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A Randomized Controlled Study to Compare the Efficacy of Ropivacaine and Bupivacaine in Spinal Anesthesia in Children

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Abstract

Aim: To evaluate the efficacy of Ropivacaine and Bupivacaine in spinal anaesthesia in children for infraumblical surgeries as regional anaesthesia in children and ambulatory setup is gaining popularity. *Materials and Methods:* This is a randomized controlled study involving 60 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 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 were noted. The hemodynamic parameters noted are pulse rate, systolic and diastolic blood pressure, oxygen saturation with pulse oximeters. *Statistical Analysis used:* Chi- Square test. *Results:* There was significant delay in onset of sensory and motor block in ropivacaine group. There was earlier two segment regression time, 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 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.

Keywords: Spinal Anaesthesia; Ropivacaine; Bupivacaine.

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].

Lignocaine has faster onset and short duration of sensory and motor blockade and used for short duration surgeries. Lignocaine produces sudden and severe hypotension and bradycardia soon after block. It also produces transient neurological symptoms in a few patients.

Bupivacaine produces intermediate to long duration of sensory and motor blockade and thus is a good alternative to lignocaine in surgeries of longer duration. But the longer duration of motor blockade makes it unsuitable for ambulatory surgeries.

Ropivacaine provides an alternative to bupivacaine, with lesser duration of motor blockade [5,6]. It has a good hemodynamic stability, with lesser systemic toxicity when compared to bupivacaine [7].

Aim

To evaluate the efficacy of Ropivacaine and Bupivacaine in spinal anaesthesia in children for infraumblical surgeries.

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Materials and Methods

Prospective randomized controlled double blind study conducted in a tertiary care centre with 60 children taken up for elective infraumblical surgeries under spinal anaesthesia. ASA I & II patients of age 7 – 12 years(both gender) were randomly allotted into two groups Group B for isobaric Bupivacaine 0.5% and Group R for isobaric Ropivacaine 0.5%. Children with bleeding disorders, hypersensitivity to local anaesthetics, local site infection, neurological deficits were excluded.

The parents and patients were educated about the study and informed written consent obtained from the parents. Premedication was avoided in these patients in order not to confound with the results. An appropriate IV line was secured in the operating room and started with ringer lactate infusion. The patient was then placed in lateral decubitus position and was held firmly by the assistant. With sterile precautions, subarachnoid block was performed at L4–L5 interspace using 27G Quinckie's needle. After confirming CSF with aspiration, local anaesthetic drug was injected according to the group allotted. The dosage of local anaesthetic drug was taken according to the weight of the child (< 5kg - 0.5mg/kg, 5 -15kg – 0.4mg/kg, >15kg–0.3mg/kg) and the maximum dose was taken as 20mg [8,9].

Parameters Recorded

1. *Hemodynamic Parameters*:

a. Pulse rate, non invasive blood pressure and oxygen saturation were recorded at base line and monitored every 2 minutes for the first 10 minutes, then every 5 minutes till first 60 min and every 15 minutes upto 90 minutes or till the surgery is over and then in recovery room

b. Any drop in mean arterial pressure 20% from baseline is taken as hypotension and ephedrine 3mg given

c. Any decrease in pulse rate less than 60/min was treated with atropine 0.04mg/kg.

2. *Sensory Blockade*:

Sensory blockade was determined by whisp of cotton along the mid axillary line at about a interval of 1 min until the level of block reached upto L1. The maximum height of the sensory blockade was noted.

Onset of sensory block was defined as the time taken from injection of drug to sensory block at L1 and offset of sensory block was determined by return of sensation at S5 dermatome. The duration of sensory block was determined by the time interval between onset and offset of sensory block.

3. *Motor Blockade*:

Motor block was determined by the modified Bromage score

0 - No motor loss

1 - unable to flex hip

2 – unable to flex knee joint

3 – unable to flex ankle joint

This is assessed at a gap of 1 minute till complete motor blockade develops. Onset of motor block was defined as the time taken from injection of drug to development of complete motor block (bromage score 3). Bromage score 0 is taken as complete recovery from motor block. The duration of motor block was determined by the time between onset and offset of motor block.

4. The highest dermatomal level of sensory block was noted.

5. The Time taken to achieve the highest dermatomal level was noted.

6. The Two segment regression time (ie., the time taken to decrease from maximum sensory level by two segments from initial level) was noted.

7. Quality of block was determined as adequate when no sedation or analgesia used, inadequate when there is need for additional analgesia, and as failed when converted to general anaesthesia. If analgesia was inadequate then fentanyl injection 1microgram/kg was given. If the regimen was switched to GA then the patient was excluded from the study.

8. Time of micturition was noted.

9. Duration of surgery was noted.

Data analysis was done with the help of computer using *Epidemiological Information Package (EPI 2010)* developed by Centre for Disease Control, Atlanta. 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.

Results

The demographic data analysis among the group was compared and no statistically significant difference was found among the groups.

The average time taken for onset of sensory block is 6.2 minutes for ropivacaine group and 4.6 minutes for bupivacaine group and this delayed onset in ropivacaine group is found to be statistically significant The time taken to achieve the maximum height of sensory block is acheived in about 8.4minutes in bupivacaine group and about 12.4 minutes in ropivacaine group and the delay is statistically significant in this study [10,11].

The onset of motor block is about 4.4 minutes in bupivacaine group and about 9 minutes in ropivacine group and delay is found to be statistically significant [10]. The two segment regression time is 63.5 minutes in bupivacaine group and about 39.8 minutes in ropivacaine group and fasterer regression is found to be stasistically significant [10].

The mean duration of sensory block is about 147.7 miutes in bupivacaine group and about 117.7 minutes in ropivacaine group and the lesser duration in ropivacaine group is statistically significant [12]. The mean duration of motor block is about 100 minutes in ropivacaine group when compared to bupivacaine group of about 118 minutes and it is found to be statistically significant [12]. The mean time of micturition is after 214 minutes in ropivacaine group when compared to bupivacaine group of after 317 minutes and it is found to be statistically significant [10]. The average level of maximum sensory block in ropivacaine group is T7, which is lower than that achieved in bupivacaine group of T5 [10].

As of the Hemodynamic parameters concerned there is no significant difference between both the groups as of drop in pulse rate, drop in blood pressure. The oxygen saturation was well maintained in both groups and there was no significant difference.

Discussion

The average time taken for onset of sensory block is more for ropivacaine group than bupivacaine group which is similar to that found in study conducted by V.Gupta, Mehta and colleagues. The lower lipid solubility character of ropivacaine is the cause for delayed onset of sensory block when compared to bupivacaine.

Table 1: Demographic datas

Group	Age(years)	Sex		Height(cm)	Weight (kg)
		Male	Female		
Group B	8.9	27	3	110.2	15.8
Group R	8.7	26	4	108.6	16.5
p-value	0.4	0.5	0.5	0.32	0.34

Table 2: Clinical Parameters

Parameters	Group B (Time in minutes)	Group R (Time in minutes)	p value
Onset of Sensory Block	4.6 ± 0.5	6.2 ± 0.6	0.0001
Time to achieve maximum height of sensory block	8.4 ± 0.5	12.4 ± 0.6	0.0001
Duration of sensory block	147.7 ± 8.6	117 ± 9.4	0.0001
Onset of motor block	4.4 ± 0.5	9.1 ± 0.8	0.0001
Duration of motor block	118.3 ± 8.7	100 ± 8.3	0.0001
Time of micturition	317 ± 13.7	214 ± 13.8	0.0001
Two segment regression time	63.5 ± 4.2	39.8 ± 4	0.0001

Table 3: Maximum height of sensory block

Level of block	Group B		Group R	
	n	%	n	%
T4	12	40	-	-
T5	16	53.3	-	-
T6	2	6.7	3	10
T7	-	-	19	63.3
T8	-	-	8	26.7
Total	30	100	30	100

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 which is similar to that found in study by Marc Malinovskgy, Charles and Montouvalou and colleagues. As less number of segments is blocked and also the level of block is lesser, it avoids cardiovascular and respiratory alterations.

The average time taken to reach the maximum height is more in case of ropivacaine group when compared to bupivacaine group which is similar to the study of Malinovsky, Florence Charles.

The mean two segment regression time is lesser in ropivacaine group compared to that of bupivacaine group which is similar to that of study conducted by Mantouvallou and colleagues where the two segment regression time is shorter in ropivacaine group.

The duration of sensory block is less in ropivacaine group when compared to bupivacaine group which is similar to that of study conducted by Metha and colleagues, Neval Boztuz and colleagues, Mantouvalou and colleagues. Early recovery of sensory block in case of ropivacaine makes the drug more suitable for ambulatory surgeries.

Thus the onset of motor block is delayed in ropivacaine group which is similar to the study found by Metha and colleagues, Neval Boztuz and colleagues, Mantouvalou and colleagues where the onset of motor block is delayed in ropivacaine group.

The duration of motor blockade is less in ropivacaine group which is similar to study conducted by those of Metha and colleagues, Neval Boztuz and colleagues, Mantouvalou and colleagues. So the patients can be mobilized early in case of ropivacaine. This property makes it ideal for short surgeries and ambulatory surgeries.

The mean time taken for micturition was earlier in case of ropivacaine group compared to bupivacaine group which is similar to that study conducted by Neval Boztuz and Zekiye and colleagues. As the patient micturates earlier in case of ropivacaine, the patient meets the discharge criteria earlier. The quality of block was adequate in both groups which is similar to that of study conducted by McChelland and colleagues.

On overall comparision, ropivacaine in spinal anaestheisa had delayed onset of sensory and motor block, but earlier regression of sensory and motor block occurred. This property may be due to lower lipid solubility of ropivacaine. The earlier regression of blockade is helpful for ambulatory and day care surgeries where discharge criteria are met at earlier stages. Thus ropivacaine proves to be good alternative to bupivacaine in case of infraumblical surgeries. Ropivacaine is more suitable for shorter duration of surgeries.

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. Hence, Ropivacaine can be used as a good alternative to Bupivacaine in case of shorter duration of surgeries especially in ambulatory setup.

Key Messages

As regional anaesthesia is gaining popularity in children, earlier discharge with shorter acting drugs like ropivacaine can be used in these surgeries.

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