Original Article

Post-operative Pain Control: A Comparison between Bupivacaine and Tramadol Local Wound Infiltration in Children Undergoing Herniotomy and Orchidopexy

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Abstract

Background: Post-operative pain control improves patient's satisfaction and affects the period of admission. Local wound infiltration following hernia surgery using xylocaine or bupivacaine has been a common practice. The use of tramadol for such infiltration is relatively new and has not been studied in our environment. This study compared the efficacy of post-operative pain control between Bupivacaine and Tramadol wound infiltration in children who underwent herniotomy and orchidopexy. **Materials and Methods:** This was a prospective randomised study involving 104 patients. A simple random method was used to allocate the study group into two equal groups (A, $n = 52$ and B, $n = 52$) using sealed envelopes with contents labelled A or B. Pre- and post-operative respiratory rate, heart rate, and C-reactive protein (CRP) were all recorded. Time to first and subsequent analgesia was determined using face, legs, activity, cry, consolability (FLACC) pain score. **Results:** Fifteen patients in Group A and 18 patients in Group B received each two doses of supplemental analgesia within the first 24 h, ($P = 0.527$). Time to first analgesia was significantly different between the two groups, (6.93 ± 0.80 h and 6.11 ± 1.08 h, $P = 0.020$). The mean FLACC pain score at the time of first analgesia in hours was 4.93 ± 0.59 and 4.72 ± 0.67 for Group A and B, respectively, $P = 0.350$. The changes in CRP were not different in the two groups, ($P = 0.665$). Four patients in Group A, but none in Group B had an episode each of post-operative vomiting. **Conclusion:** Tramadol showed comparable efficacy with bupivacaine in post-operative pain control by wound infiltration in children who had unilateral herniotomy or orchidopexy. Tramadol, however, achieves a longer duration of action before rescue analgesic is required. Caution is necessary to avoid post-operative vomiting.

Keywords: Bupivacaine, C-reactive protein, pain scores, post-operative analgesia, tramadol

Introduction

Pain as currently defined by the International Association for the Study of Pain is an unpleasant sensory and emotional experience associated with, or resembling that associated with actual or potential tissue damage.[1] Post-operative pain is caused by a deliberate/or planned tissue injury (surgical trauma) aimed to bring about the treatment of a pathologic process.[2] The goal of post-operative pain management is to reduce or eliminate this unpleasant experience with the least possible side effect and maximum cost-effectiveness.[3] The use of wound infiltration with local anaesthetic agent for post-operative pain relief is an attractive method because of its simplicity, safety, and low cost. It is also known that wound infiltration with local anaesthetic agents improves post-operative wound pain, and reduces the stress response to surgery in children.[4-6] This translates to early ambulation and discharge among surgical patients.

The control of post-operative pain by infiltration of the operation site with bupivacaine is not new; however, wound infiltration with tramadol, an opioid analgesic, is relatively new. Altunkaya *et al*.[7] demonstrated that tramadol has the

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ability, when used for local wound infiltration to decrease the demand for post-operative analgesia.

Tramadol is known to be a centrally acting drug that is effective in the treatment of moderate to severe pain, but it has also been shown to have a local anaesthetic property when used subcutaneously.[7,8] Its analgesic effects are mediated by at least three different mechanisms: It is a weak μ opioid receptor agonist; it inhibits the uptake of the neurotransmitters 5-hydroxytryptamine (5cHT) and norepinephrine in the descending inhibitory pain pathways; and facilitates 5cHT release.[8-10]

The intravenous route is a known route for administering tramadol, unlike bupivacaine. Therefore, the risk of inadvertent injection into the intravascular space is not a threat as it is for bupivacaine.

It is thought that wound infiltration with tramadol may achieve better outcomes in terms of the duration of analgesia, subsequent demand for any other form of analgesic, and cost-effectiveness when compared to bupivacaine for post-operative pain control.[11]

The C-reactive protein (CRP) is a useful acute-phase protein, the concentration of which is known to rise following the stress of trauma or surgery.[12] The use of local anaesthetic agents for post-operative wound infiltration is known to attenuate the stress of trauma or surgery.[13] Therefore the measurement of the perioperative CRP levels is a useful predictor of the effects of the local anaesthetic agents on the stress response to trauma or surgery.[14]

Materials and Methods

This was a prospective randomised study which compared the efficacy of post-operative pain control between the use of tramadol and bupivacaine for wound infiltration among children who had herniotomy or orchidopexy who met the inclusion criteria over a 12-month period (November 2015 to October 2016).

All children aged from 3 months to 10 years diagnosed with any of the following pathologies: unilateral inguinal hernia, hydrocoele or undescended testis and scheduled for unilateral herniotomy or unilateral orchidopexy were included. The American Society of Anaesthesiologists (ASA) risk grouping was either ASA I or II. In our centre, these patients are admitted the day before surgery and discharged a day after surgery.

We excluded the following group of patients: Those who are outside the age bracket, those with complicated inguinal hernias or recurrent cases going for re-operation or children for bilateral herniotomy or orchidopexy. We also excluded children with known allergy to tramadol or those with systemic disease such as neurological, neuromuscular, psychiatric disease, developmental impairment or clotting impairment or children whose parents or caregivers did not give consent.

The institutions Research and Ethics committee approval was obtained before the study was commenced. We also obtained written informed consent from the parents of the participants as well as assent from the older children before we commenced the study.

The sample size was calculated using the formula for comparison of two groups. The outcome of the proportion of patient that did not require analgesic from the first 1 h to 24 h post-operation, based on the previous similar study, was used.[15] In that study, 19.2% and 46.2% from Group A and B, respectively, did not require analgesic.

$$n' = \frac{2(Z\alpha + Z\beta)^2 \; x \; P(1-P)}{\left(P_B - P_A\right)^2}$$

where n' = Number of subject in one sample

$Z\alpha$ = 1.96 (95% confidence level; from statistical table)

$Z\beta$ = 0.842 (statistical power of 80%; from the statistical table)

P_B = 46.2% (proportion of target population not requiring analgesic in 24 h)

P_A = 19.2% (proportion of target population not requiring analgesic in 24 h)

P = The overall proportion not requiring analgesic in 24 h i.e., $([P_B + P_A] \div 2) = 32.7\%$

$(P_B - P_A)$ = The difference in the proportion

Therefore $n' = \frac{2x\left(1.960 + 0.842\right)^2 \; x \; 0.327 \; (\; 1 - 0.327)}{(0.462 - 0.192)^2} = 47$

That is a group will contain approximately 47 patients

Sample size: n' = 2n' = 2 × 47 = 94

Assuming 90% (0.90) of patients initially included will complete the study

Actual number n = 94/0.9 = 104 (i.e., 52 patients in each group)

The study population was randomly allocated into two groups by simple random sampling. Sealed envelopes, with content labelled as either Group A or B, were used, and balloting done for five consecutive sets of twenty sealed envelopes (ten 'Group A' and ten 'Group B') for the first one hundred patients, and the last group contained four sealed envelopes, (two 'Group A', and two 'Group B') to make up a total of one hundred and four patients.

Anaesthesia

This was uniformly done for all patients in both study groups. Each patient was pre-medicated with intravenous atropine at 0.02 mg/kg. Induction was with halothane via a face mask at 0.75–1.0 minimum alveolar concentration (MAC), while maintenance was with isoflurane at 1.3–1.5 MAC via a Laryngeal mask airway using a semi-closed circuit. This was tapered towards the end of surgery and completely turned off at wound dressing. Oxygen was delivered at 5–7 L/min throughout the period of anaesthesia and continued until child was fully conscious. Each child had a single dose of intravenous paracetamol at 15 mg/kg body weight and a single intravenous dose of ketorolac at 0.5 mg/kg body weight.

Most of the surgeries were performed by the first author assisted by a senior registrar or registrar in paediatric surgery department of our institution.

The bupivacaine or tramadol for infiltration was constituted by the anaesthetist on the list. The dose used was 2 mg/kg for either agents, this was diluted with 5 ml of sterile water and infiltrated into the subcutaneous plane just after the last sub-cuticular stitch was placed. During the infiltration, initial withdrawal was done to avoid intravascular injection of the agent. Group A, had 2 mg/kg tramadol diluted with 5 ml of sterile water to have sufficient volume for infiltration. Group B had 2 mg/kg of 0.5% plain bupivacaine diluted with 5 ml of sterile water, to have sufficient volume for infiltration. Both groups had the constituted agent infiltrated into the groin wound for herniotomy. However, for orchidopexy, 4/5th was infiltrated into the groin wound and 1/5th of the solution into the scrotal wound. The wounds were gently cleaned with cetrimide and methylated spirit and sterile dressing applied. The face, legs, activity, cry, consolability (FLACC) scoring system was used to assess for pain. The FLACC uses items similar to CHEOPS but with a readily understood 0–10 metric, low burden, and excellent inter-rater reliability.[16-18] The comparative assessment and scoring included hourly post-operative vital signs and FLACC pain score. These were carried out by the unit registrar who was blinded to the groups, for the first 8 h post-operation. This was followed by 4 h vital signs and FLACC pain score assessment till the 24th h post-operation, the following day. This was carried out by both the unit registrar and the unit nurses who were both blinded to the groups. Blood samples for serum CRP were collected pre-operation at presentation for surgery and 8 h post-operation. The time of administering the first post-operative analgesic and the total number of analgesic doses given over the 24 h post-operative period were also recorded.

The registrar and unit nurses that assessed the vital signs and pain scores were trained before commencing the study to reduce the inter-observer bias. They also documented the observed complication/s. Intravenous paracetamol at a dose of 15 mg/kg/dose was used as our rescue analgesic within the first 3 h post-operation, while oral paracetamol at a dose of 15 mg/kg was used as analgesic when needed from the 4th h to the 24th h post-operation. The analgesic was given when the FLACC score was 4 or more.

Patients were moved to the recovery room, where they were observed and assessed. The first assessment was done 1 h after full recovery from anaesthesia. Then patients were transferred to the paediatric surgery ward. On the ward, patients were observed and assessed till the 24th h post-operation. Patients were monitored for complication/s post-operatively. Any patient with two or more episodes of vomiting would have intravenous promethazine at 0.3 mg/kg. All patients were discharged home on oral paracetamol 15 mg/kg 6 h to last for 4 days 24 h after surgery. The patients were reviewed at the clinic on the 4th day following surgery. Presence of wound complications were noted, and documented.

Data collection and analysis

A structured proforma was used to collect data from the time of presentation for surgery, in the theatre recovery room and within the first 24 h post-operative period in the ward and on the 4th post-operation day or first clinic visit. In addition to the demographics, respiratory rate (RR), heart rate (HR), CRP value, FLACC pain scores, analgesic given and time it was given, total number of analgesic doses administered and observed complications were all documented.

International Business Machine-Statistical Package for Social Sciences IBM SPSS statistic 21 manufactured in Chicago, Illinois USA was used for data entry and analysis. Data was expressed as percentages, means and standard deviations (SD). Tables, bar charts and graphs were also used to represent variables and outcomes. Chi-square was used for categorical variables and *t*-test used for continuous variables to test for statistical significance. $P < 0.05$ were considered statistically significant at 95% confidence interval.

Results

A total of 104 patients were recruited and evaluated. There was no drop out. Ninety-eight were males and 6 were females. Seventy-seven (75.4%) patients in both Groups A and B were aged 5 years and below, while 27 (24.6%) were aged 6–10 years. Each group had 52 patients. In Group A, 46 (88.5%) were males and 6 (11.5%) were females, while all the 52 (100%) patients in Group B were males. There were 35 (67.3%) and 42 (80.8%) in Group A and B respectively aged 5 years and below. The mean age ± SD of patients in Group A and B were 3.92 ± 3.07 and 3.00 ± 2.70 years respectively, ($P = 0.108$) [Table 1].

Total number of participants with hernia in each group was 42 (80.8%) and 41 (78.8%) for Group A and B, respectively.

Table 1: Socio-demographic characteristics and diagnosis of study groups ($n=52$)

Variables	Tramadol (%)	Bupivacaine (%)	Test/*P*
Age (years), mean±SD	3.92±3.07	3.00±2.70	
5 and less	35 (67.3)	42 (80.8)	t=1.622/0.108
6–10	17 (32.7)	10 (19.2)	
Sex			
Male	46 (88.5)	52 (100)	χ^2=1.560/0.69
Female	6 (11.5)	0	
Total	52 (100)	52 (100)	
Diagnosis			
Right hernia	25 (48.1)	27 (51.9)	
Left hernia	17 (32.7)	14 (26.9)	
Right undescended testes	5 (9.6)	3 (5.8)	
Left undescended testes	5 (9.6)	8 (15.4)	
Total	52 (100)	52 (100)	

SD: Standard deviation

Those with right inguinal hernia were 25 (48.1%) and 27 (51.9%), respectively, for Group A and B, while those with left hernia were 17 (32.7%) and 14 (26.9%) for Group A and B, respectively. The total number of patients with undescended testes in each group was 10 (19.2%) and 11 (21.2%) for Group A and B, respectively; 5 (9.6%) and 3 (5.8%) patients, respectively, had right undescended testes in Group A and B, respectively, while 5 (9.6%) and 8 (15.4%) had left undescended testes also in Group A and B, respectively [Table 1].

The anthropometric and pre-operation physiologic characteristics of patients in both groups are shown in Table 2. The mean and SD of weight are 17.42 ± 9.90 and 15.54 ± 9.13 in Group A and B respectively. The mean and SD of the RR and HR are as shown in Table 2.

The mean and SD for the duration of surgery were 43.56 ± 10.68 and 40.48 ± 11.08 for Group A and B respectively. The range for Group A was 40 min (25–65) and Group B, 50 min (20–70). (P = 0.152) [Figure 1].

Respiratory and heart rate

The mean and SD of the post-operative lowest and highest RRs were 22.69 ± 3.47 and 29.58 ± 4.23 for Group A. Those for Group B were 23.31 ± 3.14 and 30.04 ± 3.93 respectively, (P = 0.001) [Table 3]. However, the mean and SD of the change in RR for patients in Group A and B were 6.88 ± 2.22 and 6.65 ± 2.53 respectively, (P = 0.622) [Table 2].

The mean and SD of the post-operative lowest and highest HRs in Group A were 97.58 ± 11.76 and 109.08 ± 12.81 respectively, and Group B had 94.88 ± 8.95 and 105.15 ± 10.02 respectively, (P = 0.001) [Table 3]. The mean and SD of the change in HR for patients in Group A and B were 11.31 ± 5.74 and 10.27 ± 4.10 respectively, (P = 0.291) [Table 2].

Supplementary analgesic use and face, legs, activity, cry, consolability pain score

Of the 52 patients in each group, 15 patients from Group A and 18 patients from Group B, who had FLACC pain scores that were greater than or equal to 4 received supplementary analgesic within the first 24 h post-operation, P = 0.527 [Figure 2]. The mean and SD of the number of supplementary analgesic used in Group A and B were 0.58 ± 0.92 and 0.69 ± 0.92 respectively, P = 0.532 [Table 4]. Each of the patients, who were given analgesics in Group A and B, equally had two doses of analgesics within the first 24 h post-operation.

First supplementary analgesic was given within 6–8 h in Group A and 5–8 h in Group B. The mean and the SD of the time (in hours) first analgesic was given were 6.93 ± 0.80 and 6.11 ± 1.08 for Group A and B respectively, (P = 0.020). The mean and SD of the FLACC pain score at the time of administration of the first analgesic were 4.93 ± 0.59 and 4.72 ± 0.67 for Group A and B respectively, (P = 0.350) [Table 4].

Table 2: Mean values of weight, physiologic indices and their changes during surgery

Variables	Mean ± SD		*t*-test	*P*
	Tramadol	Bupivacaine		
Weight (kg)	17.42±9.90	15.54±9.13	1.009	0.315 (NS)
PCV (%)	34.29±3.42	34.25±3.60	0.056	0.956 (NS)
RR (c/m)	22.81±3.39	23.27±3.17	−0.717	0.475 (NS)
HR (b/m)	96.58±16.10	95.04±9.14	0.599	0.550 (NS)
Change in RR	6.88±2.22	6.65±2.53	0.495	0.622 (NS)
Change in HR	11.31±5.74	10.27±4.10	1.062	0.291 (NS)
Change in CRP	2.02±1.28	2.12±0.96	−0.434	0.665 (NS)

PCV: Packed cell volume, RR: Respiratory rate, HR: Heart rate, CRP: C-reactive protein, SD: Standard deviation, NS: Not significance

Table 3: Lowest and highest post-operative physiological characteristics of the two groups

	Mean ± SD		*t*-test	*P*
	Lowest	Highest		
RR				
Group A	22.69±3.47	29.58±4.23	−9.065	<0.001
Group B	23.31±3.14	30.04±3.93	−9.647	<0.001
HR				
Group A	97.58±11.76	109.08±12.81	−4.770	<0.001
Group B	94.88±8.95	105.15±10.02	−5.512	<0.001

SD: Standard deviation, RR: Respiratory rate, HR: Heart rate

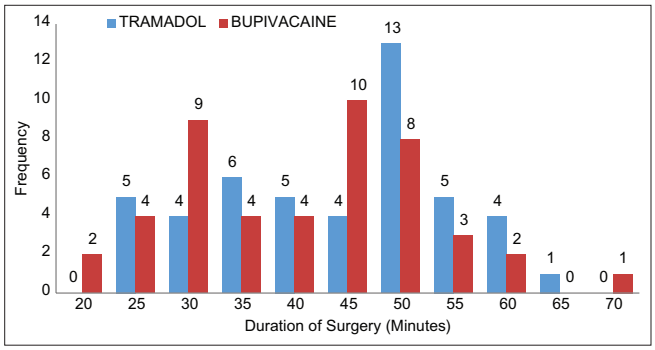


Figure 1: Duration of surgery in both groups. Mean ± SD tramadol = 43.56 ± 10.68; bupivacaine = 40.48 ± 11.08. *t*-test = 1.442; P = 0.152 (NS). SD: Standard deviation, NS: Not significance

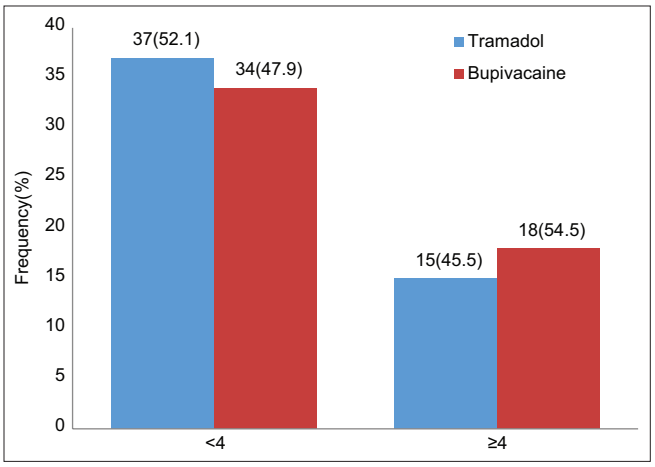


Figure 2: FLACC pain scores in the two groups. χ^2 = 0.399 and P = 0.527, mean ± SD: ≥4, tramadol = 4.93 ± 0.59; t = 0.949; P = 0.350 (NS), bupivacaine = 4.72 ± 0.67. SD: Standard deviation, NS: Not significance, FLACC: Face, legs, activity, cry, consolability

Table 4: Time and frequency of analgesic administration and face, legs, activity, cry, consolability score

Variables	Mean±SD		*t*-test	*P*
	Tramadol	Bupivacaine		
Time to 1st analgesic	6.93±0.80	6.11±1.08	2.444	0.020
FLACC score at 1st analgesic	4.93±0.59	4.72±0.67	0.949	0.350
Number of doses of analgesic	0.58±0.92	0.69±0.96	−0.627	0.532

SD: Standard deviation, FLACC: Face, legs, activity, cry, consolability

Table 5: Incidence of post-operation complications in group A and group B

	Group		Total
	Group A	Group B	
Nil	48 (92.31)	52 (100.0)	100
Vomiting	4 (7.69)	0	4
Total	52	52	104

χ^2=4.160, *P*=0.041

Values of C-reactive protein

The mean and SD of the pre-and post-operative values of the CRP among patients in Group A were 0.82 ± 0.39 and 1.43 ± 0.73. The values of the same for patients in Group B were 0.87 ± 0.50 and 1.62 ± 0.71, $P = 0.001$. However the mean and SD of the change in the values between the pre-and post-operative CRP of the patients in Group A and B were 2.02 ± 1.28 and 2.12 ± 0.96, ($P = 0.665$) [Table 2].

Post-operative complications

In Group A, 4 patients had an episode of post-operative vomiting each. All of them vomited within the first 2 h post-operation. No patient in Group B had vomiting post-operation ($P = 0.041$) [Table 5]. No other complication was noted among patients from both groups.

Wound inspection on the 4th day post-operation

The wounds were all well apposed; neither undue swelling, redness nor discharge was noted in any of the patient from both groups.

Discussion

This study found that Tramadol when used for post-operative pain control by subcutaneous wound site infiltration is of comparable efficacy with a similar use of Bupivacaine. Our findings are similar to the study by Numanoğlu *et al*.[15] who found that tramadol wound infiltration produced similar post-operative pain control as did bupivacaine wound infiltration. The average duration of surgery was similar in both groups (43.56 ± 10.68 min and 40.48 ± 11.08 min) which is also similar to what was found by Numanoğlu *et al*.[15] Cekic *et al*.[19] found that tramadol provided a longer duration of analgesia than levobupivacaine in their study. It is our finding that there was no statistically significant difference in total duration of action between the groups; however, Tramadol provided a longer period of analgesia before the need for rescue analgesia suggesting a longer duration of action than bupivacaine.

Respiratory and heart rates

There were significant differences between the pre-and post-operation mean values for both respiratory and HRs in both groups during the first 24 h post-operative period ($P = 0.001$). However, for both RR and HR, when the mean change in Group A was compared with the mean change in Group B, the difference was not significant ($P = 0.622$). This seems to suggest that the use of both agents have similar attenuating effects on the metabolic response to surgical trauma. This is similar to findings in previous studies suggesting that the use of local anaesthetic agents for post-operative wound pain control results in significantly reduced metabolic response to trauma and surgery.[4,15] This means shorter hospital stay, early mobilisation and ultimately early discharge home.

Use of supplementary analgesic and face, legs, activity, cry, consolability pain score

This study shows that wound infiltration with either tramadol or bupivacaine significantly improves post-operative pain control among paediatric surgical patients after herniotomy or orchidopexy. Out of the 52 patients in each group, only 15 and 18 patients from Group A and B, respectively, required supplementary analgesics within the first 24 h after surgery which was not significant ($P = 0.527$). This is in keeping with previous studies in which local wound infiltration with local anaesthetic agents caused significant prolongation of pain relief.[20,21] In the study by Numanoğlu *et al*.,[15] there were 26 children in each group, aged 2–7 years that had herniotomy; 14 (53.85%) and 22 (84.62%) patients from tramadol and bupivacaine group respectively required analgesic during the first 24 h after surgery. This is higher than 15 (28.85%) versus 18 (34.62%) obtained in our study. Though there were fewer patients in the tramadol group who required analgesic within the first 24 h post-operative period in our study, the difference between both groups was not statistically significant.

Time to first analgesia was significantly different between the two groups in favour of tramadol (6.93 ± 0.80 vs. 6.11 ± 1.08, $P = 0.020$). This suggests that tramadol provides longer duration of analgesia before the first rescue analgesic was required. This is similar to findings by Niyirera *et al*.[22] who also found tramadol better than bupivacaine when used for post-operative wound infilteration in terms of time to first rescue analgesic as well as duration of analgesia.

There was also no significant difference ($P = 0.350$) in the FLACC pain scores between the groups when the first analgesic was given which seems to suggest that both tramadol and bupivacaine have similar potency when used for wound infiltration in post-operative pain control.

C-reactive protein values

Although the values of serum CRP significantly increased after surgery in both groups, however, when the change in Group A was compared with the change in Group B, the difference was not significant ($P = 0.05$). This again suggests that both

agents have similar effects on the metabolic response of the patients to surgical trauma. The study by Cnar *et al*.[4] showed a comparative decrease in the stress response to surgery in children when compared with those that did not have wound infiltration with an anaesthetic agent. However, in this study, there was no control group that did not receive any local wound infiltration agent for comparison.

Post-operative complications

Four children vomited within 2 h post-operative period, and were continued on intravenous fluid for 2–4 h post-operative period. None of these patients required further treatments. Although this is a known complication from the use of tramadol as noted in other studies,[23,24] it may have occurred due to inadvertent intravascular injection of the Tramadol. A more meticulous attention to technique ensuring the syringe plunger is withdrawn at intervals could avert this. However, this complication is expected to be milder than what occurs with the systemic use of tramadol such as through intravenous, intramuscular or oral routes.[25,26] This correlates well with the expected higher peak serum tramadol concentration achieved through these routes.[19] This effect may further be reduced by using a lower dose of tramadol per kilogram body weight. There was no observed post-operative vomiting or any other complication in the bupivacaine group. However, in a number of previous studies.[7,15,19] there was no significant difference in the occurrence of post-operative vomiting between the groups compared.

Conclusion

This study shows that post-operative wound infiltration with tramadol after herniotomy or orchidopexy is effective for post-operative pain management among paediatric patients. Tramadol achieves longer period of pain control before the need for rescue analgesia than bupivacaine; however, it should be used with caution to avoid post-operative vomiting.

Limitation

There was no control group who had neither Tramadol nor bupivacaine. This will be necessary to standardise the results and better assess outcomes. Further study including a control group should be designed for further evaluation of the efficacy of the agents.

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Conflicts of interest

There are no conflicts of interest.

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