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A STUDY TO COMPARE 0.2% ROPIVACAINE WITH DEXMEDETOMIDINE AND WITH 0.25% BUPIVACAINE DEXMEDETOMIDINE FOR CAUDAL BLOCK IN PAEDIATRIC PATIENTS

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Abstract

Background: Caudal epidural anaesthesia is the most commonly practiced regional anaesthesia in children. The practice of a caudal block before incision in general anaesthesia results in reduced the use of inhalation anaesthetics intraoperatively. Caudal block is usually given after the induction of general anaesthesia and is used as an adjunct to intraoperative anaesthesia and postoperative analgesia in children. Ropivacaine, a long-acting amide local anaesthetic related structurally to bupivacaine, has been used for paediatric caudal anaesthesia. It provides pain relief with less motor blockade. Bupivacaine is a long-acting amide local anaesthetic used for anaesthesia and analgesia with differential motor and sensory blockade. Materials and Methods: 30 patients belonging to ASA I and II of both sexes divided into two groups(n=15) undergoing surgery under general anaesthesia were randomly selected for study. Patients of either sex with ASA I and II between 1 to 4 years of age undergoing herniotomy, orchidopexy, urethroplasty surgeries were taken into study. **Result & Conclusion:** Motor blockade resulting from caudal block is very distressful to children in the postoperative period and delays hospital discharge. Ropivacaine in comparison to bupivacaine, has a wider margin of safety, less motor blockade, less cardiovascular /neurological toxicity and similar duration of analgesia. It can be safely used for regional anaesthesia and analgesia in the ambulatory setting in paediatrics. Our study showed that a single pre-surgical caudal injection of Ropivacaine after induction of anaesthesia provided good quality analgesia of sufficient duration following lower abdominal and perineal surgeries. Our study showed that significant motor block was demonstrated in all our study children in the recovery room, with the ropivacaine group having statistically significant greater motor power score than bupivacaine group. This faster resolution of motor blockade in the ropivacaine group continued in the post-operative ward also. In our study, there was a delay in micturition of around five and half hours in both the groups with no significant difference between them. The aim of the study was to compare Caudal Ropivacaine 0.2% with Dexmedetomidine and caudal Bupivacaine 0.25% with dexmedetomidine in terms of the quality, onset and duration of analgesia, motor and sensory block infraumbilical surgeries. In a double-blinded comparative study, 30 children aged 1-4 years of ASA I or II physical status were randomly allocated to receive a single presurgical caudal injection of 1ml/kg of either 0.2% Ropivacaine (Group RD) with dexmedetomidine 1µg/kg or 0.25% Bupivacaine (Group BD) with dexmedetomidine 1µg/kg after induction of general anaesthesia. Apart from monitoring the vital parameters, all children were assessed for postoperative analgesia by FLACC scale and for motor blockade by Modified bromage scale.

INTRODUCTION

Regional anaesthesia plays an important role in providing pain relief both in the intra-operative and postoperative periods in paediatric patients. Caudal epidural anaesthesia is the most commonly practiced regional anaesthesia in children. The practice of placing a caudal block before incision in general anaesthesia results in reduced use of volatile anaesthetics intraoperatively. Local anaesthetics are commonly used either alone or with additives through the caudal route but the motor block produced may be a cause of distress to children in the postoperative period. Caudal block is usually placed after the induction of general anaesthesia and is used as an adjunct to intraoperative anaesthesia as well as postoperative analgesia in children undergoing surgical procedures below the level of the umbilicus. Caudal analgesia can reduce the amount of inhaled and IV anaesthetic administration, attenuates the stress response to surgery, facilitates a rapid, smooth recovery, and provides good immediate postoperative analgesia. The special features like decreased cardiovascular and neurological toxicity make Ropivacaine very useful in paediatric practice especially for day care surgery which is increasing in frequency.^[1-3]

MATERIALS AND METHODS

After obtaining Institutional Review Board and patients written informed consent. the study was conducted in 30 patients belonging to ASA I and II of both sexes undergoing surgery under general anaesthesia were randomly selected for study. Patients of either sex with ASA I and II between 1 to 4 years of age undergoing herniotomy, orchidopexy, urethroplasty surgeries were taken into study. All the patients were assessed clinically preoperatively and presence of any medical disorder and history of hypersensitivity to any of the drugs used, infection at the site of block, bleeding diathesis, pre-existing neurological or spinal disease and skeletal deformities, history of developmental delay. History regarding previous anaesthesia, surgery, any significant medical illness, medications and allergy were recorded. Complete physical examination and airway assessment were done. The study was carried out in a double-blind manner only the attending anaesthesiologist, but neither the patients nor the observer during the study period knew which study agent had been used.

GROUP RD (15 patients): 0.2% Ropivacaine 1ml/kg with Dexmedetomidine 1µg/kg

GROUP BD (15 patients): 0.25% Bupivacaine 1ml/kg with Dexmedetomidine $1\mu g/kg$

On admission, a thorough preoperative evaluation of the patient was done. A written informed consent was taken from the parents after explaining the procedure, its advantages and disadvantages. Basal vital parameters like heart rate, blood pressure and Oxygen saturation and ECG were recorded.

Intravenous access was secured with appropriate size intravenous cannula. Inj. Atropine 0.01mg/kg IV and Inj. Midazolam 0.03mg/kg IV were given as premedication. Maintenance infusion was started with Ringer Lactate (4-2-1 rule) and Children were pre-oxygenated with 100%O2 for 3 minutes and induced with inj.Fentanyl 2µg/kg iv, inj.Propofol 2mg/kg iv, inj.Succinyl choline 1.5 mg/kg iv .Under direct laryngoscopy with the appropriate size laryngoscope blade, orotracheal intubation was performed with the appropriate size endotracheal tube and the tube position confirmed by capnography and tube secured. Maintained with Oxygen, Nitrous Oxide (50:50) and sevoflurane. The child was put in the left lateral position and under aseptic precautions the sacral hiatus was identified. Caudal epidural space was identified by using the loss of resistance technique and swoosh test and the study drug was deposited after confirming negative aspiration for blood and CSF. To detect and avoid an inadvertent intravascular or subarachnoid injection, the syringe was repeatedly aspirated and the local anaesthetic was injected in increments while watching vital signs and the ECG monitor. Intra-operatively, the onset of action of the study drug and duration of surgery were noted. Heart rate, blood pressure and SPO2 were recorded before and after induction and every 5 mins thereafter till the surgery was over. Post-operatively, the vital parameters were recorded every 15 mins and also the duration of sedation, duration of analgesia, any complications like bradycardia, hypotension, dry mouth, retention of urine, respiratory depression, nausea, vomiting etc. were noted in each group. The duration of analgesia was assessed by using the subjective pain scale in children more than 3 years of age who can verbally express pain and observational pain scale for rest of the children who cannot verbally express pain. If the child complained of pain or if the pain score is >/=4, the child received Paracetamol suppository 15mg/kg as a rescue analgesic. Sedation was assessed using Sedation score. Motor block was assessed by Modified Bromage scale.

RESULTS

The information collected regarding all the selected cases were recorded in a Master Chart. Data analysis was done with the help of computer by using SPSS 16 software. Using this software, percentages, means, standard deviations were calculated and 'p' values were calculated from Student 't' test for raw data for two variables, and chi square test for consolidated data to test the significance of difference between variables.

A 'p' value less than 0.05 is taken to denote significant relationship.

Age in months	BD Group		RD Gr	RD Group		
	No.	%	No.	%	No.	%
12 - 24	12	40.00	7	23.33	19	31.67
25 - 36	6	20.00	5	16.67	11	18.33
37 - 48	3	10.00	4	13.33	7	11.67
49 - 60	2	6.67	5	16.67	7	11.67
61 – 72	7	23.33	9	30.00	16	26.67
Total	30	100.00	30	100.00	60	100.00
Mean	39.2		47.8			
SD	22.982		21.417			
p' value	0.244 N	Not Significant				

The mean age of the BD group was 39.2 ± 22.9 months and the RD group was 47.8 ± 21.4 months. The difference between the two groups was not statistically significant (P>0.05).

Table 2: On	set of action				
BD Group	(mins)	RD Group (mi	ins)	P'value	
Mean	S.D	Mean	S.D		
6.707	0.236	6.653	0.157	0.307	Not sig

The mean onset of action in group BD was 6.707±0.23mins and in group RD was 6.653±0.157. Statistically Not significant.

Fable 3: Coll	omparison o	of Haemody	namic variabl	es				
		BD Group		RD Grou	р	Difference Of Mean	t'	P'value
		Mean	S.D	Mean	S.D			
Pre op	PR	99.4	7.262	97.467	5.501	1.933	1.162	0.250
	MAP	75.6	4.344	76.333	4.373	-0.652	-0.733	0.517
	SPO2	99.53	0.571	99.5	0.572	0.033	0.226	0.822
Intraop	PR	88.708	6.357	91.675	6.564	-2.967	-1.778	0.081
	MAP	70.283	2.204	71.767	3.657	-1.483	-1.903	0.062
	SPO2	99.558	0.224	99.544	0.223	0.0139	0.241	0.811
Post op	PR	89.487	6.443	92.093	6.363	-2.607	-1.577	0.120
	MAP	71.58	2.246	71.967	2.837	-4.567	-0.586	0.560
	SPO2	99.133	0.376	99.013	0.53	0.12	1.011	0.316

The preoperative, intraoperative and post operative haemodyanamic changes between the Groups were comparable and were not statistically significant and the therapeutic interventions were not required.

Table 4: Duration of	Sedation				
Time in Hours	BD Group	BD Group			P'value
	Mean	S.D	Mean	S.D	
2	2.967	0.183	2.9	0.305	0.309
4	3	0	2.933	0.254	0.155
6	2	0	1.9	0.305	0.078
8	2.033	0.183	1.933	0.254	0.085
12	1.333	0.479	1.367	0.49	0.791

The Sedation score between the two Groups were comparable and were not statistically significant.

Table 5: Duration of Analgesia				
Group	Mean(mins)			P'value
	Estimate	S.E	CI	
BD	549.667	4.661	-115.769 -	< 0.001
RD	650.167	6.039	-85.231	

In our study the mean duration of analgesia in group BD was 549.66 ± 4.6 mins, whereas in group RD was 650.16 ± 6.039 , which was statistically highly significant. (p< 0.001).

Table 6: FLACC Score of Group BD and Group RD						
FLACC	BD Group	BD Group				
	Mean	SD	Mean	SD		
30 MINS	1.59	0.209	1.4	0.176		
1 Hr	1.797	0.161	1.6	0.138		
2 Hr	2.207	0.229	2.1	0.276		

4 Hr	2.45	0.204	2.3	0.199
6 Hr	3.67	0.178	2.89	0.18
8 Hr	4.2	0.191	3.02	0.187
10 Hr	5.6	0.149	4.4	0.157
12 Hr	6.32	0.146	5.98	0.117

There was a significant difference between the groups in the FLACC score measured 2^{nd} hourly in the post operative period. Group BD children achieved FLACC score of 4 at 8^{th} hr whereas Group RD children achieved FLACC score of 4 at 10^{th} hr.

Table 7: Post operative complications			
Post op. Complication	BD Group	RD Group	
PONV	2	1	
Respiratory depression	Nil	Nil	
Urinary retention	3	2	
Hypotension	Nil	Nil	
Bradycardia	Nil	Nil	

In our study 3 cases had urinary retention in BD Group and 2 cases in RD group.2cases in BD group had vomiting and 1 case in RD group had vomiting. No episodes of clinically significant postoperative complications such as, respiratory depression, hypotension and bradycardia were observed.

DISCUSSION

Motor blockade resulting from caudal block is very distressful to children in the postoperative period and delays hospital discharge. Ropivacaine in comparison to bupivacaine, has a wider margin of safety, less motor blockade, less cardiovascular and neurological toxicity and similar duration of analgesia. It can be safely used for regional anaesthesia and analgesia in the ambulatory setting in paediatric patients.^[4]

Our study showed that a single pre-surgical caudal injection of Ropivacaine after induction of anaesthesia provided good quality analgesia of sufficient duration following herniotomy, orchidopexy, urethroplasty surgeries. Ropivacaine has been used in different concentrations for caudal block with varying efficacy.^[5]

Da Conceicao et al used ropivacaine 0.375% for caudal block and found that it produces sufficient analgesia for lower abdominal surgery in children. But, Ivani et al in two different studies observed that 0.2% ropivacaine given through the caudal route in children is sufficient to provide sensory blockade for infra-umbilical surgeries. In our study, we used 0.25% ropivacaine that provided reliable and long duration analgesia. This finding is in conjunction with previous studies.^[6]

Many workers had observed that 1ml/kg of 0.2% ropivacaine and 0.25% bupivacaine by caudal block had similar onset and duration. They compared these concentrations in order to achieve equal volumes and to maintain blindness of the study. But, we used equal volumes of 0.25% concentration of both ropivacaine and bupivacaine, thereby achieving study blinding as done by Khalil et al and others.^[7]

In our study, the mean time from caudal block to first dose of diclofenac administration was compared

between the two groups which was slightly less than 6 hours. A similar trial using 0.25% bupivacaine or 0.25% ropivacaine showed that postoperative analgesia was required at a mean time of 11 hours for both drugs whereas another study using 0.375% bupivacaine or ropivacaine revealed that the mean time for first analgesia was around 5 hours in both drugs. On the contrary, Ivani et al compared 0.2% ropivacaine with 0.25% bupivacaine and observed that first requirement of rescue analgesia was 253 and 520 min for bupivacaine and ropivacaine groups respectively(P<0.05). But this finding was not replicated by other studies.^[8]

Our study showed that significant motor block was demonstrated in all our study children in the recovery room, with the ropivacaine group having a statistically significant greater motor power score than bupivacaine group.^[9]

The faster resolution of motor blockade in the ropivacaine group continued in the post-operative ward also. This is in conjunction with other studies that recorded quicker motor recovery with 0.25% ropivacaine than 0.25% bupivacaine. Khalil et al also found delayed motor recovery in both the groups and found that those who received 0.25% ropivacaine had slightly higher mean motor score at the end of 3 hours than those who had received 0.25% bupivacaine.^[10]

CONCLUSION

The aim of the study was to compare Caudal Ropivacaine 0.2% with Dexmedetomidine and caudal Bupivacaine 0.25% with dexmedetomidine in terms of the quality, onset and duration of analgesia, motor and sensory block in herniotomy, orchidopexy, urethroplasty surgeries.

Caudal Ropivacaine with dexmedetomidine provide long lasting analgesia than bupivacaine with dexmedetomidine. Ropivacaine caused less motor blockade than bupivacaine. These along with the lower toxicity of ropivacaine makes it an effective and safe drug for day care surgery in paediatric patients.

Ropivacaine is a safe and effective local anaesthetic for paediatric caudal anaesthesia. Ropivacaine 0.2%

1ml/kg with dexmedetomidine 1µg/kg provided good quality and adequate duration of analgesia than to bupivacaine 0.25% 1ml/kg with dexmedetomidine 1µg/kg when administered for caudal block for herniotomy, orchidopexy, urethroplasty surgeries. Ropivacaine produced significantly faster motor recovery than bupivacaine giving a distinct advantage over the latter by allowing the children to be discharged earlier.

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