RESEARCH ARTICLE

INTERNATIONAL RESEARCH JOURNAL OF PHARMACY

www.irjponline.com

ISSN 2230 – 8407

COMPARATIVE EVALUATION OF 0.25% BUPIVACAINE TO 0.25% ROPIVACAINE FOR CAUDAL ANESTHESIA DURING INFRA UMBILICAL SURGERIES IN PEDIATRIC SUBJECTS

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Article Received on: 10/04/22 Approved for publication: 21/05/2022

DOI: 10.7897/2230-8407.1303182

ABSTRACT

Background: In pediatric subjects, caudal epidural anesthesia is most commonly used to manage postoperative pain. The caudal epidural is most commonly used in surgeries of lower extremities, inguinal, rectal, and/or urogenital areas. **Aims:** The present study was conducted to compare and assess the efficacy of 0.25% Bupivacaine to 0.25% ropivacaine for caudal Anesthesia during infra umbilical surgeries in pediatric subjects. **Methods:** In 56 subjects with ASA status, I and II, who had to undergo elective surgeries of infraumbilical region were included in the study and were randomly treated with either 0.25% ropivacaine or 0.25% bupivacaine in the dose of 1ml/kg. Bromage motor scale was used to assess motor block postoperatively and observer pain scale to assess analgesia. The collected data were subjected to statistical evaluation and the results were formulated. **Results:** Time taken to reach Bromage motor block stage 0 was 4 hours in 14.28% (n=4) subjects from Group I and 21.42% (n=6) subjects from group II, whereas, the time taken to reach a score of zero was 4.5 hours in 85.71% (n=240 subjects from group I and 78.57% (n=22) subjects from group II. This difference was statistically significant with $p<0.0001$. The mean motor block duration was significantly higher in group I compared to group II with respective values of 236.2±1.87 and 204.02±2.19 minutes. This was higher for Group I with bupivacaine compared to ropivacaine Group II with $p<0.0001$. The score was 0 at 4 hours in 14.28% (n=4) subjects from Group I and 64.28% (n=18) subjects from Group II. The duration of analgesia was 266.2±1.87 mins for Group I and 251.2±2.66 mins for Group II which was significantly higher for bupivacaine compared to ropivacaine $p<0.0001$. **Conclusion:** The present study concludes that caudal epidural anesthesia using 0.25% bupivacaine resulted in a better motor block and longer duration analgesia compared to ropivacaine at 0.25%. However, no difference was seen for side-effects and hemodynamic parameters.

KEYWORDS: Bupivacaine 0.25%, Caudal block, Infra umbilical surgeries, Paediatric subjects, Ropivacaine 0.25%

INTRODUCTION

The most common regional anesthesia technique is caudal epidural in managing postoperative pain of pediatric subjects where sacral hiatus provide information concerning its patency which is suitable for the epidural block. The caudal epidural is most commonly used in surgeries of lower extremities, inguinal, rectal, and/or urogenital areas.Regional anesthesia is used with general anesthesia leads to decreased concentration of inhaled opioids and agents leading to less incidence of nausea and vomiting and faster recovery.[1]

Causal anesthesia in controlling postoperative analgesia results in adequate anesthesia with reduced hospital stay duration, minimum postoperative apnoeic spells, rapid feeding return, decreased nausea and vomiting postoperatively, minimum physiologic and biochemical changes, invasive ventilation, and adequate anesthesia without the use of many drugs.[2]

Ropivacaine, bupivacaine, and lignocaine are the drugs commonly used during caudal analgesia with various other adjuvants. However, opioids are not commonly used during daycare surgeries owing to the associated risk of respiratory depression with their use. One such agent is ropivacaine which is a newer amide local anesthetic agent which is long-acting and is associated with lesser cardiac effects and central nervous system effects showing better separation of sensory and motor effects.[3]

The sensory block is similar to bupivacaine as well as ropivacaine at equivalent doses in extradural and peripheral nerve blocks. However, motor block achieved with ropivacaine is of lesser quality, slower onset, and shorter duration compared to the motor block achieved with bupivacaine at the same dose.[4]

General anesthesia in a pediatric age group may be as-sociated with difficulty in intubation due to anatomy of the larynx, delayed recovery from muscle relaxant, more inci-dences of postoperative nausea and vomiting which may in-terfere with pain perception in the pediatric patient due to excessive crying.[5]The present study was conducted to compare and assess the efficacy of 0.25% Bupivacaine to 0.25% ropivacaine for caudal Anesthesia during infra umbilical surgeries in pediatric subjects.

MATERIALS AND METHODS

The present study was conducted to compare and assess the efficacy of 0.25% Bupivacaine to 0.25% ropivacaine for caudal Anesthesia during infra umbilical surgeries in pediatric subjects. The present study was conducted at Department Of Anesthesiology, Jay Prabha Medanta Superspeciaity Hospital, Patna, Biharafter obtaining clearance from the concerned Ethical committee. The study population was comprised of pediatric subjects undergoing elective infra-umbilical surgeries in the institute. After explaining the detailed study design, informed consent was taken from the parents of all the subjects.

The inclusion criteria for the study were subjects of age 4-7 years, ASA status I or II, undergoing elective infra-umbilical surgeries, and subjects willing to participate. The exclusion criteria were subjects whose parents denied consent, bleeding disorders, skeletal deformities, infection at the operated site, not within the desired age limit, and allergy history to study drugs. A total of 56 pediatric subjects from both genders were included in the study following inclusion criteria within the age range of 4-7 years undergoing lower extremities procedures, perineal surgeries, orchidopexy, circumcision, and/or herniotomies. Included subjects were randomly divided into two groups where Group I subjects were treated with bupivacaine 0.25% and Group II subjects with ropivacaine 0.25% in the dose of 1ml/kg. After final inclusion, detailed history was recorded for all the subjects followed by general examination and laboratory examination. 6 hours before the surgery, all subjects were kept on complete oral fasting. After establishing the i.v line, infusion of Isolyte -P was started following the bodyweight of each subject. Oxygenation was done with the face mask and premedication was done with injection midazolam 0.03mg/kg, Ondansetron 0.1 mg kg, and injection glycopyrrolate 0.004 mg kg. The parameters recorded were non-invasive blood pressure (NIBP), respiratory rate (RR), heart rate (HR),SpO2, and Electrocardiogram (ECG). 1-1.5mg/kg ketamine injection was given to immobilize subjects during caudal block and vitals were assessed to ensure spontaneous breathing. Following drug administration and ensuring block efficacy, surgery was performed. Oxygen was given throughout the surgery and ketamine injection intermittently when required.

Vitals, NIBP, HR, PR, SpO2, and ECG were recorded for all the subjects at each 5 minutes interval for 30 mins followed by every 10-minute assessment till surgery completion, and every half an hour till subjects were shifted from the postoperative recovery area. Observer Pain Score (OPS) was used to assess pain in the subjects, and in subjects with Observer Pain Score of more than/equal to 4 were given rectal 1.5mg/kg diclofenac. Efficacy of motor block was assessed using Bromage motor block scale till subjects recovered completely.

The collected data were subjected to the statistical evaluation using SPSS software version 21 (Chicago, IL, USA) and one-way ANOVA and t-test for results formulation. The data were expressed in percentage and number, and mean and standard deviation. The level of significance was kept at $p<0.05$.

RESULTS

The present study was conducted to compare and assess the efficacy of 0.25% Bupivacaine to 0.25% ropivacaine for caudal Anesthesia during infra umbilical surgeries in pediatric subjects. A total of 56 pediatric subjects from both genders were included in the study following inclusion criteria within the age range of 4-7 years undergoing lower extremities procedures, perineal surgeries, orchidopexy, circumcision, and/or herniotomies. The demographic characteristics of the study subjects are listed in Table 1. It was seen that the mean age of the

study subjects in Group I and Group II respectively was 4.5±0.17 and 4.6±0.18 years which was statistically non-significant with p=0.61. The age range in both the age groups was 4-7 years. There were 71.42% (n=20) males and 28.57% (n=8) females in group I and there were 96.42% (n=27) males and 3.57% (n=1) females in Group II. The mean weight of the study subjects from Group I and II respectively were 4.6±0.18 and 13.85±0.38 kgs which were non-significant statistically with p=0.97. The surgery duration in the Bupivacaine group was significantly higher, 85.31±1.69, compared to Group II where ropivacaine was used for 83.31±1.47 minutes. This was statistically significant with p<0.05 (Table 1).

On assessing the study parameters, it was seen that time taken to reach Bromage motor block stage 0 was 4 hours in 14.28% (n=4) subjects from Group I and 21.42% (n=6) subjects from group II, whereas, the time taken to reach a score of zero was 4.5 hours in 85.71% (n=240 subjects from group I and 78.57% (n=22) subjects from group II. This difference was statistically significant with p<0.0001. The mean motor block duration was significantly higher in group I compared to group II with respective values of 236.2±1.87 and 204.02±2.19 minutes. This was higher for Group I with bupivacaine compared to ropivacaine Group II with p<0.0001 as shown in Table 2.

The study variables assessed were observer pain score (OPS) zero, where it was seen that score was 0 at 4 hours in 14.28% (n=4) subjects from Group I and 64.28% (n=18) subjects from Group II, whereas, OPS was reached zero at 4.5 hours in 85.71% (n=24) subjects from Group I and 35.71% (n=10) subjects from Group II. This difference is statistically significant with p<0.0001. The duration of analgesia was 266.2±1.87 mins for Group I and 251.2±2.66 mins for Group II which was significantly higher for bupivacaine compared to ropivacaine p<0.0001 as shown in Table 3.

Table 1: Demographic Characteristics of the Study Subjects

Characteristics	Group I	Group II	*p*-Value
Mean age (years)	4.5±0.17	4.6±0.18	0.61
Age range (years)	4-7	4-7	1.000
Gender % (n)			
Males	71.42 (20)	96.42 (27)	
Females	28.57 (8)	3.57 (1)	
Mean weight (kgs)	13.11±0.38	13.85±0.38	0.97
Surgery duration (mins)	85.31±1.69	83.31±1.47	>0.05

Table 2: Parameters in the Two Groups of the Study Subjects

Parameters	Group I % (n)	Group II % (n)	*p*-Value
Bromage motor block stage 0 duration (hours)			
4	14.28 (4)	21.42 (6)	<0.0001
4.5	85.71 (24)	78.57 (22)	
Mean motor block duration (mins)	236.2±1.87	204.02±2.19	<0.0001

Table 3: Variables in the Two Groups of the Study Subjects

Variables	Group I % (n)	Group II % (n)	*p*-Value
Observer Pain Score 0 duration (hours)			
4 hours	14.28 (4)	64.28 (18)	<0.0001
4.5 hours	85.71 (24)	35.71 (10)	
Analgesia duration (mins)	266.2±1.87	251.2±2.66	<0.0001

DISCUSSION

The present study was conducted to compare and assess the efficacy of 0.25% Bupivacaine to 0.25% ropivacaine for caudal Anesthesia during infra umbilical surgeries in pediatric subjects. A total of 56 pediatric subjects from both genders were included in the study following inclusion criteria within the age range of 4-7 years undergoing lower extremities procedures, perineal surgeries, orchidopexy, circumcision, and/or herniotomies. It was seen that the mean age of the study subjects in Group I and Group II respectively was 4.5±0.17 and 4.6±0.18 years which was statistically non-significant with p=0.61. The age range in both the age groups was 4-7 years. There were 71.42% (n=20) males and 28.57% (n=8) females in group I and there were 96.42% (n=27) males and 3.57% (n=1) females in Group II. The mean weight of the study subjects from Group I and II respectively were 4.6±0.18 and 13.85±0.38 kgs which were non-significant statistically with p=0.97. The surgery duration in the Bupivacaine group was significantly higher, 85.31±1.69, compared to Group II where ropivacaine was used for 83.31±1.47 minutes. This was statistically significant with p<0.05. These demographics were comparable to the results of Clonidine Moss J et al[6] in 2005 and Laha A et al[7] in 2012 where authors assessed subjects with similar characteristics in their studies.

The study results showed that time taken to reach Bromage motor block stage 0 was 4 hours in 14.28% (n=4) subjects from Group I and 21.42% (n=6) subjects from group II, whereas, the time taken to reach a score of zero was 4.5 hours in 85.71% (n=240 subjects from group I and 78.57% (n=22) subjects from group II. This difference was statistically significant with p<0.0001. The mean motor block duration was significantly higher in group I compared to group II with respective values of 236.2±1.87 and 204.02±2.19 minutes. This was higher for Group I with bupivacaine compared to ropivacaine Group II with p<0.0001. These results were consistent with the studies of Anand VG et al[8] in 2011 and Sasikala P et al[9] in 2015 where similar results were seen with ropivacaine ad bupivacaine use in pediatric subjects.

The study variables assessed were observer pain score (OPS) zero, where it was seen that score was 0 at 4 hours in 14.28% (n=4) subjects from Group I and 64.28% (n=18) subjects from Group II, whereas, OPS was reached zero at 4.5 hours in 85.71% (n=24) subjects from Group I and 35.71% (n=10) subjects from Group II. This difference is statistically significant with p<0.0001. The duration of analgesia was 266.2±1.87 mins for Group I and 251.2±2.66 mins for Group II which was significantly higher for bupivacaine compared to ropivacaine p<0.0001. These results were similar to the results of Ray M et al[10] in 2003 and Melzack R et al[11] in 2000 where more anesthesia duration was seen with bupivacaine use compared to ropivacaine.

CONCLUSION

Within its limitations, the present study concludes that caudal epidural anesthesia using 0.25% bupivacaine resulted in a better motor block and longer duration analgesia compared to ropivacaine at 0.25%. However, no difference was seen for side-effects and hemodynamic parameters in pediatric subjects. However, the present study had a few limitations including a small sample size, short monitoring time, and geographical area biases. Hence, more longitudinal studies with a larger sample size and longer monitoring period will help reach a definitive conclusion.

CONFLICTS OF INTEREST

Nil

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