Section: Anesthesia

Original Research Article

A STUDY TO COMPARE THE EFFICACY OF 0.5% HYPERBARIC ROPIVACAINE AND 0.5%HYPERBARIC BUPIVACAINE FOR SPINAL ANESTHESIA IN INFRA UMBILICAL SURGERIES IN A TERTIARY CARE HOSPITAL

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Abstract

Background: Aims: The aim of our study is to compare the efficacy and hemodynamic response between intrathecal hyperbaric 0.5% Bupivacaine with hyperbaric 0.5% Ropivacaine using in patients undergoing infra umbilical surgeries. **Materials and Methods:** This is a randomized controlled study involving 60 cases of children of age between 7 and 12 years posted for elective infraumblical surgeries under spinal anaeshesia. They are allotted into two groups, Group R receiving 0.5% ropivacaine and Group B receiving 0.5% bupivcaine. The following parameters are noted in the study periods onset of sensory block, maximum height of sensory block, time taken to reach the maximum height of sensory block, two segment regression time, onset of motor block, mean duration of sensory & motor block and quality of block. The hemodynamic parameters noted are pulse rate, systolic and diastolic blood pressure, oxygen saturation with pulse oximeters. The use of atropine and vasopressors are noted. Any complications during the study are also noted.
Results: According to the study, there was significant delay in onset of sensory and motor block in ropivacaine group. There was earlier two segment regression time in ropivacaine group. There was earlier offset of sensory and motor block and time taken for micturition was earlier in ropivacaine group. The quality of block was adequate in both groups. The hemodynamic parameters were well maintained in both groups. **Conclusion:** Ropivacaine can be used as a good alternative to Bupivacaine in case of shorter duration of surgeries especially in ambulatory setup.

INTRODUCTION

Spinal anaesthesia is the most common choice for infraumblical surgeries.[1] Though general anaesthesia is most popular in children, regional anaesthesia is gaining popularity with advent of newer drugs and ultrasound techniques.[2,3] The most common drugs used for spinal anaesthesia are Lignocaine and Bupivacaine.[4]

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 hyperbaric 0.75% Ropivacaine using in patients undergoing infra umbilical surgeries.

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

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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. 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.[5,6] 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.

MATERIALS AND METHODS

A randomized study was conducted on 60 patients admitted at Osmania Medical College undergoing spinal anaesthesia for minor gynaecological and urological surgeries.

Inclusion Criteria: ASA physical status I & II, patients undergoing spinal anaesthesia for minor gynaeological and urological surgeries.

Exclusion criteria: History of drug hypersensitivity to local anaesthetics, active disease of central nervous system such as meningitis, poliomyelitis, intracranial haemorrhage, sub-acute combined degeneration of spinal cord, Spine deformities, Septicemia, Pyogenic infection of the skin at or adjacent to the site of lumbar puncture, Cardiogenic or hypovolumic shock, Coagulation disorders.

Preanaesthetic Examination and Preparation

The study protocol was approved by Hospital Ethics committee and Ethical clearance was obtained from the institution for the study. Preanaesthetic check up was done one day prior to the surgery. Patients were evaluated for any systemic diseases and laboratory investigations recorded. The procedure of spinal anesthesia was explained to the patients and written consent was obtained. Patients advised minimum period of fasting and premedicated with inj 10mg metaclopramide and 50mg ranitidine in preoperative holding. Patient was preloaded with an iv infusion of 500 ml of ringer lactate.

Sixty patients were randomly divided into two groups of thirty each.

Group P: Thirty patients received 3ml of injection of 0.5% hyperbaric bupivacaine intrathecally.

Group H: Thirty patients received 3ml of 0.5% hyperbaric ropivacaine (2ml of 0.75% plain ropivacaine and 1ml of 25% dextrose) intrathecally. hyperbaric ropivacaine was aseptically prepared immediately before the injection.

Boyle's anesthesia machine with all resuscitative equipments was kept ready before the procedure. After shifting to the operating theatre, iv access was obtained on the forearm with 18 gauge iv cannula and iv infusion started with Ringer Lactate.

Patients were monitored for heart rate (HR), non invasive blood pressure (NIBP), oxygen saturation (SpO2). Spinal anesthesia was performed with the patient in the lateral position using a 25-gauge Quincke needle at the L3–4 interspace. The spinal analgesic solution was administered in optimum period. Patient was turned gently and placed supine. After the spinal block, HR, SpO2 and NIBP were measured every 5, 10,15 20,30 minute. Hypotension was defined as 20% decrease in blood pressure from baseline values, and was treated with incremental iv boluses of Inj. mephenteramine 6 mg. Bradycardia was defined as heart rate less than 60bpm and treated with iv atropine 0.6mg.

The following variables were recorded. Haemodynamic parameters, and Time for onset of sensory block at T10, level of sensory block achieved, total duration of sensory block, time of onset of motor block, total duration of motor block.

Assessment of Sensory Blockade

The onset of sensory block was tested by pin-prick method using a hypodermic needle. The time of onset was taken from the time of injection of drug into subarachnoid space to loss of pin prick sensation at T10. The duration of sensory blockade was taken as time from onset to time of return of pinprick sensation to S1 (heel) dermatomal area.

Assessment of Motor Blockade

Motor block was assessed was by Modified Bromage scale. The time interval between injection of drug into subarachnoid space, to the patients inability to lift the straight extended leg was taken as onset time (bromage 1). The duration of motor block was taken from time of injection to complete regression of motor block (ability to lift the extended leg). (modified Bromage scale: 0=full leg movement; 1=inability to raise extended leg, can bend knee; 2=inability to bend knee, can flex ankle; 3=no movement).

Statistical Analysis

Data were expressed in mean ± SD. Comparison between groups was done using student's t-test for quantitative data and for qualitative data, chi-square test was used. Results were considered statistically significant for p values < 0.05. Data were analyzed using software SPSS. The information collected regarding all the selected cases were recorded in a Master Chart. Data analysis was done with the help of computer using Epidemiological Information Package (EPI 2010) developed by Centre for Disease Control, Atlanta. Using this software range, frequencies, percentages, means, standard deviations, chi square and 'p' values were calculated. Kruskul Wallis chi-square test was used to test the significance of difference between quantitative variables and Yate's chi square test for qualitative variables. A 'p' value less than 0.05 is taken to denote significant relationship.

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RESULTS

The mean age, sex, height, ASI 1,2 and weight are compared and it is found to be statistically not significant. [Table 1]

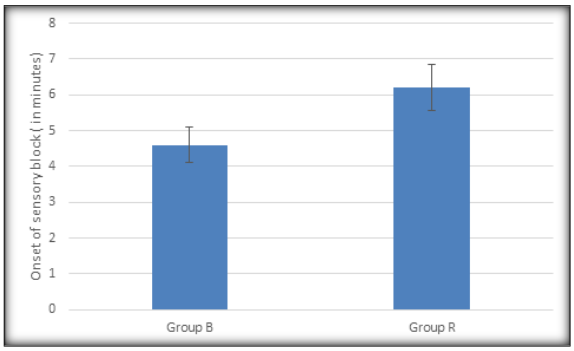

Figure 1: Onset of sensory block

The onset of sensory block is delayed in ropivacaine group when compared to bupivacaine group and it is found to be statistically significant.

The average level of maximum sensory block reached in ropivacaine group is T6, which is lower than that achieved in bupivacaine group of T4. [Table 2]

The time taken to achieve the maximum height of sensory block is more in ropivacaine group compared to bupivacaine group and it is found to be statistically significant.

The onset of motor block is delayed in ropivacaine group when compared to bupivacaine group and it is found to be statistically significant. The two segment regression time is faster in ropivacaine group when compared to be bupivacaine group and it is found to be stasistically significant. [Table 3]

The mean duration of sensory block is shorter in ropivacaine group when compared to bupivacaine group and it is found to be statistically. The mean duration of motor block is shorter in ropivacaine group when compared to bupivacaine group and it is found to be statistically significant. [Table 4]

The mean time of micturition is shorter in ropivacaine group when compared to bupivacaine group and it is found to be statistically significant. [Table 5]

The mean duration of surgery is not statistically significant between the ropivacaine and bupivacaine group. [Table 6]

There is no statistically significant difference between the groups. [Table 7]

The adequacy of block is not statistically significant between the ropivacaine and bupivacaine group. [Table 8]

Table 1: Demographic distribution in present study

Age in years	Group B	Group R	P-values
Mean in years	8.97 +/- 1.33	8.7 +/- 1.39	0.418
Males	27(90%)	3(10%)	0.5
Females	26(86.7%)	4(13.3%)	
Height (in cms)	110.2+/-8.3	108.6+/- 10.6	0.3248
Weight (in kgs)	15.87 +/-2.76	16.87 +/-2.79	0.3476

Table 2: Maximum height of sensory block

Maximum height of sensory block	Group B		Group R	
	No	%	No	%
T4	12	40	-	-
T6	2	6.7	3	10
T8	-	-	8	26.7
Total	30	100	30	100

Table 3: Time taken for achieving maximum height of block

Group	Time taken for achieving maximum height of sensory block (in minutes)		
	Range	Mean	SD
Group B	8-10	8.47	0.57
Group R	11-14	12.47	0.68
p – value	0.0001 Significant		
Onset of motor block (in minutes)			
Group B	4-5	4.43	0.5
Group R	8-11	9.13	0.82
p – value	0.0001 Significant		
Two segment regression time (in minutes)			
Group B	55-70	63.5	4.2
Group R	35-50	39.8	4.0
p – value	0.0001 Significant		

Table 4: Duration of sensory and motor block

Group	Duration of sensory block (in minutes)		
	Range	Mean	SD
Group B	130-160	147.7	8.6
Group R	100-130	117.7	9.4
p – value	0.0001 Significant		
Duration of motor block (in minutes)			
Group B	100-140	118.3	8.7
Group R	90-120	100	8.3
p – value	0.0001 Significant		

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Table 5: Time of micturition

Group	Time of micturition (in minutes)		
	Range	Mean	SD
Group B	300-350	317	13.7
Group R	200-250	214	13.8
p – value	0.0001 Significant		

Table 6: Duration of surgery

Group	Duration of surgery (in minutes)		
	Range	Mean	SD
Group B	40-60	52	5.5
Group R	30-60	48.5	8.4
p – value	0.1219 Not significant		

Table 7: Vasopressor / Atropine

Group	Vasopressor				Atropine			
	Yes		No		Yes		No	
	No	%	No	%	No	%	No	%
Group B	3	10	27	90	-	-	30	100
Group R	2	6.6	28	93.4	-	-	30	100
p - value	0.268 Not significant							

Table 8: Adequacy of block

Adequacy Block	Group B		Group R	
	No	%	No	%
Adequate	30	100	28	93.3
Inadequate	-	-	2	6.7
p – value	0.2458 Not significant			

DISCUSSION

Ropivacaine is introduced as an alternative to routinely used bupivacaine for surgeries of short duration especially in ambulatory setup. As the intensity of motor blockade is less in ropivacaine when compared to bupivacaine it is used in labour analgesia and post-operative pain relief. The differential blockade produced by ropivacaine is an advantage in situations where we want to avoid the motor blockade, thereby we can ambulate the patient early in the post-operative setup.

Ropivacaine is now available as an isobaric solution. Thus the distribution is not affected by gravity and level of blockade would be lesser than that of hyperbaric solution. Thus unnecessary high spinal blockade can be avoided. This also produces better hemodynamic stability. The long duration of motor blockade with bupivacaine may be anxious to the parents though hemodynamically stable. Early ambulation of the patients relieves the anxiety of the parents and patients themselves. This is more useful in cases of surgeries lasting for short duration and patients can be discharged in the same day. Thus the drug is fit for ambulatory surgeries. Hence this study was conducted to evaluate the efficacy of isobaric ropivacaine and bupivacaine in spinal anaesthesia in children posted for elective infraumblical surgeries.[7]

According to this study, the average time taken for onset of sensory block is 6.2 minutes for ropivacaine group and 4.6 minutes for bupivacaine group. The lower lipid solubility character of ropivacaine is the cause for delayed onset of sensory block when compared to bupivacaine. This result is similar to that found in study conducted by V. Gupta, Mehta and colleagues,[8] where the onset of sensory block is delayed in ropivacaine group when compared to bupivacaine group. According to the study, the maximum height of sensory block was T6 – T7 in ropivacaine group and T4-T5 in bupivacaine group. The maximum height of sensory block is less in ropivacaine group when compared to bupivacaine group. As less number of segments is blocked and also the level of block is lesser, it avoids cardiovascular and respiratory alterations. This is similar to that found in study by Marc Malinovskgy,[9] Charles and Montouvalou and colleagues,[10] where a higher level of maximum height of sensory block is reached in case of bupivacaine group when compared to ropivacaine group.

According to this study the mean time taken to reach the maximum height of sensory block is about 12.4 in ropivacaine group and 8.4 in bupivacaine. The average time taken to reach the maximum height is more in case of ropivacaine group. This is similar to the study of Malinovsky, Florence Charles,[9] where the time taken to achieve the maximum height is delayed in case of ropivacaine group.

Two segment regression time. According to this study, the mean two segment regression time is about 39.8 minutes in ropivacaine group compared to that of about 63.5 minutes in case of bupivacaine group. This is similar to that of study conducted by Mantouvallou and colleagues,[10] where the two segment regression time is shorter in ropivacaine group.

According to this study, the mean duration of sensory block is about 117 minutes in ropivacaine

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group compared to 147 minutes in case of bupivacaine group. Thus the duration of sensory block is less in ropivacaine group. This is similar to that of study conducted by Metha and colleagues,[8] Neval Boztuz and colleagues,[11] Mantouvalou and colleagues.[10] Early recovery of sensory block in case of ropivacaine makes the drug more suitable for ambulatory surgeries.

According to this study, the average time taken for the onset of motor block is about 9.1 minutes in case of ropivacaine group compared to 4.4 minutes in case of bupivacaine group. Thus the onset of motor block is delayed in ropivacaine group. This is similar to the study found by Metha and colleagues, Neval Boztuz,[11] and colleagues, Mantouvalou and colleagues,[10] where the onset of motor block is delayed in ropivacaine group.

According to this study, the mean duration of motor blockade is about 100 minutes in case of ropivacaine group and 118 minutes in case of bupivacaine group. Thus the duration of motor blockade is less in ropivacaine group. So the patients can be mobilized early in case of ropivacaine. This property makes it ideal for short surgeries and ambulatory surgeries. This is similar to study conducted by those of Metha and colleagues,[8] NevalBoztuz and colleagues,[11] Mantouvalou and colleagues,[10] where the duration of motor blockade is shorter in case of ropivacaine group.

Time taken for micturition

According to this study, the mean time taken for micturition was about 214 minutes in case of ropivacaine group compared to about 317 minutes in case of bupivacaine group. This is similar to that study conducted by Neval Boztuz and Zekiye,[11] and colleagues where the mean time of micturition is less in ropivacaine group. As the patient micturates earlier in case of ropivacaine, the patient meets the discharge criteria earlier. Thus ropivacaine is more useful in ambulatory surgeries. According to this study, quality of block was adequate in both groups. This is similar to that of study conducted by McChelland and colleagues,[12] where the quality of block is adequate in both groups. Thus ropivacaine can be used as an alternative drug to bupivacaine in spinal anaesthesia. According to the study, there is no significant difference between the drop in pulse rate between both groups. There is no significant difference between the drop in blood pressure, saturation between both groups. Thus ropivacaine proves to be good alternative to bupivacaine in case of infraumblical surgeries. Ropivacaine is more suitable for shorter duration of surgeries. Thus ropivacaine provides a good alternative to bupivacaine in case of short duration of surgeries. It is more suitable in cases of ambulatory surgeries where the patients meet the discharge criteria earlier and can be discharged from the hospital.

CONCLUSION

Ropivacaine used for spinal anaesthesia in children has delayed onset of sensory and motor block. It also has faster offset of sensory and motor block with adequate quality of block compared to that of bupivacaine. It is concluded that Ropivacaine can be used as a good alternative to Bupivacaine in case of shorter duration of surgeries especially in ambulatory setup.

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