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Comparative study of caudal tramadol and caudal dexmedetomidine as an adjuvant with ropivacaine in paediatric infraumbilical surgeries

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Abstract
Background and Aims: Caudal anaesthesia is one of the most commonly used regional anaesthetic technique in providing peri- and post-operative analgesia. It can serve as the sole anesthetic or can be an adjuvant to general anaesthesia. The aim of this study was to compare the clinical efficacy of the caudal block of 0.25% Ropivacaine with Tramadol or Dexmedetomidine as an adjuvant in paediatric infraumbilical surgeries.
Methods: In this prospective, randomised, double-blinded comparative study, sixty children of either gender, in the age group of 1-8 years and scheduled for elective infra umbilical surgeries were randomly divided into two groups of thirty each. Children in Group D received a caudal epidural injection of 1ml/kg 0.25% ropivacaine with 2µg/kg dexmedetomidine while Group T received a caudal epidural injection of 1ml/kg ropivacaine with 2mg/kg tramadol. The primary outcome variable was the duration of time to rescue analgesia. The secondary outcome variables were onset of action, residual motor block, sedation score and adverse effects.
Results: Results were statistically analysed using student's t- test. Mean time of rescue analgesia in group D was 718.00 ± 100.06 min i.e. 11 hours 58 minutes and in group T was 467.33± 68.94 min i.e. 7 hours 47 minutes. (P<0.001). Pain scores measured at regular intervals post operatively were lower in D group as compared to T group. Rescue analgesia requirement was more in group T as compared to group D. Haemodynamic changes and side effects were comparable between the groups
Conclusion: Caudal dexmedetomidine with Ropivacaine provides longer duration of post-operative analgesia as compared to caudal Tramadol with Ropivacaine.

Keywords: caudal, ropivacaine, Dexmedetomedine, tramadol, FLACC score

Introduction
Caudal block is one of the most popular and commonly used regional anaesthetic procedures in pediatric patients for most surgeries below the umbilicus [1]. The block can be practised by a single-shot injection or as a continuous infusion through a caudal epidural catheter. The main disadvantage of caudal analgesia is the short duration of action after a single injection [2]. Prolongation of caudal analgesia using a 'single-shot' technique has been achieved by the addition of various adjuvants, such as benzodiazepine (Midazolam), Neostigmine, Ketamine. Alpha 2 agonists, opioids etc. [3]
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 [4].
Tramadol is a synthetic 4-phenyl-piperidine analog of codeine, and 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 [5, 6].
Dexmedetomidine is stereoisomer of medetomidine and highly selective α2-adrenergic receptor agonist with eight times more specificity for α2 adrenoceptors than Clonidine (ratios of α2: α1 activity, 1620:1 for Dexmedetomidine and 220:1 for Clonidine) [7]. It provides better perioperative hemodynamic stability than many other adjuvants now in use and good quality of intraoperative and prolonged postoperative analgesia with minimal side effects.
This study was designed to compare the onset of action, analgesic effects and side-effects of Dexmedetomidine and Tramadol when added to Ropivacaine for caudal analgesia in children undergoing infraumbilical surgeries.

Methods

In this prospective randomised study, after obtaining approval from the institutional ethics committee and written informed consent from the patient's parents, this study was carried out on 60 ASA grade I and II patients aged 1 year to 8 years posted for infraumbilical surgeries. Children with history or evidence of infection at the back, allergy to local anaesthetic drugs, bleeding/coagulation disorder, history of developmental delay, sepsis, patient's parents' refusal for consent for the procedure, pre-existing neurological or spinal diseases were excluded from the study.

A thorough pre anaesthetic evaluation was done a day prior to surgery and parents were explained about the procedure. Patients were randomly divided into two groups of thirty each. Group ropivacaine with tramadol (T) patients received 0.25% ropivacaine 1 mL/kg with 2 mg/kg of tramadol and Group ropivacaine with dexmedetomidine (D) patients received 0.25% ropivacaine 1 mL/kg with dexmedetomidine 2 µg/kg.

Patients were kept nil oral for 6 hours before the surgery. Patients were shifted to the operation theatre and Pulse oximeter, non-invasive blood pressure and electrocardiography monitors were connected. RL was administered according to Holliday Segar Formula. Standard pre-induction drugs including Inj. Glycopyrrolate 0.004mg/kg, Inj. Midazolam 0.02mg/kg, Inj. Ondansetron 0.05mg/kg was given. Anaesthesia induction was carried out with intravenous Inj. Propofol 2 – 4 mg/kg with Sevoflurane and 50% N2O in oxygen till loss of consciousness. After achieving adequate depth of anaesthesia and adequate jaw relaxation supraglottic airway device of appropriate size was inserted. Anaesthesia was maintained with 50% N2O in oxygen with 0.5%-1% Sevoflurane. After securing the airway, under all aseptic precautions, caudal block was performed in left lateral decubitus position using 23G hypodermic needle by loss of resistance technique and the study drug was deposited after confirming negative aspiration for blood and CSF. Surgical incision was taken approximately 15 minutes after the caudal block. Continuous monitoring of vital parameters - heart rate (HR), ECG, respiratory rate, NIBP, SpO 2– was done, and values were recorded before premedication (baseline), after premedication, induction, caudal block, after incision and thereafter every 10 min until the surgery is over. At the end of surgery, all anaesthetic drugs were discontinued and supraglottic airway removed. 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. After surgery, patients were shifted to the post-anaesthesia care unit (PACU) for further observation and monitoring.

Postoperatively, hemodynamics, respiration, spo2 and pain was monitored in the PACU every 15 minutes for the first hour and every half-hourly for next one hour, hourly for next two hours, then two hourly until the first dose of rescue analgesia was given. motor blockade was assessed at wake up, then every 15 minutes for one hour and every 30 minutes for next hour till 180 minutes. We used the Modified Bromage Scale [8] for assessment. 0 – The patient can move hip, knee and ankle, 1 – The patient is unable to move hip, but can move knee and ankle, 2 – The patient is unable to move hip and knee, but can move the ankle, 3 – The patient is unable to move hip, knee and ankle. Significant residual motor block was defined as a motor block score of > 1 at wake up and 180 minutes after caudal block. Younger children were stimulated by tapping on the legs and feet who could not move them on command. The pain was assessed by the FLACC score [9] (Table 1) on a scale from 0-10. Inj. Paracetamol 15mg/kg was given when the score was greater than 4. The time from caudal block to first postoperative rescue analgesic administration was the endpoint of the study. The final assessment of the duration of effective analgesia was done by comparing time from caudal block to the administration of first rescue analgesia. Side effects like nausea, vomiting, retention of urine was observed. Level of sedation was assessed by Ramsay sedation scale [10] (Table 2) 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 taken from the time of extubation until Ramsay sedation score was 2 or less.

Table 1: Showing FLACC pain scale

	Scoring		
Categories	O	1	2
Face	No particular expression or smile.	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant frown, 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	Difficult to console or comfort

Note: Each of the five categories Face (F), Legs (L), Activity (A), Cry (C), and Consolability (C) is scored from 0-2, which results in a total score between 0 and 10.
From Merkel, Voepel-Lewis, Shayevitz, & Malviya (1997). The FLACC: A behavioral scale for scoring postoperative pain in young children. *Pediatric Nursing, 23* (3) 293-297.

Table 2: Showing Ramsay sedation scale

Scores	Responses
1	Anxious or restless or both
2	Cooperative, oriented, and tranquil
3	Responding to commands
4	Brisk response to stimulus
5	Sluggish response to stimulus
6	No response to stimulus
Scores 1, 2, and 3–awake; scores 4, 5 and 6–asleep.	

Statistical Analysis

IBM SPSS version 23 was used for statistical analysis.

Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables.

All Quantitative variables were checked for normal distribution within each category of explanatory variable by using visual inspection of histograms and normality Q-Q plots. Shapiro- wilk test was also conducted to assess normal distribution. Shapiro wilk test p value of >0.05 was considered as normal distribution.

For normally distributed Quantitative parameters the mean values were compared between study groups using Independent sample t-test (2 groups).

Inferential statistics

Quantitative outcome

The association between age in years, weight (kg), duration (min), intra operative and post op heart rate, systolic blood pressure, Diastolic blood pressure, MAP, RR, SPO2, FLACC scale, Time of analgesic onset, analgesia duration, ramsay sedation score for Dexmedetomidine and Tramadol was assessed by comparing the mean values. The mean differences along with their 95% CI were presented. Independent sample t-test was used to assess statistical significance. Data was also represented using appropriate diagrams like bar diagram and trend line diagram.

Categorical outcome

The association between gender, ASA grade, modified Bromage pain score for Dexmedetomidine, Tramadol was assessed by cross tabulation and comparison of percentages. Chi square test was used to test statistical significance. Data was also represented using appropriate diagrams like cluster bar diagram.

P value < 0.05 was considered statistically significant.

a power analysis was performed using an alpha error of 0.05 and a power of 0.8, the required sample size for this study comes up to- 30+30=60.

Results

The current study showed no significant differences in demographic data that included age, gender and also with regards to type and duration of surgery. (Table 3)

Table 3: Demographic and operative data

	Group D (n=30)	**Group T (n=30)**
Age (year)	3.77 ± 2.27	3.95 ± 2.09
Gender (M/F)	27/3	29/1
Body Weight (kg)	12.45 ± 4.15	13.10 ± 4.39
Duration of Surgery (Min)	80.67 ± 32.02	76.17 ± 32.74
Time of analgesic onset (min)	11.60 ± 1.61	12.03 ± 2.39

Values are expressed in terms of mean±SD. No significant differences were found between the two groups. (P>0.05), SD= Standard deviation

With regards to vital signs and hemodynamic stability pre operatively and intra operatively the recorded SPO2, MAP, HR showed no statistically significant difference between both the groups. (Figure 1)

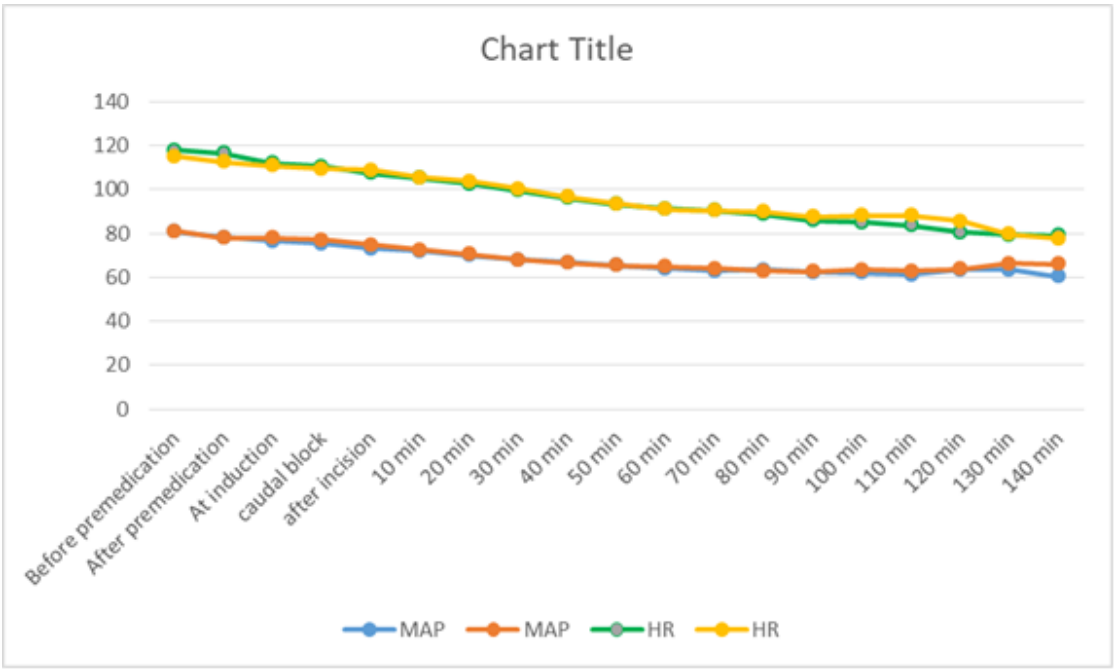

Fig 1: Showing intra operative hemodynamic parameters

Post operatively, the haemodynamic parameters (Figure 2) were comparable up to 90 minutes along with adequate analgesia as indicated by FLACC score ≤ 4 (Figure 3). However, after 90 minutes, adequate analgesia declined rapidly in group T as compared to group D and the difference was statistically significant.

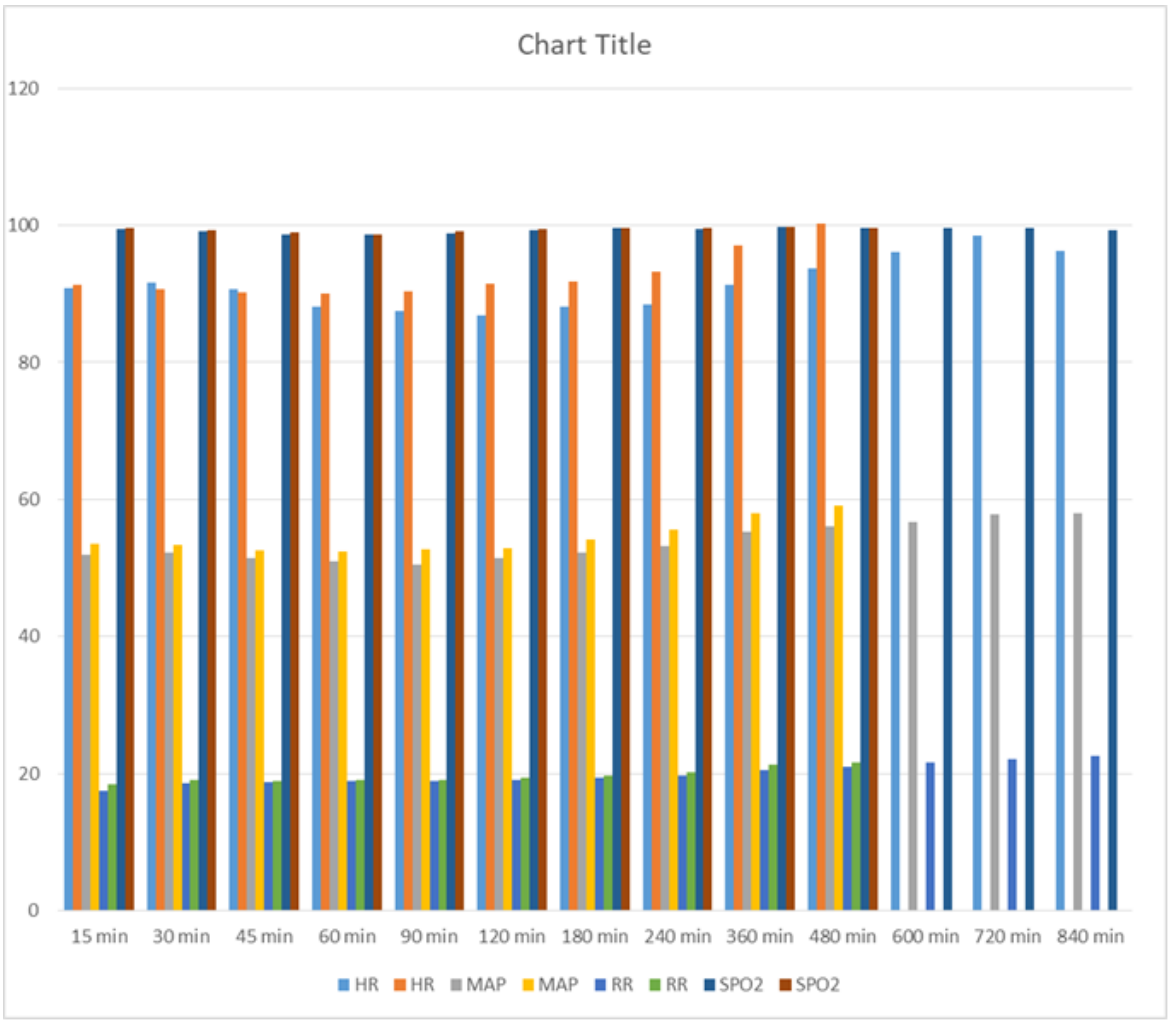

Fig 2: Showing post-operative parameters

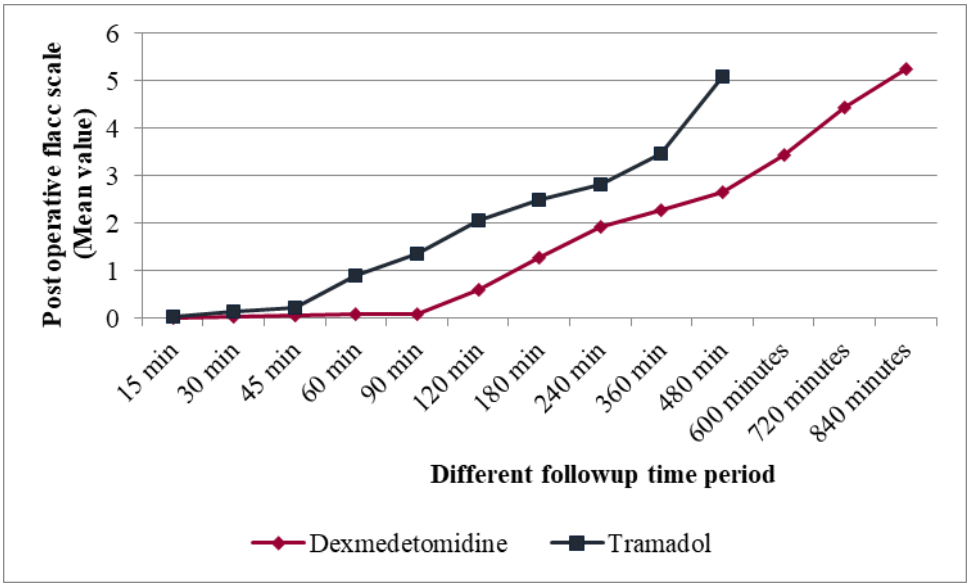

Fig 3: showing FLACC score

The duration of post operative analgesia was found to be significantly longer in group D (718.00 ± 100.06 min) as compared to group T (467.33± 68.94 min) P < 0.001. (Figure 4)

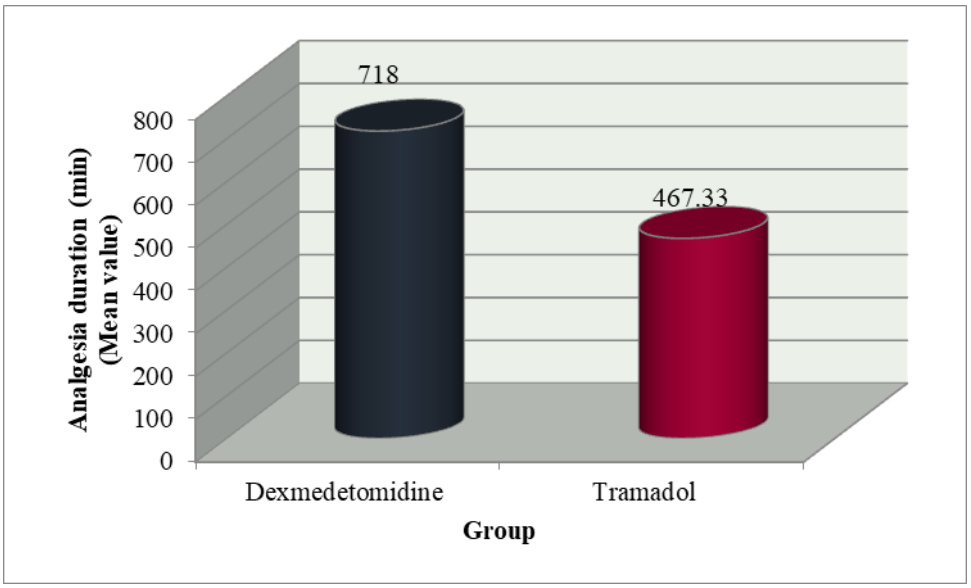

Fig 4: showing duration of post-operative analgesia

As regards to motor blockade, at wake up, group D had all 30 patients (100%) with motor score of >1 whereas in group T only 4 patients (13.3%) had motor score of >1 (p<0.001) At 180 minutes post op, group D had 4 patients (13.3%) with motor score of >1 whereas in group T none patients (0%) had motor score of >1 (p<0.001) (Figure 5)

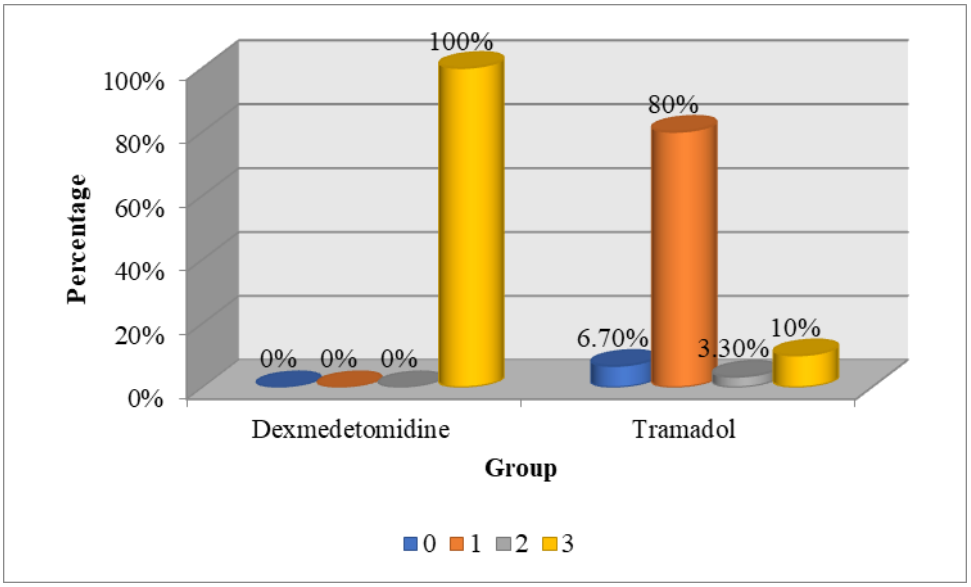

Fig 5: showing motor blockade score

Furthermore, patients of group T showed a shorter sedation time as compared to group D which was statistically significant at 15, 30, 45, 60, 120 and 180 minutes. (FIGURE 6)

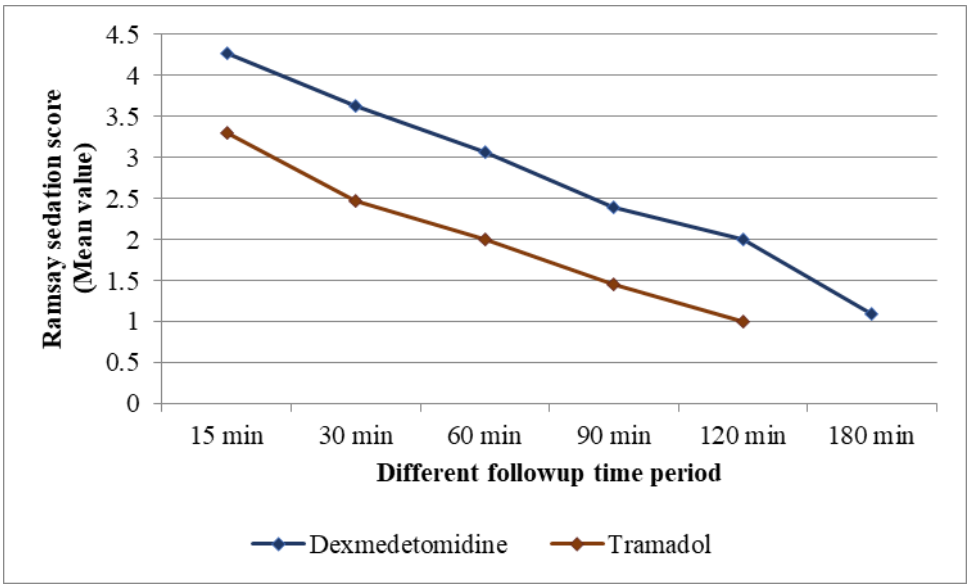

Fig 6: showing post-operative sedation scores

There was no incidence of side effects such as bradycardia, hypotension, retention of urine, PONV in group D. In group T, 3 patients (10%) had an episode of vomiting which was statistically not significant.

Discussion

In the present study, we found that the use of single dose of dexmedetomidine, as an additive to the local anaesthetic ropivacaine in caudal epidural analgesia prolongs the duration of post-operative analgesia as compared to caudal tramadol in infra umbilical surgeries; in addition, the duration of sedation was found to be longer with dexmedetomidine than with tramadol with no side effects on vital signs, with no effects on onset of action and intra and post-operative haemodynamics. Post-operative side effect of vomiting was found with tramadol rather than dexmedetomidine.

Caudal epidural analgesia is commonly used technique for providing regional anesthesia and analgesia in children undergoing infra umbilical and perineal surgeries. Additives have been used in combination with local anesthetics to prolong the effects of the latter and promote analgesia [11]. The use of additives during caudal anesthesia have increased in the last decade by 58% [12, 13], specially with ketamine 38%, clonidine 42%, whereas the use of opioids as additives has decreased from 36% to 18% due to increased incidence of side effects specially in children [14].

Dexmedetomidine potentiates the action of local anesthetics without increasing the incidence of side effects as compared to tramadol, an opioid and this facilitates the its use in larger doses for analgesia, sedation without inadvertent effects on the haemodynamics [15].

Supporting the results of our study was the results of Savita Gupta *et al.* in 2016 who conducted a prospective, randomised, double-blinded clinical study on Comparison of analgesic efficacy of caudal dexmedetomidine versus caudal

tramadol with ropivacaine in paediatric infraumbilical surgeries and proved that the duration of analgesia was found to be significantly prolonged with dexmedetomidine when added to ropivacaine, without any increase in the incidence of side-effects [16]. Furthermore, Vijay G Anand *et al*. (2011) conducted a study in 60 patients (6 months-6 years) undergoing lower abdominal surgeries. Group R received 0.25% Ropivacaine 1ml/kg and group RD received 0.25% Ropivacaine with Dexmedetomidine 2µg/kg. They also said patients were stable concerning HR, SBP, DBP, MAP intraoperatively and postoperatively and the difference is not significant [17]. Also, Manoj Kamal *et al*. (2016) did a study on efficacy of Dexmedetomidine as an adjuvant to Ropivacaine in sixty patients undergoing lower abdominal surgeries. They found out that the mean(SD) of onset of the block was 14.5 min in group RD as compared to group R 17.16 min with a p value of 0.005 [18]. Abdel-Hameed M *et al*, (2004) conducted a study on Caudal tramadol combined with bupivacaine or ropivacaine for postoperative analgesia in paediatric patients undergoing lower abdominal surgery under general anaesthesia and found that the time to complete regression of motor block was significantly more prolonged in tramadol with bupivacaine compared to tramadol with ropivacaine group [19]. In addition, in another study performed by Anand *et al*. who studied the effect of addition of dexmedetomidine to caudally injected ropivacaine on the intensity of post-operative analgesia along with its safety in the children performing abdominal surgeries, and their results showed that dexmedetomidine achieved a remarkable relief of post-operative analgesia leading to better quality of sleep and minimal agitation during recovery from anesthesia [17].

Sedation scores though higher, the level of sedation was decreased significantly in T group in the present study. In support of these findings, improved sedation and pain scores have also been observed with dexmedetomidine as intrathecal adjuvant [20].

The ropivacaine-dexmedetomidine group required a longer duration of time for 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 [21].

The haemodynamic variables were comparable between the groups intra and post- operatively and were not statistically significant and therapeutic interventions were not required. Post-operative side effects were recorded in the PACU more with tramadol rather than dexmedetomidine but were statistically non-significant.

Conclusion

Addition of Dexmedetomidine to caudal Ropivacaine 0.25% (1 ml/kg) significantly prolongs the duration of postoperative analgesia in children aged 1yr to 8yrs as compared to caudal Ropivacaine with Tramadol, undergoing lower abdominal surgeries with no significant difference in the onset of action between the two groups. Sedation score was higher in Dexmedetomidine group than the Tramadol group, but all patients were easily arousable. There were no significant side effects observed in any of the two groups.

Thus, Dexmedetomidine used as an adjunct to Ropivacaine by caudal route provided a longer duration of postoperative analgesia than Ropivacaine with Tramadol without any side effects.

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