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Original Research Article

A Prospective, Randomized, Double Blind Comparative Study on Caudal Epidural Postoperative Analgesia: Evaluation of Various Doses of Dexmedetomidine with Ropivacaine in Pediatric Infraumbilical Surgeries

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Abstract:

Objective: This study was designed to investigate the effects of two different doses of dexmedetomidine in caudal blocks on postoperative analgesia and sedation score after pediatric infraumbilical surgeries.

Methods: A total of 60 children who underwent elective infraumbilical surgeries were enrolled in this study. They were randomly divided into two groups: RD1 group receives- 0.25% ropivacaine 1 ml/kg + 1 µg/kg dexmedetomidine and RD2 Group receives- 0.25% ropivacaine 1 ml/kg + 2 µg/kg dexmedetomidine for caudal block. Primary outcome observed was duration of postoperative analgesia pain assessment using FLACC score. Postoperative sedation, haemodynamic stability and the incidence of side effects were the secondary outcomes.

Results: Mean age, weight and duration of surgery were comparable among the three groups. There was a significant difference in the FLACC score between groups RD1 versus RD2 (P-value 0.05). The sedation scores were higher for group RD2 as compared to RD1. The time to first rescue analgesia in group RD1 was 12.03 hours, whereas it for group RD2 it was 16.08 hours ($P < 0.05$).

Conclusion: prolongation of the duration of analgesia, Decreased the need for rescue analgesics, were found better with 2 µg/kg dexmedetomidine for caudal block. Stable hemodynamics, No significant prolonged postoperative sedation were found better 1 µg/kg dexmedetomidine.

Keywords: Dexmedetomidine, FLACC score, Ropivacaine, Analgesia.

Introduction

Particularly in young infants, pain is an unpleasant, subjective sensation that can only be felt and not spoken. Humanitarian concerns are the main justification for managing or preventing suffering. Pediatric pain management is the most difficult problem in anesthesiology.

Children's sense of pain is nuanced and challenging to measure. Human efforts have been focused on the alleviation of pediatric pain. Inadequate pain treatment in pediatric patients may lead to long-term psychosocial repercussions such interrupted sleep and appetite, detrimental neuroendocrine responses, hyperalgesia, and allodynia. Children who experience postoperative discomfort may become uncooperative, weep uncontrollably, and become restless. The most effective method for managing pain after surgery is multimodal or balanced analgesia. Pharmacological methods such as nonsteroidal anti-inflammatory medications (NSAIDs) and opioids, as well as neuraxial blocks such as intrathecal or epidural, intra-articular and wound infiltration using local anesthetic agents, are among the frequently employed analgesic modalities. The caudal route was selected for this investigation because it is one of the most straightforward, secure, and successful procedures in pediatric surgery.

Children's epidural space promotes the quick longitudinal dispersion of medications and helps them work well to relieve postoperative pain. Children up to the age of eight exhibit excellent blocking following caudal anesthesia due to the greater fluidity of their epidural fat. Caudal analgesia's principal drawback is how quickly it takes to start working after a single injection. Addition of adjuvants such epinephrine, opioids, ketamine, and α2 agonist has been shown to prolong caudal analgesia utilizing a single-shot approach. By adding adjuvants to local anesthetics, it is now possible to decrease the toxicity of local anesthetics and extend their duration of analgesia by up to 24 hours. When children are having

surgery below the umbilicus, caudal block is typically used as a postoperative analgesic and an adjuvant to intraoperative anesthesia. It is normally administered after general anesthesia has been induced.

For pediatric caudal anesthesia, ropivacaine, a long-acting amide local anesthetic chemically similar to bupivacaine, has been utilized. It reduces motor blockage while relieving pain. Since ropivacaine is less cardiotoxic than bupivacaine, according to the literature, it might be a better agent for caudal epidural analgesia, particularly in day care surgery. Opioids may cause postoperative respiratory depression, and an accidental intrathecal injection of ketamine may result in neurotoxicity [4]. Consequently, a great deal of research has been done on safe, efficient anesthetic-sparing drugs that also have neuroprotective effects.

An α-2 agonist is dexmedetomidine. Alpha-2 adrenergic receptor stimulation produces analgesic and calming effects without causing respiratory depression. Dextmedetomidine can be added to local anesthetics to boost their effectiveness without increasing the frequency of side effects, or it can be administered as an adjunct for pain control using a variety of ways. Due to its cardiac, renal, and neuroprotective qualities in preclinical investigations, dexmedetomidin has drawn interest from researchers [5]. In the context of newborns and children, it seems to be less neurotoxic than other currently available medicines and may even have neuroprotective effects.

The fundamental cause of dexmedetomidine's suggested neuroprotective effects is its selectivity. Through the central nervous system's α2-adrenoceptors, agonists of α2-adrenoceptors can cause drowsiness and analgesia, reduce plasma catecholamine levels, lessen stress responses brought on by surgery, and avoid shivering [9]. Dexmedetomidine causes drowsiness in a way similar to physiological sleep (cooperative sedation) due to its management of wakefulness through its influence on the ventrolateral preoptic nucleus (VLOP) neuronal circuity. It is also clear that by inhibiting the hyperpolarization-activated cation current, perineural dexmedetomidine, when combined with a local anesthetic, can extend the duration of analgesia.

In order to examine the analgesic impact, sedation score, hemodynamic changes, and side effects of two different dosages of dexmedetomidine when added to ropivacaine in the caudal epidural block in pediatric patients, this prospective, randomized, double-blind study was conducted. In contrast to greater dosages (primary outcome), we hypothesized that adding lower doses of dexmedetomidine to caudal ropivacaine would produce effective analgesia for a long enough period of time in pediatric patients undergoing infraumbilical operations. The secondary outcomes were the incidence of side effects, postoperative sedation, and hemodynamic stability.

Materials and Methods

This study was conducted after getting approval from the Ethical Committee of the Institute and informed, written consent from parents. Patients aged between 6 months and 6 years, having American Society of Anesthesiologists (ASA) physical status I and II and undergoing infraumbilical surgeries, were included in the study

Exclusion criteria included parental refusal; history of developmental delay or mental retardation, which could make pain intensity assessment difficult; children with known allergy to local anesthetics; infection at the local site; children with coexisting medical illness, preexisting neurological disease, coagulation disorders, and anatomical abnormalities of spine and sacrum.

During preoperative visit, patient's age, weight, and baseline vital parameters were recorded. Detailed history, general physical and systemic examinations were done. Routine laboratory investigations done. All patients were kept fasting as per institutional protocol (2 h for clear liquid and 6 h for semisolid and solid) and midazolam syrup 0.5 mg/kg body weight was given 30-45 min before surgery.

Randomization was done using a computer-generated list and all children were evenly assigned into two groups of 30 each, RD1 group receives- 0.25% ropivacaine 1 ml/kg + 1 µg/kg dexmedetomidine and RD2 Group receives- 0.25% ropivacaine 1 ml/kg + 2 µg/kg dexmedetomidine for caudal block.

Induction of anaesthesia was achieved with 50% N2O and 8% sevoflurane in oxygen in spontaneous ventilation. An appropriate-sized laryngeal mask airway (LMA) was inserted. After the insertion of LMA, sevoflurane concentration was reduced to 3% in 50% nitrous oxide, patients were left in spontaneous ventilation and a caudal block was performed in all patients according to the group. The inhaled concentration of sevoflurane was adjusted to achieve haemodynamic changes less than 30% of the baseline values. No other narcotics, analgesics or sedatives were used intraoperatively. Standard monitoring was used during anaesthesia and surgery. Heart rate (HR), mean arterial pressure (MAP) and oxygen saturation (SpO2) were recorded before surgery and every 5 min till the end of surgery. The occurrence of intraoperative hypotension requiring a fluid bolus, bradycardia requiring atropine, and the maximum maintenance concentration of sevoflurane (%) were recorded. Vitals were monitored continuously, and data were recorded

intraoperatively every 15 min till the end of surgery. The effectiveness of the block was assessed by haemodynamic stability and the decreased requirement for inhalational anaesthetics. The block was considered adequate if there was no increase in heart rate and systolic blood pressure by 20% following the surgical incision. If a child required additional supplemental doses of ketamine for analgesia, the case was excluded from the study, and supplemental analgesia was given. Reversal of anaesthesia was done at the end of the surgery. Once the vitals were stable and the child was awake, the child was shifted to the postoperative recovery room, where the vitals were monitored for 2 hours. After that, the child was shifted to the ward. Any other complications were also noted. Postoperative analgesia was assessed by using the paediatric observational Face, Legs, Activity, Cry, and Consolability (FLACC) scale [Figure 2]. The time from arrival in the postanaesthesia care unit (PACU) to the first time the FLACC score >4 was recorded and noted as the duration of adequate analgesia.

Ramsay Sedation

Score 1 = anxious, agitated, or restless

2 = cooperative, oriented, and tranquil

3 = responsive to commands

4 = asleep, but with brisk response to light, glabelar tap, or loud auditory stimulus

5 = asleep, sluggish response to glabelar tap, or auditory stimulus

6 = asleep, no response. Patients will be also asked about recalling of intraoperative events or any sign of awareness.

FLACC Score for Pain Assessment

Categories	0	1	2
Face	Smile or no particular expression	Occasional grimace, frown, withdrawn, disinterested	Frequent to constant frown, clenched jaw, quivering chin
Legs	Normal position or relaxed	Uneasy or restless	Kicking legs or 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 complaints	Crying steadily, screams or soabs, frequent complaints
Consolability	Content or relaxed	Reassured by occasional hugging, touching, talking, distractable	Difficult to console

Results: Mean age, weight and duration of surgery were comparable among the three groups. The mean ± standard deviation for age was 4.12 ± 1.5 years in RD1 group and 3.87 ± 1.2 years in RD2 group. The mean ± standard deviation for weight was 12.47 ± 6.40 kg in RD1 group, 13.70 ± 5.430 kg in RD2 group.

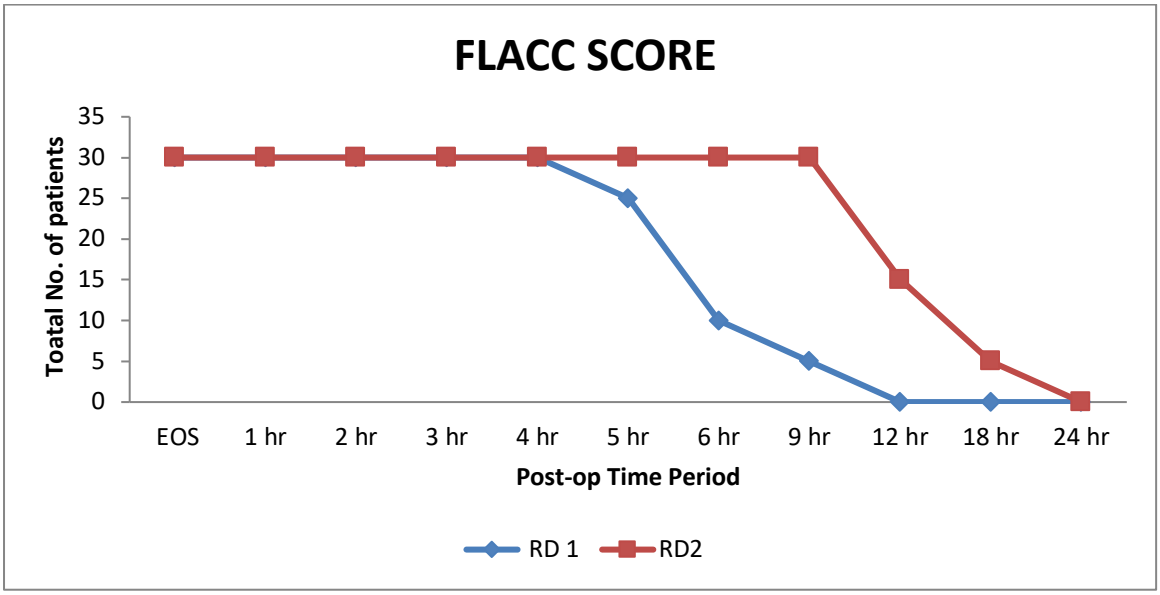

Figure 1: FLACC Score

There was a significant difference in the FLACC score between groups RD1 versus RD2 (P-value 0.05).
Ramsay Sedation Score during observation period

Table 1:

	Median (Range)	
Time	**RD1 Group**	**RD2 Group**
End of surgery	2 (1-3)	3 (2-3)
1 hr	1 (0-2)	2 (2-2)
2 hr	1 (0-1)	2 (2-2)
3 hr	1 (0-1)	1 (0-1)
4 hr	0 (0-0)	1 (0-1)
5 hr	0 (0-0)	1 (0-1)
6 hr	0 (0-0)	0 (0-0)

The sedation scores were higher for group RD2 as compared to RD1. The time to first rescue analgesia in group RD1 was 12.03 hours, whereas it for group RD2 it was 16.08 hours (P < 0.05).

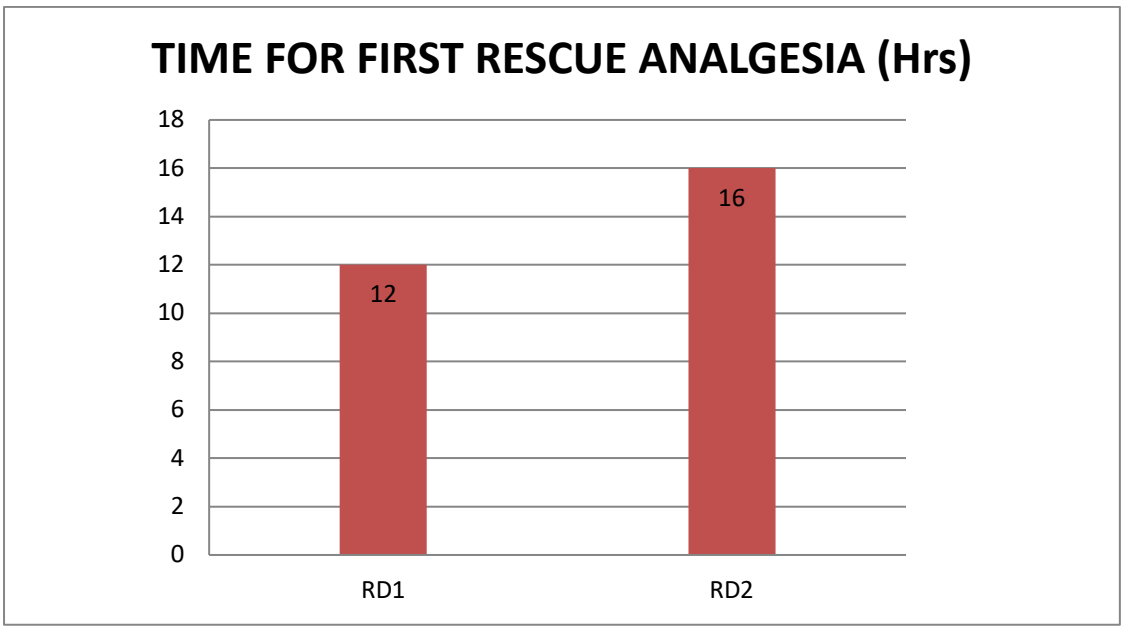

Figure 2: Time for First rescue analgesia (Hrs)

The pre-operative, intra-operative and postoperative haemodynamic changes between the groups were statistically insignificant. There were minimal complications between all the groups

Discussion

Inadequate treatment of children's pain might be partly attributed to the challenges associated with measuring and estimating pain in children, which arise from the developmental, emotional, and cognitive differences between adults and children. Children's pain is evaluated using either subjective (self-evaluation) or objective (monitoring of behavioral and physiological changes) techniques. Although self-evaluation is preferable to observational assessment, it is often the only technique accessible for younger children.

A useful measure for determining postoperative pain and the requirement for analgesics is the FLACC pain score. In children, caudal epidural analgesia is frequently utilized. Compared to bupivacaine, ropivacaine has a similar duration of analgesia, a greater margin of safety, less motor blockage, and less toxicity to the heart or nervous system. In the ambulatory context, it is safe for use in pediatric patients for both analgesia and regional anesthesia.

Due to dexmedetomidine's natural analgesic, sedative, and anesthetic sparing qualities, fewer medications are needed. With cardioprotection, neuroprotection, and renoprotection, it has a negligible respiratory depressive impact. When compared to clonidine, it is a highly selective α-2 agonist that eliminates side effects caused by α-1 receptors. Equally helpful for managed hypotension is dexmedetomidine. The primary drawbacks of a caudal block are its brief onset of effect and inadequate postoperative analgesia. A study indicated that the administration of 1-2 µg/kg dexmedetomidine in conjunction with local

anesthetics for caudal epidural blocks in children was both safe and efficacious.[3] Therefore, in the present investigation, two distinct dosages (1 µg/kg and 2 µg/kg) of dexmedetomidine combined with 0.25% ropivacaine were employed in caudal block for postoperative analgesia. We found that with larger dosages of dexmedetomidine (2µg/kg), the duration of analgesia was shorter than with 1 µg/kg.

Additionally, compared to other groups, the patients receiving 2µg/kg of dexmedetomidine had a considerably higher sedation score ($P < 0.05$). Comparable outcomes were noted by Al Zaben and associates. The three groups' changes in hemodynamic parameters were similar to one another. The possible explanation for this is that dexmedetomidine selectively acts on the α2A receptors, which can cause analgesic and sedative effects when released into the bloodstream or upon diffusion into the cerebrospinal fluid. Additionally, it has the ability to cause vasoconstriction of the microcirculation, which can delay drug absorption in the sacral canal by activating the α 2B receptors of the vascular smooth muscle cells.[5] Our results are similar to those of a recent randomised trial.[5] However, there are several restrictions attached to this study. First off, it is not entirely possible to rule out dexmedetomidine's analgesic effect through systemic absorption in the studied instances. Second, there may have been variation in the level of pain due to our inability to standardize the intensity of surgical trauma.

In our investigation, both groups saw a decrease in mean heart rate, mean systolic and diastolic blood pressure following caudal injection; however, the RD2 group experienced a greater decline than the RD1 group. Nevertheless, none of our patients needed medical attention. The premedication, which included intravenous fluid replenishment and glycopyrrolate injection, may be the cause of this.

There were no adverse effects that we saw, such as nausea, vomiting, itching, etc. After 12 hours, the RD1 group's mean pain score was higher than that of the RD2 group, which was comparable after 16 hours. Up to eighteen hours, the RD2 group's Ramsay sedation score was higher than the RD1 group's. Al-Zaben et al. studied the effects of two different dosages of dexmedetomidine combined with caudal bupivacaine for postoperative analgesia in pediatric patients having infra umbilical operations in a randomized, double-blinded research.

The trial involved three groups: group 1 received 0.25% bupivacaine at 0.8 mL/kg, group 2 received 0.25% bupivacaine at 0.8 mL/kg along with 1 mcg/kg of dexmedetomidine, and group 3 received 0.25% bupivacaine at 0.8 mL/kg along with 2 mcg/kg of dexmedetomidine. They came to the conclusion that both groups' analgesia from dexmedetomodine was similar. The third group receiving 2 mcg/kg of dexmedetomidine showed signs of hypotension, bradycardia, and urine retention.

A randomized, prospective, parallel group, double-blinded trial was carried out by Anand et al. Group R (η=30) received 0.25% ropivacaine ml/kg + 0.5 mL NS, while group RD (η=30) received 0.25% ropivacaine 1 mL/kg plus dexmedetomidine 2 mcg/kg, bringing the volume to 0.5 mL. Behavior during emergence was rated with a 4-point scale, sedation with Ramsay's sedation scale, and pain assessed with FLACC pain score. The duration of postoperative analgesia recorded a median of 5.5 hours in Group R compared with 14.5 hours in Group RD, with a p-value of < 0.001. Group R patients achieved a statistically significant higher FLACC score compared with Group RD patients. The difference between the means of mean sedation score, emergence behaviour score, mean emergence time was statistically highly significant ($p < 0.00l$).

Both groups' perioperative hemodynamics was consistent. They came to the conclusion that for pediatric lower abdominal surgeries, caudal dexmedetomidine (2 mcg/kg) with 0.25% ropivacaine (1 mL/kg) produced a significant amount of postoperative pain relief, which improved sleep quality, prolonged the duration of arousable sedation, and decreased the incidence of emergence agitation after sevoflurane anesthesia. When compared to our trial, the duration of analgesia with dexmedetomidine 2 mcg/kg is longer.

Conclusion:

Comparing the RD1 and RD2 groups, we discovered that using 0.25% ropivacaine 1 ml/kg + 2 µg/kg dexmedetomidine for caudal block improved the duration of analgesia and reduced the requirement for rescue analgesics. Stable hemodynamics and the combination of 0.25% ropivacaine 1 ml/kg and 1 µg/kg dexmedetomidine did not significantly improve the duration of postoperative sedation.

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