ORIGINAL ARTICLE

Preemptive caudal anaesthesia in children with bupivacaine-tramadol and levobupivacaine-tramadol: a randomized, double-blind, prospective study

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ABSTRACT

Background & Aim: Caudal block is the regional anesthetic technique that is used most frequently in pediatric surgery and bupivacaine and levobupivacaine are widely utilized in this technique. Opioid drugs have been added to local anesthetic solutions to prolong duration of analgesia but ideal combination were not found. We compared the postoperative analgesic efficacy of equal concentrations of bupivacaine or levobupivacaine plus tramadol in pediatric patients.

Objectives: Following objectives were monitored during study time of first analgesic requirement postoperatively, CHIPPS score for first 24 hrs, analgesic requirement in first 24 hrs, hemodynamic parameters and any side effects.

Methodology: Sixty children aged 2 to 5 years who were undergoing inguinal herniorrhaphy or orchidopexy received bupivacaine 0.25% plus tramadol 2 mg/kg (1 ml/kg) (BT group) or levobupivacaine 0.25% plus tramadol 2 mg/kg (1 ml/kg) (LT group) by the caudal route after general anaesthesia. The primary outcome of the study was to compare the duration and quality of postoperative analgesia. The postoperative pain relief was evaluated by the Children and Infants Postoperative Pain Scale (CHIPPS) at 2, 4, 6, 12, and 24 h postoperatively. In addition, the time of first analgesic requirement was noted.

Results: The CHIPPS scores were not statistically different between the groups. The duration of analgesia and requirements for rescue analgesia was similar. Urinary retention and motor blockade were observed more often in the BT group but statistically not significant. There were no significant differences between groups for arterial pressures and heart rate after caudal block and during the operation.

Conclusion: Caudal bupivacaine plus tramadol and levobupivacaine plus tramadol have similar postoperative analgesic efficacy.

Key Words: Bupivacaine; Levobupivacaine; Tramadol; Anesthesia; Caudal blockade

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INTRODUCTION

A caudal block is a type of epidural block, but the space is entered at its most distal point via the sacral hiatus, situated on the posterior aspect of the sacrum at S4.[1]

Caudal block is useful adjunct to general anesthesia for lower abdominal surgery in children as it provides intraoperative analgesia, smooth recovery period and good postoperative pain relief which reduces perioperative analgesic requirement. Caudal blockade was used most frequently in pediatric surgery and bupivacaine and levobupivacaine are widely utilized in this technique.[1,2] A large number of clinical studies have proven the clinical effectiveness and safety of bupivacaine and levobupivacaine.[3-6] However, the single caudal block with local anesthetics provides

only a short duration of analgesia and therefore the use of different additives has been advocated in order to prolong the period of postoperative analgesia. Opioid or nonopioid drugs as tramadol have been added to local anesthetic solutions to prolong caudal analgesia by a single injection.[7-12] Tramadol, a synthetic 4-phenyl-piperidine analogue of codeine. Tramadol acts by inhibiting serotonin uptake resulting in analgesia almost equivalent to that of pethidine in potency while lacking the depressant effect on respiratory system. Tramadol has a selective spinal action.[13] Tramadol has been shown to provide effective and long lasting analgesia after epidural administration in adults and children.[11] So the purpose of this study was to compare the duration of postoperative analgesia using caudally administered bupivacaine tramadol and levobupivacaine tramadol combination in children undergoing inguinal herniorraphy and orchidopexy surgeries.

METHODOLOGY

This prospective randomized double blind study was conducted at Dr. D. Y. Patil Medical College, Pimpri, Pune from January 2014 to October 2014 after college ethical committee clearance. Informed written consent of parents was obtained.

A total of 60 ASA status I children aged 2 to 5 years who were scheduled for elective inguinal herniorrhaphy or orchidopexy were enrolled. Children in whom caudal block was contraindicated (infection at the site of block, bleeding diathesis, pre-existing neurological or spinal disease, or abnormalities of the sacrum) or with a known allergy to local anesthetics were excluded.

Patients were randomly assigned to bupivacaine-tramadol group (Group BT) and levobupivacaine-tramadol group (Group LT). Patients were fasted for 6 hrs before the procedure. Clear fluids were allowed up to 3 hrs before the procedure. Peripheral IV access was secured. Patients received premedication with inj. ondansetron 0.1 mg/kg inj. glycopyrrolate 0.004 mg/kg, inj. midazolam 0.02 mg/kg and inj. fentanyl 1μg/kg IV. Induction with inj. propofol 2 mg/kg and inj. suxamethonium 2 mg/kg was done. Anesthesia was maintained with nitrous oxide, oxygen and 1-1.5% sevoflurane after endotracheal intubation. The patients were placed in a left lateral position and caudal blockade was performed under sterile conditions using a 22G hypodermic needle. Verification of successful needle placement was based on four predictors: ability to locate sacral hiatus, pop on piercing the ligament, lack of resistance to injection, and lack of subcutaneous swelling. The children in Group BT received a caudal injection of bupivacaine 0.25% plus tramadol 2 mg/kg , while those in the Group LT received a caudal injection of levobupivacaine 0.25% plus tramadol 2 mg/kg resulting in a total volume of 1 ml/kg. Study drugs were prepared by an anesthetist not involved in the trial using unlabeled syringes. The study remained blind until completion and researchers were only made aware of group allocations after statistical analysis.

Heart rate, noninvasive blood pressure and peripheral oxygen saturation were recorded before anesthesia and at 5 min intervals after caudal block. Skin incision was performed 15-20 min after caudal anesthesia. Effective analgesia was defined as hemodynamic change < 20% as compared to baseline values in response to surgical incision. In case of inadequate perioperative analgesia, supplementary fentanyl 1 μg/kg was administered (these patients were excluded from study). After surgery, patients were transferred to the recovery room.

The postoperative pain relief was evaluated using Children's and Infant's Postoperative Pain Scale (CHIPPS) (Table 1) at 2, 4, 6, 12, and 24 hr and by measuring the duration of analgesia. Postoperative assessments were made by nursing staff unaware of group allocation. Residual motor block was evaluated using a modified Bromage Scale (no motor block- score 0; able to move knees and feet- score 1; able to move feet- score 2; complete motor block of limb- score 3) 2 and 4 hours after surgery. In the case of a CHIPPS score of 4 or more,

Table 1: Children and infants postoperative pain scale[14]

Item	Structure	Points
Crying	None	0
	Moaning	1
	Screaming	2
Facial expression	Relaxed/smiling	0
	Wry mouth	1
	Grimace	2
Posture of the trunk	Neutral	0
	Variable	1
	Rear up	2
Posture of the legs	Neutral	0
	Kicking about	1
	Tightened legs	2

paracetamol 30 mg/kg was administered rectally. The duration of analgesia was defined by noting the time from caudal injection to the time of first analgesic requirement. Side effects (emesis, urinary retention, motor weakness, and sedation), time to first analgesic and the total number of analgesic doses required in the first 24 hr were recorded. Sedation score was assessed based on eye opening (spontaneous eye opening-0; eye opening to verbal stimuli-1; eye opening to physical stimuli-2 and unresponsive-3) at 2 and 4 hours. All patients were observed in the hospital for at least 24 hr for possible side effects of caudal block.

Statistical analysis

Statistical analysis were performed using a statistical software (SPSS) version 2013. All results were expressed as mean ± SD (standard deviation). Unpaired t test was used to compare demographic variables, duration of analgesia, duration of surgery and intraoperative hemodynamic variables. The p-values were generated using chi square test for comparison of proportions. A p-value of less than 0.05 was considered statistically significant.

RESULTS

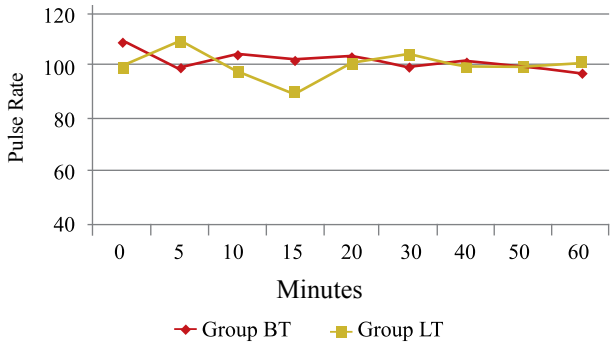
A total of 60 children were enrolled in the study and randomized in two groups of 30 each. Caudal block was successful in almost all of group and no patient required additional analgesic intraoperative.

Both groups were comparable in respect to age, weight, sex, type and duration of surgery.

Intraoperative pulse rate and mean blood pressure were comparable in both the groups and changes in both were not clinically significant clinically as well statistically.

No statistically significant difference in CHIPPS pain scoring between groups could be detected at any measurement time (Table 3).

Postoperative pain relief, which was the primary end-point of the study, was similar between the two groups. The first analgesic requirement time



There were no significant differences between groups for heart rate and arterial pressure values after caudal block and during the operation.

Figure 1: Comparison of pulse rate between two groups

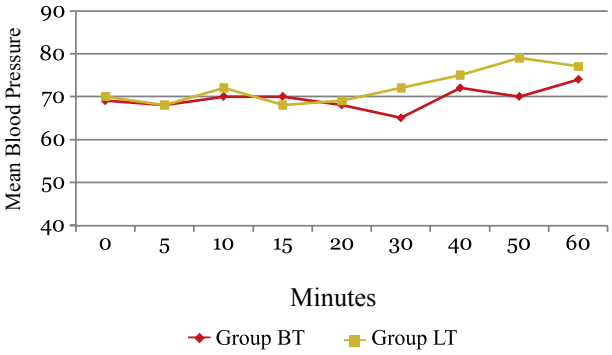


Figure 2: Comparison of mean blood pressure between two groups

was 21.41 ± 6.62 hours for Group BT while it was 17.79 ± 6.76 hours for Group LT. This difference was not significant statistically

18 patients in Group BT and 14 patients in Group LT did not required any analgesic in first 24 hours. While 9 and 11 patients required single dose of paracetamol in 24 hours in Group BT and Group LT respectively.

Sedation score was comparable in both the groups. Almost 50% of patients in both of the groups were sleeping comfortably and arousable with verbal commands.

Side effects such as urinary retention were

Table 2: Demographic data, type of surgery and duration of surgery

Parameters	Group BT	Group LT	P value
Age (years)	3.93 ± 0.86	3.9 ± 0.88	0.89
Weight (kg)	15.53 ± 5.3	14.11 ± 5.07	0.56
Gender (Male/Female)	30 / 0	30 / 0	
Type of surgery (Orchidopexy / Inguinal herniorrhaphy)	10 / 20	13 / 17	0.42
Duration of operation (min)	52 ± 13.9	58.9 ± 25.4	0.87

Table 3: CHIPPS scores for the first 24 postoperative hours

Time Intervals	Group BT (n=30)	Group LT (n=30)	P value
2 h	0.23 ± 0.34	0.13± 0.34	1.000
4 h	0.20 ± 0.40	0.23 ± 0.50	0.786
6 h	2.2 ± 0.92	0.93 ± 1.22	9.21
12 h	3.3 ± 1.46	4.00 ± 2.06	0.200
24 h	2.86± 1.43	2.63± 1.35	0.529

Table 4: The first analgesic requirement times

	Group BT (n=30)	Group LT (n=30)	*P value*
Time to first analgesic (hours)	21.41 ± 6.62	17.79 ± 6.76	0.0625

Table 5: Analgesic Requirement in first 24 hours

Number of doses of paracetamol received in 24 hrs	Group BT (n=30)	Group LT (n=30)	P-value
0	18 (70%)	14 (46.66%)	0.438
1	9 (20%)	11 (36%)	0.784
2	3 (10%)	5 (16%)	0.704
Average no of doses per patient in 24 hrs	0.5 ± 0.68	0.7 ± 0.74	0.160

observed 3(10%) patients in Group BT and in no patients in Group LT (p=0.05). In these patients, external manual compression over the bladder was able to express urine; no patient required bladder catheterization. Residual motor blockade of score 1 was found in 4 patients in Group BT and 2 patients in Group LT. while no motor blockade observed postoperatively after 2 hr.

Other side effects like nausea, vomiting occurred in one patient in Group BT. Pruritus was not observed in any of the patients.

DISCUSSION

Caudally administered single dose of local anesthetic during perioperative period has been reported to provide an adequate level of analgesia. Many studies has been reported that the effect of analgesic might vary depending upon the type of surgery , patients age, type and amount of local anesthetic agent.[11] Frawley,[3] Locatelli B[4] ,Ingelmo[5] and Brechan[6] and et al studied 0.25% of bupivacaine, levobupivacaine and ropivacaine and concluded that bupivacaine and levobupivacaine were equally potent and had longer analgesic effect. So we had choosen 0.25% bupivacaine and levobupivacaine for study. Ivani and Yao described dose response relationship for levobupivacaine in caudal block and stated that concentration of 0.2% is optimum for caudal.[15,16]

Tramadol injected into the epidural space has a prolonged duration of action because of sustained release from epidural fat and other relatively poorly perfused tissues.[10] Gunes Y[10] found epidural tramadol to provide good analgesia postoperatively and observed very low concentration of tramadol in systemic circulation compared to intravenous administration. Senel et al suggested that the duration of analgesia was longest in children receiving concurrent tramadol 1.5 mg/kg and bupivacaine 0.25%.[11] Prakash et al compared three doses of tramadol, administered caudally with bupivacaine.[17] In that study, tramadol 2 mg/kg combined with bupivacaine 0.25% provided a longer duration of postoperative analgesia and reduced the requirement for rescue analgesics as compared with tramadol 1 mg/kg or 1.5 mg/kg in children.

Yasser Majid et al and many other authors showed that addition of tramadol to bupivacaine or levobupivacaine for caudal analgesic technique provided longer lasting analgesia and lesser need for resecue analgesic in the postoperative period than when bupivacaine was used as a sole agent.[20-23]

It has been suggested that there could be a

Table 6: Side effects [n(%)]

Side Effect	BT Group	LT Group	P Value
Nausea, Vomiting	1 (3.3)	0 (0)	1.00
Sedation score at 2 hours			
Score 0	13 (43.33)	14 (46.66)	
Score 1	17 (56.66)	16 (53.33)	1.00
Urinary retention	3 (10)	0 (0)	0.23
Residual motor blockade (Bromage scale) at 2 hrs			
Score 0	25 (83.33)	28 (93.33)	
Score 1	04 (13.33)	02 (6.66)	0.63
Score 2	01 (3.33)	0 (0)	
Score 3	-	-	

synergistic effect between the local anesthetics and the additives, such as tramadol, rather than simply an additive effect, as the higher the dose of local anesthetics, the greater the additional anesthetic effect. A synergistic interaction between intrathecal clonidine and lidocaine has also studied in rats.[8,24,25]

In our study we found that caudal block with bupivacaine 0.25% with tramadol 2 mg/kg or levobupivacaine 0.25% with tramadol 2 mg/kg yields 21.41 hrs and 17.79 hrs of analgesia respectively. In our study, the concentration of levobupivacaine was determined as 0.25% equal doses of bupivacaine. This higher concentration may have prolonged analgesia more when compared with many of above study.

One limitation of this study is that we used local anesthetic concentrations of 0.25%. Comparison of local anesthetic potency has been standardized by the use of the minimum local anesthetic concentration (MLAC or ED_{50}).[3] To our knowledge, the MLAC of local anesthetics has not been assessed in pediatric patients receiving caudal block.[4] Yao et al described a dose-response relationship for levobupivacaine with caudal analgesia, and 0.15% levobupivacaine appeared to represent the optimum clinical dose for caudal block.[16] However, the researchers did not evaluate levobupivacaine concentrations of more than 0.18%. In another study, Ivani et al[15] found that 0.20% levobupivacaine may give the best caudal block in children. The local anesthetic concentrations used ranged from 0.2-0.25%, and the higher level may have reached the upper flat portion of the dose-response curve where both local anesthetics are effective and potency differences are obscured.[4] Nasreen Laiq in her study showed only 30% of patients required rescue analgesia in 24 hrs which was comparable with our study.[23] In our study 30% in Group BT and 52% in Group LT required rescue analgesia in 24 hrs postoperatively.

The residual motor blockade must increase with increasing concentrations of local anesthetics,[15] but recent studies have reported contrasting results. Astuto et al[26] did not observe motor blockade after surgery and during the study period using ropivacaine 0.25% or levobupivacaine 0.25%. In contrast to these results, Frawley et al[3] found 7% motor block in a group receiving 0.25% bupivacaine as compared with an 11% motor blockade in the levobupivacaine 0.25% group at 120 min following caudal anesthesia and no residual motor blockade after that. Locatelli et al[4] and Ivani et al demonstrated that bupivacaine 0.25% produced a significant incidence of residual motor block at 2 hrs in recovery from anesthesia as compared with levobupivacaine 0.25%. This difference was lost in the following hours. Breschan et al[6] compared the effects of 1ml/kg of 0.2% bupivacaine, levobupivacaine and ropivacaine and found that levobupivacaine and ropivacaine have significant lower motor blockade than bupivacaine in first 2 hrs and no difference after that. In our study we found motor blockade in 5(16%) and 2(6%) patients in Group BT and Group LT respectively at the end of 2 hours and no blockade after that. This difference was not statistically significant.

Postoperative dysuria affected 2% of children after caudal block for inguinal hernia procedures.[8] In our study, three patients in the BT group (bupivacaine plus tramadol) had urinary retention, but none of these patients required bladder catheterization. In Engelman and Marsala's meta-analysis study,[8] seven of the nine tramadol studies reported urinary difficulties. Pappas et al suggested that a distinct correlation between urinary retention and surgery

type exists, with patients undergoing hypospadias repair having the highest incidence of urinary retention that requires therapeutic intervention.[30]

Effectiveness of caudal analgesia was evaluated intraoperative by mean blood pressure and heart rate. Many studies related to this topic showed that effects of caudal block with local anesthetic or local anesthetic with tramadol on mean blood pressure and heart rate were similar and no difference was found.

CONCLUSION

The addition of tramadol to both levobupivacaine and bupivacaine in caudal block in children prolongs postoperative analgesia without any added side effect.

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MY MOST MEMORABLE PATIENT

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Anaesthesia at remote locations is a big challenge. Imagine a neonate with congenital goitre coming for MRI neck under monitored anaesthesia care! My patient was a 3 day old male child delivered vaginally at full term. The delivery was conducted at a very reputed maternity hospital in Hyderabad, India. A diffuse, suspicious swelling on the neck prompted the attending neonatologist to get an ultrasound neck and thyroid profile of the patient. As TSH was around 100µIU/ml, thyroxine replacement therapy was started per orally. It was decided to get an MRI of neck region to further understand the disease. The child was sent to our hospital for the imaging due to non-availability of MRI in the maternity unit.

I was informed telephonically by the MRI technician about the patient and that the child will need sedation or some anaesthetic to avoid movement for obtaining optimal imaging. When I saw the child, I experienced a brief palpitation. He was a 2.5 kg baby, with normal findings on general examination except for a diffuse swelling on neck. I was relieved to see a patent non-obstructed airway without any deviation on the chest radiograph, although airway obstruction is still possible with deep sedation. I had anaesthetised neonates before and I used to regularly provide sedation for patients with complex cardiac ailments for cardiac cath studies. But in this patient I didn't want to take any chance. I didn't want to intubate this child for MRI nor I wanted to inadvertently compromise the patency of the airway. Fortunately for me, there was a 24 G cannula in situ which on confirmation was patent. So, I was happy as there was no need to prick the patient .As expected, owing to 4 hours of nil by mouth period the child was crying vigorously. Fortunately for me (and for the patient), our MRI suite was equipped with an MRI compatible anaesthesia Boyle's apparatus, pulse oximeter with neonatal probe, laryngoscope, all sized endotracheal tubes and also has facility for suctioning. I checked the equipments myself and arranged everything in order. I soaked a cotton gauze, instilled 25% dextrose in it and asked the mother to give the child to pacify. Surprisingly, the child got quiet and in a few minutes was asleep. We took him in the gantry, wrapped him with cotton. I administered 0.3 mg of midazolam intravenously , connected a pulse oximeter probe and started supplemental oxygen, via face mask @ 4L/min and prayed to God. I asked the mother of the child to stay inside with me so that she is sure nothing went wrong with the anaesthetic. I'd already briefed her about the possibility of prolonged procedure if he moves. I even told her about the possibility of general anaesthesia if the airway gets compromised.On my request, a senior radiology technician conducted the imaging and it went on uneventfully over 15 minutes. The child started crying the moment he was unwrapped after taking him out from the gantry. I requested the mother to feed him for which she agreed immediately. After 4 hours I discharged the child from the hospital and they went to their primary hospital in an ambulance. I was so relieved as everything went on so well. I thanked everyone in the radiology suite who helped me out.

Due to busy working schedules, I totally forgot about the child and didn't enquire about the further course of his disease . After around 1 1/2 years when I was going home after a night shift, I saw a small boy running in the OPD area. I noticed him because he was screaming loudly and running vigorously in the corridor.

A lady came to me and wished me good morning which I reciprocated. I couldn't recognise the lady so I apologised and asked her if by any chance I happen to know her? On this she told me that the boy who is screaming and running is the one who was anaesthetized by me when he was 3 days old 18 months bask. Everything rewound like a flashback in front of my eyes. I went near the boy, shook hands with him and asked his name. He screamed and went running towards his mother. I was so happy to see him. His mother told me that he still is on a low dose of thyroxine and that he has achieved all milestones desirable for his age. She thanked me for the help that I provided them. It was a wonderful night duty off for me.

Amongst departmental colleagues, we were once discussing during lunch about the most memorable patient encountered till date in our practice. Most of them described patients with bad left ventricular function whom they anaesthetised successfully or a patient with unanticipated difficult airway which they secured with great difficulty or a patient who posed great problem in achieving hemodynamic stability intra-operatively. When my turn came, I described the above mentioned experience. A senior colleague was curious to know why I described this case as I didn't do any procedure neither did I encounter any mishap. Moreover, according to him it was just a procedural sedation. He suggested me to describe some high risk case as my memorable experience in future. I smiled and told everyone that the acknowledgement and the satisfaction that I saw on the mother's face after 11/2 of providing procedural sedation to the child makes this experience the most memorable for me.