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Research Article

COMPARISON OF EFFECTS OF EQUIVOLUMES OF 0.75% ISOBARIC ROPIVACAINE WITH 0.5% HYPERBARIC BUPIVACAINE FOR SPINAL ANAESTHESIA- A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Intrathecal drug administration is the commonest mode of anaesthesia for adult infra umbilical surgeries. Various drugs with differing baricities have been introduced to get particular advantages. We tried to compare equivolumes of two drugs with differing baricities. One hundred patients in the age group between 18-65 years belonging to ASA I and II undergoing elective or emergency surgeries in lower limb, inguinoscrotal and perineal region under spinal anaesthesia were enrolled in our study and were randomized into two groups by a sealed envelope technique (Group B and Group R). The study was double blinded. Group B patients received 0.5% hyperbaric bupivacaine & Group R patients received 0.75% isobaric ropivacaine in L2-L3 intrathecal space. Study parameters such as heart rate, systolic and diastolic BP, time of onset, maximum cephalad spread, duration of sensory block were recorded. Quality of sensory and motor block was also recorded as per the protocol and statistical analysis was done using SPSS software (version 19). No patients were excluded from our study. The demographic data were comparable between the two groups. There was a significant difference in the median time of onset of sensory block at L1 dermatome which was slower in the isobaric ropivacaine group (3min ± 51sec) when compared with hyperbaric bupivacaine group (2min 26sec ± 35sec) (p = 0.000). The median duration of sensory block at L1 level was significantly shorter with isobaric ropivacaine group (161 min) (Range 120- 200 min) whereas with hyperbaric bupivacaine group it was (179 min) (Range 160-200 min) (p=0.000).The maximum cephalad spread at 30 min was insignificantly lesser with isobaric ropivacaine (T6-T8) when compared with hyperbaric bupivacaine (T4-T6). Quality of motor block provided by 0.75% isobaric ropivacaine is almost similar to that of 0.5% hyperbaric bupivacaine. The side effects were similar.

INTRODUCTION

Spinal anaesthesia has a definitive advantage of producing profound nerve block in a large part of the body by a relatively simple injection of a small amount of local anaesthetic (LA). Inter patient variability in spread of local anaesthetic was observed and described as "lauenhaft" (waywardness) by August Bier (1). Barker was the first to study systematically about the factors affecting intrathecal spread using hyperbaric solutions by adding glucose and Babcock studied about hypobaric solutions by adding alcohol (1).

Various factors have been found to determine the spread of local anaesthetics in CSF, out of which baricity (density), amount (mg), concentration and volume of LA are labeled as major factors (2-4). Bupivacaine a long acting, amino amide local anaesthetic is in clinical practice for more than two decades. Extensive clinical studies have been done to establish the effects on central neuraxial blockade such as time of onset, block height, duration, and quality of motor and sensory blockade with various volume, baricity and concentrations (2,4-8).

Ropivacaine is a new-long acting, amino amide local anesthetic with a high pKa and low lipid solubility. It is a monohydrate of the hydrochloride salt of 1-propyl' 2'-6'-pipecoloxylidide and is prepared as pure s-enantiomer with purity of 99.5%. Ropivacaine provides a wider safety margin while preserving the desirable pharmacodynamic properties of bupivacaine which has been showing an unsatisfactory safety profile over

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cardiovascular system (9). Ropivacaine is less cardio toxic and has a significantly higher threshold for central nervous system toxicity than equivalent concentration of racemic bupivacaine (10-12). Ropivacaine is considered to block sensory nerves to a greater degree than motor nerves (11), with a shorter duration of motor blockade (5,13,14) and hence more rapid post-operative recovery of motor function (7).

Extensive clinical studies have shown that ropivacaine is effective and safe for regional anaesthetic techniques such as epidural and brachial plexus block (7,14-16). However, experience of intrathecal anaesthesia with ropivacaine is not so well documented. Ropivacaine is commercially available as isobaric solution, studies shows that the dose-effect ratio of ropivacaine to bupivacaine was 3:2 (5). Onset and upper extent of sensory block is similar in both isobaric ropivacaine and bupivacaine (15). Hyperbaric solutions are not commercially available and have to be prepared by adding glucose to the plain solution. Compared with commercial preparation of bupivacaine, it has been shown that the hyperbaric ropivacaine preparation produces slower onset and less extensive sensory blockade (6). We have designed this study to analyse and compare the effects of equivolume (3ml) of commercially available 0.75% isobaric ropivacaine& 0.5% of hyperbaric bupivacaine administered in spinal anaesthesia. The aims and objectives of the study were to compare 1. Onset, Spread, Duration of Sensory Blockade. 2. Quality of Motor Blockade.3. Haemodynamic parameters. 4. Side effects, when equivolume dose (3ml) of either 0.75% isobaric ropivacaine or 0.5% hyperbaric bupivacaine is used for spinal anaesthesia.

METHODOLOGY

The study was conducted at a tertiary care institute. After getting approval from the hospital ethics and research committee, patients admitted to our hospital, who were undergoing elective or emergency surgeries were randomly selected for the study. During the pre anaesthetic visit patients were explained about the study purpose, merits and demerits of the study procedure and instructed to demand analgesia as per the need. After a through pre-operative checkup, one hundred patients between 18-65 years of age belonging to American Society Of Anaesthesiologist (ASA) physical status class I or II of either sex who were undergoing elective or emergency surgeries in lower limb, inguinoscrotal and perineal region under spinal anaesthesia satisfying inclusion and exclusion criteria were enrolled for the study. Patients who were not consenting for spinal anaesthesia, patients with compromised cardiovascular, respiratory function and bleeding diathesis were excluded from the study. An informed written consent was taken from all the patients recruited for the study.

Patients who were enrolled in the study were premedicated with tab. Diazepam 10mg, tab. Metoclopromide 10mg and tab. Ranitidine150 mg, in the night, the day before and in the morning on the day of surgery. In the operation theater base line reading of the study parameters such as heart rate, noninvasive blood pressure, SpO2, respiratory rate were done using a standard multiparameter hemodynamic monitor. After recording the baseline parameters, patients were randomized into one of the two groups (B-Bupivacaine & R-Ropivacaine) by closed envelope technique. The anesthetist who injects the drug was blinded about the study drug. The study drug that has to be injected was written on a slip and placed in an envelope. Random selection of an envelope was done by a person who was not involved in the study and the drug to be injected is identified which was written in a slip and the slip is put back into the cover and sealed. The study drug was loaded by a person who is not involved in the study and was given to the anesthetist who injected it intrathecally, thereby he was blinded about the study drug. Sealed envelopes were opened only at the end of the study to find out what drug has been injected.

In the operating room with strict aseptic precaution an intravenous cannula (18G) was inserted, patients were preloaded with 15ml/kg of Ringer lactate solution before giving spinal anaesthesia. Under strict aseptic precaution, patient in the right lateral position, subarachnoid space was identified. The study drugs was injected by the anesthetist who was blinded about the study drug in L2-L3 interspace using a 25 gauge quinke's spinal needle (Becton Dickinson Guadalix Madrid, Spain) after confirming free flow of CSF. Group R patients received 3ml of 0.75% isobaric ropivacaine (Ropin 0.75%, Neon Laboratories) and Group B patients received 3ml of 0.5% hyperbaric bupivacaine (Anawin 0.5% Heavy Neon Laboratories). The drug was injected into the intrathecal space with the spinal needle bevel facing upwards at the rate of 0.2ml/sec and patients were turned immediately to supine position. The time of injection was noted. Heart rate, Blood pressure, SpO_2 were recorded every 5 min for first 30 min and every 10 min there after till the sensory level regresses to L1.

The sensory & analgesic levels were assessed by lack of appreciation of cold temperature and pin prick respectively for every minute following injection of local anaesthetic agent. The onset time for sensory block was taken from the time of injection of local anaesthetic to the loss of sensation to cold temperature and pin prick at L1 segment. The sensory and analgesic levels were monitored for every 5 minutes following onset of block for first 30 min and every 10 min till it regressed to L1 segment. This is labeled as duration of sensory block. The quality of motor block was measured with "Bromage" scale (0-No Paralysis, 1-Inability to raise Extended Leg, 2-Inability to flex the Knee, 3-Inability to flex the ankle (complete motor blockade) at 10 min after spinal and at the end of surgery.

Rescue measures adapted were oxygen supplementation with 35% venturi mask if SpO2 declined below 94%. Bradycardia (heart rate below 50/min) is treated with inj. Atropine 0.6mg and hypotension (systolic blood pressure below 90 mmHg) was treated with inj. mephentermine in titrated bolus doses of 3mg.

Sample size was calculated to evaluate the block characteristics with intrathecal isobaric ropivacaine and hyperbaric bupivacaine in terms of onset and duration of sensory block. On simple interactive statistical analysis, a sample size of minimum 45 in each group was derived using the formula for sample size calculation for multiple comparison (two-tailed) based on the assumption of a (type 1 error) = 5%, b (type 2 error) = 0.2 and power of the study = 80% to detect a difference of 25%.All calculations were made after finding mean and SD and two tailed unpaired t test was used to detect differences between two groups with a p value of < 0.05.

RESULTS

The distribution of patients in the two groups included in the study did not differ significantly with respect to age. The mean age of patients in group R is found to be 37.98 ± 13.41 years and the mean age of patients in group B is found to be 40.46 ± 13.77 years and was statistically not significant (p Value = 0.364)The male : female ratio were similar in both groups(42:8 Vs 44:6).The mean weight and height were comparable. Both the groups underwent similar infra umbilical procedures with comparable duration. Time of onset for ropivacaine was found to be 180 sec (median) (range 45 –300) but for bupivacaine it was 135 sec (median) (range 50-240) (figure 1). Statistical analysis showed that the time of onset of analgesia was significant between two groups (p Value = 0.000). Isobaric ropivacaine is found to have slower time of onset compared with hyperbaric bupivacaine.

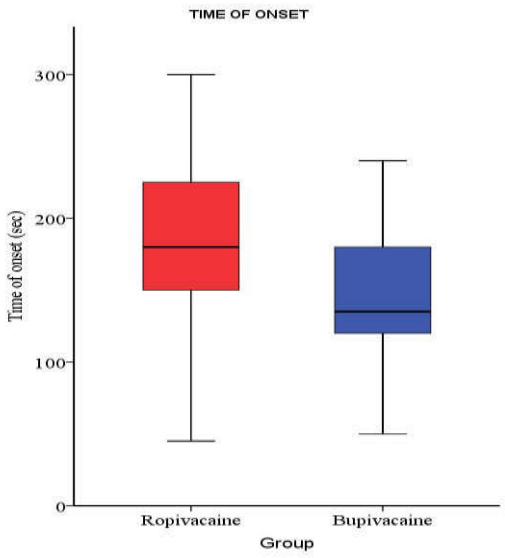

Figure 1 showing time of onset of different groups

The time for regression of analgesia to L1 is found to be faster with isobaric ropivacaine group 161 min (median) (range 120 - 200) than with hyperbaric bupivacaine group 179 min (median) (range 160-200). (figure 2)

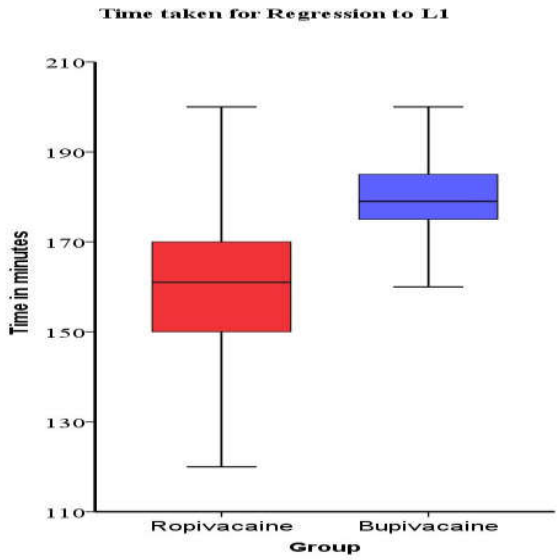

Figure 2 showing time taken for regression to L1.

As the onset is slightly slower, the level achieved at different times is slightly less in Group R than Group B at different times. Still the maximal cephalad spread is T4-6 in Group B while it is T6-8 in group R. This is not clinically significant especially when considering infra umbilical surgeries. Bromage scales between the two groups at ten minutes after spinal anaesthesia and at the end of surgery were comparable. Regarding the side effects, heart rate in group R and group B were comparable and not found to be statistically significant throughout the study. Similarly the mean systolic and diastolic blood pressures were comparable and similar in both the groups throughout the study period. The adverse effects which were not clinically significant are tabled below.

Table 1 showing adverse effects

Adverse Events	Gr. Bupivacaine	Gr. Ropivacaine
Vomiting	1	-
Shivering	-	2
Arrhythmia	1	-
Bradycardia	2	2
Hypotension	4	-
Pain	-	1

DISCUSSION

Primary aim of this investigation is to study the relative efficacy of 0.75% isobaric ropivacaine versus 0.5% hyperbaric bupivacaine when administered intrathecally in equal volumes for patients undergoing lower limb, perineal and ilioinguinal surgeries. In our study onset of sensory block was defined as the time from injection of LA to loss of sensation to pin prick / cold temperature at L1 dermatome)This was approximately 2 minutes with bupivacaine but around 3 minutes with ropivacaine, eventhough there is a statistical significance, the clinical utility is none. Jean Marc Malinovsky, in their study on intrathecal isobaric bupivacaine 10mg and isobaric ropivacaine 15mg found out that the onset time to T10 anaesthesia was not different (bupivacaine 13 ± 8 min, ropivacaine 11 ± 7 min) between the two drugs (17). In contrast the study done by J.B.Whiteside (18)on hyperbaric ropivacaine and hyperbaric bupivacaine showed that the mean time of onset of sensory block at T10 with hyperbaric ropivacaine is slower when compared with hyperbaric bupivacaine (ropivacaine 5 min; bupivacaine 2 min; P<0.005), P.D.W Fettes *et al* in their study found out that there was a significant difference in onset of sensory block at T10 dermatome between hyperbaric and plain solutions of ropivacaine (plain 10 min; hyperbaric 5 min; P<0.001) (19). Most of these studies have a different end point. Jean-Marc Malinovsky showed that the maximum cephalad spread of sensory block was higher with isobaric bupivacaine (cold T4 and pin prick T7) than with isobaric ropivacaine. This goes along with our results. In our study we found out that the mean time for regression of sensory block to L1 is 160 ± 16 min with isobaric ropivacaine whereas the mean time for regression with hyperbaric bupivacaine is 180 ± 8 mins which clearly shows that the duration of sensory block with isobaric ropivacaine is shorter than that of hyperbaric bupivacaine, which correlates with previous studies done by J.B.Whiteside in which the mean duration of sensory block at T10 for hyperbaric ropivacaine is 56.5 min and for hyperbaric bupivacaine it is 118 min (P=0.001) (7).Shorter duration of sensory block with isobaric ropivacaine may be attributed to the physico-chemical properties of ropivacaine mainly the protein binding which is lesser than bupivacaine (20).The

speed at which the levels were achieved were almost similar in both the groups in an observation of 30 minute duration.In our study we found out that, 49 patient in group R had the Bromage scale of 3 at 10 min after spinal anaesthesia; whereas all 50 patients had Bromage scale of 3 in group B. M. Mantouvalou *et al* compared plain ropivacaine, bupivacaine and levobupivacaine for lower abdominal surgeries they found that the onset of motor block was significantly faster in bupivacaine group (8±5 min) compared with ropivacaine group (12±5 min) and 11±7 min in levobupivacaine group (15).

CONCLUSION

We conclude that the onset of sensory block with 0.75% isobaric ropivacaine is slower yet clinically insignificant. The duration of sensory block is less when compared with 0.5% hyperbaric bupivacaine. The motor block with 0.75% isobaric ropivacaine is almost similar to that of 0.5% hyperbaric bupivacaine. The maximum cephalad spread of sensory block is insignificantly lower with isobaric ropivacaine. Haemodynamic stability was comparable between the groups. Hence we conclude that 0.75% isobaric ropivacaine can provide similar and effective anaesthesia as 0.5 % hyperbaric bupivacaine for infra umbilical surgeries

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