Original Article

A study to compare caudal levobupivacaine, tramadol and a combination of both in paediatric inguinal hernia surgeries

Address for correspondence:
Dr. Rajat Dadheech,
F2, Akshaya Appartments,
Plot No. 28A, Path No. 4,
Laxmi Nagar, Niwaru Road,
Jhotwara, Jaipur - 302 012,
Rajasthan, India.
E-mail: rajatdadheech.rd@gmail.com

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Neelam Dogra, Rajat Dadheech, Mahipal Dhaka, Anupama Gupta

Department of Anaesthesiology, S.M.S. Medical College and Attached Hospitals, Jaipur, Rajasthan, India

ABSTRACT

Background and Aims: Caudal block is a safe and simple method of pain relief in young children with the drawback of a short duration of analgesia which can be overcome by adding various adjuvants to the injected local anaesthetic. We compared the effects of caudal levobupivacaine, tramadol and a combination of both in paediatric patients undergoing inguinal herniotomy. **Methods:** A total of 78 children aged 1–7 years, planned for inguinal herniotomy were randomly allocated into three groups. Group L received levobupivacaine 0.125% 1 ml/kg, Group T received tramadol 1.5 mg/kg in 0.9% NS and Group LT 1 ml/kg of 0.125% levobupivacaine with 1.5 mg/kg tramadol caudally. The primary outcome was the duration of analgesia. Rescue analgesic doses required, the duration of motor blockade and adverse effects were recorded for 12 h post-operatively. Data was analysed by analysis of variance test, Kruskal-Wallis and Chi-square tests. **Results:** All groups were comparable with regard to age, sex and duration of surgery. No motor block was observed in any of the patients. The mean duration of analgesia in Group L was 321.46 ± 84.76 min, in Group T was 565.19 ± 107.08 min, and in Group LT was 720 min ($P < 0.001$). The requirement for rescue analgesia in tramadol group was significantly less as compared to levobupivacaine group. Sedation scores and adverse effects were comparable among all groups. **Conclusion:** Addition of tramadol to caudal levobupivacaine significantly increased the duration of postoperative analgesia.

Key words: Caudal block, inguinal herniotomy, levobupivacaine, tramadol

INTRODUCTION

Pain is an unpleasant subjective sensation that can be better felt than expressed. The expression of pain is even more difficult in the case of children. Postsurgical pain can not only be agonising for the child but may also result in harmful adverse physiologic response and delayed recovery. The ease of performance and the safety of caudal block make it a very popular method of pain relief in young children undergoing infraumbilical surgeries.[1] Not only does caudal blockade provide satisfactory postoperative analgesia, it also decreases the intraoperative requirement for anaesthetic agents and attenuates the stress response to surgery.[2] A major limitation of single-shot caudal block is its relatively short duration of analgesia.[3] Caudal catheters are also rarely used due to increased risk of infection and soiling. Various additives have been used to increase the duration of caudal analgesia.

Levobupivacaine, an S-enantiomer of bupivacaine, is shown to have safer pharmacological profile[4] with decreased cardiovascular and neurologic adverse effects[5] attributed to its faster protein binding rate.[6] Tramadol is a synthetic opioid which when given epidurally has shown to provide effective,

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long-lasting analgesia[7] with no significant respiratory depression in children.[8]

Studies have demonstrated that the use of tramadol as an adjuvant to bupivacaine and ropivacaine resulted in significant prolongation of duration of analgesia during the postoperative period in paediatric patients.[8-10] We hypothesised that adding tramadol to caudal levobupivacaine would prolong the duration of analgesia in comparision to caudal tramadol or levobupivacaine alone in paediatric inguinal herniotomy surgeries.

The aim of this prospective, double-blinded study was to compare the effect of caudal levobupivacaine, tramadol and a combination of both in paediatric patients undergoing inguinal hernia surgeries.

METHODS

After due permission from the Hospital Ethics Committee, this randomised, double-blinded interventional study was conducted on 78 children aged 1–7 years, of either sex, belonging to the American Society of Anesthesiologists Grade I and II undergoing elective herniotomy following informed parental consent [Figure 1]. Patients undergoing emergency procedures, parental refusal to participate and children having a bleeding disorder or vertebral defects were excluded from the study.

A pre-anaesthesia evaluation was done 1 day before surgery and parents were explained about the anaesthetic technique and perioperative course. Patients were randomly allocated to one of the following three groups by pulling out a chit from a partially sealed box containing 78 folded chits (26 of each group) mixed together.

Group L was administered 1 ml/kg of 0.125% levobupivacaine caudally prepared by diluting 0.5% levobupivacaine with 0.9% normal saline. Group T received 1.5 mg/kg of tramadol with 0.9% normal saline to make the total volume of caudal solution 1 ml/kg; Group LT was given caudal 1 ml/kg 0.125% levobupivacaine with 1.5 mg/kg tramadol. Total volume of the solution in Group LT was kept 1 ml/kg without affecting the concentration of levobupivacaine by diluting 0.5% levobupivacaine with normal saline containing 1.5 mg/kg tramadol.

The same investigator who pulled the chit prepared the solutions according to the group mentioned in the chit and labelled it as caudal solution without mentioning the group or drug. Another investigator, being unaware of the composition of the caudal solution, administered the block and made the observations.

Baseline vitals of the patient were recorded in the preparation room following which midazolam (0.05 mg/kg intravenous) and glycopyrrolate (0.005 mg/kg intravenous) was given before shifting the patient in the operating room. Induction of general anaesthesia was achieved following attachment of multiparameter monitor with injection propofol (3 mg/kg intravenous) and an appropriate size laryngeal mask airway was inserted.

Patients were placed in the lateral position, and a caudal block was administered using a 5 cm short bevelled 22G needle. The study drug prepared for that particular patient was injected epidurally through the caudal route and time of block was noted. Maintenance of anaesthesia was by 1% halothane delivered in 60% N_2O and 40% oxygen. Heart rate, blood pressure and oxygen saturation were recorded every 5 min throughout the procedure. Adequate intraoperative analgesia was defined by the absence of gross movements and haemodynamic stability, as indicated by the absence of an increase in heart rate or systolic blood pressure >20% compared to baseline values. All anaesthetic agents were discontinued at the end of surgery, and the duration of surgery was noted.

The primary outcome measure of the study was the duration of analgesia defined as the period from the administration of block until the requirement of first rescue analgesia. Secondary outcomes were total number of rescue analgesic doses required, the duration of motor blockade, and recording of any adverse effects in the form of respiratory depression (rate <10/min), bradycardia, nausea and vomiting during the 12 h study period.

Post-operative pain status, degree of sedation and motor block were evaluated and recorded using the Children and Infants Post-operative Pain Scale (CHIPPS) score[11] [Table 1], University of Michigan Sedation Scale[12] and Modified Bromage Scale,[13] respectively, every 15 min for 1 h and then every hour until 12 h post-surgery. Rescue analgesia in the form of a paracetamol suppository (30 mg/kg) was given if the CHIPPS score was >4. The duration of analgesia was defined as the period from administration of block until the time CHIPPS score was >4. A total number of doses of rescue

analgesia required during the 12 h study period and any adverse effect such as respiratory depression (rate <10/min), bradycardia, nausea and vomiting was also noted.

Expecting minimum detectable difference of duration of analgesia among the three groups to be 150 min and standard deviation (SD) of 180 min as demonstrated by a previous study;[7] the sample size was calculated as 26 patients for each group at an alpha error of 0.05 and power 80%.

Data collected were analysed using SPSS version 20.0 (IBM, Armonk, New York, U.S.A and online GraphPad software (Prism 5 for Windows) version 5.01 (GraphPad Software Inc, San Diego, California, U.S.A.). Quantitative data have been presented as mean ± SD Qualitative data have been expressed regarding number and percentage.

The data collected was analysed by one-way analysis of variance test for normally distributed quantitative variables. In the case of non-normal distribution of quantitative variables, Kruskal–Wallis test was used to compare the difference between the means of the groups. Pearson's Chi-square test used to compare qualitative variables. All tests were performed at a 5% level of significance, thus an association was significant if the value was <0.05 ($P < 0.05$).

RESULTS

Figure 1 shows the flow of patients through the trial. There was no statistically significant difference among the groups with respect to age, weight and duration of surgery [Table 2]. Intraoperative haemodynamic parameters were maintained within 20% of base value in all the three groups.

The mean duration of analgesia in Group L was 321.46 ± 84.76 min, and in Group T, it was 565.19 ± 107.08 min [Figure 2] ($F = 0.168$, $P < 0.001$). None of the patients in Group LT had CHIPPS score >4 during the 12 h study period. For the sake of comparison, the duration of analgesia was taken as 720 min in all patients who did not have a CHIPPS score >4 during the 12 h study period. Thus, the duration of analgesia in Group LT was 720 min. The difference was highly significant among all the three groups ($P < 0.001$ among all groups).

As many as, 61.5% patients in the levobupivacaine group required rescue analgesics twice in the study period while 88.5% patients in the tramadol group required rescue analgesics only once [Figure 3]. None of the patients in Group LT required additional analgesia during the study period. The difference was highly significant among all the three study groups ($P < 0.001$ among all the groups).

There was no significant difference regarding sedation scores post-operatively . None of the patients in the study had motor block. Pain scores were higher in tramadol group in the early post-operative period while patients in levobupivacaine group had higher scores in the late post-operative period [Table 3]. One patient in the tramadol group had vomiting. No other adverse events were noted.

Table 1: CHIPPS score

Item	Response	Score
Crying	None	0
	Moaning	1
	Screaming	2
Facial expression	Relaxed/smiling	0
	Wry mouth	1
	Grimace (mouth and eyes)	2
Posture of the trunk	Neutral	0
	Variable	1
	Rear up	2
Posture of the legs	Neutral/released	0
	Kicking about	1
	Tightened	2
Motor restlessness	None	0
	Moderate	1
	Restless	2

Table 2: Demographic profile and duration of surgery

Parameters	Group L	Group T	Group LT	*P*
Age (yrs)	3.88±3.21	4.08±2.13	3.58±1.88	0.765
Weight (kg)	12.23±4.82	13.54±4.19	13.04±4.22	0.564
Duration of surgery (min)	27.12±5.32	28.08±4.70	28.08±5.49	0.743

DISCUSSION

Caudal epidural anaesthesia is one of the safest and simplest techniques used in paediatric surgeries with high success rate. As children are rarely cooperative, caudal block is mostly given to provide post-operative analgesia, and surgery is performed under general anaesthesia. A longer duration of analgesia with less motor blockade is desirable. In this study, we observed that the use of tramadol, as an adjuvant to levobupivacaine in caudal epidural block, significantly prolonged the duration of analgesia following inguinal hernia repair surgeries as compared to caudal levobupivacaine or tramadol alone in paediatric patients.

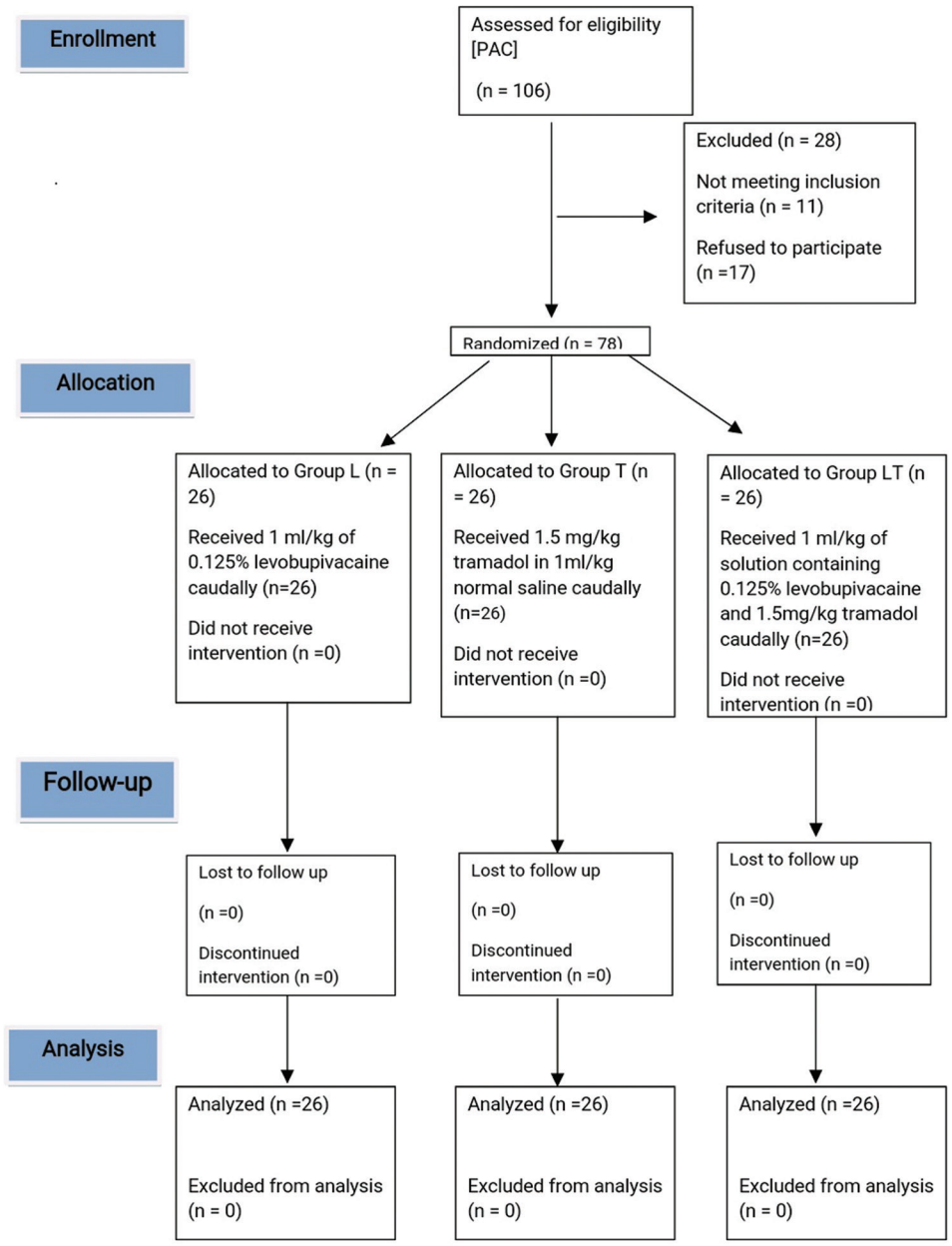

Figure 1: Consolidated Standards of Reporting Trials flow diagram showing patient progress through the study phases

The lower lipid solubility and greater intrinsic vasoactivity of levobupivacaine decreases absorption and produces differential neural blockade with less motor block.[14,15] It has been demonstrated that patients who received 0.125% levobupivacaine caudally were free from post-operative motor block.[16,17] In our study, we also observed that there was no motor block with caudal 0.125% levobupivacaine. The mean duration of analgesia observed was 321.46 min. Similar durations of analgesia were reported in other studies using 0.125% levobupivacaine[17] or 0.2% levobupivacaine.[14,18] However, another study observed a very short duration of analgesia with 0.125% levobupivacaine.[16]

Tramadol is a synthetic opioid with moderate mu receptor affinity and weak kappa and delta activity. It also has serotonin and norepinephrine reuptake inhibiting effects and does not cause significant respiratory depression.[19] Caudal tramadol has been shown to be superior to bupivacaine in analgesic efficacy and in reducing the need for additional analgesia during the post-operative period in paediatric patients.[20]

In our study, we observed that the CHIPPS scores in the tramadol group were comparatively higher in the early post-operative period indicating a slower onset

Table 3: Mean postoperative children and infants postoperative pain scale score

Duration after surgery	Group L		Group T		Group LT		*P*
	Mean	Standard deviation	Mean	Standard deviation	Mean	Standard deviation	
15 min	0	0	0	0	0	0	1.000
30 min	0	0	1.11	1.17	0.04.	0.19	<0.001
45 min	0	0	0.88	0.95	0.08	0.27	<0.001
1 h	0	0	0.5	0.64	0	0	0.007
2 h	0.08	0.39	0	0	0.04	0.19	0.551
3 h	0.6	1.17	0	0	0	0	0.003
4 h	0.8	1.27	0.12	0.58	0.12	0.40	0.012
5 h	1.23	1.36	0.04	0.19	0.08	0.27	<0.001
6 h	1.34	1.46	0.11	0.58	0	0	<0.001
7 h	0.77	1.36	0.27	0.53	0.08	0.27	0.014
8 h	0.35	0.68	0.73	1.21	0.04	0.19	0.011
9 h	0.92	1.59	0.99	1.28	0.08	0.27	0.013
10 h	0.69	1.34	0.96	1.48	0.12	0.51	0.082
11 h	0.88	1.50	0.31	0.61	0.08	0.32	0.013
12 h	0.61	1.47	0.50	1.17	0.12	0.43	0.245

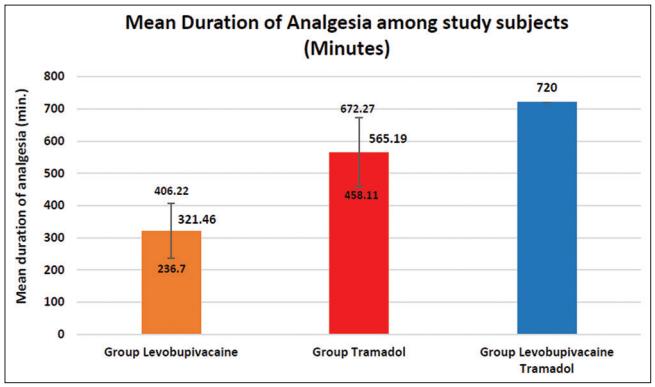

Figure 2: Mean duration of analgesia

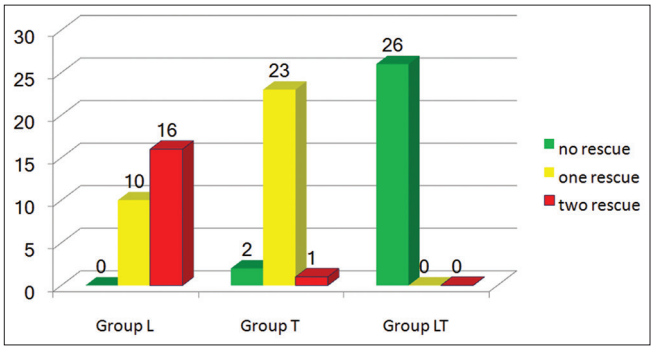

Figure 3: Rescue analgesia requirement

of action [Table 3]. However, none of the patients had a CHIPPS score of >4. Batra *et al*. also reported higher pain scores with caudal tramadol as compared to bupivacaine in the early post-operative period.[21] Prosser *et al*.[7] observed that caudal tramadol produced useful analgesia for up to 12 h after hypospadias surgery. However, if the period between performing the caudal injection and recovery of the child from anaesthesia was <2 h; the incidence of immediate pain (requiring rescue analgesia) was high (30%) demonstrating a slow onset of action of caudal tramadol.

The reason for the slow onset of caudal tramadol may be because of lower lipid solubility resulting in slower uptake across the duramater and a slower release of tramadol into the circulation. Thus, it is recommended to use additional analgesic in the immediate post-operative period or to combine tramadol with a local anaesthetic during caudal administration.

The mean duration of analgesia (565.19 min) was significantly higher in the tramadol group than the levobupivacaine group ($P = 0.0$). Similar observations were made with caudal tramadol in other studies.[7,22] In addition, significantly fewer number of rescue analgesic doses were required in tramadol group as compared to levobupivacaine group during the 12 h study period. Another study had also demonstrated significantly decreased requirement of rescue analgesics with caudal tramadol as compared to caudal bupivacaine.[21]

On combining 1.5 mg/kg of tramadol with 1 ml/kg of 0.125% levobupivacaine and administering it caudally, we achieved long-lasting analgesia for up to 12 h. No further analgesics were required in any of the patients belonging to Group LT during our study period, and there were no incidence of adverse effects. The results are in accordance with other studies combining tramadol with levobupivacaine[23,24] or bupivacaine[8,21] for caudal analgesia. It has been suggested that there could be a synergistic effect between the local anaesthetics and adjuvants, such as tramadol, rather than simply an additive effect, as the higher the dose of local anaesthetics, the greater

the additional anaesthetic effect.[25] Some studies have also demonstrated <12 h of analgesia with levobupivacaine and tramadol combination.[17,26] One of the previous studies had failed to demonstrate a significant increase in the duration of analgesia on adding tramadol with caudal bupivacaine.[7] They also observed a mean duration of analgesia of 540 min with caudal bupivacaine, which is considerably longer when compared to our findings.

One of the limitations of our study was that patients could be followed up only up to 12 h post-surgery. Further studies are needed to observe the analgesia patterns and requirements beyond 12 h when levobupivacaine and tramadol are used caudally. We used levobupivacaine in concentration of 0.125% and added 1.5 mg/kg of tramadol. Effects on analgesia after increasing the levobupivacaine concentration or dose of tramadol can be further observed. In addition, the efficacy of tramadol, once additional analgesia has been used in the early post-operative period, can be further studied.

CONCLUSION

A combination of 1.5 mg/kg of tramadol and 0.125% levobupivacaine-administered caudally provided long-lasting analgesia without any adverse effects following inguinal hernia surgery.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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