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ORIGINAL ARTICLE

A COMPARATIVE CLINICAL STUDY BETWEEN EQUAL VOLUMES AND CONCENTRATIONS OF CLONIDINE AND DEXMEDITOMIDINE AS ADJUVANTS TO 0.25% ROPIVACAINE IN PAEDIATRIC CAUDAL BLOCK FOR CIRCUMCISION

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ABSTRACT: BACKGROUND: Caudal epidural block is a simple, safe, effective and reliable technique. Different techniques, drugs, drug combinations, doses and concentrations have been tried by many anesthesiologists. Ropivacaine produces differential neural blockade with less motor block and reduced cardiovascular and neurological toxicity compared to Bupivacaine. Adjuvants like Clonidine and Dexmeditomidine, which are alpha 2 agonists, are used along with local anesthetics to increase the duration of analgesia. Hence we are comparing 0.5µg/kg of clonidine with 0.5µg/kg of dexmedetomidine as adjuvants to 0.25% ropivacaine at a volume of 0.5ml/kg in children undergoing circumcision. **AIMS AND OBJECTIVES:** To assess the efficacy, safety and duration of analgesia of equal volumes and concentrations of clonidine and dexmedetomidine as adjuvants to low volume and concentration of ropivacaine. **MATERIAL AND METHODS:** Study design: comparative randomized study Sampling method: purposive sampling Statistical analysis: using student's t test and chi square test Sample size: 60 children aged between 1 to 6 years posted for circumcision. GROUP I: 30 children received 0.25% ropivacaine 0.5ml/kg + 0.5µg/kg clonidine GROUP II: 30 children received 0.25% ropivacaine 0.5ml/kg + 0.5µg/kg dexmedetomidine. Postoperatively the duration of analgesia was assessed using the observational pain scale, the duration of sedation was assessed using the sedation score and the duration of motor block was assessed using the modified bromage scale. **RESULTS:** The mean duration of analgesia in group I was 430.52±20.58 mins and in group II was 555.6±18.22mins. **CONCLUSION:** The onset of action between the two groups was observed to be similar. There was about 20mins increase in the duration of sedation with the dexmedetomidine group. There was no case of motor blockade and no complications in both the groups. We observed that there was a statistically increased duration of analgesia with the dexmedetomidine group compared to clonidine group. Hence we summarize that dexmedetomidine is a better adjuvant than clonidine in prolonging the duration of analgesia when used with ropivacaine in pediatric caudal block.

KEYWORDS: Caudal block, clonidine, dexmeditomidine, ropivacaine.

INTRODUCTION: Postoperative analgesia in children is a challenging task before the anesthesiologist. Good postoperative analgesia not only relieves pain in the children but also relieves anxiety in the parents.

Caudal epidural block is a simple, safe, effective and reliable technique. Since Campbell first described caudal epidural analgesia in children in 1933, anesthesiologists witnessed many advances in postoperative pain relief. Different techniques, drugs, drug combinations, doses and concentrations have been tried by many anesthesiologists.

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Bupivacaine is the most frequently used local anesthetic agent in adults and children. Despite its clinical efficacy, a life threatening neuro and cardiac toxicity can occur on inadvertent intravascular injection or on overdose. Hence research has been carried out to look for alternative and possibly safer drugs.[1]

Ropivacaine produces differential neural blockade with less motor block and reduced cardiovascular and neurological toxicity compared to Bupivacaine. These features are particularly useful for day care surgeries in children.[2]

The use of adjuvants is fundamental to increase the duration of analgesia and the safety margin because of their synergistic action. Several drugs like opioids, epinephrine, midazolam, ketamine, neostigmine, alpha 2 agonists, etc. have been used as adjuvants with various advantages, disadvantages and adverse effects.

Clonidine and dexmeditomidine are the alpha 2 agonists which produce analgesia by their central action. Alpha 2 agonists have both analgesic and sedative properties when used as an adjuvant in regional anesthesia. Dexmeditomidine is a highly selective alpha 2 agonist with an affinity of eight times greater than clonidine.[3]

There are limited studies which have compared equal volumes and concentrations of both the alpha 2 agonists in caudal block. So we wanted to know the efficacy and duration of analgesia when lower concentrations and equal volumes of these adjuvants are used with lower concentrations of ropivacaine.

For short surgical procedures like circumcision where postoperative analgesia is the main concern and motor blockade is not required, lower concentration and volume of ropivacaine and lower doses of adjuvants can be used so that the adverse effects of these drugs can be minimized.

Hence we are comparing 0.5μg/kg of Clonidine with 0.5μg/kg of Dexmeditomidine as adjuvants to 0.25% Ropivacaine at a volume of 0.5ml/kg in children undergoing circumcision.

AIMS AND OBJECTIVES: To assess the efficacy, safety and duration of analgesia of equal volumes and concentrations of clonidine and dexmeditomidine as adjuvants to low volume and concentration of ropivacaine.

MATERIAL AND METHODS: Source of the data: it was conducted in the department of Anesthesiology at KIMS hospital and research Centre, Bangalore.
Study design: comparative randomized study.
Sample size: 60 children aged between 1 to 6 years posted for circumcision.
Sampling method: purposive sampling
Statistical analysis: using student's t test and chi square test

Inclusion criteria: Children between 1 to 6 years posted for circumcision with informed written consent from their parents with ASA I physical status.

Exclusion criteria: Children with weight > 25 kgs, parental unwillingness, bleeding diathesis, infection at the site of block, abnormalities of the sacrum, children with pre-existing neurological or spinal diseases, cardiovascular, respiratory, renal, hepatic or any other systemic diseases and chronic use of anti- inflammatory drugs were excluded from the study.

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Study groups:

GROUP I: 30 children received 0.25% Ropivacaine 0.5ml/kg + 0.5µg/kg Clonidine.

GROUP II: 30 children received 0.25% Ropivacaine 0.5ml/kg + 0.5µg/kg Dexmeditomidine.

After obtaining ethical committee clearance for the study, a thorough preoperative evaluation of the patient was done which included, history by the parents, general physical examination, systemic examination and laboratory investigations. A written informed consent from the parents was taken after explaining the procedure, advantages and its consequences in their own language.

Baseline vital parameters like heart rate, blood pressure and oxygen saturation were recorded. An intravenous line was secured and isolyte P was connected. Inj atropine 0.01mg/kg IV and Inj midazolam 0.1mg/kg IV was given as premedication. Patients were induced with Inj propofol 2mg/kg IV and maintained on spontaneous ventilation with oxygen, nitrous oxide and halothane by using Jackson Rees circuit.

The child was put in the left lateral position and under aseptic precautions, the sacral hiatus was identified. Loss of resistance technique was used to identify the caudal epidural space and the drug was deposited after confirming negative aspiration for blood and CSF.

Intraoperatively the onset of action was noted. The onset of action is defined as the time in minutes between local anesthetic injection and the absence of gross movements or absence of significant increase in heart rate on application of mechanical stimulus. Heart rate, blood pressure and SPO_2 were recorded before and after induction and every 5 mins thereafter till the surgery were over. Any rescue doses of propofol needed was noted.

Postoperatively the vital parameters were recorded every 15mins. The duration of sedation, duration of analgesia, any complications like bradycardia, hypotension, xerostomia, retention of urine, respiratory depression, nausea and vomiting, etc. were noted in each group.

The duration of analgesia is defined as the time of onset of analgesia after caudal deposition of the drug to the time of appreciation of pain by the child postoperatively. In 2005 Locatelli et al[4] evaluated the postoperative pain using the children and infants postoperative pain scale (CHIPPS) which includes: crying, facial expression, posture of the trunk, posture of the legs and motor restlessness. Yildiz et al [5] in 2006 assessed the analgesic effects using modified children's hospital of eastern Ontario pain scale (mCHEOPS) for children < 5yrs and visual analogue scale for those > 5yrs. CHEOPS includes cry, facial expression, verbal response, torso and leg position.

In our study we have assessed the duration of analgesia using the observational pain scale in children who could not verbally express pain. If the child complained of pain or if the pain score is>/=3 the child was given paracetamol suppository 15mg/kg as a rescue analgesic.

CRITERION		SCORE
Heart rate	>10% to <20% of preoperative level	0
	20% to 30% of preoperative level	1
	>30% of preoperative level	2
Blood pressure	>10% to <20% of preoperative level	0
	20% to 30% of preoperative level	1
	>30% of preoperative level	2
Crying	Not crying	0
	Crying but responds to tender loving care	1
	Crying and does not respond to tender loving care	2
OBSERVATIONAL PAIN SCALE		

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Sedation was assessed using the sedation score where the duration of sedation was defined as the time from onset of analgesia to spontaneous eye opening (sedation score < 1).

CRITERION	SCORE
Eyes open spontaneously	0
Eyes open in response to speech	1
Eyes open in response to physical stimulation	2
SEDATION SCORE	

Motor block was assessed by Modified Bromage scale.

CRITERION	SCORE
No motor block, child moves limbs freely	0
Inability to raise legs	1
Inability to flex knees	2
No movement possible in legs	3
MODIFIED BROMAGE SCALE	

RESULTS:

The total number of children studied was 60.

30 children in group I and 30 children in group II.

Onset of action: Table 1 shows the mean onset of action in the two groups. The mean onset of action in group I was 7.47±0.58 mins and in group II was 7.01±0.32 mins.

Onset of action in mins	Group I	Group II	P value
Mean	7.47±0.58	7.01±0.32	0.119
Table 1: Mean Onset of action			

Intraoperative Heart rate variations: The mean baseline heart rate in group I was 131.7±10.22mins and in group II was 130.2±9.22mins as shown in table 2. At the end of 30 mins the mean heart rate in group I was 106.33±7.48mins and in group II was 104.67±7.16mins.

HR (bpm)	Group I	Group II	P value
0 min	131.7±10.22	130.2±9.22	0.7046
5 min	125.90±9.78	126.8±9.12	0.7210
10 min	121.77±9.46	122.63±9.04	0.3676
15 min	116.37±9.08	116.67±8.74	0.7581
20 min	111.50±8.52	111.60±8.54	0.8313
25 min	106.80±7.31	106.70±7.05	0.8515
30 min	106.33±7.48	104.67±7.16	0.7100
Table 2: Comparison of heart rate in two groups of patients			

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Intraoperative Mean arterial pressure variations: Table 3 shows the intraoperative mean arterial pressure in group I and group II. The basal mean arterial pressure in group I was 70.09±3.62mmHg and in group II was 70.08±2.71 mmHg. After 30 mins it was 68.12±2.45 mmHg in group I and 69.02±2.54 mmHg in group II.

MAP (mm Hg)	Group I	Group II	P value
0 min	70.09±3.62	70.08±2.71	0.7973
5 min	68.90±3.32	68.88±3.52	0.8837
10 min	68.56±3.80	68.18±3.54	0.8329
15 min	68.31±3.56	68.98±3.45	0.2926
20 min	68.25±2.74	68.96±3.80	0.3018
25 min	68.18±2.53	68.78±3.50	0.1955
30 min	68.12±2.45	69.02±2.54	0.1145

Table 3: Comparison of mean arterial pressure in two groups of patients

Intraoperative SPO_2 variations: There were not many variations between the 2 groups.

Postoperative vital parameters: There was not much variation in the postoperative heart rate, mean arterial pressure and SPO_2 in both the groups.

Duration of sedation: As shown in table 4 the mean duration of sedation in group I was 132.00±15.62mins and in group II was 152.50±10.52mins.

Sedation	Group I	Group II	P value
Duration in mins	132.00±15.62	152.50±10.52	<0.001

Table 4: Duration of sedation

Duration of analgesia: The mean duration of analgesia in group I was 430.52±20.58 mins and in group II was 555.6±18.22mins as shown in table 5.

Duration of analgesia	Group I	Group II	P value
Mean duration in mins	430.52±20.58	555.6±18.22	<0.001

Table 5: Duration of analgesia

Complications: We did not observe any complications like bradycardia, hypotension, xerostomia, retention of urine, respiratory depression, nausea and vomiting, etc. in both the groups.

DISCUSSION: Caudal analgesia is the most popular and commonly used regional block in pediatric anesthesia. Identification of the caudal epidural space is easy in children younger than 7 years, later it may be difficult because as the child grows there is a reduction in the size of the sacral hiatus and the sacral vertebrae fuse. Bernard et al [6]observed high failure rates in children above 7 years of age. In 2000 Ivani et al[7] studied children aged between 1-7 years for caudal blockade.

In our study we have chosen children aged between 1-6 years posted for circumcision.

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Various additives to local anesthetics have been used to enhance the duration of caudal blockade in children.

Clonidine an alpha2 agonist is the adjuvant of choice with minimal side effects like sedation and xerostomia, which are useful in children during both intraoperative and postoperative periods. Dexmeditomidine an alpha 2 agonist has an eight fold greater affinity for alpha 2 adrenergic receptors than clonidine.[3, 8]

In our study we observed that the onset of action was similar in both the groups. There were minimal variations in intraoperative and postoperative heart rate and mean arterial blood pressure in both the groups. The duration of sedation was observed to be 132.00±15.62mins with clonidine as adjuvant and 152.50±10.52 mins with dexmeditomidine as adjuvant. We observed an increase of about 20 mins in the duration of sedation with dexmeditomidine compared to clonidine. The mean duration of analgesia in group I was 430.52mins and in group II was 555.6mins which was statistically significant. We did not observe any complications in both the groups.

Constant et al [9] in 1998 showed that clonidine may be the drug of choice to prolong the duration of analgesia in children. In 2012 Akilandewari et al, [10] compared ropivacaine 0.1% 1ml/kg with clonidine 1µg/kg to that of plain 0.1% 1ml/kg and 0.2% ropivacaine 1ml/kg for caudal analgesia in children and concluded that the addition of clonidine prolongs the duration and quality of postoperative analgesia. Arpita et al[11] in 2013 studied plain ropivacaine 0.2% 1ml/kg and mixture of ropivacaine0.2% 1ml/kg with clonidine 2µg/kg and observed that clonidine improved the quality of postoperative analgesia without any significant degree of postoperative sedation.

El Hennawy [12] et al in 2009 studied the analgesic effects of dexmeditomidine 2µg/kg as an adjuvant caudally. In 2008, Mostafa et al, [13] studied the efficacy of dexmeditomidine 1.5µg/kg, clonidine 2µg/kg, tramadol 2mg/kg and fentanyl 2µg/kg as adjuvants to 0.25%bupivacaine 1ml/kg in caudal analgesia and observed the duration of analgesia to be 347 mins with dexmeditomidine, 350mins with clonidine, 280mins with tramadol and 275 mins with fentanyl.

Whereas in 2010, Mausumi et al[14] compared ropivacaine 0.25% 1ml/kg, ropivacaine 0.25% 1ml/kg with clonidine 1µg/kg and ropivacaine 0.25% 1ml/kg with dexmeditomidine 1µg/kg and summarized that the duration of analgesia with plain ropivacaine was 6.32hrs, 13.17hrs with clonidine as adjuvant and 15.26 hrs. with dexmeditomidine as adjuvant. Here the increased duration of analgesia could be due to the increased volume of ropivacaine used and the higher dose of clonidine and dexmeditomidine used when compared to our study.

In 2011, Sukhminder Jit et al,[15] compared the efficacy of 0.75% ropivacaine with dexmeditomidine 1.5µg/kg and clonidine 2µg/kg for epidural anesthesia and concluded that dexmeditomidine is a better adjuvant than clonidine as far as patient comfort, stable cardiorespiratory parameters, intraoperative and postoperative analgesia is concerned.

Differences in the dose of clonidine, dexmeditomidine and the local anesthetics used, concomitant use of premedication, drugs used for rescue analgesia, various methods used to assess pain and the statistical analysis may all account for the variability in the duration of analgesia.

This study shows that caudal epidural technique using clonidine and dexmeditomidine as adjuvants to ropivacaine prolongs the duration of analgesia. The onset of action between the two groups was observed to be similar. There was about 20mins increase in the duration of sedation with dexmeditomidine group. There was no case of motor blockade and no complications in both the groups.

We observed that there was a statistically increased duration of analgesia with the dexmeditomidine group compared to clonidine group. Hence we summarize that dexmeditomidine is a better adjuvant than clonidine in prolonging the duration of analgesia when used with ropivacaine in pediatric caudal block.

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