A COMPARATIVE STUDY OF POSTOPERATIVE ANALGESIA BY CAUDAL EPIDURAL ROUTE USING BUPIVACAINE WITH TRAMADOL AND BUPIVACAINE WITH FENTANYL IN PAEDIATRIC BELOW UMBILICAL SURGERIES

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ABSTRACT: The aim of this study was to compare the effectiveness of Bupivacaine (0.25%) 0.5 ml/kg with Fentanyl 1 μ g/kg and Bupivacaine (0.25%) 0.5 ml/kg with Tramadol 2 mg/kg in caudal block for postoperative analgesia. In the present study, 60 children of ASA I and II, aged between 5-12 years who were scheduled for below umbilical surgical procedures were randomly allotted into 2 groups (30 each) to receive either bupivacaine with fentanyl or bupivacaine with tramadol. Caudal block was performed after induction of general anesthesia, no analgesics were given intraoperatively. Postoperative analgesia was evaluated by Numerical Rating Scale and sedation was assessed by five point sedation score. Postoperative analgesia was supplemented with Syrup Paracetamol (10mg/kg) when Numerical Rating Scale was 4. Any adverse effect like respiratory depression, urinary retention, nausea and vomiting were recorded in all patients. Caudal tramadol with bupivacaine produced significant increased postoperative analgesia. The duration of analgesia was 861±23 minutes in tramadol with bupivacaine group, as compared to 353.46±31.79 minutes in fentanyl with bupivacaine group. No significant difference found in sedation score in both groups in first hour postoperatively. Two cases in fentanyl with bupivacaine and three cases in tramadol with bupivacaine group developed urinary retention in postoperative period. Four cases in fentanyl with bupivacaine and three cases in tramadol with bupivacaine group developed nausea and vomiting. Our study showed that caudal tramadol with bupivacaine provided longer duration of postoperative analgesia without having significant side effects.

KEYWORDS: Caudal analgesia, Bupivacaine, Tramadol, Fentanyl, Postoperative analgesia.

INTRODUCTION: Pain is perhaps the most feared symptom of disease which a man is always trying to alleviate and conquer since ages. Pain is defined by the International Association for Study of Pain as a "unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in term of such damage".¹ Acute pain is one of the most common experiences a child will have as a result of injury, illness or medical procedures. Historically children have been undertreated for pain and for painful procedures because of the wrong notion that they neither suffer or feel pain, nor respond to or remember the experience of pain to the same degree that adult did. Previous studies have suggested that the children do not feel pain, and giving them powerful analgesics is associated with risk of the addiction.²

Under treatment of postoperative pain even in children and newborn may trigger biochemical and physiological stress response and cause impairment in pulmonary, cardiovascular, neuroendocrinal, gastrointestinal, immunological and metabolic functions^{3.} The society of Pediatric anaesthesia⁴ on its 15th annual meeting at New Orleans, Louisiana (2001) clearly defined the alleviation of pain as a "basic human right" irrespective of age, medical condition, treatment, primary service response for the patient care or medical institution. Finley et al⁵ observed that many types of so called minor surgeries (e.g. Circumcision) can cause significant pain in children so the main goal of postoperative pain relief is to reduce or eliminate pain with minimum side effects.

There are various regional anaesthetic procedures which have gained popularity for postoperative analgesia because in addition of providing adequate postoperative analgesia they also reduce the requirement of general anaesthetic agents intra-operatively without significant side effects. Caudal block has proved useful in a variety of below umbilical operations⁶ in children for providing both intra-operative and postoperative analgesia as a single shot injection of local anaesthetic agents with adjuvant can provide good intra-operative and postoperative analgesia in children.

The addition of other drugs (additives) such as ketamine, clonidine or opioids to solutions of local anaesthetics has been routine practice in the UK.⁴

Objectives of present study was to compare the quality and duration of analgesia after single shot caudal block using bupivacaine with tramadol and bupivacaine with fentanyl and thereby try to find out which can be effective adjuvant to bupivacaine for providing postoperative analgesia in children undergoing below umbilical surgeries.

METHODS: After obtaining Institutional Ethical Committee approval and parental written informed consent, 60 children aged between 5-12 years, weighing between 15-35 kg of ASA I and II physiological status were enrolled for study. All these patients were scheduled for below umbilical surgeries like herniotomy, circumcision. The patients were randomly allotted into the two groups, Group A and Group B consisting of 30 patients each.

All the patients were pre-medicated with Syrup Promethazine 0.1mg/kg body weight on previous night of surgery and induced with Sevoflurane and 50% N2O in Oxygen via face mask. IV cannulation was done using 22 G cannula, then Injection Atropine 0.02mg/kg, Injection Ondansetron 0.1 mg/kg and Injection Midazolam 0.1 mg/kg were given IV as pre-medications. After discontinuing sevoflurane and N₂O, patients were induced with Injection Thiopentone 5mg/kg and intubation aided by administering Injection Succinylcholine 2mg/kg. ET intubation was done with appropriate size ETT, position confirmed and ET tube secured in place, caudal block was given in right lateral position by using 22 G needle under aseptic conditions.

Syringe containing equal volumes of either 0.25% bupivacaine 0.5ml/kg plus Injection tramadol 2mg/kg or 0.25% bupivacaine 0.5 ml/kg plus Injection Fentanyl 1 μ g/kg were prepared and given to the investigator who was blinded to the identity of drugs, and caudal block was given.

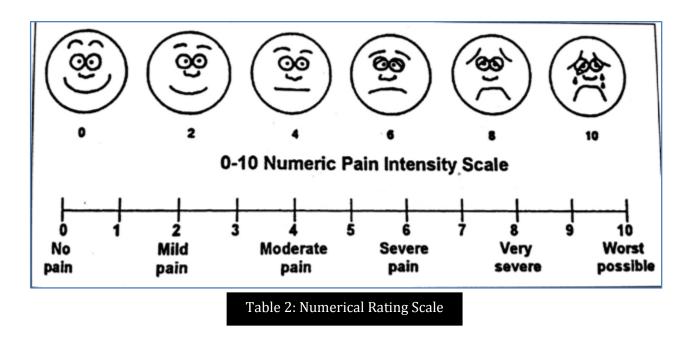
Group A patients received Injection Bupivacaine 0.25%, 0.5 ml/kg with Injection Tramadol 2mg/kg and

Group B patients received Injection Bupivacaine 0.25%, 0.5 ml/kg with Injection Fentanyl 1μ g/kg into caudal epidural space.

Surgery was conducted with $O_2 + N_2O +$ Sevoflurane 1% + Vecuronium bromide on IPPV. No analgesics were used intra-operatively. Intra-operative Heart rate (HR), pulse oximetry saturation (SPO2), Mean Arterial Pressure (MAP) and end tidal CO_2 (ETCO2) were monitored. After reversal of Non Depolarising Muscle Relaxants (NDMR) and after recovery from General anesthesia, the patients were shifted to Post Anesthesia care unit and vitals and pain was assessed by one of the self-report pain assessment tools.

Scale	Appropriate age	Validated	Reliable	Usefulness	Comments
	range (years)				
Faces	3-8	Yes	Yes	Simple, quick	Can be confused with happiness measure
Visual analogue	≥5	Yes	Yes	Quick, simple, versatile	Requires understanding of concept of proportionality
Numerical rating	≥ 5	Yes	Yes	Quick, simple	Child needs to be numerate
Poker-chip tool	≥ 4	Yes	Yes	Simple	Wide age-range
Colour	≥3	Yes	Yes	Exact site of pain described	Fun, engages interest

Table 1: Shows Different Types Of Self Report Pain Assessment Tools



In our study we used numerical rating scale by a blinded investigator. The child's motor power, any side effects and sedation score (1= fully awake and oriented, 2=drowsy, 3=eyes closed but arousable to command, 4=eyes closed but arousable to mild physical stimulation, 5=eyes closed but unarousable to mild physical stimulation) was also noted. Assessment was done every 15 min for first 1 hour and every hour for next 24 hours by the same blinded investigator. Analgesics were given

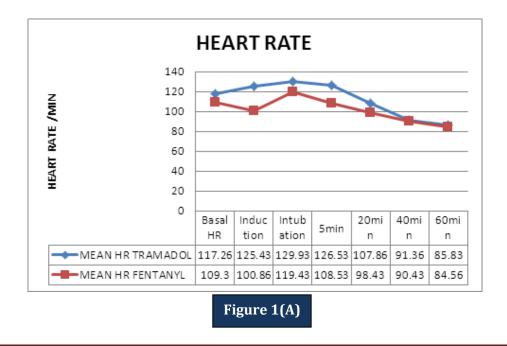
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when patient complains of moderate pain (Numerical Rating Scale of 4) Duration of analgesia was taken from the interval between the caudal injection to the administration of first rescue analgesia (in minutes).

RESULTS: Statistical analysis was done using student T-test. The two groups were comparable in age, weight and duration of surgery

Variables	Group A (n=30)	Group B (n=30)		
Age (years)	10.1 ± 1.72	9.36 ± 2.23		
Weight (kg) 28.26 ± 4.17 24.7 ± 6.86				
Table 3: Patient Data – Demographic profile				

	Basal BP MAP	Induction	Intubation	5 min	20 min	40 min	60 min
MEAN MAP GROUP A	84.46	76.83	91.8	86.73	81.73	78.5	76.6
MEAN MAP GROUP B	89.4	74.16	84.53	80	74.83	71.9	69.86
	Basal HR	Induction	Intubation	5 min	20 min	40 min	60 min
MEAN HR GROUP A	117.26	125.43	129.93	126.53	107.86	91.36	85.83
MEAN HR GROUP B	109.3	100.86	119.43	108.53	98.43	90.43	84.56
Table 4: Mean Arterial Pressure and Heart Rate variation between the two groups intraoperatively							



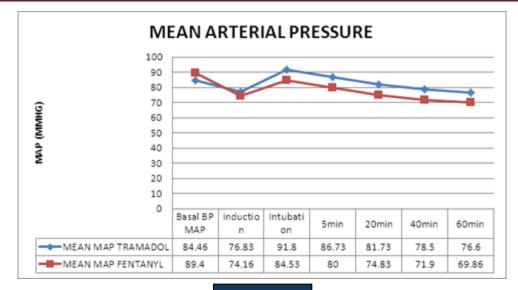
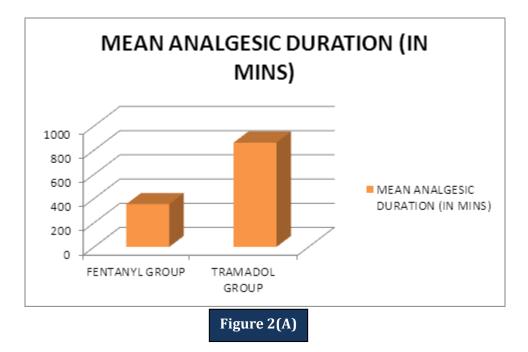
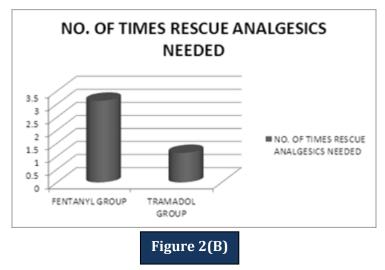


Figure 1(B)

Variables	Group A (n=30)	Group B (n=30)	p Value	
Duration of surgery (min)	82.06 ± 22.24	78.73 ± 20.63		
Mean Analgesic Duration (min)	861.23 ± 56.83	353.46 ± 31.79	< 0.0001	
No. of times analgesics needed in first 24 hrs post-op	1.13 ± 0.345	3.13 ± 0.345	< 0.0001	
Table 5: Average Time Interval between Caudal Analgesia and First Dose of Analgesic				



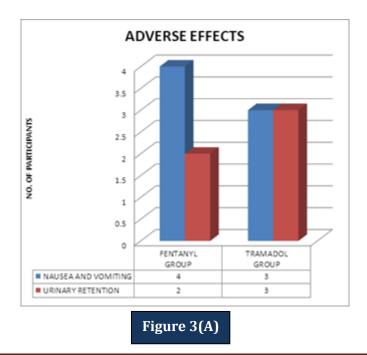


There was not much difference in the level of sedation in two groups in first postoperative hour; sedation was assessed by using Five Point Sedation Score system.

	Score 1	Score 2	Score 3	Score 4	Score 5
Group A	27	3	0	0	0
Group B	25	5	0	0	0

Table 6: Showing Sedation Scoring in Two Groups

Side effects	Group A (n=30)	Group B (n=30)			
Urinary retention	3	2			
Nausea and vomiting34					
Table 7: Incidence of Adverse Effects in 2 Groups					



While comparing the quality of analgesia in the two groups it was seen that the Group B started having mild pain after 4 hours and pain was significant after 6 hours, whereas in Group A the children were pain free for about 13 hours and there was significant pain after 16 hours during which time supplementary analgesics considered (Syrup Paracetamol 10 mg/kg). The significant pain is described as one that has a pain score of more than 4 on Numerical Rating Scale.

The vitals of patients in both groups remained stable during surgery. There was no major difference in sedation score between the two groups in first hour after recovery. 3 patients in tramadol with bupivacaine group had vomiting and 4 patients in fentanyl with bupivacaine group had vomiting. 3 patients had urinary retention in fentanyl with bupivacaine group and 3 patients in tramadol with bupivacaine group.

In bupivacaine with fentanyl group requirement of analgesics in first 24 hour is more compared to tramadol with bupivacaine group [Table 5; Figure 2(A) and 2(B)].

DISCUSSION: Caudal blockade provides reliable and good quality analgesia which is particularly useful for day care surgery. The technique is relatively simple and has a favourable risk to benefit ratio. Caudal administration of bupivacaine is a wide spread regional anaesthetic technique for intra and postoperative analgesia during lower limb, anoperineal, penoscrotal and abdominal surgical procedures in children.^{8, 9, 10}

Fentanyl, a lipophilic opioid is very commonly used as an additive to local anaesthetics in children to improve analgesia in postoperative period¹¹. However, few studies have addressed the benefit of fentanyl for single shot procedure. The addition of fentanyl produced only a slight change in the quality and duration of analgesia after administration of 2% lidocaine with epinephrine for a short surgical procedures.¹²

Tramadol is a centrally acting opioid analgesic, used to treat moderate to severe pain. It is a synthetic agent, made of racemic mixture of two enantiomers (+) tramadol and (-) tramadol it appears to have action at μ opioid receptor as well as the noradrenergic and serotonergic systems.⁹

In our study we found that by adding tramadol 2 mg/kg body weight to caudal bupivacaine 0.25%, 0.5 ml/kg in children undergoing below umbilical surgeries, significantly increased the duration of pain free period postoperatively when compared to the postoperative analgesia produced by adding 1 μ g/kg body weight of fentanyl to caudal bupivacaine 0.25%, 0.5 ml/kg body weight in children undergoing below umbilical procedures.

The addition of tramadol to caudal bupivacaine in this study prolonged the duration of postoperative analgesia. The mean duration of analgesia in bupivacaine with tramadol group was 861.23 ± 56.83 minutes when compared to 353.46 ± 31.79 minutes of bupivacaine and fentanyl group. Our results are consistent with previously published results.^{13, 14}

Prakash and colleagues studied caudal tramadol plus bupivacaine and used different doses of 1 mg, 1.5mg and 2 mg/kg tramadol plus 0.5 ml/kg of 0.25% bupivacaine. They observed that prolonged postoperative analgesic period was observed when 2 mg/kg of tramadol was used¹⁵. In the present study our results are consistent with the above study. In another study by Senel and colleagues the efficacy of tramadol with bupivacaine in children undergoing inguinal herniorraphy the results showed that patients who received bupivacaine 0.25 ml/kg body weight and tramadol 1.5 mg/kg body weight had a significant longer time to administration of first analgesic (13±2 hours).¹⁶

In our study the first dose of analgesic required postoperatively in tramadol with bupivacaine group was also at 861.23 \pm 56.83 minutes which is consistent with the above study. But in fentanyl with bupivacaine group the first rescue analgesic was required very early in about 353.46 \pm 31.79 minutes (Table 5).

The frequency of nausea and vomiting was quite low in present study which was the concern in other study with a dose of 2 mg/kg of tramadol¹⁷ [Table 7; Figure 3(A)].

CONCLUSION: Tramadol 2 mg/kg when administered caudally with bupivacaine provided prolonged analgesia when compared to analgesia produced by fentanyl $1\mu g/kg$ with bupivacaine and the use of tramadol as adjuvant with bupivacaine in caudal epidural space for providing postoperative analgesia was safe in children.

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