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Randomized Comparative Study of Analgesic Efficacy of Dexamethasone and Tramadol as Adjuvants with Bupivacaine for Paediatric Caudal Analgesia

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ABSTRACT

Understanding pain and its management has been the focus of continuing human efforts over centuries. More often pain is underestimated in smaller age group. Caudal blocks, being relatively simple technique provides good perioperative analgesia in paediatrics undergoing infra-umbilical surgeries. This study aims at comparing the analgesic efficacy of dexamethasone and tramadol as adjuvants in paediatric caudal analgesia. This was a prospective randomized comparative study. 90 children aged between 6months to 8 years, undergoing elective infra-umbilical surgeries were allocated into three groups. Group B received 0.5ml/kg of 0.25% Bupivacaine. Group BD received 0.2mg/kg of Dexamethasone with 0.25% Bupivacaine, Group BT received 2mg/kg of Tramadol with 0.25% Bupivacaine. Caudal block was performed after securing airway with LMA. Pain was assessed intraoperatively, by monitoring changes in HR (Heart Rate) and postoperatively, using FLACC (Face, Leg, Activity, Cry, Consolability) scale. Paracetamol 15mg/kg was used as rescue analgesia. The study ended with the use of rescue analgesia. Intraoperatively mean HR was not significant between the three groups with p values >0.2. Post-operatively, FLACC score progressively increased after 30min in all three groups. The FLACC score was significant at 2 and 4hours ($p<0.001$) and 8hours(p value 0.029). The mean duration of analgesia was 212.30±16.48 minutes in group B, 478.73±56.83 minutes in group BD and 365.76±44.43minutes in group BT with p value <0.001. Dexamethasone has better analgesic efficacy and less side effects when compared to tramadol as adjuvant in paediatric caudal analgesia.

INTRODUCTION

Pain management in paediatric population has always been a big challenge. It has been observed that the management of acute pain, especially post-operative pain, has been consistently and systematically inadequate in children. In children of smaller age group, it is a big challenge to differentiate distress or crying due to pain from that of hunger or fear[1]. Stress response to surgery in paediatric patients due to inadequate anaesthesia causes increase in catecholamines, aldosterone, glucagon, cortisol and other steroid hormones[2]. An adequate intraoperative and postoperative analgesia will attenuate this stress response. Lonnqvist *et al* in 2005 found that regional anaesthesia produces excellent postoperative analgesia and attenuation of the stress response in infants and children[3]. In 2008 Leopoldo *et al* studied that analgesia causes significant reduction in emergence agitation in children[4].

Caudal blocks are one of the most popular regional analgesia methods in children[5]. Different caudal adjuvants have been studied to prolong the duration of caudal epidural analgesia such as opioids, clonidine, ketamine, midazolam and neostigmine[6,7]. Although these drugs successfully increased the duration of analgesia, many of them were associated with undesirable adverse effects. Dexamethasone and tramadol are the few other drugs studied as adjuvants in caudal analgesia[8,9]. However no study has compared analgesic efficacy between dexamethasone and tramadol as adjuvants. Our study compares the duration and adequacy of analgesia between dexamethasone and tramadol as caudal adjuvants to bupivacaine in paediatrics.

Objectives: The main objective of our study was to compare the analgesic efficacy of tramadol and dexamethasone as caudal adjuvants in children.

MATERIALS AND METHODS

As no study comparing between tramadol and dexamethasone was available, sample size was calculated based on study conducted by Meena Dodda al, where caudal Bupivacaine and Bupivacaine plus Tramadol were compared[10]. with 95% Confidence limits. Sample size was calculated using the below mentioned formula. Mean interval between administration of caudal anaesthesia and time to first dose of analgesic, which was 6.3hrs in bupivacaine Group and 9.1hrs in bupivacaine plus tramadol group was taken.

$$\text{Sample Size} = \frac{(Z_{(1-a)}+Z_{\beta})^{2*}\ p^2}{d^2}$$

a is the level of significance

Z is the Standard Normal Variate for 95% of Confidence Interval=1.96 for 1-α and 0.84 for β.

p=9.1

d=2.8

Accordingly sample size calculated was 83, rounded of to 90. Hence 30 study subjects were included in each group. 90 Paediatric patients of ASA I and II aged between 6 months to 8 years undergoing infra umbilical surgery were recruited for the study after approval from hospital ethical committee. Children with developmental delay, suspected coagulopathy or infection in the sacral region were excluded from study. Informed written consent was obtained from parents or guardians . Patients were asked to fast for 6 hrs and clear fluids was allowed up to 3hrs before the procedure.

The 90 children were randomly allocated into 3 groups (30 in each group) using shuffled sealed opaque envelope technique

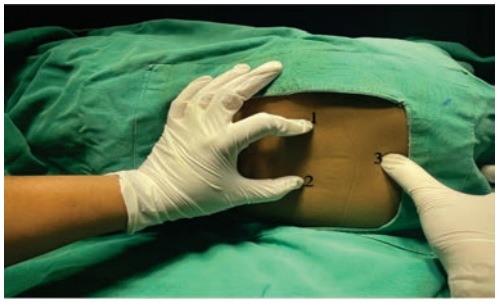
Group B received 0.5ml/kg of 0.25% bupivacaine

Group BD received 0.2mg/kg of dexamethasone with 0.25% bupivacaine, to a total of 0.5ml/kg

Group BT received 2mg/kg of tramadol with 0.25% bupivacaine, to a total of 0.5ml/kg. (normal saline was used for dilution)

Patients with prior venous access were pre-medicated with iv midazolam 0.05mg/kg, glycopyrrolate 0.005mg/kg and fentanyl 2µg/kg, 5min prior to induction. Patients without prior venous access were induced with sevoflurane and then the iv access was secured and pre-medication was given. Heart rate (HR), electrocardiogram (ECG), non-invasive blood pressure (NIBP), oxygen saturation (SpO2) were recorded before surgery and every 10min till the end of surgery. Anaesthesia was induced with propofol or sevoflurane in 100% oxygen. Airway was secured with appropriate sized Laryngeal Mask Airway (LMA). Anaesthesia was maintained with isoflurane in 50% nitrous oxide and oxygen. Injection Ondansetron 0.1mg/kg iv was given as antiemetic.

Under general anaesthesia caudal block was performed. Depending on the group allocated B/BD/BT, drug was injected to the caudal space through the needle after negative aspiration for blood and cerebro-spinal fluid (CSF). No other narcotics, analgesics or sedatives were used intra-operatively. During surgery, adequate analgesia was defined by hemodynamic stability, as indicated by the absence of an increase in HR or systolic blood pressure(SBP) of more than 15% of the baseline values obtained just before the surgical incision. Rescue analgesia with iv paracetamol 15mg/kg was given if >15% variability was observed from baseline values. Anaesthesia was discontinued after wound dressing and LMA was removed after ensuring adequate respiratory rate and depth.



Picture1: Landmarks for Caudal Space
1 and 2-PSIS, 3-Sacral hiatus

Patient in left lateral position. Posterior superior iliac spines and sacral hiatus identified. Two sacral cornua felt at sacral hiatus and needle advanced between them at an angle of 45degree till a pop is felt (Piercing sacrococcygeal membrane). Needle further advanced 1-2mm. Drug injected after negative aspiration of blood and CSF.

Parameters used for Assessment:

Intra-Operative Parameters:

- Intraoperative analgesia was assessed by changes in HR and SBP.
- Ineffective analgesia defined as a rise in HR and SBP by more than 15% from the baseline.
- HR and SBP was noted soon after induction, after caudal block and every 10 minutes thereafter throughout the surgery.

Post-Operative Parameters: The following parameters were observed at intervals of 1/2hr, 4hr, 8hr and 12hr after surgery.

- Using the paediatric observational FLACC (Face, Leg, Activity, Cry, Consolability) pain scale (table 1) with its 0-10 score range, each study participant's pain intensity was assessed.

0 No Pain, 1-3 Mild Pain, 4-7 Moderate Pain, 8-10 Severe Pain.

If the FLACC pain scale score noted at any time to be 4 or more, iv paracetamol 15mg/kg was administered to achieve a FLACC scale score of 3 or less. Duration of caudal analgesia was defined as the time between the injections of the drug caudally to the first administration of rescue analgesia.

- Post-operative sedation was assessed by an objective score based on eye opening.

0-eyes open spontaneously.
1-eyes open in response to verbal stimulation
2-eyes open in response to physical stimulation.

Duration of sedation- defined as the time from the end of removal of LMA to spontaneous eye opening.

- Duration of motor blockade-defined as the time from administration of caudal block to first spontaneous movement of legs.
- Side effects like nausea, vomiting, pruritis.
- Urinary retention-No spontaneous voiding of urine within 2 hours after surgery.

Data was entered into Microsoft Excel (Windows 7., Version 2007) and analyses were done using the Statistical Package for Social Sciences (SPSS) for Windows software (version 22.0., SPSS Inc, Chicago). Descriptive statistics such as mean and standard deviation (SD) for continuous variables, frequencies and percentages were calculated for categorical Variables were determined. Association between anaesthesia Group and other categorical Variables like Gender were analysed using chi-square test of independence. Comparison of mean of various quantitative variables like Heart rate were analysed using ANOVA (Analysis of Variance). Level of significance was set at 0.05.

RESULTS AND DISCUSSIONS

Demographic and surgical parameters were comparable between the three groups. The differences in mean age, weight and sex distribution of the three groups were not statistically significant. Mean HR at various intervals was also not significant between the three groups with p-values at all the time intervals >0.2. The differences in the mean duration of surgery between the three groups was insignificant with a p value of 0.934 .

The FLACC pain score which was zero at 30 minutes in all the three groups progressively increased at further intervals. However group B reached FLACC score of >4 earlier at <4hours when compared to group BT at approximately 6hours followed by group BD around 8hours. The FLACC score was significant at 2 and 4hours with p value <0.001 and at 8hours with p value of 0.029 (table 2). All the three groups had received the first rescue analgesia by 12 hours.

The mean duration of analgesia between the three groups was 212.30±16.48 minutes in group B, 478.73 ± 56.83 minutes in group BD and 365.76±44.43minutes in group BT with a highly significant p<0.001 (table 3).

The mean duration of sedation between the three groups was 10.5±2.84minutes in group B, 10.23±7.95 minutes in group BD and 39.55±13.97 minutes in group BT with a highly significant p<0.001 (table 4).

In our study, PONV was compared between the three groups using chi square test. 3 patients in group BT had PONV which was statistically significant with p value of 0.045. The incidence of motor blockade between the three groups was compared using chi square test. Only one patient in group BT had motor blockade which was not statistically significant with p value of 0.363.

Postoperative pain relief in a child is a main concern to the anaesthesiologist as pain not only affects the patient but also increases anxiety in the parents, more so in the first 24-48hours post-surgery. Adequate pain

Table1: The FLACC (Face, Leg, Activity, Cry, Consolability) pain scale

Parameter	0	1	2
Face	No Particular expression or smile	Occasional grimace or frown, withdrawn	Frequent to constant quivering chin
Legs	Normal position or relaxed	Uneasy, restless, tense	Kinking or legs drawn up
Activity	Lying Quiet, normal	Squirming, shifting back and forth tense	Arched, rigid or jerking
Cry	No Cry	Moans or Whimpers	Crying steadily
Consolability	Content, Relaxed	Reassurance, hugging	Difficult to console

Table2: Comparison of FLACC Pain Score Between the three Study Groups at Various Intervals (N=90)

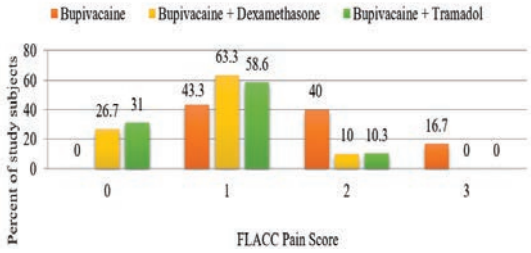
FLACC Pain Score	Group B (n=30), n (%)	Group BD (n=30), n (%)	Group BT (n=30), n (%)	p-value
Post-operative 30 min				
	0 (0.0)	0 (0.0)	0 (0.0)	NA
At 2 hrs				
0	0	8 (26.7)	9 (31.0)	<0.001*
1	13 (43.3)	19 (63.3)	17 (58.6)	
2	12 (40.0)	3 (10.0)	3 (10.3)	
3	5 (16.7)	0	0	
At 4 hrs				
0	-	1 (3.3)	0	<0.001*
1	-	9 (30.0)	12 (41.4)	
2	-	13 (43.3)	11 (37.9)	
3	-	6 (20.0)	5 (17.2)	
4	30 (100.0)	1 (3.3)	1 (3.4)	
At 8 hrs				
1	-	2 (6.9)	-	0.029*
2	-	3 (10.3)	-	
3	-	3 (10.3)	-	
4	-	21 (72.4)	29 (100.0)	
At 12 hrs				
4	-	8 (100.0)	-	NA

Table 3: Comparison of Duration of Analgesia Between the three Groups(N=90)

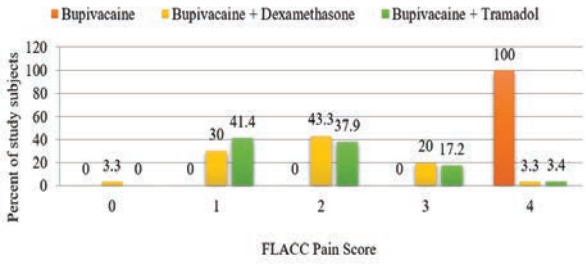
Duration (in minutes)	Group B (n=30) Mean (SD)	Group BD (n=30) Mean (SD)	Group BT (n=30) Mean (SD)	p-value
Duration of Analgesia	212.30 (16.48)	478.73 (56.83)	365.76 (44.43)	<0.001*
ANOVA, P Value *Significant				

Table 4: Comparison of Duration of Sedation Between the three Groups(N=90)

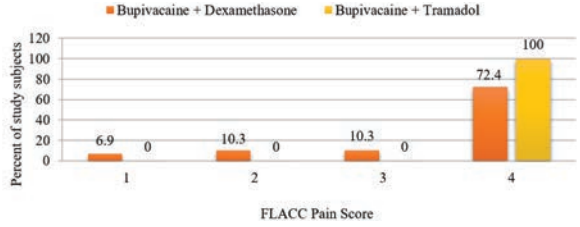
Duration (in minutes)	Group B (n=30) Mean (SD)	Group BD (n=30) Mean (SD)	Group BT (n=30) Mean (SD)	p-value
Duration of Sedation	10.5(2.84)	10.23 (7.95)	39.55 (13.97)	<0.001*
ANOVA, P Value *Significant				



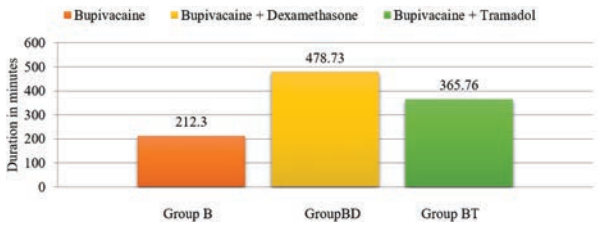
Graph 1: FLACC Pain Score at 2 hrs



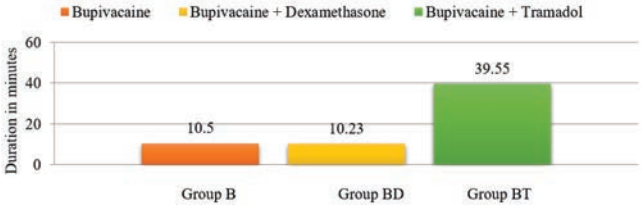
Graph 2: FLACC Pain Score at 4hrs



Graph 3: FLACC Pain Score at 8hrs



Graph 4: Comparison of Duration of Analgesia



Graph 5: Comparison of Duration of Sedation

relief also allows rapid recovery from anaesthesia. Several methods have been employed in paediatric pain relief. Caudal epidural block is one of the common methods used in paediatric anaesthesia. It provides good perioperative analgesia in infra-umbilical surgeries when combined with general anaesthesia[11]. It is a relatively simple technique with a good success rate even in preterm neonates[12]. Various caudal additives like opioids, midazolam, ketamine,

neostigmine, clonidine, dexmedetomidine, dexamethasone, tramadol etc. have been tried to increase the duration of analgesia.

Dexamethasone has been found to effectively increase the duration of caudal epidural block, with no side effects. It also increases beta endorphin levels, however increase in blood glucose levels is not significant. The anti-emetic properties of dexamethasone are well established. Tramadol is a synthetic analogue of codeine with a striking lack of respiratory depressant effect despite an analgesic potency equal to that of pethidine.

Girgis *et al* studied the effect of adding dexamethasone to bupivacaine on the duration of postoperative analgesia after caudal anaesthesia in children[13]. Postoperative pain was assessed using a modified Objective Pain Score (mOPS). They found that the duration of the caudal block in the bupivacaine-dexamethasone group was 11.2±3.5 h which was more than in the bupivacaine group 7.1±3.2 h with a significant P<0.001. In our study the duration of caudal block in group BD was 478.73±56.83 minutes and group B was 212.30±16.48 minutes. The shorter duration of analgesia in our study compared to above study can be attributed to difference in total volume of drug used and difference in assessment of postoperative pain scale. In our study postoperative pain was assessed using FLACC scale and the total volume of drug used in caudal block was 0.5ml/kg, which is half the volume in above study. However both the studies conclude that addition of dexamethasone causes significant prolongation of duration of analgesia.

Somasundaran *et al* compared ketamine and tramadol as caudal additives to plain bupivacaine in 100 children aged between 1-7years, undergoing infra-umbilical surgery[7]. Postoperative pain was assessed using a mOPS scale. They found that the mean duration of analgesia after addition of ketamine and tramadol to bupivacaine by the caudal epidural route was 9.3 h (559.39±27.15 minutes) and 7.9 h (478.48±54.15 minutes) respectively as compared to caudal bupivacaine 4.0h. They also observed that the duration of sedation was 18.12 minutes for control group, 24 minutes for ketamine group and 25minutes for tramadol group .In our study the duration of caudal block in group BT was 365.76±44.43minutes and group B was 212.30±16.48 minutes. The discrepancy in duration of post-operative analgesia can be attributed to difference in total volume of drug used in caudal blocks and also pain scale used to assess the pain. Postoperative sedation in our study was, 10.5 minutes in control group, and 39.55±13.97 minutes in tramadol group. This difference can be attributed to difference in duration of surgery. In the above the study duration of surgery lasted for up to 90 minutes where as in our study it was approximately the mean of 45 minutes. Also the difference can be attributed to probable difference in concentration of inhalational agents used in intraoperative period.

Observations similar to our study were made by many other authors like, Shrestha *et al* in their study observed that addition of tramadol to bupivacaine in paediatric caudal analgesia provides longer analgesia and lesser need for rescue analgesics[14].

Neelam *et al* in their study concluded that addition of tramadol to caudal levobupivacaine significantly increased the duration of postoperative analgesia[15].

Solanki *et al* in their study observed that dexamethasone provided longer duration of post-op analgesia with no sedation when compared to clonidine as paediatric caudal adjuvant[16].

The volume of drug used and pain scale used for pain assessment might be different in above mentioned studies but there was a definite prolongation in postoperative analgesia when dexamethasone or tramadol was used as caudal adjuvant.

In a study by Mohamed *et al,* analgesic efficacy of dexamethasone and neostigmine as caudal adjuvants were compared[17]. They observed no significant sedation among the study and control groups which was similar to our dexamethasone group.

Hence we conclude that dexamethasone has better analgesic efficacy and less side effects when compared to tramadol as paediatric caudal adjuvant. However we couldn't evaluate some of the potential adverse effects of dexamethasone such as hyperglycaemia, adrenal suppression and surgical site infection as further invasive techniques for blood sampling in paediatric patients was difficult. Further studies comparing dexamethasone and tramadol as paediatric caudal additives with a larger study group would yield more reliable results.

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