

## Efficacy of Local Infiltration of Tramadol and Bupivacaine for Postoperative Analgesia in Children Following Herniotomy: Randomized Control Trial

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### ABSTRACT



**Background:** Inguinal herniotomy is a common surgical procedure in children. Wound infiltration of local anesthetics during the procedure is a standard technique for post-operative analgesia. Recently, tramadol is shown to be effective analgesic if used locally also. This study was conducted to compare the post-operative pain after local infiltration of bupivacaine and tramadol.

**Methods:** This study was a double blinded randomized controlled trial conducted at pediatric surgery unit of Tribhuvan University Teaching Hospital, Institute of Medicine, Kathmandu, Nepal. A total of 76 children were operated for inguinal hernia during the study period and sixteen children were excluded. Remaining 60 children were randomized into 2 groups: tramadol (T group) and bupivacaine (B group). T group received tramadol and B group received bupivacaine as local wound infiltration at the time of herniotomy. Post - operative pain was evaluated by 'Modified pain score for children'. Pain score and other variables were compared between the groups.

**Results:** A total of 60 children were randomized into T and B group. Demographic data was comparable. Pain free interval in T group was  $7.43 \pm 4.41$  hours and B group was  $6.70 \pm 2.46$  hours. It was statistical not significant ( $P=0.42$ ). Pain score at 1, 4, 8, 12 and 24 hours was also similar in the two groups.

**Conclusion:** Local infiltration of Tramadol is as effective as Bupivacaine for postoperative analgesia in children undergoing herniotomy. Tramadol can be used as local infiltration for effective post - operative analgesia.

**Keywords:** Pediatric herniotomy, Tramadol, Bupivacaine, Post - operative pain

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## INTRODUCTION

Inguinal hernia is a common surgical problem of children and early surgery is indicated to prevent serious complication of strangulation. Inguinal herniotomy in children is a day care surgical procedure. Effective post-operative analgesia is essential to ensure safe discharge from hospital. Inadequate analgesia not only increases morbidity but also delays hospital discharge. There are multiple approaches of analgesia in current practice. These include non-steroidal anti-inflammatory drugs through oral, injectable or rectal route and administration of local anesthetics through local infiltration, nerve block and caudal block.<sup>1-3</sup> Lignocaine and bupivacaine are good local anesthetic agents for various procedures for a long time. Apart from these local anesthetic agents, opioids are known for locally acting anesthetics if used locally alone or in combination with local anesthetic agents. Tramadol is a weak opioid commonly used for post-operative analgesia. It also has local anesthetic action on peripheral nerves.<sup>4</sup>

Demiraran et al showed that tramadol has effective local anesthesia when used locally by infiltration in children following herniotomy.<sup>5</sup> Though uncommon, lignocaine and bupivacaine may have severe side effects neurotoxicity, cardiac arrhythmias and hypersensitivity. Tramadol provides a better alternative to traditional local anesthetic drugs. Being a weak opioid, it has fewer side effects than other strong opioids. This study was conducted to compare the post-operative pain after local infiltration of bupivacaine and tramadol. Post-operative pain was assessed using modified pain score.<sup>6</sup>

## MATERIALS AND METHODS

This study was a prospective double blinded randomized control trial. It was conducted at pediatric surgery unit of Tribhuvan University teaching Hospital, Maharajgunj, Kathmandu over a period of one year. The sample size was determined by using the formula for comparison of two means. Significance level as 0.05, power of study as 80% and clinical significance as 3 was taken for sample size calculation. Sample size in each arm was 30. Consecutive patients during the period were taken for study till the desired number of patients reached. Operating surgeon and resident surgeon who evaluated pain were blinded. Anesthesiologist prepared the medicine and it was given to surgeon. Approval for conducting the study was taken from Institutional Review Board of Institution of Medicine (Ref: 92(6-11-E)2/071/072). Informed consent was taken from parents. All children between 2 to 11 years undergoing inguinal herniotomy were included in this study. Exclusion criteria were bilateral inguinal herniotomy, redo herniotomy and any additional procedures that may increase pain. All children were randomized into 2 groups, Tramadol (T group) and Bupivacaine (B group) by computer generated randomization. Each group consisted of 30 patients.

Induction of general anesthesia was done by injection propofol (2-3mg/kg) and injection Fentanyl (1µg/kg) and laryngeal mask airway insertion. Intraoperative anesthesia was maintained by sevoflurane gas. Herniotomy was performed by pediatric surgery faculty by open inguinal approach. At the end of surgery, local infiltration of tramadol or bupivacaine was done by the operating surgeon as per randomization. In T group, tramadol (2mg/kg

in 0.2 ml/kg solution) and in B group, bupivacaine (0.2 ml/kg of 0.25%) was used.

After completion of surgery, Modified pain score for children (MOPS) was assessed by pediatric surgery resident at 1, 4, 8, 12, 24 hours or if child complains of pain. Pain score more than 2 at any time after surgery was treated with 15-20 mg/kg paracetamol per rectally. All patients were discharged after 24 hours unless contraindicated. The components of MOPS are mentioned in table no. 1.<sup>6</sup>

Demographics, pain score, first analgesic requirement were analyzed and compared between the two groups. For statistical analysis, SPSS version 20 was used. P value less than 0.05 was taken as statistical difference.

Table 1: Components of modified pain score

Criteria	Findings	Points
Crying	None	0
	Consolable	1
	Not Consolable	2
Movement	None	0
	Restless	1
	Thrashing	2
Agitation	Asleep	0
	Calm	0
	Mild	1
Posture	Hysterical	2
	Normal	0
	Flexed	1
Verbal	Holds injury site	2
	Asleep	0
	No complaint	0
	Complains but cannot localize	1
	Complains and localize	2

Minimum score – 0; Maximum score – 10

## RESULTS

During study period, a total of 76 children with inguinal hernia were operated. Among them, 60 were enrolled in the study. The reason for exclusion were bilateral herniotomy, redo herniotomy and release of prepuceal adhesion. They were randomly divided into two groups i.e. T and B group with 30 in each group. T group received tramadol local infiltration and B group received bupivacaine local infiltration at incision site. Mean age of patient was  $6.01 \pm 2.06$  years, with Male: female ratio 5:1. The age, sex, body weight, duration of surgery and anesthesia were comparable in both groups (Table 2)

Three patients have one episode of vomiting in each group. No other immediate complications eg drug reaction, hemorrhage, fever, respiratory distress were noted.

Table 2: Demographics in T and B group

Characteristics	T Group (n=30)	B Group (n=30)	P Value
Age (mean $\pm$ SD) in years	5.8 $\pm$ 2.1	6.23 $\pm$ 3.1	0.52
Sex (M:F)	13:02	4:01	0.48
Body weight (mean $\pm$ SD) in kg	18.9 $\pm$ 5.9	19.8 $\pm$ 8.2	0.64
Surgery duration (mean $\pm$ SD) in mins	28.2 $\pm$ 4.1	27.8 $\pm$ 5.1	0.78
Anesthesia duration (mean $\pm$ SD) in mins	40.2 $\pm$ 4.1	39.8 $\pm$ 5.0	0.71
Immediate post op complications	3	3	

Overall pain score in all patients was less. Mean pain score at 1,4,8,12 and 24 hours was similar in both T and B groups as shown in table 3.

Table 3: Pain score at different time interval

Pain score at	T group (n=30) (Mean $\pm$ SD )	B group (n=30) (Mean $\pm$ SD )	p-value
1hr	0.53 $\pm$ 0.50	0.70 $\pm$ 0.75	0.31
4 hrs	0.97 $\pm$ 1.12	0.83 $\pm$ 1.08	0.64
8 hrs	0.57 $\pm$ 1.03	0.60 $\pm$ 1.07	0.9
12 hrs	0.17 $\pm$ 0.37	0.27 $\pm$ 0.78	0.53
24 hrs	0.20 $\pm$ 0.61	0.10 $\pm$ 0.30	0.42

First rescue analgesia was required in 5 patients in T group and 2 patients in B group within 4 hours. All children needed rescue analgesia within 24 hours. Number of patients requiring first analgesia within 1, 4, 8, 12 and 24 hours is mentioned in table 4. There was no difference in T and B group.

Table 4: Need of first rescue analgesia in time interval in two groups

Post operative time for rescue analgesia (hrs.)	T group (N=30)	B group (N=30)	p value
within 1 hr	0	0	-
1 - 4 hrs	5	2	0.42
4 - 8 hrs	15	21	0.18
8 - 12 hrs	6	4	0.72
12 - 24 hrs	4	3	0.99

Pain free interval in T group was  $7.43 \pm 4.41$  hours and B group was  $6.70 \pm 2.46$  hours. It was statistical not significant ( $P=0.42$ ).

## DISCUSSION

Post - operative analgesia is one of the utmost important parts of pediatric surgical practice. The current modalities of practices are systemic analgesia through oral, intravenous or rectal route as well as use of local anesthetics. Use of local anesthesia at the time of surgery ensures analgesia right from the recovery period. Recent studies suggest that tramadol provides sufficient and effective

analgesia if used locally also.<sup>7-10</sup> It has advantage over bupivacaine that tramadol has no hypersensitivity and cardiovascular compromise.<sup>10,11</sup>

In this study, pain free interval was slightly more in T group ( $7.43 \pm 4.41$  hours) than in B group ( $6.7 \pm 2.46$  hours), but it was not statistically significant. Different studies from the different parts of world showed longer effect of tramadol over lidocaine / bupivacaine.<sup>12-14</sup> Demiraran et al showed that tramadol has significantly longer duration of analgesia than bupivacaine.<sup>5</sup> They recommended it as good choice of analgesia. Pain score at different time interval was also significantly lower than bupivacaine. The present study showed no difference of pain score at different time interval. Gereck et al showed that tramadol proved effective analgesia and may have anti-inflammatory effect also.<sup>10</sup> Caudal tramadol was compared with caudal morphine to study quality and duration of pain relief in a study by Ozcengiz D et al. There was no difference in post - operative analgesia in this group.<sup>15</sup>

The analgesic effect of tramadol, when used locally, is shown by different authors and different types of surgery. Sahmeddini et al, Sachidananda et al showed local infiltration of tramadol or addition of tramadol in bupivacaine gives effective pain relief after Caesarian section. It increases patient satisfaction without significant complications.<sup>16,17</sup> Robaux et al demonstrated that addition of tramadol in mepivacaine for brachial plexus block extends the duration and quality of post - operative analgesia.<sup>8</sup> Another study by Ahmed SR showed, local infiltration of tramadol with bupivacaine provided effective

analgesia and less post-operative opiate requirement after lumbar disc surgery.<sup>18</sup> The additive effect of tramadol when uses with bupivacaine is similar as that seen in other opiates like morphine and pethidine.

Table no 5 showed the time of pain free interval in different studies. The present study showed prolonged analgesia with tramadol, but failed to show statistical difference. Kaki AM et al and Malik AI et al also demonstrated better post - operative analgesia of tramadol than bupivacaine in adult population.<sup>19, 20</sup>

Table 5: Comparison of Pain free interval in two groups among various studies.

Studies	Sample size	Bupivacaine	Tramadol	P- value	Side-effects
Demiraran et al <sup>5</sup>	75	6.04 ± 3.7	6.72 ± 4.09	< 0.05	Not seen
Lone AQ et al <sup>21</sup>	75	-	-	-	Vomiting (T= 6, B= 2)
Kaki AM et al <sup>19</sup>	43	3.70 ± 0.74	6.60 ± 0.99	< 0.05	Not seen
Malik AI et al <sup>20</sup>	60	8.20 ± 2.94	11.60 ± 3.49	< 0.05	Not seen
Numanoglu KV et al <sup>14</sup>	52	-	-	NS	Not seen
Our study	60	6.70 ± 2.46	7.43 ± 4.41	0.42	Vomiting (T= 3, B= 3)

T= Tramadol group, B= Bupivacaine group, NS= Not significant

The safety of tramadol is well established. It may have respiratory distress or vomiting if used intravenously or oral. As it is local infiltration and much lower dose than usual intravenous dose, fewer side effects are expected. In this study, no patient had respiratory problem. Three patients had post - operative vomiting in each group. So the cause of vomiting as tramadol could not be ascertained. Other studies also did not demonstrated serious side effects except vomiting.

## REFERENCES

1. Splinter WM, Reid CW, Roberts DJ, Bass J. Reducing Pain after Inguinal Hernia Repair in Children Caudal Anesthesia versus Ketorolac Tromethamine. *Anesthesiology*. 1997;87(3):542-6. [\[Google Scholar\]](#) [\[Pub Med\]](#)
2. Splinter WM, Bass J, Komocar L. Regional anaesthesia for hernia repair in children: local vs

## CONCLUSION

Local infiltration of Tramadol is as effective as Bupivacaine for postoperative analgesia in children undergoing herniotomy. If Bupivacaine cannot be used as local infiltration in some patients, Tramadol infiltration is best alternative for post-operative analgesia in children.

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- caudal anaesthesia. *Canadian journal of anaesthesia*. 1995;42(3):197-200. [\[Cross Ref\]](#) [\[Google Scholar\]](#) [\[Pub Med\]](#)
3. Schindler M, Swann M, Crawford M. A comparison of postoperative analgesia provided by wound infiltration or caudal analgesia.

- Anaesthesia and intensive care* 1991;19(1):46-9. [\[Cross Ref\]](#) [\[Google Scholar\]](#) [\[Pub Med\]](#)
4. Pang WW, Huang PY, Chang DP, Huang MH. The peripheral analgesic effect of tramadol in reducing propofol injection pain: a comparison with lidocaine. *Regional Anesthesia and Pain Medicine*. 1999;24(3):246-9. [\[Cross Ref\]](#) [\[Google Scholar\]](#) [\[Pub Med\]](#)
5. Demiraran Y, Ilce Z, Kocaman B, Bozkurt P. Does tramadol wound infiltration offer an advantage over bupivacaine for postoperative analgesia in children following herniotomy? *Pediatric Anesthesia*. 2006;16(10):1047-50. [\[Cross Ref\]](#) [\[Google Scholar\]](#) [\[Pub Med\]](#)
6. Wilson GA, Doyle E. Validation of three paediatric pain scores for use by parents. *Anaesthesia*. 1996;51(11):1005-7. [\[Cross Ref\]](#) [\[Google Scholar\]](#) [\[Pub Med\]](#)
7. Acalovschi I, Cristea T, Margarit S, Gavrus R. Tramadol added to lidocaine for intravenous regional anesthesia. *Anesthesia & Analgesia*. 2001;92(1):209-14. [\[Cross Ref\]](#) [\[Google Scholar\]](#) [\[Pub Med\]](#)
8. Robaux S, Blunt C, Viel E, Cuvillon P, Nouguier P, Dautel G et al. Tramadol added to 1.5% mepivacaine for axillary brachial plexus block improves postoperative analgesia dose-dependently. *Anesthesia & Analgesia*. 2004;98(4):1172-7. [\[Cross Ref\]](#) [\[Google Scholar\]](#) [\[Pub Med\]](#)
9. Hashemi K, Middleton MD. Subcutaneous bupivacaine for postoperative analgesia after herniorrhaphy. *Annals of the Royal College of Surgeons of England*. 1983;65(1):38-9. [\[Pub Med\]](#) [\[Full Text\]](#)
10. Gerçek A, Eti Z, Göğüş FY, Sav A. The analgesic and anti-inflammatory effects of subcutaneous bupivacaine, morphine and tramadol in rats. *Agri. The journal of the Turkish Society of Algology*. 2004;16(3):53-8. [\[Google Scholar\]](#) [\[Pub Med\]](#)
11. Guven M, Mert T, Gunay I. Effects of tramadol on nerve action potentials in rat: comparisons with benzocaine and lidocaine. *International journal of neuroscience*. 2005;115(3):339-49. [\[Cross Ref\]](#) [\[Google Scholar\]](#) [\[Pub Med\]](#)
12. Altunkaya H, Ozer Y, Kargi E, Ozkocak I, Hosnuter M, Demirel CB, et al. The postoperative analgesic effect of tramadol when used as subcutaneous local anesthetic. *Anesthesia & Analgesia*. 2004;99(5):1461-4. [\[Cross Ref\]](#) [\[Google Scholar\]](#) [\[Pub Med\]](#)
13. Iqbal A, Liaqat N, Dar SH. Comparison of Local Infiltration of Bupivacaine and Tramadol in Post-Operative Pain Management in Children after Inguinal Herniotomy. *Iranian Journal of Pediatric Surgery*. 2018;4(2):54-60. [\[Cross Ref\]](#) [\[Full Text\]](#)
14. Numanoğlu KV, Ayoğlu H, Er DT. Efficacy of tramadol as a preincisional infiltration anesthetic in children undergoing inguinal hernia repair: a prospective randomized study. *Therapeutics and clinical risk management*. 2014;10:753-8. [\[Cross Ref\]](#) [\[Google Scholar\]](#) [\[Pub Med\]](#)
15. Ozcengiz D, Gunduz M, Ozbek H, Isik G. Comparison of caudal morphine and tramadol for postoperative pain control in children undergoing inguinal herniorrhaphy. *Paediatric Anesthesia*. 2001;11(4):459-64. [\[Cross Ref\]](#) [\[Google Scholar\]](#) [\[Pub Med\]](#)
16. Sahmeddini MA, Azemati S, Motlagh EM. Local infiltration of tramadol versus bupivacaine for post cesarean section pain control: a double-blind randomized study. *Iranian journal of medical sciences*. 2017;42(3):235-41. [\[Google Scholar\]](#) [\[Pub Med\]](#) [\[Full Text\]](#)
17. Sachidananda R, Joshi V, Shaikh SI, Umesh G, Mrudula T, Marutheesh M. Comparison of analgesic efficacy of wound infiltration with bupivacaine versus mixture of bupivacaine and tramadol for postoperative pain relief in caesarean section under spinal anaesthesia: A double-blind randomized trial. *Journal of Obstetric Anaesthesia and Critical Care*. 2017;7(2):85-9. [\[Cross Ref\]](#) [\[Full Text\]](#)
18. Ahmed SR, Dowidar AE, Al Zeftawy AA, SN SM, Mostafa AD, Al Sayed AA, et al. A comparative study on the analgesic effect of tramadol or magnesium sulfate added to bupivacaine infiltration for postoperative pain management after lumbar disk surgeries. *Tanta Medical Journal*.

2018;46(3):203-9. [\[Cross Ref\]](#) [\[Google Scholar\]](#) [\[Full Text\]](#)

19. Kaki AM, Al Marakbi W. Post-herniorrhaphy infiltration of tramadol versus bupivacaine for postoperative pain relief: a randomized study. *Annals of Saudi medicine*. 2008;28(3):165-8. [\[Cross Ref\]](#) [\[Google Scholar\]](#) [\[Pub Med\]](#)

20. Malik AI, Sheikh IA, Qasmi SA, Adnan A. Comparison of tramadol with bupivacaine as local anaesthetic in postoperative pain control. *Journal of Surgery Pakistan (International)*. 2011;16(1):10-3. [\[Google Scholar\]](#) [\[Full Text\]](#)

21. Lone AQ, Nazir N, Gilani S, Ommid M, Nengroo SH, Naqib A, et al. Comparative evaluation of tramadol wound infiltration over bupivacaine for postoperative analgesia in children undergoing inguinal herniotomy and orchidopexy. *SKIMS Journal of medical sciences*. 2011;14(2):52-5. [\[Cross Ref\]](#) [\[Google Scholar\]](#) [\[Link\]](#)