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Dr. Nisarga R
Ex registrar, Department of Anaesthesiology, Bangalore Medical College and Research Institute, Bangalore, Karnataka, India

Dr. Nandini RT
Ex registrar, Department of Anaesthesiology, Bangalore Medical College and Research Institute, Bangalore, Karnataka, India

Dr. Ramesh R
Associate professor, Department of Anaesthesiology, Bangalore Medical College and Research Institute, Bangalore, Karnataka, India

Corresponding Author:
Dr. Nisarga R
Ex registrar, Department of Anaesthesiology, Bangalore Medical College and Research Institute, Bangalore, Karnataka, India

A comparative study of plain and hyperbaric solutions of 0.75% ropivacaine in spinal anaesthesia in elective lower abdominal and lower limb surgeries

Dr. Nisarga R, Dr. Nandini RT and Dr. Ramesh R

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Abstract
Background and objective: Spinal anaesthesia is the most common technique of regional anaesthesia used for lower abdominal and lower limb surgeries. Bupivacaine is the commonly administered drug. Ropivacaine, is an amino amide local anaesthetic, which has less cardiovascular and central nervous systems toxicity compared with bupivacaine. This study is undertaken to compare plain and hyperbaric solutions of ropivacaine in spinal anaesthesia.
Methods: 80 patients of ASA I/II physical status undergoing elective lower abdominal and lower limb surgeries were randomised into 2 groups. Group C (n=40) patients received 3ml of 0.75% plain ropivacaine with 0.4 ml of normal saline and Group D (n=40) patients received 3 ml of 0.75% plain ropivacaine with 0.4 ml of 25% dextrose. Hemodynamic parameters, time of onset and duration of sensory and motor blockade, maximum height of block, total duration of sensory and motor blockade and time to mobilise were recorded.
Results: Hemodynamic parameters were comparable between the two groups except at few intervals. Demographic data and duration of surgery were comparable. The onset of block to T10 in group C 10.1 ± 1.6 min, group D 4.6 ± 0.9 (p value <0.001), mean time to maximum block in group C 13.0 ± 2.7 min, group D 8.9 ± 0.9 (p value <0.001) were statistically significant. Mean duration of block at T10 in group C was 94.7± 24.7 min, group D 146.1 ± 31.9 (p value <0.001), duration of sensory regression in group C 291.6 ± 74.3 min, group D 239.9 ± 39.8 (p value <0.001), duration of motor regression in group C 225.4 ± 68.4 min, group D 186.0 ± 41.0 (p value 0.003) and time to mobilise in group C was 309.1 ± 76.3 min, group D 251.0 ± 41.1 min (p value <0.001) which were statistically significant.
Conclusion: Hyperbaric ropivacaine has early and faster onset, spreads more to higher levels, has more denser block and is early to regress compared to plain ropivacaine.

Keywords: Spinal anaesthesia, plain, hyperbaric, Ropivacaine, dextrose

Introduction
Spinal anaesthesia is the most common technique of regional anaesthesia used for lower abdominal and lower limb surgeries. First spinal anaesthesia was performed by August Bier in 1898 by using 0.5% cocaine. Subarachnoid block provides effective sensory and motor blockade. A wide variety of local anaesthetic drugs are available for spinal anaesthesia namely Lidocaine, Bupivacaine.
Lignocaine was the local anaesthetic of choice for decades due to its rapid onset of action and good motor block. But its use was limited by its short duration of action and its implication in causation of transient neurological symptoms and cauda equina syndrome following intrathecal injection [1, 2]. Bupivacaine is one of the commonest local anaesthetics used which has longer duration of action and its potency is higher than lignocaine [3]. But it can cause profound myocardial depression and even cardiac arrest when used in higher concentration or when accidentally administered intravascularly [4].
Ropivacaine, is a long acting amino amide local anaesthetic structurally similar to bupivacaine. It produces effects similar to other local anaesthetics via reversible inhibition of sodium ion influx in nerve fibres. It is a racemate, pure S(-) enantiomer, developed for the purpose of reducing potential toxicity and improving sensory and motor block [5].
Ropivacaine is less lipophilic than bupivacaine and is less likely to penetrate large myelinated motor fibres. The reduced lipophilicty is associated with decreased potential for central nervous system toxicity and cardiotoxicity [5]. It produces similar sensory block and reduced motor block to that of an equivalent dose of bupivacaine due to its less

Lipophilicity [5].

Various factors can affect the distribution of local anaesthetic solutions in CSF. These include patient's age, height, anatomical configuration of spinal column, site of injection, direction of needle during injection and density of CSF, baricity [6], density and volume of local anaesthetic solution and position of the patient. Higher concentration of glucose free isobaric ropivacaine solutions results in variable spread of analgesia but with good quality of motor block with higher concentration, adequate for the proposed surgery [7, 8, 9]. However in comparison with bupivacaine, plain ropivacaine produces rapid postoperative recovery of sensory and motor blockade [10].

Previous studies had shown that, hyperbaric solution of ropivacaine produces predictable and consistent anaesthesia for surgery than plain one [10, 11], but with a duration shorter than bupivacaine [12, 13]. Although several studies have examined the effects of intrathecal ropivacaine in both women in labor [14] and patients undergoing minor surgery. Less number of studies have evaluated its use in anaesthesia for major surgery. Hence this study is undertaken to compare plain and hyperbaric solutions of ropivacaine in spinal anaesthesia in patients undergoing elective lower abdominal and lower limb surgeries.

Our aim was to compare the efficacy of plain and hyperbaric solutions of 0.75% ropivacaine in spinal anaesthesia given in L2 –L3 space in elective lower abdominal and lower limb surgeries regarding, Time of onset of sensory and motor blockade, Time to achieve maximum dermatomal level, Haemodynamic parameters, Total duration of sensory and motor blockade, Time to mobilise and Side effects, if any.

Methodology

After approval from institutional ethics committee, this prospective randomized double blind study was conducted from November 2016 to May 2018. Those patients who were posted for infraumbilical surgeries who gave written informed consent of either sex in the age group of 20-60 years with ASA physical status I and II were included in the study. Patients with allergy to local anesthetics, Contraindications to spinal anaesthesia like raised intracranial tension, progressive neurodegenerative disorder, CNS infections, local infections, Spine deformities and patients with uncontrolled diabetes mellitus, hypertension, recent myocardial infarction, Psychiatric disorder, hypovolaemic shock, Bleeding diathesis and coagulopathy were excluded from the study.

Preoperative evaluation of the patient was done on the day before surgery. After explaining the procedure, written and informed consent was obtained. Patient was advised overnight fasting and were premedicated with tablet alprazolam 0.5 mg the night before and on the day of surgery. In the operating room, intravenous line was secured with 18G cannula and patients were preloaded with ringer's lactate solution at 15ml/kg. Monitors including pulse oximeter, noninvasive arterial blood pressure, electro cardio graph were connected to the patient and baseline vitals recorded.

The 80 patients were randomised using numbers generated from www.random.org website and divided into two groups, 40 patients each,

Group C (n=40): 0.75% Plain ropivacaine 3 ml + normal saline 0.4 ml

Group D (n=40): 0.75% Plain ropivacaine 3 ml + 25% dextrose 0.4 ml

Under strict aseptic precautions subarachnoid block was performed by using 25 G Quincke Babcock spinal needle in the L2- L3 interspace with patient in left lateral position. The study drug was loaded in a 5ml syringe by a senior anaesthesiologist who was not involved in the study. Just before spinal anaesthesia, syringe was handed over to the anaesthesiologist performing the subarachnoid block, who was also the observer of the study. The patients were not aware of the drug being administered to them. Thus both the observer and the patient were blinded. The study drug was injected over 10-15 seconds. The time at which injection was completed was considered as zero time of the study and all measurements were recorded from this point. Patients were made to lie down in the supine posture immediately after the subarachnoid injection of the study drug, keeping the table flat. All patients were given supplementary oxygen through a venturi mask at 6L/min.

Sensory testing was assessed by loss of pinprick sensation to 23 G sterile hypodermic needle for the onset and dermatomal levels were tested every 2 minutes until the highest level had been achieved and stabilized for four consecutive tests. Time of onset of motor block was assessed by using Modified Bromage Scale.

Haemodynamic variables were recorded every minute for first five minutes, at 5 minutes for next half an hour after the administration of subarachnoid block and at every 10 minutes thereafter upto the end of the surgery. Hypotension was defined as 20% fall in systolic blood pressure from baseline and was treated with intravenous fluids and intravenous injection Mephenteramine 6mg. Bradycardia was defined as 20% fall in heart rate from baseline and was treated with intravenous injection Atropine 0.6 mg.

Data regarding the time to reach highest dermatomal level of sensory blockade from the time of injection, time for sensory regression at T10 were recorded. In case of failure of subarachnoid block and conversion to general anaesthesia, were excluded from the study.

After the surgery, patients were shifted to the post anaesthesia care and recovery unit where they remained until complete recovery of sensory and motor blockade was achieved. Post operatively, the hemodynamic variables and oxygen saturation were recorded upto 24 hours postoperatively. The incidence of any adverse effects such as hypotension, bradycardia, shivering, nausea, vomiting, pruritis, respiratory depression and ECG changes were noted and treated.

Sample size was chosen based on outcome variable i.e time to mobilize with minimum difference of 70, SD OF 75, 90% statistical power and 5% level of significance, the sample size of 50 (25 in each group) was adequate for the study. For better results, we had chosen sample size of 80 (40 in each group).

Data was entered into Microsoft excel data sheet and was analyzed using SPSS 22 version software. Categorical data was represented in the form of Frequencies and proportions. Chi-square test or Fischer's exact test (for 2x2 tables only) was used as test of significance for qualitative data. Yates correction was applied were ever chi-square rules were not fulfilled (for 2x2 tables only).

Graphical representation of data: MS Excel and MS word was used to obtain various types of graphs such as bar

diagram, Pie diagram and Scatter plots. p value of <0.05 was considered as statistically significant after assuming all the rules of statistical tests.

Results

All the patients included in the study received the assigned intervention and were followed up till the end of study. There were no exclusions or drop outs. Patient demographic characteristics were comparable in both groups(age, gender, weight, height) (Table 1). Number of patients belonging to ASA class I and II were uniformly distributed between both the groups (Table 2). There was no significant difference in mean duration of surgery between two groups.

In the study there was no significant difference in mean Heart rate between two groups at all the intervals of followup. In Plain Ropivacaine, there was significant difference in mean HR at 1 hr, 2 hr, 6 hr and 24 hr compared to baseline values. In Hyperbaric Ropivacaine, there was significant difference in mean HR at 3 min, 5min, 15 min, 20 min, 30 min, 50 min, 1 hr, 2 hr, 6 hr, 12 hr and 24 hr compared to baseline values.

In the study there was no significant difference in mean SBP between two groups at all the intervals of followup. In Plain Ropivacaine group there was significant difference in mean SBP from 1 min to 24 hrs compared to baseline. Initially there was decrease in SBP and after 40 min SBP started to increase towards baseline value. In Hyperbaric Ropivacaine group there was significant difference in mean SBP from 15 min to 50 min compared to baseline. Initially there was decrease in SBP and after 25min SBP started to increase towards baseline value.

In the study there was significant difference in mean DBP between two groups from 30 min to 24 hrs. At these intervals mean DBP was significantly higher in hyperbaric ropivacaine group. At other intervals there was no significant difference in mean DBP between two groups.

In the study there was no significant difference in mean MAP between two groups at all the intervals except at 1 hr.In plain ropivacaine group there was significant difference in mean MAP from 5 min to 24 hrs compared to baseline. Initially there was decrease in DBP and after 30 min DBP started to increase towards baseline value. In hyperbaric ropivacaine group there was significant difference in mean MAP from 1min to 24 hrs compared to baseline. Initially there was decrease in DBP and after 25 min DBP started to increase towards baseline value.

In the study there was no significant difference in mean SpO2 between two groups at all the intervals.

In plain ropivacaine group, mean duration of surgery was 90.4 ± 31.3 min and in hyperbaric ropivacaine group, mean duration of surgery was 107.8 ± 61.6. There was significant difference in mean duration of surgery between two groups.

In plain ropivacaine group, mean Onset to T-10 was 10.1 ± 1.6 min and in hyperbaric ropivacaine group, mean Onset to T-10 was 4.6 ± 0.9. There was significant difference in mean Onset to T-10 between two groups.

In plain ropivacaine group, mean time to maximum block was 13.0 ± 2.7 min and in hyperbaric ropivacaine group, mean time to maximum block was 8.9 ± 0.9. There was significant difference in mean time to maximum block between two groups.

In plain ropivacaine group, mean duration at T10 was 94.7 ± 24.7 min and in hyperbaric ropivacaine group, mean duration at T10 was 146.1 ± 31.9. There was significant difference in mean duration at T10 between two groups.

In plain ropivacaine group, mean duration for sensory regression was 291.6 ± 74.3 min and in hyperbaric ropivacaine group, mean duration for sensory regression was 239.9 ± 39.8. There was significant difference in mean duration for sensory regression between two groups.

In plain ropivacaine group, mean duration for motor regression was 225.4 ± 68.4 min and in hyperbaric ropivacaine group, mean duration for motor regression was 186.0 ± 41.0. There was significant difference in mean duration for motor regression between two groups.

In plain ropivacaine group, mean time to mobilise was 309.1 ± 76.3 min and in hyperbaric ropivacaine group, mean time to mobilise was 251.0 ± 41.1. There was significant difference in mean time to mobilise between two groups. (Table 3)

In Plain Ropivacaine group, majority of subjects had Median Maximum Block at T6 (62.5%) and in Hyperbaric Ropivacaine majority of subjects had Median Maximum Block at T4 (65%). This difference in Median maximum block between two groups was statistically significant.

Table 1: Demographic parameters of subjects in two groups

	Group				P value
	Group C		Group D		
	Mean	SD	Mean	SD	
Age in years	39.50	11.752	44.18	10.546	0.126
Weight in KG	62.98	6.306	59.68	5.274	0.013
Height in M	158.38	3.102	156.38	2.976	0.004

Patient demographic characteristics were comparable in both groups.

Table 2: ASA grade comparison between two groups

		Group			
		Group C		Group D	
		Count	%	Count	%
ASA	1	28	70	20	50
	2	12	30	20	50

$\chi 2 = 3.333$, df = 1, p= 0.068

Table 3: Durations comparison between two groups

	Group				P value
	Plain Ropivacaine		Hyperbaric Ropivacaine		
	Mean	SD	Mean	SD	
Duration of surgery (min)	90.4	31.3	107.8	61.6	0.115
Onset to T-10 (min)	10.1	1.6	4.6	0.9	<0.001*
Time to Maximum Block(min)	13.0	2.7	8.9	0.9	<0.001*
Duration at T10 (min)	94.7	24.7	146.1	31.9	<0.001*
Sensory Regression (min)	291.6	74.3	239.9	39.8	<0.001*
Motor Regression (min)	225.4	68.4	186.0	41.0	0.003*
Time to mobilise (min)	309.1	76.3	251.0	41.1	<0.001*

Discussion

Spinal anaesthesia is the most common technique of regional anaesthesia used for lower abdominal and lower

limb surgeries. Ropivacaine produces similar sensory block and reduced motor block to that of an equivalent dose of bupivacaine due to its less lipophilicity. However in comparison with bupivacaine, plain ropivacaine produces rapid postoperative recovery of sensory and motor blockade. Glucose free solutions are marginally hypobaric and quality of block is unpredictable because gravity does not affect their spread in the supine position. Addition of glucose will lead to more rapid spread to higher median level and less variation in maximum sensory and motor block. The increase in density produced by adding glucose results in more even distribution of the local anaesthetics, gravity presumably encouraging spread of the bolus of drug down the slopes of the lumbar curve. Various studies have been conducted with other local anaesthetics which improved the quality of block by adding glucose along with them.

In this study, there was no statistical significance in the demographic data, type of surgery and duration of surgery. In the study there was no significant difference in mean heart rate, SBP, DBP, MAP and SpO2 between two groups at all the intervals. There was significant difference in mean Onset to T-10, mean time to maximal block, mean duration at T-10and between two groups. There was significant difference in mean duration for sensory and motor regression between two groups. There was significant difference in mean time to mobilise, and Median maximum block between two groups.

The study conducted by P D W Fettes *et al*. [11] "comparison of plain and hyperbaric solutions of ropivacaine for spinal anaesthesia was similar to our study. In their study, they had recorded pulse rate and blood pressure at 2, 5, 10, 15, 20, 25 and 30 min intervals after injection and found that there was no significant difference in hemodynamic parameters among two group. The Mean time of onset of sensory block at T10 is rapid in hyperbaric ropivacaine compared to plain group. There was significant difference in mean time of onset to T-10 between two groups and hyperbaric ropivacaine produced a more rapid onset and more extensive, but less variable sensory block compared to plain ropivacaine. The median maximum block height was at T8 in plain Ropivacaine group and T4 in hyperbaric Ropivacaine group. Median time to regression of sensory block to T10 (an indicator of useful duration for surgery) was longer in the hyperbaric group 115 min (50- 178) compared to plain ropivacaine group 25 min (0-208). Median time to complete regression of motor block were longer in the plain group 180 min (90- 270) compared to hyperbaric group 120 min (30- 150) with p value of <0.001 which was statistically significant, which were similar in our study.

The study of spinal anaesthesia with ropivacaine 5 mg/ml in glucose 10 mg/ml or 50 mg/ml conducted by Whiteside JB *et al*. [12] found that onset of pinprick analgesia at T10 was more rapid (p=0.03) with greater concentration of glucose 50 mg/ml solution (median 5 min) than with 10 mg/ml solution (10 min) which was statistically significant. The maximum extent of cephalad spread was same in both the groups with range T3 -T10 (median T6/7) in 10 mg/ml group and range of T3- T10 (median T6) in 50 mg/ml group. The above study compares well with the findings of our study.

Hence the present study concludes that Hyperbaric ropivacaine has early and faster onset, spreads more to higher levels, has more denser block and is early to regress compared to plain ropivacaine. This study had few limitation like the Baricity of the obtained solution after addition of 25% dextrose to the study drug was not measured in our study due to lack of facilities.

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