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COMPARISION OF ANALGESIC EFFICACY OF CAUDAL DEXMEDETOMIDINE VERSUS CAUDAL TRAMADOL WITH ROPIVACAINE IN PEDIATRIC INFRAUMBILICAL SURGERIES

Anaesthesiology

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ABSTRACT

Introduction: Caudal epidural analgesia is regional block technique in children undergoing infraumbilical surgeries but has a short duration of action after single shot local anaesthetic injection. This study is designed for the comparison of caudal dexmedetomidine and ropivacaine in combination to caudal tramadol and ropivacaine for paediatric infra umbilical surgeries. **Method:** The study is prospective, randomized, interventional study of evaluation of the analgesic effect of caudal dexmedetomidine versus caudal tramadol with ropivacaine in pediatric infraumbilical surgeries. This study was conducted on 60 patients, aged 1 year to 7 years of both gender, ASA grade I & II, 30 patients in each group. GROUP A Ropivacaine (0.25%) 1ml/kg + dexmedetomidine 1mcg/kg as dosage for caudal block. GROUP B: Ropivacaine (0.25%)1ml/kg + tramadol 1mg/kg as dosage for caudal block. **Result:** The duration of analgesia is prolonged in the group A. The mean duration of analgesia in minutes in group A is 486.2 min and in group B is 279.7 min., the mean number of rescue analgesia given in hours in group A is 1.03 and in Group B is 1.43, patients in both groups were vitally stable and statistically heart rate, BP,SPO2,RR,Temperature did not have significant changes. There was no significant incidence of postoperative complications. **Conclusion:** we conclude that addition of Dexmedetomidine to Ropivacaine is superior to Tramadol with Ropivacaine in caudal analgesia in paediatric patients posted for infraumbilical surgeries.

KEYWORDS

Analgesia; caudal block; dexmedetomidine; ropivacaine; tramadol.

INTRODUCTION

IASP (International Association for Study of Pain) defines pain as "An unpleasant emotional and sensory experience associated with actual or potential tissue damage". Caudal block is one of the most popular and commonly used regional anaesthetic procedures in paediatric patients for most surgeries below the umbilicus. The block can be practised by a single-shot injection or as a continuous infusion through a caudal epidural catheter. For continuous infusion, use of a caudal catheter is usually not preferred due to high risk of catheter contamination from faecal soiling. Ropivacaine, the S-enantiomer of the amide local anaesthetic, is suitable for day-care surgery in children as it produces differential neural blockade, with less motor blockade, cardiovascular and neurological toxicity.

To extend the duration of post-operative analgesia provided by the 'single shot' caudal technique, various additives, such as tramadol, ketamine, ephedrine, morphine, fentanyl and clonidine with local anaesthetics, have been investigated. Tramadol, a synthetic 4-phenyl-piperidine analogue of codeine, is a racemic mixture of two enantiomers, both of which contribute to the analgesic activity through different mechanisms enhancing inhibitory effects on pain transmission in the spinal cord. The (+) enantiomer has moderate affinity for the opioid μ-receptor, which is greater than that of the (−) enantiomer. In addition, the (+) enantiomer stimulates the pre-synaptic release of serotonin and inhibits serotonin reuptake, and the (−) enantiomer is a norepinephrine reuptake inhibitor. The complementary and synergistic actions of the two enantiomers improve the analgesic efficacy and tolerability profile of the two. Tramadol has a striking lack of respiratory depressant effect despite having analgesic potency approximately equal to that of pethidine.

To improve the quality and duration of analgesia in recent years, studies are being conducted to evaluate dexmedetomidine as an adjuvant in regional anaesthesia. Dexmedetomidine, a stereoisomer of medetomidine, is a highly selective α2-adrenergic receptor agonist with eight times more specificity for α_2 adrenoceptors than clonidine (ratios of α_2:α_1 activity, 1620:1 for dexmedetomidine and 220:1 for clonidine). It provides better perioperative hemodynamic stability than many other adjuvants now in use and good quality of intraoperative and prolonged post-operative analgesia with minimal side effects. It has sympatholytic, analgesic and sedative effects and is remarkably free from side effects except for manageable hypotension and bradycardia. We hypothesized that adding dexmedetomidine to the caudal ropivacaine would prolong the duration of analgesia in comparison to tramadol-ropivacaine (primary outcome) and duration of the motor block, post-operative sedation as well as the incidence of any side effect (secondary outcome) in paediatric patients undergoing infraumbilical surgeries.

MATERIAL AND METHODS

Source of data: 60 patients admitted to civil hospital satisfying the inclusion and exclusion criteria undergoing infraumbilical surgeries and general anaesthesia during the period from 2020-2021 were included in the study after obtaining ethical committee clearance (ethical committee reference number-53/2020).

Prospective study of 60 patients scheduled for infraumbilical surgery was assigned randomly divided into two groups, 30 each by simple randomization method.

Group A: Ropivacaine (0.25%) 1ml/kg + dexmedetomidine 1mcg/kg as dosage for caudal block.

Group B: Ropivacaine (0.25%) 1ml/kg + tramadol 1mg/kg as dosage for caudal block.

Type of study : A Comparative two-group study was conducted in patients of both sex undergoing infraumbilical surgeries.

Inclusion Criteria:

ASA I, II and III Patient aged 1 to 7 yrs, Patients scheduled for Infraumbilical surgeries, Elective surgeries.

An anaesthesiologist not participating in the study kept the table of random numbers and prepared the drugs as per patient's body weight in syringes Preoperative assessment was done a day before surgery. Patients were kept nil per orally before surgery. On the day of surgery patients were re assessed in the preoperative room. In the operating room standard monitors including ECG, NIBP, SPO2 were attached and intravenous line was secured.

The patient was premedicated with Inj. Glycopyrolate(4mcg/kg), Inj. Ondansetron(150mcg/kg), Inj. Fentanyl(1 mcg/kg). After pre oxygenation with 100% oxygen for 3 minutes patient induced using balanced general anaesthesia. Trachea secured with an appropriately sized endotracheal tube / I gel. Thereafter, patients were placed in a lateral position and the skin of the back over the sacrum was disinfected using povidone-iodine solution, and under aseptic precautions, single-dose caudal epidural injection was performed using a 24-gauge needle. Needle position was confirmed by the pop

sensed during penetration of the sacrococcygeal ligament, which was followed by the whoosh test using 0.5 ml of air. After negative aspiration of blood or cerebrospinal fluid, caudal medication was given as per the group assigned. The intraoperative monitoring and post-operative observation were done by an experienced anaesthesiologist. The time of caudal block was recorded, and the surgery was allowed to start 10 min after caudal injection. The inhaled concentration of sevoflurane was adjusted to achieve hemodynamic changes within 20% of the baseline values. No other analgesics, sedatives or narcotics were used intraoperatively. Time taken for the administration of block was noted. Anaesthesia was maintained with sevoflurane and oxygen 50% and N_2O 50%. All the patients were monitored by a standard protocol in a uniform pattern during anaesthesia and surgery. Continuous monitoring of vital parameters - heart rate (HR), ECG, respiratory rate, NIBP, SpO_2 - was done, and values were recorded before and after pre-medication, induction, caudal block, after incision and thereafter every 10 min until the surgery was over. At the end of surgery, all anaesthetic drugs were discontinued. Total time of surgery was recorded. Any side effects such as breath holding/apnoea, hypotension, involuntary movements, nausea and vomiting were noted. The occurrence of intraoperative Hypotension (fall in blood pressure > 20% from baseline) requiring a fluid bolus and bradycardia (fall in heart rate > 20% from baseline) requiring atropine was recorded. The primary outcome was the duration of analgesia, defined as the time period between administration of block until the time face, legs, activity, cry, consolability (FLACC) score reached ≥4. Secondary outcomes were the duration of the motor block, post-operative sedation by 5-point sedation score, and emergence time.

After surgery, patients were shifted to the post-anaesthesia care unit (PACU) for further observation and monitoring. Adverse events such as nausea, vomiting, hypotension, bradycardia, respiratory depression and urinary retention were monitored for 24 h and treated accordingly. Post-operative respiratory depression was defined as respiratory rate <10/min or decrease in SpO_2 of <95% requiring supplementary oxygen. Fall in blood pressure (BP) and HR by >20% from the pre-operative values was defined as hypotension or bradycardia, respectively, and was treated by fluid bolus, mephentermine, or atropine, as necessary. Nausea and vomiting were treated with IV ondansetron. Post-operative pain status and degree of sedation were evaluated and recorded. Using the paediatric observational FLACC pain score with its 0–10 score range, each patient's pain intensity was assessed every hour till 6 h, every 3 h till 12 h and every 6 h till 24 h until the first dose of rescue analgesia was given. Rescue analgesia was with paracetamol suppository 15 mg/kg, given when the FLACC score was ≥4. The number of doses of rescue medication required and the time to first administration of rescue medication were also noted. Pain was assessed by the nursing staff blinded to the group of the patients. Motor block was assessed in the PACU on awakening by using a modified Bromage scale that consisted of 4 points: 0 = full motor strength (flexion of knees and feet), 1 = flexion of knees, 2 = little movement of feet only, 3 = no movement of knees or feet. However, younger children who could not move their legs on command were stimulated by tapping on the legs and feet. Level of sedation was assessed by Ramsay sedation scale at 15 min, 30 min, and 60 min after extubation and thereafter hourly until the Ramsay sedation score became 1 in all patients. Duration of post-operative sedation was deemed from the time of extubation until Ramsay sedation score was 2 or less. The times recorded were anaesthesia time (time from induction of anaesthesia to the end of surgery, when sevoflurane was discontinued), time from caudal block to skin incision, time from caudal block to end of surgery and emergence time (time from the end of surgery to opening the eyes on calling). Anaesthetic emergence was considered as delayed if the time elapsed from the end of surgery to exiting the operating theatre was greater than 20 min. The criteria for transferring the patient from operating room to PACU were being awake, moving all limbs, patent airway and normal respiratory pattern, normal oxygen saturation with no need for mandible support, stable hemodynamics, normothermia, and pain free.

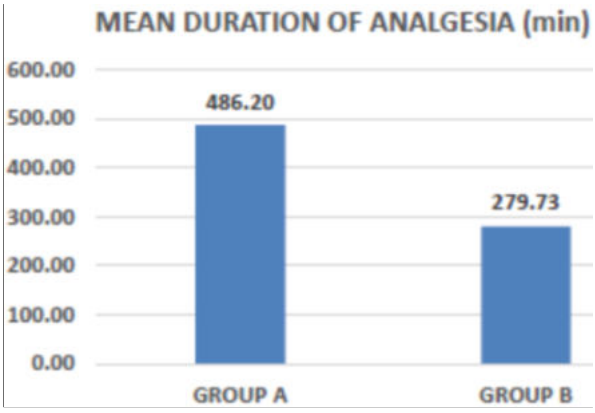
Failure of the caudal block was defined as any increase in HR or mean arterial pressure (MAP) more than 20% of the pre-incision values. Failure of the caudal block was not reported in any patient.

Data was entered and analyzed into Microsoft Excel (Windows 10; Version 2007). Descriptive statistics such as mean and standard deviation (SD) for continuous variables, frequencies and percentages were calculated for categorical variables. Line, Bar and Pie charts were used for visual representation of data. To check for association between scores and group, chi square test was used. To compare the distribution of median ramsay scores in both groups Mann Whitney U test was used. Level of significance was set at 0.05.

RESULTS:

Table 1: Duration Of Analgesia

DURATION OF ANALGESIA	Group A		Group B		P VALUE
	MEAN	SD	MEAN	SD	
	486.20	4.19	279.79	11.97	0.00

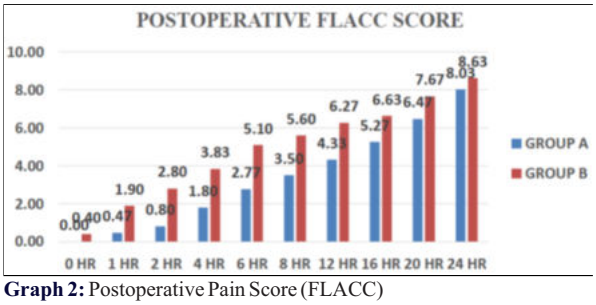


Graph 1 : Duration Of Analgesia

Duration of analgesia between two groups was statistically significant showing mean of 486.20 min in Group A and 279.73 min in Group B.

Table 2: Postoperative Pain Score (FLACC)

FLACC SCORE	Group A		Group B		p VALUE
	MEAN	SD	MEAN	SD	
0 HR	0.00	0.00	0.40	0.50	-
1 HR	0.47	0.51	1.90	0.48	<0.000
2 8HR	0.80	0.41	2.80	0.61	<0.000
4 HR	1.80	0.61	3.83	0.59	<0.000
6 HR	2.77	0.50	5.10	0.61	-
8 HR	3.50	0.51	5.60	0.67	<0.000
12 HR	4.33	0.48	6.27	0.58	-
16 HR	5.27	0.69	6.63	0.61	<0.000
20 HR	6.47	0.73	7.67	0.55	<0.000
24 HR	8.03	0.32	8.63	0.49	<0.000



Graph 2: Postoperative Pain Score (FLACC)

Table 2 and Graph 2 shows the changes in FLACC score at different time interval like 0,1,2,4,6,8,12,16,20 And 24 hours. In our study, there was statistically significant difference in FLACC score.

Duration Of Analgesia- The duration of analgesia is prolonged in the group A. The mean duration of analgesia in minutes in group A is 486.2 min and in group B is 279.7 min.

Total Rescue analgesia – In our study**,** the mean number of rescue analgesia given in hours in group A is 1.03 and in Group B is 1.43.

Hemodynamic Variables – In our study, patients in both groups were vitally stable and statistically heart rate, BP,SPO2,RR,Temperature did not have significant changes**.**

Postoperative Complications – There was no significant incidence of postoperative complications. Nausea and vomiting was more in group

B which has the mean value of 7% compared to group A mean value was 3%. Sedation was compared, but it was insignificant in both the groups.

DISCUSSION:

In this study, we found that the use of dexmedetomidine, as an additive to ropivacaine in caudal epidural analgesia, prolonged the duration of analgesia following infraumbilical surgeries as compared with caudal tramadol in children.

Tramadol, a centrally acting synthetic analgesic with low affinity for opioid receptors, appears to modify the transmission of pain impulses by the inhibition of monoamine reuptake. Few studies have shown that in caudal epidural block, addition of tramadol to ropivacaine showed significant prolongation of post-operative analgesia as compared to ropivacaine alone. Studies have established the safety of tramadol as caudal adjuvant without significant adverse effects.

Dexmedetomidine enhances the effects of local anaesthetics without increasing the incidence of side effects. Dexmedetomidine in comparison to other sedatives has minimal respiratory effects in adults and children which make it a good adjuvant. Sedation caused by dexmedetomidine can be easily reversed with slight stimulation and do not cause respiratory depression even at high doses. Furthermore, respiratory rate, oxygen saturation and carbon dioxide tension are generally maintained during dexmedetomidine sedation in children.

We observed that the duration of analgesia (FLACC <4) without the need of a rescue analgesic was significantly longer in the group receiving ropivacaine-dexmedetomidine mixture than the group receiving ropivacaine with tramadol. These results are similar to those reported in a study where dexmedetomidine as an adjuvant with 0.25% ropivacaine caudally was used and observed that the duration of analgesia was significantly higher in the group receiving ropivacaine-dexmedetomidine mixture than the group receiving ropivacaine alone. Similarly, in another study, dexmedetomidine and clonidine, both in a dose of 2 μg/kg as an adjuvant with 0.25% bupivacaine, were given caudally. They found that the duration of analgesia was significantly higher in the group receiving bupivacaine-dexmedetomidine mixture or bupivacaine-clonidine mixture than the group receiving bupivacaine alone.

A study with caudal dexmedetomidine (1 μg/kg) with 0.25% ropivacaine (1 mL/kg) for paediatric lower abdominal surgeries achieved significant post-operative pain relief and consequently a better quality of sleep, prolonged duration of arousable sedation and lower incidence of emergence agitation following sevoflurane anaesthesia.

The ropivacaine-dexmedetomidine group required significantly less number of rescue analgesics as compared to the ropivacaine-tramadol group in this study. These results are similar to a study conducted on the effect of dexmedetomidine on bupivacaine in the caudal block in paediatric patients.

The pre-, intra- and post-operative hemodynamic variables between the groups were comparable and were not statistically significant and therapeutic interventions were not required. Post-operative side effects, including vomiting, shivering and hypotension, were recorded in the PACU more with tramadol rather than dexmedetomidine but were statistically non-significant.

There are few limitations of our study. First, the present study is the postoperative pain, which is subjective experience and can be difficult to quantify objectively especially in children. Second, as for all additives in regional anaesthesia, the analgesic role of dexmedetomidine and tramadol through systemic absorption cannot be completely excluded from our study design. Hence, comparing the potential local effects to a systemic administration particularly when additives are used is difficult since we did not have a control group with IV dexmedetomidine and IV tramadol. Third, ultrasound guidance for caudal block administration should be considered in cases where the detection of sacral anatomy is difficult, especially by palpation.

CONCLUSION:

From our study, we conclude that addition of Dexmedetomidine to Ropivacaine is superior to Tramadol with Ropivacaine in caudal analgesia in paediatric patients posted for infraumbilical surgeries in prolonging the duration of analgesia, decreasing the need for more rescue analgesia in first 24 hours without significant changes in hemodynamic parameters and without significant sedation and postoperative complications.

Finally, we conclude that dexmedetomidine is a safe and better adjuvant in caudal blocks than Tramadol with Ropivacaine for paediatric postoperative analgesia.

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