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A PROSPECTIVE STUDY OF COMPARISON OF ANALGESIA PRODUCED BY CAUDAL EPIDURALLY ADMINISTERED ROPIVACAINE V/S BUPIVACAINE IN CHILDRENS OF AGE GROUP(2 TO 8 YEARS) OF AGE''

Anaesthesiology

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ABSTRACT

AIM: To study the efficacy and safety of ropivacaine for caudal analgesia for lower abdominal, urogenital and perineal surgeries by comparing it with bupivacaine.

MATERIAL AND METHODS: A prospective, randomized study was done over a period of 18 months among paediatric population of 2-8 years posted for various surgeries in lower abdominal, urogenital and perineal surgeries at the Department of Anaesthesiology in R.C.S.M. Govt. Medical College &CPR hospital, Kolhapur, Maharashtra, during the period from December 2014 to May 2016 after approval from the ethics committee and written informed consent from the parents/ guardians.

RESULTS: There were no significant differences in demographic and hemodyanamic data. The hemodynamic parameters heart rate and mean blood pressure were comparable in both the groups, with P value of (0.290) and (0.249) respectively, and found not significant. Post operative analgesia in both the groups also not significant with P value of (0.222)

CONCLUSION : we conclude that Ropivacaine in comparison with Bupivacaine is equal in terms of efficacy and safety and provides equal quality of analgesia and maintains haemodynamic stability.

KEYWORDS

Ropivacaine, Bupivacaine, analgesia, heart rate, mean arterial pressure

INTRODUCTION

The International Association for Study of Pain has defined it as 'an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage[1].

Caudal epidural analgesia is one of the most popular, commonly practiced, safe and reliable regional blocks in pediatric anaesthesia with a predictable level of blockade.Caudal block is a useful adjunct to the general anaesthesia for lower abdominal surgery in children, as it reduces peri-operative narcotic requirement[2]. It provides intra- and post-operative analgesia in patients undergoing lower abdominal, urological and lower limb surgeries. Gradual offset usually provides analgesia beyond the duration of surgery, with a smooth recovery period and good postoperative pain control. This benefit is especially important in ambulatory and day care surgery patients because it reduces analgesic requirements and facilitates early discharge. However, this technique does depend on the duration of action of the local anesthetic.

Bupivacaine, a long acting local anaesthetic, via caudal route is well entrenched in pediatric anaesthesia practice. Bupivacaine has proven its efficacy in producing adequate analgesia, when given caudally[3]. However its main disadvantage is longer duration of motor blockade and lower margin of safety, thus associated with increased association of cardiovascular and cerebrovascular toxicity. Unfortunately, motor blockade resulting from it may be a cause of distress in the post-operative period and may lead to delayed hospital discharge[4]

Ropivacaine is the first local anaesthetic to be prepared as S-enantiomer which has been extensively evaluated in adults and older children. Ropivacaine has several properties which may be useful in paediatric practice, namely the potential to produce neural blockade with less motor block and reduced cardiovascular and neurological toxicity. These features are particularly attractive for day case surgery in children which is increasing in frequency. Sensory block produced by Ropivacaine is equivalent to Bupivacaine but motor block is slower in onset, less intense and shorter in duration. Ropivacaine is local anesthetic, which has been reported to cause less motor block and less cardiovascular events than bupivacaine[5]

MATERIALS AND METHODS

Study site and study population:

A prospective, randomized study was done over a period of 18 months among paediatric population of 2-8 years posted for various surgeries in lower abdominal, urogenital and perineal surgeries at the Department of Anaesthesiology in R.C.S.M. Govt. Medical College &ChhatrapatiPramilaraje hospital, Kolhapur, Maharashtra, during the period from December 2014 to May 2016 after approval from the ethics committee and written informed consent from the parents/ guardians.

Inclusion criteria:

1. Children undergoing lower abdominal, urogenital and perineal surgeries likeurethroplasty, herniotomy, herniorraphy, orchidopexy, circumcision, phimosis, stoma closure, etc.
2. ASA grade I and II
3. Age between 2 to 8 years

Exclusion criteria:

1. Parent's refusal for child's participation
2. ASA grade III and IV
3. Age< 2years and≥8years
4. Coexisting severe cardiovascular, respiratory or neurological disorders
5. Children with neuromuscular disease
6. Back problems: Marked spinal deformity
7. Known history of coagulation disorders and history of taking anticoagulants
9. Inflammatory skin lesions at caudal area
10. Mental retardation
11. Past history of allergy to local anaesthetics

Sample size

On the basis of data available from previous years, sample size of 80 taken.

Study design:

"A prospective, randomized, double blind study."

All the 80 cases were admitted through surgical and urological Out Patient Departments. At the first pre-anaesthetic visit, detailed histories were taken and patients were examined clinically and evaluated by senior consultants to rule out systemic diseases and findings were noted. Routine investigations like blood grouping, complete haemogram, routine urine examination with urine albumin, sugar, microscopy and other relevant investigations were done.

Written valid informed consents from parents/guardians prior to scheduled surgeries were taken. Patients were divided into two groups on the basis of randomization.

Group A- Receiving 0.5% Bupivacaine2mg /kg body wt.
Group B- Receiving 0.5% Ropivacaine 3mg/kg body wt.

METHODOLOGY:
Patients fulfilling the inclusion criteria and not having any of the exclusion criteria were included in the study. Baseline physical examination assessing airway, pulse, blood pressure, RS, CVS, airway, spine examination was done. Baseline investigations like Hb, CBC, Urine- routine and microscopy, chest x-ray was done. Study procedure including risks and benefits and also the pain score that was used post operatively was explained to the patient's guardian. Queries were cleared. Informed consent was taken. Starvation was confirmed.

PREMEDICATION:
Intravenous access was taken by 22/24 G cannula on forearm and fixed. Following premedications were given:
Inj. Glycopyrrolate 4mcg/kg i.v
Inj.Midazolam 0.03 mg/kg i.v
Inj.Pentazocine 0.3mg/kg i.v

Pre-induction following monitors were attached:
Cardioscope lead II, Pulse oximeter and Sphygmomanometer.

Baseline Heart Rate [HR], systolic Blood Pressure [BP], diastolic BP, Mean Arterial Pressure [MAP], Saturation of oxygen [SpO2] and ECG rhythm were noted.

Pre-oxygenation was done with 100% oxygen at rate of 6L/min and maintenance fluid Isolyte P/ Ringer Lactate at rate of 4ml/kg/hr was started intravenously.

INDUCTION:
After pre-oxygenating the patient with 100% oxygen for 3 min, patient was induced with Inj. Ketamine 2mg/kg i.v till eye lash reflex was lost. After confirming adequate mask ventilation, Inj. Atracurium bromide 0.5 mg/kg i.v was given. Laryngoscopy and intubation with adequate size endotracheal tube was done to secure the airway.HR, MAP, SpO_2 noted. Anaesthesia hence on was maintained on Oxygen: Nitrous oxide [40:60], volatile inhalational agent and intermittent intravenous bolus of Inj. Atracurium.

After securing the airway, patient was turned to left lateral position for caudal block. Position was maintained by an assistant. Patient received caudal block with 22G hypodermic needle and drug was injected as per the group to which the patient was allotted. Patient was randomly assigned to 2 groups – Group A and Group B. Patient as well as the principal investigator were not revealed as to which group the patient is assigned.

Group A: patient received 0.5% Inj. Bupivacaine.
Group B: patient received 0.5% Inj. Ropivacaine.

Patient was immediately turned supine after injection of drug via caudal route.

HR, MAP, SpO_2 were monitored and noted at caudal block and every 30min then on till end of surgery. At the end of surgery, patient was reversed with Inj. Neostigmine 0.05mg/kg i.v and Inj. Glycopyrolate 8mcg/kg i.v and extubated.

Post operatively in the ward, pain score were monitored hourly by the Principal Investigator.

RESULTS
DEMOGRAFIC DATA
TABLE NO.1

PARTICULARS	BUPIVACAINE	ROPIVACAINE	P VALUE
AGE	4.5125±1.645	4.0758±1.546	0.1107
WEIGHT	18.175±4.8879	17.538±4.4641	0.544
SURGERY TIME	1.7000±0.72102	1.5938±0.69496	0.504

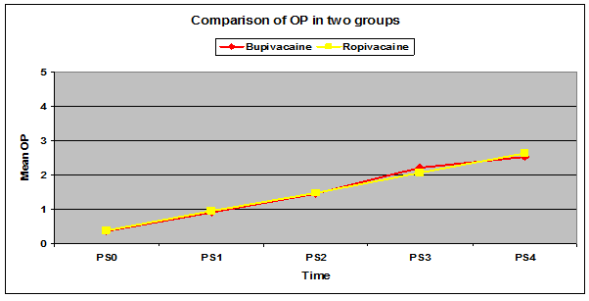
Above table shows demographic parameters were comparable and not significant

TABLE NO 2.

PARTICULARS	BUPIVACAINE	ROPIVACAINE	P VALUE
Heart Rate	108.75 + 14.00	112.5 + 13.68	0.290
MAP	86.55 ± 2.94	86.08 ± 3.64	0.249

Above Table shows hemodynamic parameters were comparable and not significant.

DIAGRAM 1.



Above graph shows the post operative analgesia at different intervals.

DISCUSSION
Caudal epidural analgesia is one of the most popular regional blocks in paediatric anaesthesia, but its main disadvantage is longer duration of motor blockade and lower margin of safety, thus associated with increased association of cardiovascular and cerebrovascular toxicity. The potential to produce neural blockade with less motor block and reduced cardiovascular and neurological toxicity has made Ropivacaine very popular.

We designed a prospective, randomized, double blind study to compare efficacy and safety of Ropivacaine with Bupivacaine for caudal analgesia for lower abdominal, urogenital and perineal surgeries.

Demographical data:
We included 80 patients undergoing lower abdominal/urologic surgeries. After inductionwith general anesthesia, the patients were randomly distributed to receive either 0.5%Inj Bupivacaine (Group A) or 0.5% InjRopivacaine (Group B); 40 in each group.

The patients included belonged to age group 2-8yrs with mean age of 4.5125 years in Bupivacaine group and 4.0750 years among Ropivacaine group which was statistically not significant (p value 0.1107). In our study, the mean weight of the patients was comparable in both the groups with mean weight of (18.175) kg in Bupivacaine group and (17.538) kg in Ropivacaine group (p value 0.544). In our study, all patients were male in both the groups due to type of surgeries chosen. All patients belonged to ASA grade I and II. In 2000, in astudy wherein J.S Tan[6]compared Ropivacaine 0.2% (0.5-1 ml/kg) with Bupivacaine 0.2% (0.5-1 ml/kg), he observed no significant difference in age (in months),weight and duration of surgery with mean age (in months), mean weight and mean duration of surgery being 85±29, 23±6 and 10±2 in Bupivacaine group and 91±24, 24±5 and 10±2 respectively in Ropivacaine group. In 2002, Omar Elsafty[7] conducted a study in children comparing Ropivacaine 0.375% (1 ml/ kg) and Bupivacaine 0.375% (1 ml/ kg) wherein he concluded that two groups were comparable in terms of age, weight and duration of surgery with mean age, mean weight and mean duration of surgery being 4±1.3, 16±5 and 38±21 in Bupivacaine group and 5±2.1, 17±6 and 36±19 in Ropivacaine group respectively. In 2003,Dr Manjushree Ray[8] et al compared Ropivacaine 0.25% (0.75 ml/kg) with Bupivacaine 0.25% (0.75 ml/kg) where it was concluded that there was no significant difference in age, weight and duration of surgery with the mean age, weight and duration of surgery being 51.3±16.2, 15.8±7 and 59.5±22 in Bupivacaine group and 49.8±19.3, 16.0±7.3 and 63.2±17 in Ropivacaine group. In our study, baseline heart rate between both the groups were comparable with (108.75± 14.00) bpm in Bupivacaine group and (112.5± 13.68) bpm in Ropivacainegroup(P value 0.290). With intubation, heart rate increased in both the groups, which were comparable. After giving caudal block heart rate fell in 15- 30 min, and remained so for the next 1-2 hrs, the lowest recording being (91.08± 11.56) bpm in Bupivacaine group and (92.82± 11.68) bpm in Ropivacaine group (P value 0.503) which were comparable between

the two groups. Heart rate at any recording time was comparable between the two groups. In each group the fall in heart rate from baseline was statistically significant (p value <0.001), but the fall was never less than 30% of baseline (Bupivacaine group: 17.67%, Ropivacaine group: 19.68%) and hence was not treated with Inj. Atropine.

In our study, baseline mean arterial pressures (MAP) were comparable, with (86.55 ± 2.94) mmHg in Bupivacaine group and (86.08 ± 3.64) mmHg in Ropivacaine group (P value 0.249). With intubation, the MAP increased in both the groups, which were comparable. After 15-30 min of giving caudal block, MAP fell in both the groups and remained so for next 1-1.5 hrs and were comparable, lowest being (84.00 ± 2.16) mmHg in Bupivacaine group and (83.5 ± 3.62) mmHg in Ropivacaine group (P value 0.115). Although there was statistically significant fall from baseline (P value < 0.001) in MAP in each group, it was 2.55% and 2.58% in Bupivacaine group and Ropivacainegroup, never less than 30% and hence was not treated with fluids or Inj Ephedrine. In 2000, a study of 112 children,ASA 1 and 2, aged between 5-12 years, undergoing elective circumcison, J.S Tan et al[6] evaluated haemodyanmic parameters in children receiving Ropivacaine 0.2% and bupivacaine 0.2% in which no significant difference in heart rate and mean arterial pressure was found throughout study. In 2003, in a study of 30 children, ASA 1 and 2, aged 5-8 years, undergoing urogenital operations like urethroplasty, herniotomy and orchidopexy, Dr. Manjushree Ray et al[8] evaluated the haemodyanmic parameters in children receiving 0.25% ropivacaine (0.75 ml/kg) and 0.25% Bupivacaine (0.75 ml/kg) where there was a significant fall in the heart rate from baseline heart rate (124.5±19.3) to (120.8±16.5) and no fall in the mean arterial pressure from the baseline mean arterial pressure of (86.2±10.6) to (87.7±9.6) at 30 min in Bupivacaine group and fall in heart rate from baseline heart rate (127.2±18.4) to (120.8±16.5) and no fall in the mean arterial pressure from the baseline mean arterial pressure of (88.1±9.5) to (89.7±9.3) at 30 min in Ropivacaine group.

CONCLUSION:

Thus we conclude that Ropivacaine in comparison with Bupivacaine is equal in terms of efficacy and safety and provides equal quality of analgesia, maintains haemodynamic stability, does not cause significant respiratory depression, causes lesser duration of motor blockade, is free of postoperative nausea vomiting and hence aids early discharge after day care surgeries.

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