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A comparative study between caudal bupivacaine and bupivacaine-tramadol combination for postoperative analgesia in paediatric infraumbilical surgeries

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Abstract

Background & Objectives: Caudal epidural analgesia is one of the most commonly performed regional blocks in pediatric anaesthesia for intra and post-operative analgesia. However, the mean duration of analgesia provided by local and aesthetics alone is limited. Caudal opioids is associated with side effects like respiratory depression, urinary retention, pruritis, vomiting etc. Tramadol, an opioid agonist, is known for its analgesic effects with lesser side effects. Hence, this study was conducted to know the efficacy and safety of addition of tramadol to bupivacaine in a single shot caudal block in children.

Methods: This study was conducted among 50 children in the age group of 1 – 13 years coming for various infraumbilical surgical procedures. They were divided into two groups of 30 each. Group B received caudal 0.25% bupivacaine (1ml/kg) and group BT received caudal 0.25% bupivacaine (1ml/kg) with tramadol (1mg/kg). The various parameters studied were hemodynamic changes, duration of analgesia and incidence of side effects. Pain assessment was done at the 1st, 2nd, 3rd, 4th, 8th, 12th and 24th hour after the surgery.

Results: The groups were similar in age, sex and weight. The hemodynamic parameters like heart rate, blood pressure, respiratory rate were also similar between the two groups after administering caudal block. The mean duration of analgesia in group BT (425.3±33.4 min) was significantly longer ($p < 0.05$) than group B (219.3±19.1 min). The pain score in the two groups were similar up to 2 hours after surgery but was higher in group B at the end of 3rd and 4th hour compared with group BT. Sedation score was similar in both the groups. Incidence of vomiting was comparable in both the groups while there were no incidence of bradycardia, hypotension or respiratory depression in both the groups.

Conclusion: This study showed that the addition of tramadol in the dose of 1mg/kg to 0.25% bupivacaine (1ml/kg) improved the analgesic duration and efficacy after a single shot caudal block with minimal side effects in children.

Keywords: Caudal, bupivacaine, tramadol, children

Introduction

In past children had received inadequate analgesia due to lack of basic understanding or data on development of pain and nociceptive mechanisms. Recently pain pathways have been identified in children. So postoperative analgesia in children is gaining importance [1].

The goal of post-operative pain relief is to reduce or eliminate with minimum side-effects. Effective pain relief means a smooth postoperative period, increased patient compliance and early discharge from hospital [3].

Over the years various regional an aesthetic procedures have gained popularity for postoperative analgesia. Regional anaesthesia is safe and effective in pediatric population. Along with providing postoperative analgesia, it reduces requirements of inhalational and intravenous agents with minimum sedation [2].

Caudal anaesthesia is a commonly performed regional block in children for abdominal and lower limb surgeries. It is a reliable and safe technique that can be used with general anaesthesia for intra and postoperative analgesia [3].

Many local anaesthetic drugs of variable concentrations are used. The use of caudal catheter to administer repeated doses or infusions of local anaesthetic is not popular because of concerns about infection. However, the mean duration of surgical analgesia provided by single shot caudal procedure is limited by the duration of local anaesthetic being chosen.

Caudal opioids have advantages of prolonging the duration of analgesia over bupivacaine

alone, but has side effects such as nausea, vomiting, pruritis and late respiratory depression, which can be minimized by reducing concentration^[3].

Tramadol, an opioid agonist, is a synthetic analogue of codeine. It is a potent norepinephrine inhibitor and also inhibits serotonin uptake with facilitation of its release. It has moderate affinity for mu receptor and has an analgesic potency equal to that of pethidine and 1/5th to 1/10th potent as morphine with lack of respiratory depressant effect^[4, 5].

Hence here is an attempt to study addition of TRAMADOL, an opioid with striking lack of respiratory depressant effect to bupivacaine with regards to analgesic potency and side effects.

This study has been undertaken to compare bupivacaine 0.25% (1ml/kg) alone and bupivacaine 0.25% (1ml/kg) with tramadol 1mg/kg as a single shot caudal block in infraumbilical surgeries in children aged between 1 to 13 years, with respect to the following parameters

- Hemodynamic changes like heart rate, blood pressure.
- Duration of post-operative analgesia.
- Adverse effects.

Methodology

This study was conducted at Dr. VRK Womens Medical College and Research Hospital from December 2018 to July 2019.

This study included 50 children, of either sex, coming for various infra-umbilical surgical procedures such as herniotomy, circumcision, orchidopexy, perineal surgery and minor lower extremity procedures.

Inclusion criteria

- Age group of 1-13yrs
- ASA grade I and II
- Patients coming for infraumbilical surgeries

Exclusion criteria

- ASA grade III and IV
- Infection at the site of injection
- Coagulopathy or anticoagulation
- Congenital abnormalities of lower spine and meninges
- Active disease of the CNS
- History of allergy to local anaesthetics

This study was approved by the Ethics and Standards committee of this institution. Informed consent was obtained from the parent before including the children in the study.

Equipment

- 23G needle (hypodermic)
- 5 cc syringe (for whoosh test)
- Sterile swabs, bowl, sponge holding forceps, sterile hole towel and spirit.
- Drugs – Bupivacaine 0.5% vial, Tramadol 50 mg ampoule
- Boyle's apparatus with halothane vaporizer, Jackson Rees circuit.
- Patent I.V line with infusion of crystalloid.
- Sterile water for dilution
- Emergency equipment included:
- Working laryngoscope, with assorted blades
- Endotracheal tubes of appropriate sizes
- Appropriate airways with masks

- AMBU bag of paediatric size
- Suction apparatus
- Emergency drugs – drugs necessary for administration of general anaesthesia and resuscitation were kept ready.

Methods

Pre-anaesthetic assessment

All patients were visited on the pre-operative day and a detailed general physical examination, systemic examination including airway and spine examination were done. Baseline parameters like heart rate, blood pressure and respiratory rate

Equipment: All patients were visited on the pre-operative day and a detailed general physical examination, systemic examination including airway and spine examination were done. Baseline parameters like heart rate, blood pressure and respiratory rate were noted. Laboratory investigations done bleeding time and clotting time, chest x-ray if required, HIV and HBs Ag were done in all patients. Informed consent was obtained from the parent.

Pre-operative fasting

Solid foods were restricted for 6 hours, milk for 4-5 hours and clear fluids for 2-3 hours prior to surgery.

Pre-medication

All patients were pre-medicated with syrup Promethazine 1 mg/kg on the previous night and 1hr before the surgery.

Procedure

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

Caudal block

Patient was gently placed in the Sim's position (left lateral), vitals were recorded including adequacy of spontaneous breathing. Under strict aseptic conditions, sacral hiatus was identified by running the thumb up from coccyx towards the sacrum.

After identifying the sacral hiatus, a 23G hypodermic needle with its bevel facing anteriorly was inserted at an angle of 60-70° to the skin till the Sacro-coccygeal membrane was pierced, when a distinct "pop" was felt.

After injection was complete, the needle was removed and the child was placed in supine position. No analgesia was given by any route pre-operatively or intra-operatively. Anaesthesia was maintained with oxygen, nitrous oxide and halothane (0.5-2%) with patient on spontaneous ventilation throughout the surgery.

Drug and dosage

The patients were randomly divided into 2 groups of 30 each.

Group B received caudal 1 ml/kg of 0.25% of bupivacaine.

Group BT received caudal 1 ml/kg of 0.25% of bupivacaine with Tramadol 1mg/kg.

Monitoring

Monitoring included precordial stethoscope, pulse-oximetry, NIBP, respiratory rate and ECG. The time of caudal block and duration of surgery was noted.

Parameters studied

Hemodynamic parameters

Patients were monitored for heart rate, respiratory rate and blood pressure after administration of caudal block at 0,5,15,30,45,60,120 and 180 minutes and the values were recorded.

Duration of action

Duration of action of drug is defined as the time interval between the administration of caudal block and the first requirement of supplementary analgesia for the patient.

Post-operative analgesia

Post-operative analgesia is assessed by Paediatric Objective Pain Scale. The assessment was done for a period of 24 hours after caudal block. If the pain score was more than 6 for 2 consecutive intervals of 10 minutes, then supplementary analgesia with syrup Paracetamol (15mg/kg) was given. These assessments were made at 1, 2, 3, 4, 8, 12 and 24 hours after caudal block.

Side effects

Patients were monitored for intra-operative and post-operative complications.

Nausea and vomiting

Any episodes were noted.

Bradycardia

Defined as the decrease in the heart rate of more than 30% of the baseline value. It was subsequently treated with Inj. Atropine 0.01mg/kg.

Hypotension: Defined as a decrease in the mean arterial pressure of greater 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

Defined as a decrease in the SpO₂ of <93% that required administration of supplemental oxygen via face mask or a respiratory rate of < 10 breaths per minute.

Sedation Score

A 4 point objective score based on eye opening was used as follows

Statistical analysis

The results of continuous variables are given as mean \pm SD and proportion as percentage. The difference between the two groups was assessed by students – t test and chi-square test. For all the tests a ‘p’ value of 0.05 and less was considered for statistical significance.

Results

A total number of 60 children in the age group of 1 – 13 years belonging to ASA grade B and BT were enrolled in this study. They were divided into two groups of 30 each.

Children in group B received caudal bupivacaine 0.25% (1ml/kg).

Children in group BT received caudal bupivacaine 0.25% (1ml/kg) with tramadol (1mg/kg).

Table 1: Mean Age of Patients

Group	No of individuals	Mean age (yrs.) \pm SD	Mean difference	p value
Group B	25	6.02 \pm 1.9	0.2	0.80 (NS)
Group BT	25	6.0 \pm 1.9		

The mean age in group B was 6.02 \pm 1.9 years and in group BT was 6.0 \pm 1.9 years. The two groups did not differ significantly (p = 0.80) with respect to their age, which is depicted in table 1.

Table 2: Sex Wise Distribution

Gender	Group B n (%)	Group BT n (%)
Male	19(73)	21(83)
Female	6(27)	4(17)
Total	25(100)	25(100)

In group B there were 19 (73%) males and 6 (27%) females. Group BT had 21 (83%) males and 4 (17%) females. The groups were comparable with respect to sex, which is depicted in table 2.

Table 3: Mean weight of the patients

Weight (kg)	Group B	Group BT	Mean difference	p value	t value
Mean Weight \pm SD	14.8 \pm 3.2	14.4 \pm 3.4	0.4	0.40 (NS)	0.43
Range	8 – 20kg	8 – 22kg			

The weight of the children in group B ranged from 8 to 20 kg with a mean weight of 14.8 \pm 3.2 kg. In group BT the weight ranged from 8 to 22 kg with a mean weight of 14.4 \pm 3.4 kg. The two groups did not differ significantly with respect to weight (p = 0.40). The weight distribution is depicted in table 3.

Table 4: Types of surgical procedures

Types of surgery	Group B n (%)	Group BT n (%)
Circumcision	7 (23.3)	8 (26.7)
Herniotomy	14 (46.7)	14 (46.7)
Orchidopexy	2 (6.7)	1 (3.3)
Anorectal surgeries	5 (16.6)	4 (13.3)
Others	2 (6.7)	3 (9.9)
Total	30 (100)	30(100)

The different surgical procedures performed during the study in the two groups are shown in table 6 and graph 4. In our study, herniotomy accounted for 14 (46.7%) in both the groups and circumcision were done in 7(23.3%) and 8(26.7%) cases in group B and BT respectively. Orchidopexy accounted for 2(6.7%) cases in group B and 1(3.3%) in group BT. Anorectal surgeries like polyp excision, thierch stitch were done in 5(16.6%) and 4(13.3%) in group B and BT respectively. Other surgeries included wound debridement and skin grafting which accounted for 2(6.7%) in group B and 3(9.9%) in group BT.

Table 5: Changes in heart rate

Time interval (min)	Group B Mean ± SD	Group BT Mean ± SD	Mean Difference	P* Value	Significance
Baseline	93.0±6.8	92.1±6.7	0.9	0.62	NS
0	93.1±6.8	93±6.7	0.1	0.94	NS
5	99.9±7.2	99.6±7.1	0.2	0.90	NS
15	96.9±6.9	95.9±6.4	1.1	0.54	NS
30	95.1±6.6	93±7.0	2.1	0.23	NS
45	93.5±6.2	91.5±7.1	2.0	0.25	NS
60	91.6±5.3	89.9±6.9	1.7	0.29	NS
120	89.8±5.4	88.8±6.9	1.0	0.52	NS
180	88.1±5.4	87.4±6.7	0.7	0.67	NS

In group B, the mean baseline heart rate was 93±6.8 per minute which increased to 99.9±7.2 at 5 min. The heart rate gradually decreased to 88.1±5.4 per minute at 180 minutes. The mean baseline heart rate in group BT was 92.1±6.7 per minute which increased to 99.6±7.1 at 5 minutes and gradually decreased to 87.4±6.7 at 180 min. However, there was no significant difference in the heart rate between the two groups at any time interval ($p > 0.05$) as shown in table 5.

Table 6: Changes in systolic blood pressure

Time interval (min)	Group B Mean±SD	Group BT Mean±SD	Mean Difference	P* Value	Significance
Baseline	96.0±5.9	97.5±5.8	-1.5	0.34	NS
0	96.0±5.9	97.3±6.0	-1.3	0.41	NS
5	104.0±5.9	104.7±5.8	-0.7	0.66	NS
15	100.9±5.7	102.1±5.9	-1.2	0.43	NS
30	98.7±5.5	98.9±5.4	-0.2	0.89	NS
45	97.1±5.3	97.0±4.9	0.1	0.92	NS
60	95.9±5.5	95.7±4.4	0.3	0.84	NS
120	94.2±5.6	94.1±3.9	0.1	0.96	NS
180	92.7±5.6	92.5±4.6	0.2	0.88	NS

The mean baseline systolic blood pressure was 96±5.9 mm Hg in group B. It increased to 104±5.9 mm Hg at 5 min and then gradually decreased to 92.7±5.6 mm Hg at 180 minutes. In group BT, the mean baseline systolic blood pressure was 97.5±5.8 mm Hg, which increased to 104.7±5.8 at 5 minutes and then gradually decreased to 92.5 ± 4.6 mm Hg at 180 minutes. At all-time interval, the p value was > 0.05 and hence the differences in the systolic blood pressure were insignificant at all-time intervals. Changes in systolic blood pressure are shown in table 6.

Table 7: Changes in diastolic blood pressure

Time interval (min)	Group B Mean±SD	Group BT Mean±SD	Mean Difference	P* Value	Significance
Baseline	60.1±3.3	60.9±4.5	-0.8	0.44	NS
0	60.4±3.8	60.9±4.2	-0.5	0.65	NS
5	66.0±3.8	66.7±4	-0.7	0.47	NS
15	63.6±3.8	64.5±3.9	-0.9	0.35	NS
30	62.2±3.7	62.5±4.1	-0.3	0.79	NS
45	60.3±4.2	60.7±4.3	-0.5	0.67	NS
60	59.5±3.8	59.1±4.6	0.4	0.71	NS
120	57.8±3.8	57.9±4.0	-0.1	0.90	NS
180	56.6±3.9	56.5±4.1	0.1	0.95	NS

The mean baseline diastolic blood pressure in group B was 60.1±3.3 mm Hg which increased to a maximum of 66±3.8 mm Hg at 5 minutes and gradually decreased to 56.6 ± 3.9 at 180 minutes. In group BT the mean baseline diastolic blood pressure was 60.9 ± 4.5 mm Hg, increased to 66.7±4 mm Hg at 5 minutes and progressively declined to 56.5±4.1 at 180 minutes. There was no significant difference in the diastolic blood pressure ($p > 0.05$) at all the time intervals, as depicted in table 7.

Table 8: Changes in respiratory rate

Time interval (min)	Group B Mean ± SD	Group B T Mean ±SD	Mean Difference	P* Value	Significance
Baseline	23.0±2.1	23.7±2.4	-0.7	0.22	NS
0	23.0±2.2	23.8±2.4	-0.8	0.20	NS
5	26.9±2.0	27.5±2.4	-0.6	0.27	NS
15	25.0±1.9	25.4±2.1	-0.4	0.45	NS
30	23.9±2.0	24.5±1.8	-0.6	0.26	NS
45	22.7±2.2	23.3±2.1	-0.7	0.24	NS
60	21.7±2.0	22.1±2.2	-0.3	0.54	NS
120	20.8±2.1	21.2±2.3	-0.4	0.49	NS
180	20.3±2.1	20.4±2.0	-0.2	0.75	NS

In group B the mean baseline respiratory rate was 23±2.1 per minute, which increased to 26.9±2 at 5 min and gradually decreased to 20.3±2.1 at 180 min. The mean baseline respiratory rate in group BT was 23.7 ± 2.4 which increased to 27.5±2.4 at 5 min and reduced to 20.4±2 per min at 180 min.

The difference in the respiratory rate between the two groups was statistically not significant ($p > 0.05$) at any time interval, as depicted in table 8.

Table 9: Pain incidence at various time intervals

Time interval (hours)	Group B n (%)	Group BT n (%)	P* Value	Z value *
1	0	0	-	-
2	0	0	-	-
3	8 (27)	0	< 0.01, S	3.5
4	11 (37)	1 (3)	< 0.01, S	3.64
8	10 (33)	9 (30)	0.80, NS	0.25
12	8 (27)	9 (30)	0.79, NS	0.26
24	8 (27)	10 (33)	0.61, NS	0.51

The distribution of subjects in the two study groups according to pain score ≥ 6 at various monitoring intervals are shown in table 9.

The Paediatric Objective Pain Score was below 6 at the end of first and second hour in both the groups and did not require any analgesia. At the end of third hour, 8(27%) of the patients in group B had a pain score of ≥ 6 whereas none of the patients had a score of ≥ 6 in group BT, which was found to be statistically significant ($p < 0.01$). At the end of fourth hour, 11(37%) of patients in group B had a pain score of ≥ 6 and only 1(3%) in group BT had a similar pain score which was statistically significant ($p < 0.01$).

The pain score was ≥ 6 in 10(33%) of patients in group B and 9(30%) in group BT by the end of eight hours which was not statistically significant.

At the end of 12th and 24th hour, group B had 8(27%) and 8(27%) patients with pain score of ≥ 6 and group BT had 9(30%) and 10(33%) with similar pain score respectively. The differences were found statistically insignificant.

The subjects with a pain score of ≥ 6 were significantly lower in group BT compared to group B at the end of 3rd and 4th hour.

Table 10: Duration of analgesia

Duration of analgesia (min)	Group B	Group BT
Mean duration \pm SD	219.3 \pm 19.1	425.3 \pm 33.4
Range	180 - 255	380 - 500

The mean duration of analgesia was 219.3 \pm 19.1 min in group B with a range of 180 to 255 min. In group Bt, the mean duration of analgesia was 425.3 \pm 33.4 min with a range of 380 to 500 min. The difference in the mean duration of analgesia was statistically highly significant ($p < 0.001$) which is shown in table 10.

Table 11: Sedation score at various time intervals

Time interval (hours)	Group B mean	Group BT mean
1	1	1
2	1	1
3	1	1
4	1	1
8	1	1
12	1	1
24	1	1

The mean sedation score was 1 in both the groups at all the time intervals, indicating no significant difference in the sedation score between the groups as shown in table 11.

Table 12: Incidence of complications

Complications	Group B	Group BT
Hypotension	0	0
Bradycardia	0	0
Vomiting	2(6.7%)	4(13.3%)
Dural puncture	0	0
Blood vessel puncture	0	0
Respiratory depression	0	0
Pruritis	0	0

The incidence of nausea and vomiting was 2(6.7%) in group B compared to 4(13.3%) in group BT. However this was not statistically ($p=0.43$) significant. There was no incidence of hypotension, bradycardia, Dural or vessel puncture and respiratory depression in the two groups.

Discussion

Treatment of acute pain is one of the most important tasks of perioperative pediatric 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 [6].

Postoperative analgesia through the caudal route is considered to be the most appropriate and satisfactory analgesia for small children undergoing anoperineal, inguinal and urogenital surgeries. It allows rapid recovery from anaesthesia with effective post-operative analgesia. The main disadvantage is the short duration of action following single shot caudal using only local anaesthetic, so various additives to local anaesthetic solutions have been tried [7].

The use of caudal opioids does prolong the duration of analgesia but associated with side-effects like respiratory depression, pruritis, urinary retention, nausea and vomiting.

Tramadol, an opioid has been shown to provide long lasting analgesia almost equivalent to that of pethidine with striking lack of respiratory depressant effect [3].

In this study, caudal epidural block using bupivacaine alone and bupivacaine with tramadol combination was conducted in 50 children in the age group of 1 to 13 years of ASA grade I and II coming for various infra-umbilical surgeries.

Age, sex and weight

In the present study, there was no significant difference in the two groups with regards to age, weight and sex.

The mean age was 6.02 \pm 1.9 years in group B and 6.0 \pm 1.9 years in group BT. The mean weight was 14.8 \pm 3.2 kg in group B and 14.4 \pm 3.4 kg in group BT. In both the groups males were more (> 70%). This could be due to inclusion of surgeries like herniotomy, orchidopexy and circumcision in our study. Nasreen laiq *et al.* [8] studied the effect of caudal analgesia in pediatric patients in the age group of 2-6 years, undergoing only hypospadias surgery, hence all the cases were males (100%).

Concentration and dosage of the drug

Gunter JB *et al.* [9] have reported that 0.175% bupivacaine offered the best combination of effectiveness and rapid recovery and discharge for pediatric surgical outpatients.

Armitage [10] has recommended 0.25% bupivacaine in a dose of 0.5 ml/kg for Lumbosacral, 1 ml/kg for Thoracolumbar, 1.25 ml/kg for mid-thoracic level of block and the plasma bupivacaine levels were always below 1.2 μ g/ml, which was below toxic levels.

In our study also, we have used a single dose of 0.25% bupivacaine (1ml/kg). Higher concentration can produce motor blockade in the immediate post-operative period and delay discharge. Since all the patients are monitored for 24 hours post-operatively in our hospital, 0.25% bupivacaine was used for post-operative analgesia.

S. Somasundaran *et al.* [11] and Saleem Sabbar *et al.* [12] used tramadol (2mg/kg) with 0.25% bupivacaine (0.75 ml/kg) for infraumbilical and inguinoscrotal surgeries respectively.

In our study, we chose 0.25% bupivacaine which provides better quality of analgesia when compared to lower concentrations and tramadol 1mg/kg which prolongs the duration of analgesia significantly, while avoiding the side effects like excessive nausea and vomiting associated with higher doses.

Changes in hemodynamic parameters

In the present study, heart rate and blood pressure of all the patients were monitored at regular intervals.

The mean baseline heart rates were similar in both groups. The mean baseline rate was 93 \pm 6.8 per minute in group B and 92.1 \pm 6.7 per minute in group BT. Initially there was a rise in heart rates to 99.9 \pm 7.2 and 99.6 \pm 7.1 per minute respectively in both the groups. This might be attributed to the premedication with atropine and the surgical procedure itself. On commencement of action of caudal block, there was a decrease in heart rate in both the groups which gradually reached baseline. The mean heart rate was 88.1 \pm 5.4 in group B and 87.4 \pm 6.7 in group BT at 180 minutes. There was no significant difference in the heart rates between the two groups at any time interval.

Similarly, there was no significant difference in the blood pressure (both systolic and diastolic) between the two groups at any time interval. The mean baseline systolic

blood pressure was 96.0 ± 5.9 mm Hg in group B and 97.5 ± 5.8 mm Hg in group BT. After an initial rise at 5 minutes, there was a gradual fall in the systolic blood pressure to 92.7 ± 5.6 mm Hg and 92.5 ± 4.6 mm Hg at 180 minutes in group B and BT respectively.

The mean baseline diastolic blood pressure was 60.1 ± 3.3 mm Hg in group B and 60.9 ± 4.5 mm Hg in group BT. After an initial rise at 5 minutes, which could be due to surgical procedure itself it gradually decreased to 56.6 ± 3.9 and 56.5 ± 4.1 mm Hg at 180 minutes. There was no incidence of bradycardia or hypotension in both the groups.

S. Prakash *et al.* [13] in their study on addition of tramadol to bupivacaine have reported no significant changes in haemodynamic parameters between the two groups which correlates with our study.

Changes in respiratory parameters

In the present study, no significant difference in the respiratory rate between the two groups was observed. There were no cases of respiratory depression in patients of either group as evidenced by a fall in the respiratory rate of less than 10 breaths per minute or a fall in the oxygen saturation of less than 90% S Prakash *et al.* [13] in their study of analgesic efficacy of 3 doses of tramadol - bupivacaine mixture reported no significant changes in the respiratory rate compared to the bupivacaine alone group. They also found that there was no incidence of respiratory depression in any of the groups, which correlates with our study.

Post-operative analgesia

Pain assessment is the most important and critical component of pain management. Assessing pain in children is an ever challenging as well as a difficult task, mainly because so far no reliable, universal method of assessing and measuring child's pain is available. In our study, we have used Pediatric Objective Pain scale.

The duration of analgesia was significantly prolonged in bupivacaine- tramadol group (425.3 ± 33.4 min) compared to bupivacaine alone group (219.3 ± 19.1 min) in our study. This is in agreement with a study done by S. Prakash *et al.* [13], which found that addition of tramadol to bupivacaine prolongs the duration of analgesia after a single shot caudal block. They had reported an increase in the mean duration of analgesia (8 ± 0.9 hrs) after the addition of tramadol (1mg/kg) when compared to bupivacaine alone (4 ± 1.0 hrs). Shahid khan *et al.* [14] in a study of children aged 13-53 months undergoing hypospadias surgery reported addition of tramadol (1mg/kg) to bupivacaine provides prolonged and effective postoperative analgesia (10.4 ± 1.69) compared to plain bupivacaine (7.93 ± 1.52).

Sedation score

In our study, a child with a sedation score of >1 was considered sedated. The mean sedation score was 1 at all the time intervals in both the groups as all patients were active and alert postoperatively.

Somasundaran S. *et al.* [18] and Saleem sabbar *et al.* [12] have reported no significant difference in sedation scores and all patients were alert and active in the postoperative period which correlates well with our study.

Complications

In our study, 2(6.7%) of the children in group B and 3(13.3%) of them in group BT had an episode of vomiting

which was treated with Inj metoclopramide (0.1–0.2 mg/kg) IV and the incidence of vomiting were comparable in both the groups. The addition of tramadol to bupivacaine in our study did not result in increase in the incidence of any other side effects.

The main side effect of epidurally administered tramadol is nausea and vomiting. Saleem sabbar *et al.* [12] and Prakash *et al.* [13] have reported addition of tramadol did not result in any significant increase in incidence of vomiting, which correlates well with our study.

Conclusion

The present study demonstrated that caudal administration of bupivacaine 0.25% (1ml/kg) with tramadol (1mg/kg) resulted in superior analgesia with longer duration of action when compared with 0.25% bupivacaine (1ml/kg) alone, without any significant difference in the hemodynamic parameters and the incidence of side-effects.

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Conflict of Interest

None

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