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Original Research Article

Comparing the efficacy and haemodynamic response between intrathecal hyperbaric 0.5% bupivacaine with isobaric 0.75% ropivacaine using fentanyl as adjuvant in patients undergoing infra umbilical surgeries

R Arun Kumar[1],*, I Preetha[1]

[1]*Dept. of Anaesthesiology, PSG Institute of Medical Science and Research, Coimbatore, Tamil Nadu, India*

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ABSTRACT

Background: Central neuraxial blockade is the most widely used form of regional anesthesia in surgeries involving abdominal, urological, obstetric, gynaecological and lower limb. The nerve blocking properties of the R and S-enantiomers were similar but that the S-enantiomer was less cardiotoxic. The aim of our study is to compare the efficacy and haemodynamic response between intrathecal hyperbaric 0.5% Bupivacaine with isobaric 0.75% Ropivacaine using Fentanyl as adjuvant in patients undergoing infra umbilical surgeries.

Materials and Methods: 60 patients of age group between 25 – 65 years belonging to American Society of Anaesthesiologist (ASA) 1 and 2 posted for general surgical, urological, orthopaedic and gynaecological procedures involving lower abdominal surgeries under spinal anaesthesia divided into two groups of 30 each and randomly allocated to one of the two below mentioned groups:
Bupivacaine group (Group B) n=30; Ropivacaine group (Group R) n=30

Observation and Results: Chi-square test and Student's 't' test were used to analyse the results. The sensory block in Bupivacaine group B was significantly higher compared to Ropivacaine group R attaining statistical significance. The 3 minutes motor block, incidence of hypotension was denser and higher in Bupivacaine group compared with Ropivacaine group. Incidence of bradycardia was not significantly different between the two groups. Although the onset of motor blockade was denser in Bupivacaine group, the total duration of motor blockade was similar between the groups.

Conclusion: We conclude from our study that 0.75% isobaric Ropivacaine produces similar duration of efficacy with stable haemodynamics, as compared with 0.5% hyperbaric Bupivacaine.

1. Introduction

Central neuraxial blockade is the most widely used form of regional anesthesia in surgeries involving abdominal, urological, obstetric, gynaecological and lower limb. The advantages being well established, widely accepted, ease of subarachnoid puncture and studies suggest that spinal anaesthesia may be superior to general anesthesia. The endocrine - metabolic response to surgery is blunted when spinal anaesthesia is employed compared to the response during general anaesthesia (GA).[1]

Various local anaesthetic agents such as cocaine, procaine, etidocaine, tetracaine, lignocaine, bupivacaine and ropivacaine were tried for sub arachnoid blockade. Bupivacaine was marketed as a long acting local anaesthetic, its advantages compared to Lignocaine being long duration of action and differential sensory-motor block; but untoward adverse effects like arrhythmias, prolonged duration of sensory and motor blockade require a need to overcome these problems. Hyperbaric 5% Lidocaine has been reported to be associated with transient radicular irritation following single-dose of spinal anaesthesia and is not being used much now-a-days.

* *Corresponding author.*
E-mail address: shivaaniarun76@gmail.com (R. A. Kumar).

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In 1977, the propyl derivative of the pipecoloxylidides was less toxic than the butyl derivative (Bupivacaine). The nerve blocking properties of the R and S-enantiomers were similar but that the S-enantiomer was less cardiotoxic. Thus Ropivacaine a single (S) stereoisomer was chosen for further development.[2] Ropivacaine, structurally resembling Bupivacaine, is a relatively new amino-amide local anaesthetic agent, similar in chemical structure to Bupivacaine, having various advantages like early onset and shorter duration of action and having lesser cardio toxicity. Ropivacaine relieves the psychological distress of being immobile for a longer period of time after lower abdominal surgeries. In view of the above context, the present study was undertaken to compare these two drugs.

2. Aim

The aim of our study is to compare the efficacy and haemodynamic response between intrathecal hyperbaric 0.5% Bupivacaine with isobaric 0.75% Ropivacaine using Fentanyl as adjuvant in patients undergoing infra umbilical surgeries.

3. Materials and Methods

A study titled "Comparing the efficacy and haemodynamic response between intrathecal hyperbaric 0.5% Bupivacaine with isobaric 0.75% Ropivacaine using Fentanyl as adjuvant in patients undergoing infra umbilical surgeries" was done in PSG Institute of Medical Sciences and Research, Coimbatore, after obtaining institutional human ethical committee clearance and informed written consent from all the patients who participated in this study.

This is a randomized, single blind study where the person assessing the response (observer) was blinded to the group the patient belonged to and the person administering the spinal was aware of the drug he is administering. 60 patients of age group between 25 – 65 years belonging to ASA 1 & 2 posted for general surgical, urological, orthopaedic and gynaecological procedures involving lower abdominal surgeries under spinal anaesthesia were included in the study.

60 patients were divided into two groups of 30 each and randomly allocated to one of the two below mentioned groups as Bupivacaine group (Group B) n=30 and Ropivacaine group (Group R) n=30. The Inclusion criteria in our study includes ASA Grade 1 and 2 patients, age ranging from 25 to 65 years, procedures done under spinal anesthesia and patients posted for general surgery, urological, orthopaedic and gynaecological procedures expected to last not more than 3 hours. Exclusion criteria includes patient denial, absolute contraindication for regional anesthesia, inability to communicate with the patient, combined spinal and general anesthesia, pregnancy, patchy or failed spinal.

All patients were premedicated orally with Tablet Pantoprazole 40 mg and Tablet Alprazolam 0.25 mg the previous night and 2 hours prior to surgery. In the receiving room an 18G intravenous cannula was inserted and an infusion of Ringer's lactate solution started at 2ml/ kg/ hr. On arrival in the operation theatre Electocardiogram, Non invasive blood pressure and pulsoxymeter were connected as pre-induction monitors and recording of these parameters started after noting the baseline values. The patient was placed in lateral position, sterile painting and draping done and spinal puncture was made in L_3L_4 interspace with 26G Quinke spinal needle. After establishment of free flow of Cerebrospinal fluid, intrathecal administration of 2.6ml 0.75% Ropivacaine with Fentanyl 25 μg or 2.6ml 0.5% Bupivacaine with Fentanyl 25 μg was given over a period of 30 seconds as per the random allocation and patient was turned supine post spinal injection. No tilt was given to any patients.

The haemodynamic parameters were monitored. Hypotension when Systolic Blood Pressure recorded < 90mmHg was treated with Intravenous (IV) crystalloids and Vasopressors Injection Ephedrine or Mephentremine 6 mg IV bolus, as and when needed if there was persistent hypotension. Bradycardia was noted when the Heart rate was <50 beats per minute and treated with Injection Glycopyrrolate 0.02mg per kilogram IV bolus, as and when needed. The density and recovery of the motor blockade were monitored using Bromage scale and the height of sensory level was determined bilaterally using loss of sensation to pin prick.

Description of the bromage scale

Grade	Criteria	Degree of block
I	Free movement of legs and feet	Nil (0%)
II	Just able to flex knees with free movement of feet	Partial (33%)
III	Unable to flex knees, but with free movement of feet	Almost complete (66%)
IV	Unable to move legs or feet	Complete (100%)

Assessment of motor blockade was done three minutes after intrathecal injection, after completion of surgery, every 15 minutes till the patient completely recovers, during discharge in recovery room.

3.1. Statistical analysis

The observations and results were compiled and analysed by Chi-square test and Student's 't' test to see if there was any significant difference in the onset and density of motor blockade between the two groups. Haemodynamic parameters like hypotension, bradycardia, nausea, vomiting and ventricular arrhythmias (ectopics) were also compared and analysed statistically.

Qualitative variables like sex, ASA gradings, incidence of hypotension, bradycardia, arrhythmia, nausea and vomiting were compared between the two groups using Chi-square test and Quantitative variables like age, weight, height, duration of surgery, Bromage score and total duration of motor blockade between the two groups were compared by using Student's 't'test.

4. Observation and Results

Table 1 to Table 5.

5. Discussion

The first clinical report of spinal anaesthesia was made in the year 1899 by Dr August Bier, who described the intrathecal administration of cocaine.[3] The greatest challenge of the technique is to control the spread of the local anaesthetic through the cerebrospinal fluid (CSF) in order to produce a block that is adequate for the proposed surgery without producing a needless extensive spread.

Subarachnoid block is a commonly employed anaesthetic technique for performing lower abdominal and lower limb surgeries. It is a safe, inexpensive and easy-to-administer technique which also offers a high level of post–operative satisfaction with good pain relief to the patients. The technique is simple, has rapid onset and the risk of general anaesthesia including mishaps due to airway management are avoided by this technique.

The selection of the local anaesthetic to be used for spinal anaesthesia is usually based on the expected duration of surgery and need for early patient discharge. Though cardiotoxicity is not a concern in subarachnoid block, the quality of sensory blockade, motor blockade, hemodynamic changes and side effect profile are some considerations in selecting a drug for spinal anaesthesia.

The use of long acting agents is associated with a lower risk for transient neurologic dysfunction.[4–7] Bupivacaine is the local anaesthetic used routinely for surgeries because of its high potency and minimal neurological symptoms. The efficacy and safety of intrathecal administration of both plain and hyperbaric solutions of Ropivacaine have been evaluated in different clinical settings including orthopaedic,[8] urological surgery,[9] caesarean section and labour pain.[10,11]

Ropivacaine, a S-enantiomer of Bupivacaine is being increasingly used for spinal anaesthesia and the advantages claimed are shorter duration of motor block with similar sensory block properties and lesser cardiotoxic property compared to Bupivacaine; thus it minimizes the psychological discomfort of being immobile for a long time.

In our study, a single blinded clinical trial was undertaken to compare the duration and density of motor blockade and haemodynamic instability between intrathecal hyperbaric 0.5% Bupivacaine and isobaric 0.75% Ropivacaine using Fentanyl as adjuvant in 60 patients between the age group of 25 to 65 years of age either gender, belonging to ASA Grade I and II scheduled for general surgical, gynaecological and orthopaedic procedures (Infra umbilical surgeries).

Demographic data such as age, sex, weight and height between the two groups were comparable and there was no statistical significance since p value was > 0.05 between the two groups. The duration of surgery was 57.67±34.16 mins in Ropivacaine group and 48.17±19.49 mins in Bupivacaine group and p value 0.191 was found to be statistically insignificant.

In our study, maximum cephalad spread is assessed after 3 minutes of injection of local anaesthetic by using loss of sensation to pinprick T10 level. In Bupivacaine group (B) the mean sensory level was T4 to T6 (4.93± 0.828) which is higher when compared to Ropivacaine group (R) where the mean level was T5 to T8 (5.70± 1.055). This is in contrast with the study conducted by Jean-Marc Malinovsky et al[12] (Mean level for Bupivacaine: T7 & Ropivacaine: T9), Whiteside et al[13] (Mean level for Bupivacaine: T5 & Ropivacaine: T7). A study by Koltka k et al[14] reported spread of sensory block was higher in Bupivacaine than Ropivacaine. we infer that the maximum cephalad spread or height of sensory level was significantly lower in Ropivacaine group in out study.

The 3 minutes motor block was denser in Bupivacaine group than Ropivacaine group with statistical significance. The difference in motor blockade between both the group was statistically significant since p < 0.05 and this score was comparable with the study by Mantouvalou et al[15] & Erturk E et al[8] who reported onset of motor block was significantly faster in Bupivacaine group. The total duration of motor blockade was similar in both the groups and there was no statistical significant difference in the discharge time of the patient.

Miller C G et al[16] determined level of sensory (cold sensation) and motor blockade (Bromage) and measured heart rate, blood pressure and oxygen saturation. With the exception of maximum spread of sensory blockade, there was no difference with regard to demographics, sensory or motor blockade and hemodynamic variability.

Mc Namee DA et al[17] recorded the onset and duration of sensory block at dermatome level T10, maximum upper and lower spread of sensory block and the onset, intensity and duration of motor block. Onset of motor and sensory block was rapid with no significant differences between the two groups. But the median duration of complete motor block (modified Bromage Scale 3) was significantly shorter in the Ropivacaine group compared with the Bupivacaine group (220±22.67 versus 228±32.09 mins) in our study.

Y.Y.Lee et al[18] used Fentanyl 15 μg as an adjuvant in both Ropivacaine and Bupivacaine group and achieved sensory block to the T10 dermatome or higher at 15 min after intrathecal injection revealing the duration of complete

Table 1: Demographic details - Group B and Group R

Parameters	Group B	Group R	t- value	p value	Significance
Age					
Mean age in yrs ± S.D	38.37±10.50	37.7±11.91	0.230	0.819	Not significant
Sex distribution					
Male	18	17	0.069	1	Not significant
Female	12	13			
Weight	66.13±9.06	64.33±10.26	0.720	0.474	Not significant
Height	164.27±6.96	163.07±7.85	0.627	0.533	Not significant
ASA Grading					
I	21	24	0.800	0.0552	Not significant
II	9	6			

Table 2: Duration of surgery and height of sensory level between two groups

Parameters	Group	Values	t value	p value	Significance
Duration of Surgery Mean(mins)	B	48.17±19.49	1.323	0.191	Not significant
	R	57.67±34.16			
Height of sensory level (Mean thoracic level)	B	4.93±0.828	3.131	0.003	Statistically Significant
	R	5.70±1.055			

Table 3: Bromage score after 3 minutes in Group B and Group R

Bromage Score	Grade III	Grade IV	X^2	p value	Significance
Group B	6 (20%)	24 (80%)	26.786	0.000	Statistically Significant
Group R	26 (86.7%)	4 (13.3%)			

Table 4: Hemodynamic parameters – Group B and Group R

Parameters	Group B	Group R	X^2	p value	Significance
1. Incidence of hypotension					
Yes	17	7	6.994	0.017	Statistically Significant
No	13	23			
2. Bradycardia					
Yes	9	9	0.00	1	Not significant
No	21	21			
3. Nausea/Vomiting					
Yes	8	1	6.405	0.026	Statistically Significant
No	22	29			
4. Ventricular arrthymia					
Yes	2	2	2.069	0.492	Not significant
No	28	30			

Table 5: Total duration of motor blockade

Group	Mean (mins)	t value	p value	Significance
Group B	228±32.09	1.034	0.305	Not significant
Group R	220±27.67			

motor block shorter in the Ropivacaine group compared with the Bupivacaine group. But in our study we used 25 μg as an adjuvant and had similar results, which was also similar to Erturk et al[8] studies who had used 20 μg fentanyl with Ropivacaine or Bupivacaine.

Koltka K et al[14] performed his study in Ropivacaine and Bupivacaine with Fentanyl 50 μg to make 3 ml total spinal fluid volume. The primary outcome, the duration of motor block, was significantly shorter in the Ropivacaine group as compared with our study. No patient had pruritus, eczema, shivering, respiratory depression intraoperativelyNausea and Vomiting

5.1. Definition

Nausea is the sensation of being about to vomit. Vomiting, or emesis, is the expelling of undigested food through the mouth. ..... Click the link for more information. In our study, none of the patient had residual neurological deficit, post-dural puncture headache or transient neurological symptoms at the postoperative follow-up.

In our study the hypotension was a significant statistically in consistent with the study conducted by Lopez-soriano F et al,[5] Whiteside et al,[19] Mantouvalou et al[6] & Erturk E et al.[8] In their studies it is shown that there is increased incidence of hypotension and higher requirements of vasoactive drugs in Bupivacaine group than in Ropivacaine group of patients. This can be attributed to the higher cephalad spread of hyperbaric Bupivacaine causing more sympathetic blockade than isobaric Ropivacaine. Incidence of hypotension is higher in Bupivacaine group compared to Ropivacaine group.

The increased incidence of nausea and vomiting in group B can be explained due to higher incidence of hypotension and maximum cephalad spread. The study by Mantouvalou et al[6] showed occurrence of nausea and vomiting is equally distributed between the two groups, thereby not agreeing with our study.

In our study, the incidence of bradycardia is similar between two groups. 9 patients in each group had bradycardia and were treated with anti-cholinergics. This is in contrast with the study done by Kessler P et al,[12] Boztug N et al[2] and Koltka k et al[10] which reported no significant bradycardia between the two groups (Bupivacaine and Ropivacaine). Regarding intra-op arrhythmias only 2 patients in Bupivacaine group had ectopics and was not statistically significant.

In our study, total duration refers to the time after intra-thecal injection to the complete recovery of the patients from motor block. In Bupivacaine group, the mean duration was 228 minutes whereas in ropivacaine group it was 220 minutes. P value is 0.305 and is statistically insignificant. This is in complete agreement with the studies done by Gautier PE et al,[19] Liu et al,[20] Jean-Marc Malinovsky et al[7] andKessler P et al[12] compared isobaric Ropivacaine and Bupivacaine, which showed similar motor blockade between the two groups.

In our study, there was no failed spinal cases and there was no need for supplementation with general anesthesia.

6. Conclusion

We conclude from our study that 0.75% isobaric Ropivacaine produces similar duration of motor blockade with stable haemodynamics, as compared to 0.5% hyperbaric Bupivacaine producing denser motor blockade with hypotension when Fentanyl is used as adjuvant in both the groups.

7. Source of Funding

None.

8. Conflict of Interest

None.

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Author biography

R Arun Kumar Associate Professor

I Preetha Senior Resident

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