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Original article

COMPARISON OF ANALGESIC EFFICACY OF CAUDAL DEXMEDETOMIDINE VERSUS CAUDAL TRAMADOL WITH BUPIVACAINE 0.25% IN PEDIATRIC INFRA-UMBILICAL SURGERIES

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Abstract

Introduction: *Postoperative analgesia is very important parameter for overall management of pediatric patients.* **Aims:** *To compare the analgesic efficacy of caudal dexmedetomidine versus caudal tramadol with bupivacaine 0.25 % in paediatric Infra-umbilical surgeries.* **Objectives:** *To study hemodynamic changes. The duration of post-operative analgesia and to compare motor block and post – operative sedation in both groups, as well as the side effects associated with analgesia in both the groups.* **Methods:** *The study was carried out in 60 patients of either sex belonging to ASA Grade-I/II between age group of 1 to 8 years undergoing infra umbilical surgeries. After taking written informed consent from all the patient's care taker, pre-anaesthetic evaluation was carried out and procedure was explained to patient's care taker. Patients were randomly devided into 2 groups. Group BT: Patient received 1 ml/kg 0.25% bupivacaine with tramadol 1 mg/kg. Group BD: Patient received 1 ml/kg 0.25% bupivacaine with dexmedetomidine 1 μg/kg. Our method of anaesthesia was G. A. with caudal block. Postoperative analgesia was assessed by FLACC score for 24 hours and If FLACC ≥ 4, Paracetamol suppository (15 mg/kg) was given as rescue analgesia. Post-operative sedation was assessed by Ramsay sedation score up to 6 hr postoperatively. Postoperatively, all the patients were monitored for any complications like Nausea, Vomiting, Shivering, Bradaycardia, Hypotension and Respiratory depression.* **Results:** *Patients were comparable in both the groups regarding age, weight, sex distribution ($P > 0.05$). Mean duration of surgery in group BT was 55.3 ± 9.6 mins, in group BD was 56.7 ±12.8 mins. There was no statistically significant difference in the duration of surgery between the two groups on intergroup comparison ($p > 0.05$). There was no statistically significant difference in mean heart rate, mean arterial pressure and mean oxygen saturation between the groups on intergroup comparison intraoperatively and postoperatively ($p > 0.05$). Ramsay Sedation score was 2.0 ± 0.4 at 1 hr posto-operatively in Group BT patients. So, after 1 hr of surgery, patients of BT group remained anxious, restless and agitated. While in group BD, Sedation score was 2.0 ± 0.3 at 6 hr postoperatively. Thus all patients remained co-operative, oriented and tranquil up to 6 hr post-operatively. Group BD had significant sedation compared to Group BT for 6 hrs postoperatively ($p < 0.05$). We observed significant difference between the groups in terms of FLACC score. Group BT patients achieved statistically significantly higher FLACC score compared with Group BD.($P < 0.05$). The mean duration of analgesia was 6.9 ± 1.2 hr in Group BT, 13.2 ± 2.8 hr in Group RD ($p < 0.05$). There was a statistically significant prolongation in the duration of analgesia in Group BD ($p < 0.05$). In present study, incidence of nausea and vomiting occurred in 5 (16.7%) of patients in Group BT and 3 (6.7%) in Group BD. None of the patients had Shivering, Bradycardia, Hypotension, Respiratory depression, Neurological sequale in both the groups.*

Keywords: *Caudal epidural analgesia, Caudal Dexmedetomidine, Caudal Tramadol , Caudal Bupivacaine ,pediatric patients, FLACC score*

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Introduction

> "For all the happiness mankind can gain is not in pleasure, but in relief from pain".
>
> John Dryden

Pain is defined by the international association for study of pain as "An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage"[1].

The society of Paediatric anaesthesia, on its 15th annual meeting at New Orleans, Louisiana (2001) clearly defined alleviation of pain as a "basic human right", irrespective of age, medical condition,treatment, primary service response for the patient care or medical institution.·In past pain has been underestimated in children and many times they received inadequate analgesia. Later pain pathways have been identified in children and therefore postoperative analgesia in children is also gaining importance[2].

Regional anaesthesia is safe and effective in pediatric patients. It provides postoperative analgesia and reduces requirements of inhalational and intravenous agents with minimum sedation[3].

Caudal epidural block is one of the most popular, reliable and safe techniques in paediatric analgesia that can be used with general anaesthesia for intra and postoperative analgesia in patients undergoing infraumbilical surgeries. The block can be practiced by a single shot injection or as a continued infusion, use of a caudal catheter is usually not preferred due to a high risk of catheter contamination from feacal soiling. Caudal analgesia could reduce the requirement of inhaled anesthetics and opioids, attenuate the stress response to surgery, facilitate a rapid, smooth recovery, and provide good immediate postoperative analgesia[4,11,21,32].

The main disadvantage of caudal analgesia is the short duration of action after a single injection even with the use of long acting local anesthetic like bupivacaine . Prolongation of caudal analgesia using a single shot technique has been achieved by the addition of various adjuvants, such as opioids, ketamine, neostigmine and α2 agonists. Caudal opioids have advantages of prolonging the duration of analgesia over bupivacaine alone, but have side effects such as nausea, vomiting, pruritis and late respiratory depression, which can be minimized by reducing concentration[5].

Bupivacaine is a long-acting amide local anaesthetic that has provided reliable anaesthesia and analgesia with differential motor-sensory blockade. It acts by inhibiting sodium channels in the nerve membrane. 0.25% bupivacaine produces adequate motor and sensory blockade in lower abdominal surgery, but it has some disadvantages like short and finite duration of anesthesia, and larger doses required for analgesics in the postoperative period. This can be avoided by using higher doses of bupivacaine which again can produce cardiac toxicity/ Duration of analgesia due to bupivacaine in caudal anaesthesia can be increased by using adjuvants[5,6,7].

Dexmedetomidine, a stereoisomer of medetomidine, is a 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). It provides better perioperative haemodynamic 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[8].

Tramadol, a synthetic analogue of codein, is a racemic mixture of two enantiomers, both of which contribute to the analgesic activity through different mechanisms enhancing the inhibitory effect on pain trasmition in the spinal cord. Tramadol interacts with μ, δ and κ receptors where it exhibits purely agonist. It has moderate affinity for μ receptor and weak affinity for δ and κ receptors. Tramadol is approximately one-tenth as potent an analgesic as morphine with lack of respiratory depressant effect. Tramadol interacts the re-uptake of noradrenaline and serotonin. These neurotransmitters elevate the pain threshold there by producing inhibition of pain[9,10].

Considering the above facts, the present study was designed to compare caudal analgesia of 0.25% Bupivacaine 1 ml/kg with tramadol 1 mg/kg and 0.25% Bupivacaine 1 ml/kg with dexmedetomidine 1 μg/kg for duration of post-operative analgesia, hemodynamic stability, post-operative sedation and any adverse effects in children undergoing infra-umbilical surgeries.

Materials and methods

The present study was carried out as prospective observational study. After approval from institutional Ethical commitees, written informed consent from all the patients' caretakers before surgery was performed.

Patient Selection: age group of 1-8 years, ASA grade I and II, patients coming for infra-umbilical surgeries.

Exclusion criteria: patients with ASA grade III and IV, infected wounds at sacrum, coagulopathy or anticoagulation, congenital sacral anomalies, meningitis patients, history of allergy to local anaesthetics, immunocomprised patients, bleeding disorders, patients who are not willing to participate in study.

After enrollment, patient's detailed history was elicited including medical history and history of drug allergy. Though general examination has been carried out including general condition of patient, vitals (temperature, pulse, B. P.), pallor, edema and icterus. Systemic examination including detailed respiratory and CVS examination was done.

Pre-anaesthetic assessment: The children were seen on the day before surgery and a general, systemic examination including airway and spine were done. Parameters like heart rate, blood pressure and respiratory rate was measured. Blood and urine examinations, chest x-ray if required, HIV and HBsAg was done in all patients. Informed consent was obtained from the parent.

Pre-operative fasting: Solid foods were restricted for 6 hours, milk for 4 hours and clear fluids for 3 hours prior to surgery.

Procedure: Patients were induced with oxygen, nitrous oxide (50:50) and Sevoflurane (in increasing concentration) using Jackson Rees modification of Ayre's 'T' piece and intravenous line was secured. Injection atropine 0.02 mg/kg was given intravenously after securing iv access. An infusion of Ringer Lactate with 1% dextrose was started and fluid was administered according to the calculated requirements.

Induction of anaesthesia to be achieved with 50% oxygen and nitrous oxide and 8% sevoflurane in oxygen in spontaneous ventilation. Once adequate depth of anaesthesia was achieved, LMA of appropriate size was inserted. Bilateral air entry was checked, if equal then secured. Then sevoflurane concentration to be reduced to 3% with 50% oxygen and 50% nitrous oxide.

Caudal block[21,32]: Then the anaesthetized patients were placed in lateral decubitus position with hip and knee in 90° flexion. The skin was prepared observing antiseptic precautions and draped. Initially coccyx was palpated with the thumb just above the intergluteal cleft. The thumb was then withdrawn cephaled to palpate the sacral hiatus. It was felt as a depression proximal to the sacrococcygeal joint. After sacral hiatus was identified, the index and middle finger of the palpating hand were placed on the sacral cornu, and the 23G hypodermic needle was inserted at an angle of 45° to the sacrum. While advancing the needle, a decrease in the resistance to needle insertion was appreciated as the needle pierced sacrococcygeal ligament and entered the caudal epidural space. The needle was advanced until bone (i.e. dorsal aspect of the ventral plate of the sacrum) was contacted and then slightly withdrawn, and the needle was redirected so that the angle of insertion relative to the skin surface was further reduced. The needle was advanced approximately 1 to 2 cm into the caudal space. Aspiration was done for blood or CSF. If negative, 1-2 cc of air as injected to rule out incorrect position as a superficially placed needle will produce subcutaneous crepitations. Then study drug solution, 0.25% bupivacaine in a dose of 1 ml/kg with tramadol in a dose of 1 mg/kg or dexmedetomidine in a dose of 1 μg/kg, appropriate for the group was injected. The children were then turned supine. Skin incision followed 10 minutes after caudal injection. For maintainance of sedation, sevoflurane concentration was reduced to 1% with 50% oxygen and 50% nitrous oxide.

A minimum of 10 minutes was allowed after giving the block for the surgeon to begin the surgery.

Patients have been on continuous monitoring of vital parameters, heartrate, respiratory rate, ECG, mbp, spO2 and value has been recorded baseline, before and after incision and thereafter every 5 min untill 20 minutes post incision, then every 10 min untill 1 hour post incision, then hourly untill 24 hours post incision. After completion of surgery LMA was removed after oral suction was done. All patients were observed for 2-3 hr in the recovery room before returning to the ward. At the end of

the surgery any side effects such as nausea, vomiting, shivering, bradycardia, hypotension, respiratory depression, neurological sequale were noted.

Bradycardia is defined as the decrease in the heart rate of more than 30% of the baseline value or HR below 80 beats/min for age 1 years and 60 beats/min for age above 1 years. It was subsequently treated with inj.atropine 0.01 mg/kg.

Hypotension is defined as decrease in the mean arterial pressure of gretter than 30% of the baseline value. It was treated with rapid infusion of iv fluids and if that was unsuccessful, then inj. ephedrine 0.1-0.3 mg/kg.

Respiratory depression is defined as a decrease in the spO2 of <95% that required administration of supplement oxygen via face mask or a respiratory rate of <10 breaths per minute.

Patients were assessed for long term neurological sequale following caudal blockage.

The duration of analgesia, defined as the time face, legs, activity, cry, consolability (FLACC) score (Table 1) reached 4 or more. Patients pain intensity has been assessed every hourly untill the 6th hour, every 3 hours untill the 12th hour, every 6 hours untill the 24th hour, before the first dose of rescue anaesthesia with paracetamol suppository (15 mg/kg) has been given, a time for rescue analgesia has been noted. Level of sedation has been assessed by RAMSAY sedation scale at end of surgery, 15 min, 30 min, 60 min and thereafter hourly untill Ramsay scale become 2 in all patients.

Ramsay Sedation Scale

1. Patient is anxious and agitated or restless, or both
2. Patient is cooperative, oriented and tranquil
3. Patient responds to commands only
4. Patient exhibits brisk response to light glabellar tap or loud auditory stimulus
5. Patient exhibits a sluggish response to light glabellar tap or loud auditory stimulus
6. Patient exhibits no response

The FLACC scale is scored between ranges of 0–10 with, 0 = relaxed and comfortable; 1 to 3 = mild discomfort; 4 to 6 = moderate pain; 7 to 10 = severe pain.

Group allocation: – In present study total 60 patients included . Patients has been randomly

Table 1: Flacc score(20)

	0	1	2
FACE	No expression or smile	Occasional grimace or frown withdrawn	Frequent to constant frown, quivering chin, clenched jaw
LEGS	Normal position or relaxed	Uneasy, Restless, Tense	Kicking or legs drawn up
ACTIVITY	Lying quietly, Normalposition, Moveeasily	Squirming, shifting back and forth, Tense	Arched, rigid or jerking
CRY	No cry	Moans or whimpers occasional complaint	Crying steadily, screams, sabs, frequent complaints
CONSOLABILITY	Content, relaxed	Reassured by touching, Hugging, Distractible, talking	Difficult to console or comfort

The FLACC scale is scored between ranges of 0–10 with, 0 = relaxed and comfortable; 1 to 3 = mild discomfort; 4 to 6 = moderate pain; 7 to 10 = severe pain.

divided in two groups. Randomization was done by odd and even numbers put in opaque sealed envelope.Randomization was done at time of giving caudal analgesia after induction of general anaesthesia.

1) Group A: (n=30) Patients receiving bupivacaine 0.25% 1 ml/kg with tramadol in a dose of 1 mg/kg.
2) Group B: (n=30) Patients receiving bupivacaine 0.25% 1 ml/kg with dexmedetomidine in a dose of 1 μg/kg.

Study periods:- July - 2017 to July -2019

Data analysis: collected data was entered in the excel data sheet and data analysis was done with the help of Epi. Info 7.2 software.

Statistical methods: Data was cleaned, Validated and Analysed by Epi. Info 7 software.

Descriptive Statistics: For continuous variable range, mean and standard deviation were calculated and for categorical variables proportion and percentage were obtained.

Bi-Variate analysis: To know the association between dependent and independent variable chi-square, t-test applied accordingly.

Results

Mean age, weight, gender distribution were comparable in both group. Majority of patients were aged between 2-7 yrs and male in both group. Majority of the surgeries were herniotomy,

Table 2: *Socio-clinical characteristics distribution of study participants (N=60)*

Characteristics	**Number (%)**		**P value**
	Group BT	**Group BD**	
Age (years)	4.2 ± 1.6	4.4 ± 1.7	p > 0.05**
Gender (male/female)	26/4	25/5	p > 0.05*
	15.7 ± 4.7	15.1 ± 3.5	p > 0.05**
Surgery			p > 0.05*
➢ Circumcision	6	4	
➢ Herniotomy	12	11	
➢ Orchidopexy			
➢ Urethroplasty	7	4	
➢ Cystolithotomy	5	8	
	0	3	
Duration of surgery(min)	55.3 ± 9.6	56.7 ± 12.8	p > 0.05**

* – Chi-square Test, ** – Student 't' Test. value expressed as mean ± sd

circumcision, orchidopexy, urethroplasty in both group. Duration of analgesis was compareble in both group.There was no statisticaly significant differance in mean age, weight, gender and duration of surgery among both of groups ($p < 0.05$). (Table 2)

There was no significant differance in spO2 intra- operative and post-operative up to 24 hours.($p > 0.05$). (Figure 2)

Group BD has significant sedation compared to Group BT up to 6 hr postoperatively ($p < 0.05$). Grou9 BD patients were more traquil but easily arousable.

No patient had sedation score of 6 (unresponsive patient).

Sedation score was 2.0 ± 0.4 up to 1 hr post-operatively in Group BT patients. So, after 1 hr of surgery, patients of BT group remained anxious, restless and agitated.While in group BD, Sedation score was 2.0 ± 0.3 up to 6 hr post-operatively. Thus all patients remained co-operative, oriented and tranquil up to 6hr postoperatively. (Figure 3)

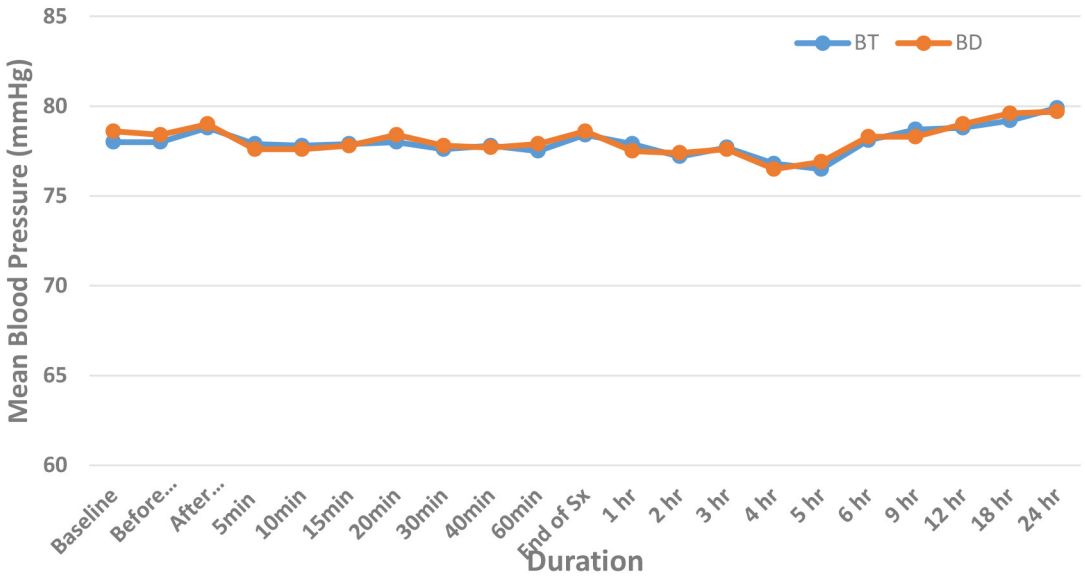

Figure 1: Mean Blood Pressure
MBP was comparable in both groups ($p > 0.05$)

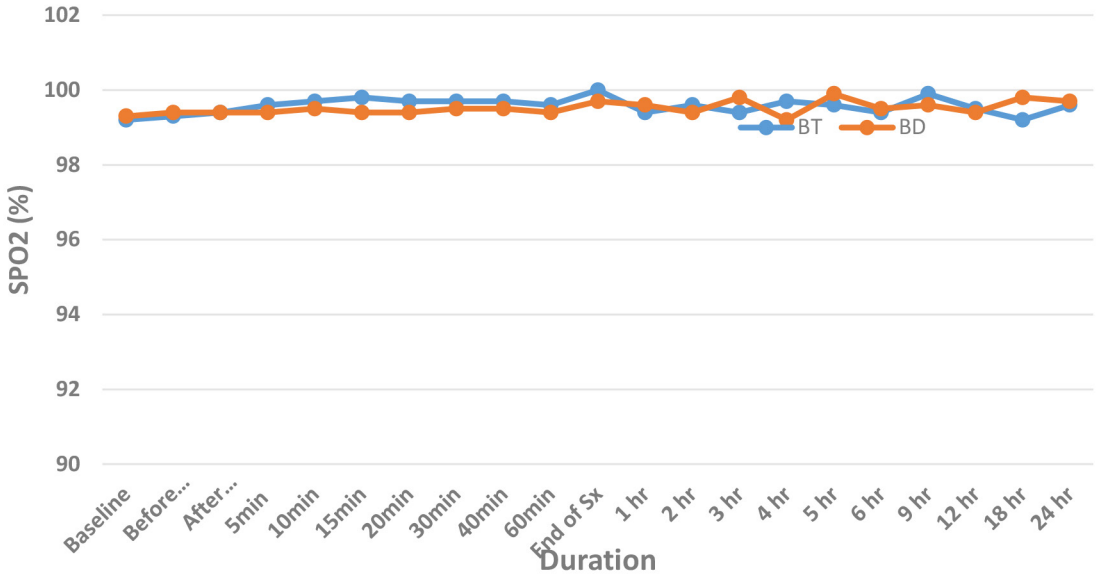

Figure 2: Value spO_2

FLACC score was analysed between the two groups at various interval of time at end of 1 hr, 2 hr, 3 hr, 4 hr, 5 hr, 6 hr, 9 hr, 12 hr, 18 hr, 24 hr post-operatively. The FLACC score of less than 4 was assumed as effective analgesia and score 4 or more was assumed as pain. (Figure 4)

At the 6th hr post-operatively, the FLACC score in BT group was 4.1 ± 0.06 and in BD group was 2.7 ± 0.5, which was statistically significant ($p < 0.05$). Group BT patients felt pain at 6 hr post-operatively.

At the 12th hr post-operatively, the FLACC score in BT group was 3.2 ± 0.9 and in BD group was 4.1 ± 0.6, which was statistically significant ($p < 0.05$). Group BD patients felt pain at 12th hr postoperatively.

As per shown in above table, effective analgesia as indicated by the FLACC score of less than 4 was observed for upto 12 hr in BD group and upto 6 hr in BT group postoperatively. Group BT patients achieved statistically significantly higher FLACC score compared with Group BD. ($p < 0.05$)

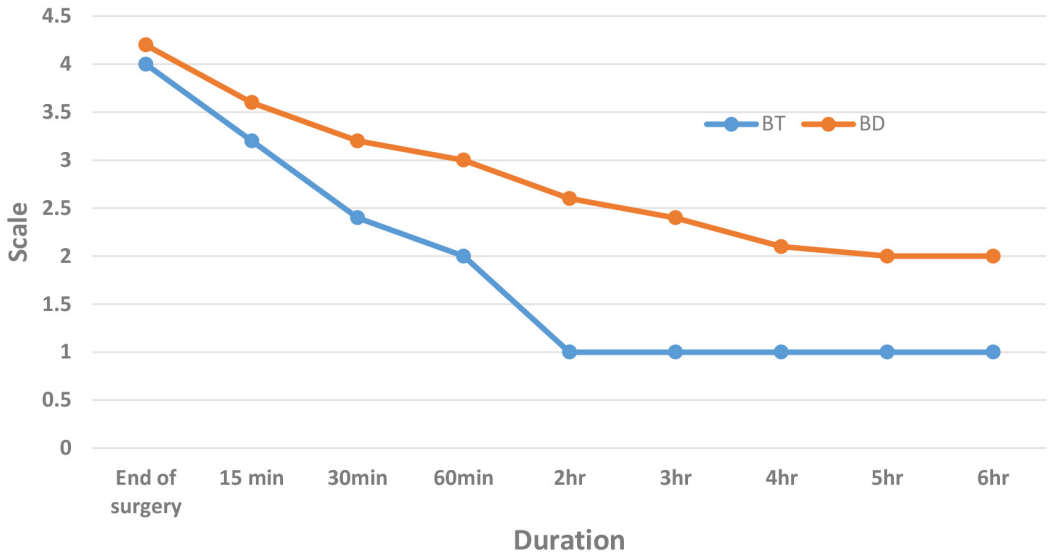

Figure 3. Ramsay Sedation Scale distribution

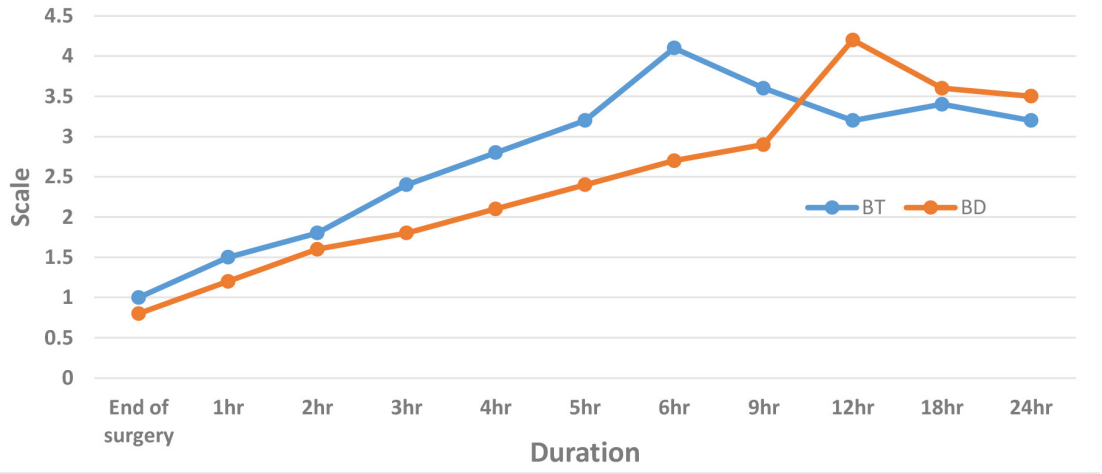

Figure 4. FLACC score distribution

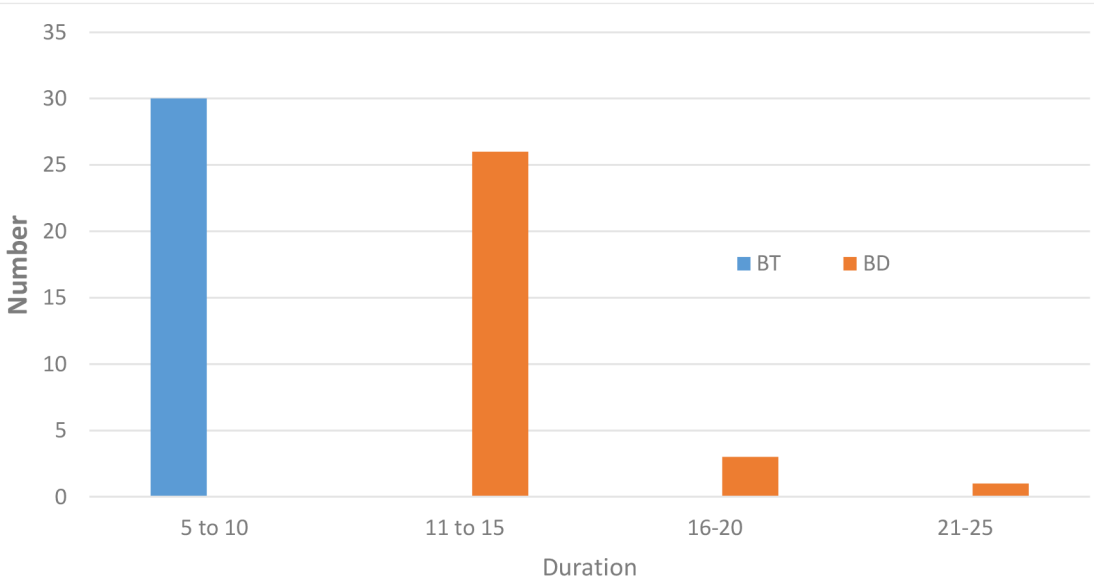

Figure 5. Duration of analgesia

The mean duration of analgesia was 6.9 ± 1.2 hours in group BT, 13.2 ± 2.8 hours in group BD. The duration of post operative caudal analgesia in group BD was significantly prolonged as compared to group BT. ($p < 0.05$). (Figure 5)

Nause and vomiting was seen in both group which was comparable. None of the patients had shivering, hypotension, bradycardia, respiratory depression, neurological sequale in both group. (Table 3)

Table 3: *Adverse effects among study participants (N=60)*

Side Effect	Number (%)		P value
	Group BT	Group BD	
Shivering	0	0	p>0.05*
Nausea & Vomiting	5 (16.7 %)	2 (6.7 %)	
Bradycardia	0	0	
Hypotension	0	0	
Respi. Depression	0	0	
Neurological sequale	0	0	

* – Chi-square Test

Discussion

Acute pain management is one of the most important tasks of perioperative paediatric anaesthesia. Pain relieving agents are usually administered on the basis of the concept of balanced analgesia, which involves a combination of analgesics with either synergistic or additive effects[11]. It allows rapid recovery from anaesthesia with effective postoperative analgesia. Caudal epidural blockade is one of the most popular regional block used in paediatric anaesthesia. This reliable and safe technique is used widely for many surgical procedures in combination with general anaesthesia. It allows rapid recovery from anaesthesia with effective post-operative analgesia. It reduces the stress hormone levels produced during anaesthesia. It reduces the intraoperative and postoperative analgesic requirements in the form of narcotics and NSAIDs. It also helps in early ambulation and less hospital stay, thereby alleviating most of the anxiety and burden of the child's parents. Local anaesthetics alone, especially Bupivacaine, were commonly used in the past in caudal technique for providing pain relief. Bupivacaine has some disadvantages like short duration of regional anesthesia and larger doses require for analgesics in the postoperative period. This resulted in the usage of various adjuvants to the local anaesthetics to prolong their analgesic effect postoperatively, like morphine, tramadol, adrenaline, ketamine, neostigmine, clonidine, dexmedetomidine etc[6].

Bupivacaine is a long-acting amide local anaesthetic that has provided reliable anaesthesia and analgesia with differential motor-sensory blockade for more than 40 years. In our study also, we have used a single dose of 0.25% bupivacaine (1 ml/kg). we choose 0.25% bupivacaine which provides better quality of analgesia when compared to lower concentrations. Saleem sabbar et al[26], Khalid et al[18] Senel AC et al[29] used 0.25% bupivacaine (1 ml/kg) for pediatric infra-umbilical surgeries, as a single shot caudal block.

Tramadol is one of the most commonly used adjuvants with local anesthetic in caudal block. Few studies have shown that in caudal epidural block, addition of tramadol to local anaesthetic drugs showed significant prolongation of post-operative analgesia as compared to bupivacaine alone[22,28,29]. Studies have established the safety of tramadol as

caudal adjuvant without significant adverse effects.[4,19,30,32].

Shrestha S. K. et al[28], Nasreen laiq[22] and Senel AC et al[29] used tramadol (1mg/kg) with 0.25% bupivacaine (1 ml/kg) for infraumbilical surgeries. They concluded addition of tramadol prolongs the duration of analgesia without producing significant adverse effects.

Dexmedetomidine is the most recent alpha-2 agonist agent approved by FDA IN 1999 for use in humans for analgesia and sedation. It provides prolonged postoperative analgesia when added & compare as adjuvant to various local anaesthetic agent & provide haemodynamic stability. It provides better perioperative haemodynamic stability than many other adjuvants now in use and good quality of intraoperative and prolonged post-operative analgesia with minimal side effects[7,9,12].

Dexmedetomidine enhances the effects of local anaesthetics without increasing the incidence of side effects[16]. One of the major advantages of dexmedetomidine over other sedatives is its respiratory effects, which are minimal in adults and children[1]. Dexmedetomidine provides an interesting quality of sedation that permits arousal with gentle stimulation[3,8,23].

Al Zaben et al[2] was assesed analgesic efficasy and side effect of two doses (1 μg/kg and 2 μg/kg) of dexmedetomidine administered with bupivacaine and concluded that increasing dose increased side effect such as bradycardia, hypotension, respiratory depression, whereas duration of post operative analgesia was comparable. So we choose dose of 1 μg/kg dexmedetomidine as additive in our study for prolong post-operative analgesia without any side-effect.

This study was planned to compare the effects of dexmedetomidine (1 μg/kg) and tramadol (1 mg/kg) to 0.25% bupivacaine (1 ml/kg) for caudal epidural block in pediatric patients undergoing infra umbilical surgeries.

Total 60 pediatric patients having age group of 1 to 8 years undergoing infra umbilical surgeries were selected for study. All Patients were kept NBM (solid food) for 6 hours and procedure was explained to patient's parents. Written informed consent was obtained. In O.T, vital parameters were measured and considered as basal parameter for this study. IV line was secured and Inj.atropine 0.01 mg/kg i.v. given to all patients. General Anaesthesia was given in all patients.

All patients were induced with: 50% O_2+50% N_2O+Sevoflurane (8%). Once adequate depth of anaesthesia was achieved, LMA of appropriate size was inserted. Bilateral air entry was cheched, if equal then secured. Maintenance was achieved by O_2+N_2O+Sevoflurane (3%) [maintain pulse & mean BP 30% of baseline with Sevoflurane]. Patients were divided into 2 groups.Caudal block was performed in all patients and study drug was injected according to group assigned and time was noted.

Group BT: Patient received 1 ml/kg 0.25% bupivacaine with tramadol 1 mg/kg.

Group BD: Patient received 1 ml/kg 0.25% bupivacaine with dexmedetomidine 1 μg/kg .

For maintainance of sedation, sevoflurane concentration to be reduced to 1% with 50% oxygen and 50% nitrous oxide after caudal block.

A patient was handed over to surgeon for surgery, after minimum 10 min of caudal block.

Savita Gupta and Rasmi Sharma et al[14] Vijay G Anand et al[3], in their study all patients were induced with 50% nitrous oxide with sevoflurane in increased concentration with oxygen. After adequate depth of anaesthesia, airway was secured with adequate size of LMA. After that caudal block was given.

HR, MBP, spO2 were recorded intraoperatively and postoperatively for 24 hours. Postoperative analgesia was assessed by FLACC score for 24 hrs postoperativly and If FLACC ≥ 4, First rescue analgesia was given with Paracetamol Suppository 15 mg/kg rectally. Duration of analgesia was defined as time of drug injection in caudal space to FLACC ≥ 4 or time of first rescue analgesia. Postoperative sedation was assessed by Ramsay sedation score up to 6 hr postoperative periods. Postoperatively all the patients were monitored for any complications like Nausea, Vomiting, Shivering, Bradycardia and Hypotension and Respiratory depression.

The statistical analysis was done by chi square test for demographic data, independent t-test for intergroup comparison with the use of Epi. Info 7 software.

Demographic data:

Individual patient characteristics such as age, gender, and body weight are important factors influencing any pharmacologic therapy.

In present study, mean age, weight and sex distribution were comparable and no statistically significant differance among both of groups (p>0.05).

Total duration of surgery:

In present study, mean duration of surgery in Group BT was 55.3 ± 9.6 mins,in Group BD was 56.7 ± 12.8.There was no statistically significant difference in the duration ofsurgery, among the two groups on intergroup comparison (p > 0.05).

In present study ,variety of infra-umbilical surgeries like herniotomy, circumcision, orchidopexy, urethroplasty, cystolithotomy were included.

Vital Parameters:

In the present study, heart rate, mean blood pressure and spO2 of all the patients were monitored intraoperative and postoperatively up to 24 hours.

The mean baseline heart rates were similar in both groups. The mean baseline rate was 110.4 ± 12.6 per minute in group BT and 110.0 ± 12.9 per minute in group BD. There was no significant difference in the heart rates between the two groups at any time interval(p < 0.05)

Similarly, there was no significant difference in the MAP between the two groups at any time interval(p < 0.05). The baseline mean MAP was 78.0 ± 5.4 mm Hg in group BT and 78.6 ± 4.3 mm Hg in group BT. (Figure 1)

Hemodynamic data in the study might be influenced by the pre-medication with atropine, intraoperative use of inhalational agent and postoperative arousal reactions that might have changed the extent of the hemodynamic responses

Intraoperatively oxygenation was maintained with 50% oxygen with nitrous oxide.there was no fall in saturation in either group. Postoperatively spO2 was above 97% in all patients in room air none of them required oxygen supplementation. And hence there was no incidence of respiratory depression in both of group.

No patient in either group had a decrease or increase in HR and MAP to 30% of basal value. so no need of any therapeutic intervention in our study.

In present study, there was no statistically significant difference in mean heart rate, mean arterial pressure and mean oxygen saturation were observed among both of groups on intergroup comparison intraoperatively and postoperatively up to 24 hours (p > 0.05)

Savita Gupta and Rasmi Sharma et al[14], in their study compared the analgesic efficacy of caudal dexmedetomidine versus caudal tramadol with ropivacaine 0.25% in 60 children aged 1 to 8 yrs for paediatric infra-umbilical surgeries. They concluded that there was no significant difference between the two group for intraoperative and postoperative HR, MAP and spO2 which correlates with our study.

S.Prakash et al[31], Shrestha S.K. et al[28], Nasreen Laiq and Senel AC et al[16], Choudhuri A.H. et al[4] and Doda M, Mukherjee S[7], in their study in addition to tramadol to bupivacaine 0.25% in caudal anaesthesia, have reported no significant changes in haemodynamic parameters which correlates with our study.

El-Hennawy et al[8], Debarati Goswami et al[13], in their study in addition to dexmedetomidine (1 µg/kg) to bupivacaine (0.25%, 1 ml/kg) in caudal anaesthesia, have reported no significant changes in haemodynamic parameters between the two groups which correlates with our study.

Ramsay sedation score-

In present study, postoperative sedation was assessed by Ramsay sedation score.

Sedation score was analysed between the two groups at various interval of time at end of surgery, 15 min, 30 min, 60 min, 2 hr, 3 hr, 4 hr, 5 hr and 6 hr postoperatively.

Ramsay's sedation score of atleast 2 (co-operative, oriented, tranquil) was assumed as adequate sedation. No patient had sedation score of 6 (unresponsive patient).

As, Sedation score was 2.0 ± 0.4 at 1 hr postoperatively in Group BT patients. After 1 hr of surgery, patients of BT group remained anxious, restless and agitated, while in group BD the sedation score was 2.0 ± 0.3 at 6 hr postoperatively . Thus all patients remained co-operative, oriented and tranquil up to 6 hr post-operatively.

Group BD has significant sedation compared to Group BT for 6 hr postoperatively (p < 0.05). Group BD patients were more tranquil but easily arousable.

Savita Gupta and Rasmi Sharma[14], compared the analgesic efficacy of caudal dexmedetomidine (2 µg/kg) versus caudal tramadol (2 mg/kg) with

ropivacaine (0.25%, 1 ml/kg) in 60 children aged 1 to 8 yrs for paediatric infra-umbilical surgeries. Ramsay sedation scoring was done at end of surgery, then hourly untill the 6th hour. Mean sedation scores were significantly higher in group BD compared to group BT.

Saadaway I et al[27] in their study on effect of dexmedetomidine (1 μg/kg) on the bupivacaine (0.25%, 1 ml/kg) in a caudal block in pediatrics. Sedation was rated with Ramsay's sedation scale. They concluded that the duration of sedation was prolonged in group BD(210 ± 72 min) compared with group BT (24 ± 72min)

Solanki N M et al[30], in their study of comparison of caudal tramadol (2 mg/kg) versus caudal fentanyl (2 μg/kg) with bupivacaine (0.25%, 1 ml/kg) for prolongation of postoperative analgesis in pediatrics, sedation was rated with a four point sedation score. They concluded that duration of sedation was prolonged in group BD(2 hr) than group BT(< 1 hr). So sedation with caudal tramadol was below one hour which corelates well with our findings.

Face, Leg, Activity, Cry, Consolability (FLACC) pain score

To assess the quality and duration of analgesia, postoperative pain assessment was done using FLACC scoring system in our study. Merkel et al[20] used FLACC scoring for assessing pain in children and found that it is reliable and valid in quantifying pain in non verbal children.

FLACC score was analysed between the two groups at various interval of time at end of sx, 1 hr, 2 hr, 3 hr, 4 hr, 5 hr , 6 hr, 9 hr, 12 hr, 18 hr, 24 hr postoperatively. The FLACC score of less than 4 was assumed as effective analgesia and a score of 4 or more was assumed as pain, so rescue analgesia (paracetamol suppository 15 mg/kg) was given to maintain the score below 4.

At the 6th hr postoperatively, the FLACC score in BT group was 4.1 ± 0.06 and in BD group was 2.7 ± 0.5, which was statistically significant ($p < 0.05$). Group BT patients felt pain at 6 hr postoperatively and resque analgesia was given.

At the 12th hr postoperatively, the FLACC score in BT group was 3.2 ± 0.9 and in BD group was 4.1 ± 0.6, which was statistically significant($p < 0.05$). Group BD patients felt pain at 12th hr postoperatively and resque analgesia was given.

Effective analgesia as indicated by the FLACC score of less than 4 was observed for upto 12 hours in BD group and upto 6 hours in BT group postoperatively. This shows that the effective analgesia lasted longer in bupivacaine with dexmedetomidine when compared to bupivacaine with tramadol group.

In present study, Group BT patients achieved statistically significantly higher FLACC scores compared with Group BD($p < 0.05$).

Savita Gupta and Rasmi Sharma et al[14], compared the analgesic efficacy of caudal dexmedetomidine (2 μg/kg) versus caudal tramadol (2 mg/kg) with ropivacaine in 60 children aged 1 to 8 yrs for paediatric infra-umbilical surgeries. Mean FLACC scores were significantly lower in caudal dexmedetomidine group than caudal tramadol group .

El–Hannawy et al[8], FLACC score of 4 was attained at 16 hr in the bupivacaine (0.25%, 1 ml/kg) with dexmedetomidine (2 μg/kg) group compared with 3.6 hr in bupivacaine group ($p < 0.001$).) The FLACC score of 4 was attained for longer in BD group in this study when compared to our study, this is probably due to the varying amount of dexedetomidine administered (2 μg/kg in this study and 1 μg/kg in our study).

Regmi UK et al[25], used tramadol (1 mg/kg) with 0.25% bupivacaine (1 ml/kg) for infraumbilical surgeries. FLACC score of 4 was attained at 7.8 hr in the bupivacaine with tramadol (1 mg/kg) group compared with 4 hr in bupivacaine group ($p < 0.001$).

Duration of analgesia :

In present study, duration of analgesia was defined as time of drug injection in caudal space to FLACC ≥ 4. The duration of analgesia was compared between the groups.

The mean duration of analgesia was 6.9 + 1.2 hours in Group BT, 13.2 + 2.8 hours in Group BD. There was a statistically significant prolongation in the duration of analgesia in Group BD , when compared with Group BT. ($p < 0.05$)

The findings of the above present study were consistent with the following studies:

Savita Gupta and Rasmi Sharma et al[14] compared the analgesic efficacy of caudal dexmedetomidine (2 μg/kg) versus caudal tramadol (2 mg/kg) with ropivacaine in 60 children aged 1 to 8 yrs for paediatric infra-umbilical surgeries. The mean

duration of analgesia was 10.9 ± 1.30 hr in group BT and 13.00 ± 1.19 hr in group BD. Caudal dexmedetomidine provided longer duration of analgesia than caudal tramadol .

Saadaway et al[27], in their study on the effect of dexmedetomidine (1 μg/kg) on the bupivacaine (0.25%, 1 ml/kg) in a caudal block in pediatrics, observed a mean duration of analgesia 18.5 ± 2.8 hr in group BD and 6.2 ± 2.8 hr in group B.

Choudhari AH et al[4], their study to compare caudal bupivacaine with bupivacaine plus tramadol (1 mg/kg) and bupivacaine with ketamine, concluded that mean duration of analgesia was significantly longer in group BT (8.5 ± 3.1 hr) compare to group B (6.5 ± 4.1 hr).

Prakash S et al[31], in a study of efficacy of three doses of tramadol (1 mg/kg, 1.5 mg/kg, 2 mg/kg) with bupivacaine (0.25%, 0.75 ml/kg) for caudal analgesia in pediatric inguinal herniotomy concluded that the duration of analgesia was longer in group BT2 (12.0 ± 0.9hr) compared to the group BT1 (8.0 ± 0.9 hr) and group B (4.0 ± 0.9hr). ($p < 0.01$).

Adverse effects:

In present study, incidence of nausea and vomiting occurred in 5 (16.7%) of the patients in Group BT and 2 (6.7%) of them in Group RD, which was treated with antiemetics and inj. ondansetron 0.06 mg/kg. The incidence of vomiting were comparable in both group.

None of the patients had shivering, hypotension, bradycardia, respiratory depression, neurological sequele in both the groups. The addition of dexmedetomidine or tramadol to bupivacaine in our study did not result in increase in the incidence of any other side effects.

Savita Gupta and Rasmi Sharma[14], compared the analgesic efficacy of caudal dexmedetomidine versus caudal tramadol with local anaesthetic in 60 children aged 1 to 8 yrs for paediatric infra-umbilical surgeries **.** They concluded that postoperative side effects like vomiting, shivering, hypotention were more present with tramadol than dexmedetomidine but were statistically non-significant.

Debarati Goswami[13] comapred the duration of analgesia and level of sedation after a single dose caudal bupivacaine versus caudal bupivacaine -dexmedetomidine. Incidence of side effects like nausea and vomiting was equal between the two groups.

The main side effect of epidurally administered tramadol is nausea and vomiting**.** Meena Doda et al[7,19], Saleem sabbar et al[26] and S. Prakash et al[31] have reported addition of tramadol did not result in any significant increase in incidence of vomiting, which correlates well with our study.

Dalens B et al[5] found that there were no major complications or neurological sequale following caudal anaesthesia and had a overall success rate of 96% following caudal block. In our study there were no cases of hypotension, bradycardia, vessel or dural puncture or any incidence of broken needles.

Conclusion

- Caudal block in pediatric infra-umbilical surgery is very beneficial to produce longer duration and powerful analgesia.
- Caudal Dexmedetomidine 1 μg/kg with 0.25% bupivacaine 1 ml/kg provided significant postoperative pain relief up to 13.2 ± 2.8 hr with prolonged duration of arousable sedation .
- Comparable, while using caudal tramadol 1 mg/kg with 0.25% bupivacaine also provided significant post operative pain relief up to 6.9 ± 1.2 hr but less duration than Dexmedetomidine.
- All patients remained hemodynamically stable perioperatively in present study.

In a nutshell, we concluded that Dexmedetomidine offers an advantage over tramadol as adjuvant to caudal bupivacaine, as it produces clinically and statistically significant prolonged duration of post operative pain relief and tranquility. Thus dexmedetomidine with bupivacaine can be used as an alternative to tramadol with bupivacaine for pediatric infre-umbilical surgeries through the caudal route as a safe and effective adjuvant.

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