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EFFICACY OF DEXMEDETOMIDINE AS AN ADJUVANT TO BUPIVACAINE FOR CAUDAL ANALGESIA IN PAEDIATRIC PATIENTS UNDERGOING LOWER ABDOMINAL SURGERIES

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ABSTRACT: CONTEXT: Various adjuvants such as opioids or $\alpha 2$ agonists are being used to improve the quality and duration of caudal analgesia with local anesthetics. Dexmedetomidine a $\alpha 2$ agonist is used frequently in adult patients to enhance the local anesthetic effect. However there is little literature regarding its effectiveness in pediatric caudal analgesia. The objective of this study was to assess the efficacy of dexmedetomidine when used as an adjuvant to bupivacaine in increasing the duration of caudal analgesia. **AIM:** The aim of this study was to investigate the effect of adding Dexmedetomidine to caudal Bupivacaine and observe the effect on the duration of analgesia in the post-operative period. **SETTINGS AND DESIGN:** One year hospital based Double Blind Randomized Controlled Trial. **METHODS AND MATERIAL:** Sixty children, aged 1-6 years, undergoing lower abdominal surgeries were included in this prospective randomized double-blind study. The patients were randomly divided into two groups: Group I received Bupivacaine (0.25%) 1ml/kg plus 1 ml of normal saline in the caudal epidural space. Group II was administered Bupivacaine (0.25%) 1ml/ with Dexmedetomidine 2 mcg/ ml diluted to 1 ml of normal saline in the caudal epidural space. All anesthetic and surgical techniques were standardized. Heart rate, blood pressure, oxygen saturation, respiratory rate were monitored continuously. Surgery was started 10-15 minutes after the injection and confirming adequacy of caudal block. Duration of analgesia was assessed using FLACC scale (Face, Legs, Activity, Cry, Consolability scale). The time from administration of caudal anesthesia to the first time the FLACC score equal or greater than 4 was considered as the duration of caudal analgesia. Paracetamol suppository was used as rescue analgesia with a loading dose of 40mg/kg. **STATISTICAL ANALYSIS:** Mann-Whitney test and Student 't' test was used to compare the data obtained in the two groups. **RESULTS:** The demographic parameters, duration of surgery and the types of surgery were comparable in the two groups. The mean duration of analgesia was 261.33 ± 31.04 min in Group I compared to 532.67 ± 47.12 min in Group II. Hence the duration of analgesia was found significantly prolonged in Group II than in Group I with p value <0.0001 . **CONCLUSION:** We conclude that addition of Dexmedetomidine to Bupivacaine prolongs the duration and quality of caudal analgesia.

KEYWORDS: Caudal anesthesia, Bupivacaine, Dexmedetomidine, Sensory blockade.

INTRODUCTION: Caudal epidural analgesia is one of the most common, safe and accepted anesthetic techniques used in children to provide intra and post-operative analgesia for infra-umbilical surgeries. It can be used as a sole technique or in combination with general anesthesia, where in turn, it reduces the requirement of inhalational and intravenous anesthetics, attenuates the stress of surgery and facilitates rapid and smooth recovery with good immediate postoperative analgesia.¹

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Bupivacaine, being a time tested drug, has proved its efficacy in caudal anesthesia at various doses and concentrations.² However, the disadvantage of caudal analgesia was the short duration of action and limited post-operative pain relief. So the need arose to use adjuvants that could enhance the quality and duration of caudal analgesia.

Dexmedetomidine is a highly selective α_2 receptor agonist with sedative and analgesic properties. Dexmedetomidine has a higher affinity for α_2 adrenergic receptors than clonidine, which is responsible for its hypnotic and analgesic effects.³ Various studies are being done to evaluate the use of Dexmedetomidine in regional anesthesia to improve quality and duration of analgesia. Very few studies have been done to evaluate the effect of Dexmedetomidine as an adjuvant to Bupivacaine in caudal anesthesia in children.⁴

Hence this study was conducted to investigate the effect of adding Dexmedetomidine to caudal Bupivacaine on the duration of analgesia.

METHODS:

Patients' Selection: The study protocol was approved by the Institutional Ethics' Committee. This prospective, double-blind, randomized study took place in the KLE'S Dr. Prabhakar Kore Hospital, Belgaum and included 60 patients. Written, informed consent was obtained from the parents or legal guardians. Patients aged 1-6 years, ASA I-II, undergoing lower abdominal surgeries were included. Exclusion criteria were patients with ASA physical status III-IV, known history of hypersensitivity to any of the drugs used, infection at the site of block, bleeding diathesis, pre-existing neurological or spinal disease and abnormalities of the sacrum.

General Procedure: A thorough pre-anesthetic check-up including detailed history and physical examination was done. Routine investigations such as Complete Blood Count, Haemogram, Coagulation Profile and Chest X-Ray were done. The patients were kept fasting for 6 hours before the procedure. Intra-venous access was secured in the pre-operative room with a 22G/24G cannula. The patients were premedicated with inj. Glycopyrrrolate 0.005mg/kg, inj. midazolam 0.05mg/kg and inj. fentanyl 2mcg/kg i.v.

After the patients were shifted to the operating room, standard monitoring included 5 lead electrocardiogram, non-invasive automated blood pressure and pulse oximeter. The patients were sedated with inj. Ketamine 1-2 mg/kg i.v. and turned to the lateral position to perform caudal block. Patients were randomly allocated using a computer-generated program to one of the two groups: Group I received Bupivacaine 1 ml/kg of 0.25% with 1 ml of Normal saline. Group II received Bupivacaine 1ml/kg of 0.25 % with Dexmedetomidine 2mcg/ml diluted to 1 ml with Normal saline.

The dosage of Bupivacaine was decided based on Armitage formula and upper limit of volume of Bupivacaine 0.25 % was fixed to 20 ml in both the groups.

The study drugs were prepared by an anesthesiologist who was not involved in the further management or observation of the patients, in similar unlabeled syringes, that were handed over to the anesthesiologist who was blind to the identity of the drugs. Under strict aseptic precautions the skin overlying the sacral hiatus was infiltrated with 2 % lignocaine.

After 2 minutes, caudal block was performed with 22G short beveled needle and confirmed by Woosh Test. Depending on the group to which the patient belonged, following mixture of drugs were administered into caudal epidural space.

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Group I	1ml/kg of 0.25% Bupivacaine + 1ml of Normal saline
Group II	1ml/kg of 0.25% Bupivacaine +Dexmedetomidine (2mcg/ml of local anesthetic) diluted to 1ml with Normal saline.

The patients were then turned to the supine position. Surgery was started 10-15 minutes after the injection and confirming adequacy of the caudal block.

Onset of sensory blockade was confirmed by pinprick method and adequacy of block was defined by absence of gross movement, change in heart rate and respiratory rate more than 20 % of baseline on application of forcep to skin in surgical area.

The heart rate and blood pressure were monitored and recorded at every 5 min intra operatively. At the end of surgery child was shifted to post anesthesia care unit. Duration of analgesia was assessed by FLACC scale in the post- anesthesia care unit (PACU).

Categories	Score 0	Score 1	Score 2
FACE	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested.	Frequent to constant quivering chin, clenched jaw.
LEGS	Normal position or relaxed.	Uneasy, restless, tense	Kicking, or legs drawn up
ACTIVITY	Lying quietly, normal position moves easily.	Squirming, shifting back and forth, tense.	Arched, rigid or jerking.
CRY	No cry, (awake or asleep)	Moans or whimpers; occasional complaint	Crying steadily, screams or sobs, frequent complaints
CONSOLABILITY	Content, relaxed.	Reassured by occasional touching hugging or being talked to, distractable.	Difficulty to console or Comfort

Table 1: FLACC scale for pain assessment in children. There are 5 categories, each given a score of 0-2 and the total score is taken to assess pain. 0- No pain, 1-3 = Mild pain, 4-7= Moderate Pain, 8-10= Severe Pain. The time from administration of caudal anesthesia to the first time the FLACC score equal or greater than 4 was recorded and noted as the duration of caudal anesthesia.

In the post anesthesia care unit, the necessity for rescue medication was decided by the pain score. Paracetamol suppository was used as a rescue medication with a loading dose of 40 mg/ kg when the FLACC score was ≥ 4

Statistical Analysis: The statistical analysis was done using SPSS for Windows version 15.0 software. Data are presented as median, mean (SD) or frequencies as appropriate. Duration of analgesia was compared using the Mann-Whitney test and Student's t test for the two groups. p value <0.05 was considered significant.

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Parameters	Group I (n=30)	Group II (n= 30)	P value
Age (years)	4.37 ±1.10	4.48± 1.18	0.69
Sex (M:F)	14:16	15:15	
Weight (kg)	16.07 ±3.69	16.31 ±3.44	0.931
ASA I-II (n)	22:8	23:7	0.90
Duration of Surgery (min)	73.62 ± 9.81	76.17 ± 9.35	0.31

RESULTS: Subject characteristics and clinical details were very similar between the two groups. All the 60 patients were included for analysis and no patient was excluded after inclusion in the study and randomization in the groups.

It was observed during analysis that there was a significantly more clinically acceptable increased duration of analgesia in Group II as compared to Group I ($p < 0.0001$). The mean duration of analgesia in Group I was 261.33 ± 31.04 minutes while in Group II was 532.67 ± 47.12 minutes.

	Group I	Group II	p value
Duration of analgesia (min)	261.33	532.67	0.0001

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DISCUSSION: Caudal anesthesia is a common, safe, and effective technique but the duration of action with only local anesthetics is less. Increasing bupivacaine dosage, however could potentially lead to increased toxicity and inadvertent high block. Hence the use of adjuvants such as opioids or α_2 agonists seems logical.

Dexmedetomidine is a potent alpha 2 agonist which acts by binding to central nervous system alpha 2 receptor which in turn causes decreased release of catecholamine. Its specificity for alpha2 receptors helps in minimizing side effects associated with alpha 1 blockade.⁵

The clinical effects of dexmedetomidine by any route result in bradycardia, hypotension and reduced stress response to surgery.

Various adjuvants to caudal local anesthetics are used to improve the quality of block but the hunt for ideal agent continues in view of safety profile of these agents in pediatric age group.

Dexmedetomidine is widely used and has proven benefits in ICU sedation, spinal anesthesia and peripheral nerve blocks. These observations encouraged the understanding of wider areas of action of dexmedetomidine. Dexmedetomidine enhances the action of local anesthetics by acting on peripheral alpha-2A adrenergic receptors and when used in spinal anesthesia it enhances local anesthetic action by virtue of its spinal alpha 2 receptors.^{6, 7}

The observed results of our study indicate that addition of Dexmedetomidine significantly enhances the duration of caudal analgesia when compared to bupivacaine alone. These observations are also supported by the study by in which they observed that addition of clonidine and dexmedetomidine to caudal bupivacaine significantly prolongs postoperative analgesia.⁸

Neogi et al. compared clonidine 1 μ g/kg and dexmedetomidine 1 μ g/kg as adjuncts to ropivacaine 0.25% for caudal analgesia in pediatric patients and concluded that addition of both clonidine and dexmedetomidine with ropivacaine administered caudally significantly increases the duration of analgesia.⁹

Prolongation of sensory blockade in caudal anesthesia by dexmedetomidine can also be attributed to its vasoconstrictor effect on blood vessels which in turn prevents its systemic uptake.¹⁰ This vasoconstrictor property also helps in minimizing local anesthetic toxicity chance in caudal anesthesia.

CONCLUSION: We conclude that duration of caudal analgesia increases significantly when Dexmedetomidine is used as an adjuvant to Bupivacaine in pediatric lower abdominal surgeries.

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