieved(min.)	Ropivacaine	43	4.26	2.46	-1.863	-3.168	-0.559	-2.841	0.006
	Bupivacaine	42	6.12	3.51					
Motor block receded(min.)	Ropivacaine	43	158.49	43.25	-48.345	-64.293	-32.397	-6.03	<0.0001
	Bupivacaine	42	206.83	29.13					
MAP fall (mm Hg)	Ropivacaine	43	67.60	11.57	-0.229	-5.233	4.776	-0.091	0.928
	Bupivacaine	42	67.83	11.62					
Time to max. MAP fall (min.)	Ropivacaine	43	24.88	19.92	2.812	-5.824	11.449	0.648	0.519
	Bupivacaine	42	22.07	20.11					

Max fall in SBP (mm Hg)	Ropivacaine	43	109.35	15.88	5.373	-0.725	11.47	1.753	0.083
	Bupivacaine	42	103.98	12.07					
Time to max. SBP fall(min.)	Ropivacaine	43	24.56	18.87	5.701	-0.932	12.334	1.71	0.091
	Bupivacaine	42	18.86	10.66					
Max fall in DBP (mm Hg)	Ropivacaine	43	63.28	7.67	0.231	-3.157	3.62	0.136	0.892
	Bupivacaine	42	63.05	8.03					
Time to max. DBP fall (min.)	Ropivacaine	43	17.35	14.37	-1.223	-6.624	4.179	-0.45	0.654
	Bupivacaine	42	18.57	10.29					
Max fall in MAP (mm Hg)	Ropivacaine	43	77.91	9.72	3.05	-0.941	7.041	1.52	0.132
	Bupivacaine	42	74.86	8.74					
Time to max. MAP fall (min.)	Ropivacaine	43	23.81	16.29	3.171	-2.753	9.095	1.065	0.29
	Bupivacaine	42	20.64	10.47					



Graph 1:

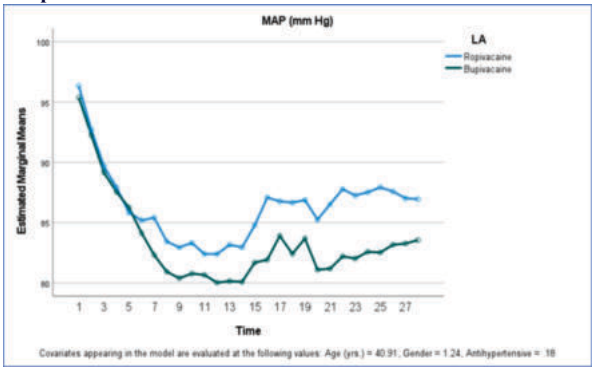


Figure 1:

DISCUSSION:

There is a paucity of literature on spinal preservative-free, heavy Ropivacaine 0.75% as it has been recently launched in India. So far most of the literature is based on studies done on 0.5% isobaric ropivacaine or isobaric made hyperbaric after the addition of dextrose. These studies have shown a faster onset of the motor and sensory block with bupivacaine as compared to ropivacaine, but in the present study, the time taken for complete motor block and the highest sensory level was comparable in both groups with no statistical significance. According to minimum local anesthetic concentration (MLAC) studies, which are based on effective analgesia in 50% of patients ropivacaine has a similar potency to bupivacaine at higher doses, it is less potent than bupivacaine and levobupivacaine at lower doses. So Ropivacaine in peripheral nerve blocks is supposed to have a better action than when used for intrathecal anesthesia. In the present study, intraoperative surgical anesthesia was found to be comparable in both groups. This finding correlates with a study done by Osama Al Abdulhadi et al,[3] and J.F Luck et al, [4] who also reported insignificant differences in the quality of anesthesia between both groups.

Wahedi et al,[5] had a failure rate of 20 % with intrathecal plain ropivacaine 0.5 % in abdominal surgeries and Malinovsky et al,[6] found 16 % failure of spinal anaesthesia with plain ropivacaine 0.5 % for urological surgeries.

In the present study, 24 mg of ropivacaine and 16 mg of bupivacaine were used in respective groups. Van Kleff et al,[7] and Wahedi et al,[5] used either 15 mg or 22.5 mg of ropivacaine for gynecological, orthopedic or urological surgery and found that the intensity of motor block was lower in the 15mg group. In the present study, in spite of 24 mg, the duration of sensory and motor block was lesser than bupivacaine. In the ropivacaine group, the time taken for the motor block to recede was faster than that required for the sensory level but even after lower limb movements were seen, the patient continued to have pain relief.

This may be due to the fact that ropivacaine is less lipid soluble which causes the drug to penetrate the large, myelinated A fibers more gradually than the more lipid soluble bupivacaine. It blocks nerve fibers involved in pain transmission (A∂ and C fibers) to a greater degree than motor fibers (Aβ fibers).

In the present study, the onset and time to achieve the highest sensory level were comparable. The median highest sensory level was T6 and the time to achieve this was comparable in both groups there was no statistical significance but the onset of motor block was faster with ropivacaine, which is contrary to previous studies, such as done by Subba et al,[8] Singh et al,[9] Chari et al,[10], etc. In most of the prior studies, either isobaric or 0.5% hyperbaric ropivacaine has been used, however, 0.75% hyperbaric ropivacaine was used in the present study. The hyperbaric drug spreads more evenly and gravity probably spreads the drug along the slopes of the lumbar curve once the patient is placed supine. There is a predictable cephalad spread and prolonged duration of a clinically useful block.

Hemodynamic parameters were comparable and statistically not significant, but clinically hemodynamics were stable in the ropivacaine group in spite of using 24mg which was a higher dose as compared to earlier studies. Only one patient in the ropivacaine group had bradycardia and three patients in the bupivacaine group had hypotension and two patients had bradycardia which was treated with Atropine 0.6mg. Hypotension was treated with ephedrine 6mg aliquots. These findings were comparable to studies done by S Purohit et al,[11]

The present study shows that hyperbaric ropivacaine, in a dose of 24 mg, produces predictable and reliable spinal anesthesia for lower abdominal and lower limb surgeries of relatively longer duration without any significant fall in blood pressure or heart rate. Surgical anesthesia was comparable to bupivacaine without any supplemental sedation or analgesia as seen in studies done by R Gupta et al, [12] and Kallio et al,[13]where the isobaric ropivacaine group required supplemental sedation.

Time for the first onset of micturition was not analyzed in the present study, but a study done by S Purohit et al showed that the first onset of micturition was 236.38 ± 90.44 minutes in the ropivacaine group and 289.85 ± 73.21 in the bupivacaine group, p=0.037. These findings were consistent with those of Kulkarni et al,[14], and Whiteside et al,[15].

CONCLUSION:

Hyperbaric Ropivacaine 0.75% has a predictable response and provides optimum surgical anesthesia without any significant effects on hemodynamic parameters. It produces a quick onset of the motor and sensory block with a quick offset as well. These properties make it a better alternative to hyperbaric bupivacaine for lower limb and lower abdominal surgeries. In daycare setting and early ambulation, it would be the preferred drug of choice.

Conflict Of Interest: none declared

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