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Postoperative analgesia after wound infiltration of Tramadol as an adjuvant to Ropivacaine and Ropivacaine alone in Paediatric ambulatory surgery

Khaleel Ahmad Najar[1], Aftab Ahmad Khan[2], Rukhsana Najeeb[3]

[1](Senior Resident Department of anaesthesia, Government Medical College Srinagar (J&K), India)
[2](Ex Associate Professor, Department of anaesthesia, Government Medical College Srinagar (J&K), India)
[3] (Professor and Head, Department of anaesthesia, Government Medical College Srinagar (J&K), India)

ABSTRACT
BACKGROUND AND AIM: Infiltration of longer acting local anaesthetics around the surgical wound offers the advantages of simplicity and low cost and has been an important component of multimodal analgesia in recent years. We designed this prospective study to determine the efficacy and duration of postoperative analgesia by wound infiltration of tramadol as an adjuvant to Ropivacaine in Comparison to Ropivacaine alone in children undergoing ambulatory surgery.
METHODS : Children of ASA I–II (age group 1 to 7 years) and scheduled to undergo unilateral inguinal hernia and undescended testis surgery were included in the study. Patients were randomized to receive either 2 mg/kg of tramadol wound infiltration (Group A), 0.2 mL/kg of 0.2% Ropivacaine (Group B), and 0.2 mL/kg of a combination of tramadol (2 mg/kg) and Ropivacaine (0.2%). Post-operative pain was assessed using the FACES pain scale at 1 h, 4 h, 8 h, 12 h and 24 h. Total rescue analgesia required, time to first rescue analgesia and Side effects were also recorded.
RESULTS : Patients in group C recorded lowest average pain score (2.96±1.71), heart rate and respiratory rate compared to Group A (4.01±1.98) and group B (5.26±1.59) during the 24 hour postoperative period (P <0.05). Average rescue analgesic requirement was less and time to first rescue analgesia was longer in group C (16.5±5.9) than Group A (9.78±3.82) and Group B (4.57±2.67) (P<0.5). The incidence of postoperative nausea and vomiting was higher in group A (P >0.05).
CONCLUSION: we conclude that wound infiltration of Tramadol as an adjuvant to Ropivacaine provides significantly better and prolonged postoperative analgesia than Ropivacaine or Tramadol alone in children undergoing ambulatory surgery.
KEYWORDS
Tramadol, Ropivacaine, ambulatory surgery, postoperative analgesia, prospective, children

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I. Introduction

Standardized approaches for postoperative nausea/vomiting and pain control are both important factors to be optimized in outpatient children undergoing minor surgical procedures. Local anaesthetics administered either by neuraxial techniques, peripheral nerve blocks, or local infiltration provide excellent pain control, fewer opioid side effects and faster recovery. Tramadol has been demonstrated to have local analgesic like effects in children . Besides being a weak synthetic opioid, tramadol inhibits the reuptake of monoaminergic neurotransmitters (5-hydroxytryptamine and noradrenaline) and has a local anaesthetic–like action on peripheral nerves similar to lidocaine 1% . The addition of tramadol to local anaesthetics in peripheral nerve block prolongs the duration of the analgesia and has an analgesic effect similar to levobupivacaine when injected subcutaneously.[1]

As infiltration of the surgical wound with local anaesthetics and adjuvants remains an important part of multimodal analgesia in the management of postoperative pain in children, thus we aimed to compare efficacy and duration of postoperative analgesia provided by wound infiltration of tramadol as an adjuvant to Ropivacaine and Ropivacaine alone in children undergoing various ambulatory surgical procedures.

II. Methods

After obtaining approval from local Ethical Committee and informed written consent from the parents/guardian of the children, the study was undertaken at a teritiary care institution. In this prospective, single blinded, randomised study, 84 children aged 1 to 7 years (ASA-I and II) and undergoing elective

unilateral inguinal hernia repair and undescended testis surgery, were selected for this study. Randomisation was done by computer generated simple random allocation and only participants (patients) were blinded as to which group they belong.

Exclusion criteria were Patients allergic to any of the study drugs (Ropivacaine or Tramadol), Patients with known neurological, neuromuscular psychiatric diseases, Patients with known clotting disorders and Patients with bilateral or recurrent hernia

All the patients selected for the study, were admitted at least 24 hours prior to surgery. Pre-anaesthetic check-up was done at that stage. A thorough history including history of any comorbid disease, pre-anaesthetic exposure, medication intake and allergy to any drug was also elicited.

General physical examination as well as systemic examination of cardiovascular system, respiratory system and central nervous system was performed. Airway assessment was done to predict the airway status of the patient. Minimum basic investigations were advised. The patients were advised to remain fasting as per guidelines gor paediatric patients prior to surgery.

Patients were randomly assigned to three groups as below, in whom wound infiltration was done at the end of surgery.

1. Group A: Incisional infiltration with 2 mg/kg tramadol as 0.2 mL/kg. total volume
2. Group B: Incisional infiltration 0.2% Ropivacaine as 0.2 mL/kg. total volume
3. Group C: Incisional infiltration with Ropivacaine (0.2%) and Tramadol (2mg/kg) as 0.2 ml/kg total volume.

After recording preoperative baseline Heart Rate, Blood Pressure and SPO2 , intravenous access was established using 20/22G cannula. Standard General Anaesthesia included Inj. fentanyl (1 µg/kg body wt.) as Premeditation followed by intravenous induction with Inj. Thiopentone sodium (2-3 mg/kg body wt.) in all the patients. LMA of appropriate size was placed after giving Inj. Atracurium (0.5 mg/kg body wt.) as muscle relaxant and anaesthesia was maintained with Halothane (0.2-0.6%) in a mixture of N2O/O2 (50:50). All the patients were ventilated to normocapnia. Standard intraoperative monitoring included ECG, NIBP, HR, EtCO2 and SPO2. Ringers lactate was used for replacement and maintenance fluid as per standard guidelines of perioperative fluid administration. At the end of surgery, just before skin closure, infiltration of the surgical wound was performed by the surgeon in all the patients. Residual neuromuscular block was reversed and LMA was removed. Patients were shifted to PACU for assessment of pain scores and other vital parameters. Children were discharged from PACU to surgical ward when they achieved a modified Aldrete score of 9.

Postoperative pain was assessed using Faces Pain Scale . Pain scores were recorded at 1, 4, 8, 12 and 24 hours postoperatively. Patients with pain score of ≥4 received paracetamol (20 mg/kg body wt.) rectal suppository as rescue analgesia. Heart rate and Respiratory rate were recorded at similar intervals.[2] The incidence of PONV, pruritus, local allergic reaction, total rescue analgesic consumption and time to first rescue analgesia was also recorded.

The recorded data was compiled and entered in a spreadsheet (Microsoft Excel) and then exported to data editor of SPSS Version 20.0 (SPSS Inc., Chicago, Illinois, USA). Statistical software SPSS (version 20.0) and Microsoft Excel were used to carry out the statistical analysis of data. Continuous variables were expressed as Mean±SD and categorical variables were summarized as percentages. Analysis of variance (ANOVA) was employed for inter group analysis of data and for multiple comparisons, least significant difference (LSD) test was applied. Chi-square test or Fisher's exact test, whichever appropriate, was used for comparison of categorical variables. Graphically the data was presented by bar and line diagrams. A P-value of less than 0.05 was considered statistically significant. All P-values were two tailed.

Using GPOWER software (Version 3.0.10), it was estimated that the least number of patients required in each group with 80% power and 5% significance level is 28. Since we have to compare three groups in our study, thus we have included 84 patients in our study without any dropouts reported.

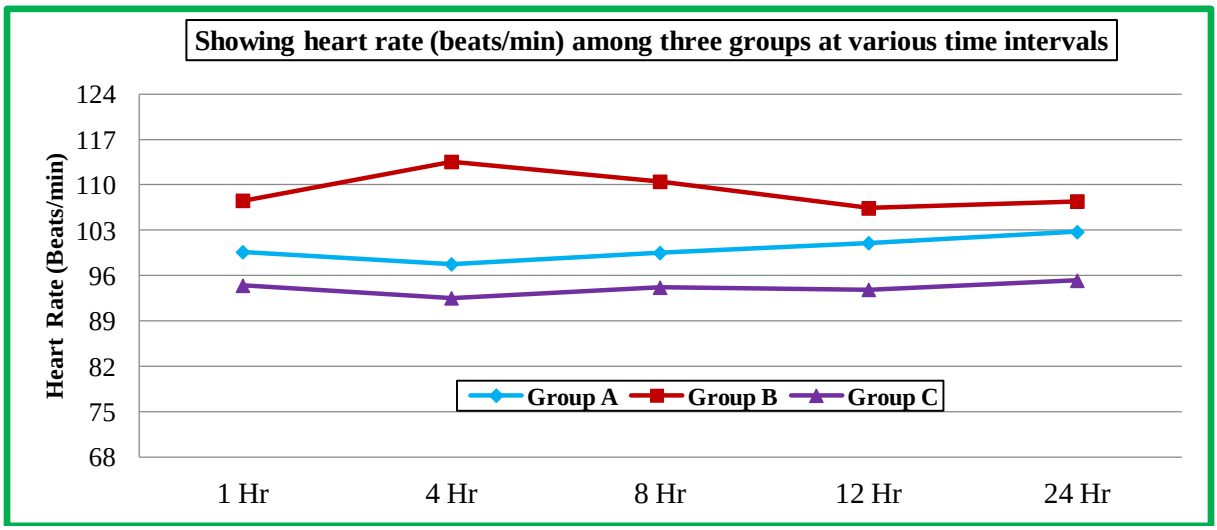
III. Results

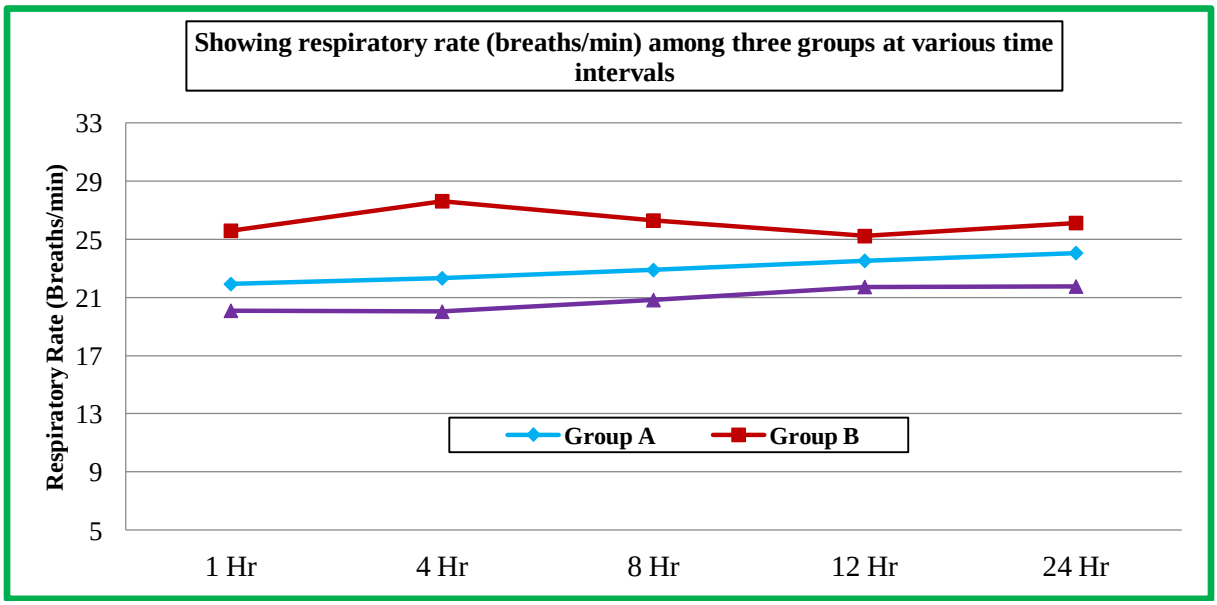
There was no significant difference among the studied groups as regards demographic characteristics and duration of surgery (P>0.05).(Table 1)

Table 1: Demographic profile of study patients

Parameter	Group A	Group B	Group C	P-value
Age (Years)	3.34±1.53	3.51±2.17	3.45±1.87	0.943
Weight (Kg)	15.89±2.97	16.57±3.12	16.41±2.76	0.667
Duration of Surgery (Minutes)	49.2±3.78	48.7±3.25	48.9±2.91	0.853

Physiologic indicators of pain I,e heart rate and respiratory rates were lower in group C than group A and group B throughout the 24 hour postoperative period as shown (Figure 1 & 2 respectively).





Analysis of pain scores in the three groups reveals patients in group C felt less pain as compared to group A and group B at 1st hour , 4th hour ,8th hour , 12th hour and at 24th hours of the postoperative period. Further, intergroup comparison of pain scores (A vs B, A vs C, B vs C) at various time intervals was statistically significant (P value of <0.05). (Table 2)

Table 2: Comparison of Pain Score at different time intervals

Time Interval	Group A	Group B	Group C	P-value A vs B	A vs C	B vs C
1 Hr	1.94±1.51	2.89±1.97	1.21±0.94	0.047*	0.034*	<0.001*
4 Hrs	2.64±1.94	3.97±2.03	1.63±1.75	0.015*	0.045*	<0.001*
8 Hrs	3.31±2.09	5.39±2.16	1.87±1.52	<0.001*	0.005*	<0.001*
12 Hrs	4.19±1.65	4.94±1.78	2.68±1.93	0.107	0.003*	<0.001*
24 Hrs	4.05±1.98	5.26±1.59	2.96±1.71	0.015*	0.032*	<0.001*

Average rescue analgesia consumption was lowest in Group C (only 5 patients at 12th hour and 3 patients at 24th hours) as compared to Group A (1 patient at 1st hour, 3 patients at 4th hour, 8 patients at 8th hour, 15 patients at 12th hour and 10 patients at 24th hour) and Group B (7 patients at 1st hour, 10 patients at 4th hour, 16 patients at 8th hour,13 patients at 12th hour and 14 patients at 24th hour). However, the difference was statistically insignificant at 1 and 4 hours between Group A and C and at 12 and 24 hours between Group A and B (P value of >0.05). (Table 3)

Table 3: Percentage of patients requiring postoperative rescue analgesia at various time intervals

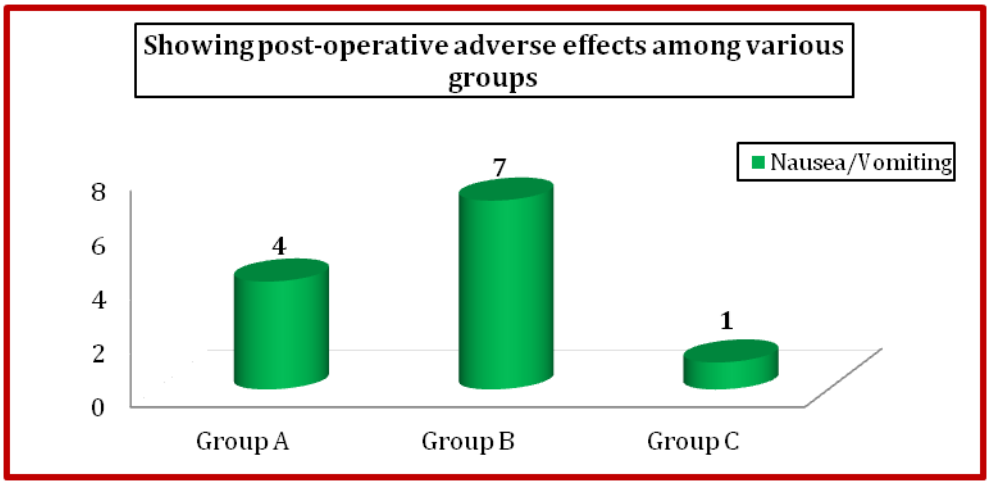
Time Interval	Group A	Group B	Group C	P-value		
				A vs B	A vs C	B vs C
1 Hr	1 (3.6%)	7 (25%)	0 (0%)	0.021*	1.000	0.010*
4 Hrs	3 (10.7%)	10 (35.7%)	0 (0%)	0.027*	0.236	<0.001*
8 Hrs	8 (28.6%)	16 (57.1%)	0 (0%)	0.031*	0.004*	<0.001*
12 Hrs	15 (53.6%)	13 (46.4%)	5 (17.9%)	0.593	0.005*	0.022*
24 Hrs	10 (35.7%)	14 (50%)	3 (10.7%)	0.281	0.027*	0.002*

Time to first Rescue analgesia was longer in Group C (16.5±5.9) followed by Group A (9.78±3.82) and Group B (4.57±2.67). Intergroup difference (A vs B, B vs C and A vs C) was significant (P value of <0.05) (Table 4)

Table 4: Time to first rescue analgesic (hours) in various groups

Group	Mean	SD	Comparison	P-value
Group A	9.78	3.82	A vs B	<0.001*
Group B	4.57	2.67	B vs C	<0.001*
Group C	16.51	5.95	A vs C	<0.001*

Comparison of side effects among the three groups was statistically insignificant. Seven patients in Group A, four patients in Group B and only one patient in Group C had postoperative nausea and vomiting (0.075). None of the patients in Group A, B or C had any local reaction (P value of 1.000). (Figure 3)



IV. Discussion

Several past studies have shown that pain following ambulatory surgery in children is poorly managed. In a study by Hegarty , approximately 40% of the children experienced moderate to severe pain. Nearly one-third reported moderate to severe pain at home after orchidopexy or herniotomy . In another study by finish et al, 36% of children were assessed as having moderate to severe postoperative pain after discharge and Shum et al found pain scores were significantly higher at home compared to in-hospital care.[3]

The most commonly performed ambulatory surgeries in children include inguinal hernia repair with or without orchidopexy.[4] For postoperative pain with these surgeries, a regional analgesic modality such as caudal analgesia (CA), inguinal and iliohypogastric nerve block (INB), or local infiltration (INF) is combined with a general anaesthetic (GA). When compared to intravenous (IV) opioids, regional techniques reduce the risk of side effects such as somnolence, respiratory depression, emesis, and ileus.[5] Caudal block (CB) involves the introduction of local anaesthetic (LA) into the caudal epidural space. It requires the child to be positioned appropriately and is a common practice to administer under deep sedation or a GA. However, it can cause complications such as needle trauma, infection, haematoma, and inadvertent subarachnoid or intravascular injection of the LA.[6] Other adverse effects include urinary retention and possible motor blockade. Inguinal nerve blocks including ilioinguinal and iliohypogastric nerve blocks can provide effective ipsilateral analgesia. Local infiltration of the wound can be done by the anaesthesiologist or the surgeon. This potentially effective, but minimally invasive procedure could offer the advantage of lower costs, time, and risks.[7]

We designed this prospective study to compare the analgesic efficacy of local wound infiltration of Tramadol added to Ropivacaine and Ropivacaine alone for management of postoperative pain following Inguinal hernia repair and undescended testis surgery in pediatric patients.

Bahanur Cekıc et al (2013)[8] carried out a similar retrospective study of 80 (ASA I-II) children between the ages of 1-6 divided in two groups. Group T was given 2mg.kg-1 tramadol in saline solution prepared as 0.2 ml.kg-1 into the surgical wound and Group L who were given 0.25% levobupivacaine as 0.2 ml.kg-1. Hemodynamic data, CHEOPS pain score, additional analgesic consumption, adverse effects were recorded from the files. Patients' CHEOPS were significantly higher in Group L compared to Group T at 4 and 6 hours ($p<0.01$). In respect to supplementary analgesic administration, paracetamol consumption in Group T was lower than in Group L during home period ($p<0.05$). They concluded wound infiltration of tramadol provided longer-lasting analgesia compared to levobupivacaine in children undergoing unilateral inguinal hernia repair and undescended testis surgery, and that the requirement for additional analgesic was lower.

Fu-Sheng W. Et al (2017)[9] studied the effect of ropivacaine combined with dexamethasone local infiltration on the pain level and inflammatory stress response after pediatric tonsillectomy. A total of 84 children who underwent selective tonsillectomy were divided into two groups; combined group received ropivacaine combined with dexamethasone local infiltration, and control group accepted ropivacaine local infiltration anesthesia. Serum levels of pain mediators, inflammatory mediators and stress mediators were detected 6 h, 12 h and 24 h after surgery. They concluded that Ropivacaine combined with dexamethasone local infiltration provide more durable and superior pain relief than ropivacaine local infiltration alone and hence, reduce the inflammatory stress response after pediatric tonsillectomy.

Yukitoshi Niiyama et al (2016)[10] studied continuous wound infiltration (CWI) of 0.2% Ropivacaine with a single a single shot 0.75% intercostal nerve block (ICNB) for postoperative pain after costal cartilage graft harvest in children. Forty-eight patients were randomly divided into two groups of 24 each. In Group I, a single ICNB with 10 ml of 0.75% ropivacaine was performed at the end of surgery. In Group C, a catheter was inserted into the space between the abdominal external oblique muscle and the rectus abdominis muscle. Then, a 0.4-ml/kg bolus of 0.2% ropivacaine was administered, followed by continuous infusion at 2–4 ml/h for 48 hours. They concluded that CWI of 0.2% ropivacaine is a better and safe technique for postoperative pain management after costal cartilage graft harvest in children.

In our study, patients who received wound infiltration with Tramadol as an adjuvant to 0.2% Ropivacaine group (C) recorded significantly lower pain scores, heart rate and Respiratory rate than Tramadol alone (A) and 0.2% Ropivacaine (B) alone groups. Average 24 hour postoperative pain scores were 2.96±1.71, 4.05±1.98 and 5.26±1.59 in Group C, A and B respectively. Except at 12 hours between groups A and B, Intergroup Comparison of pain scores was statistically significant ($P<0.5$).

Average rescue analgesia consumption was significantly less in Tramadol added to Ropivacaine group (C) than Tramadol alone (A) and Ropivacaine alone groups (B). Also, time to first Rescue analgesia requirement was longer in Tramadol added to Ropivacaine group (16.5±5.9) followed by Tramadol alone (9.78±3.82) and Ropivacine alone groups (4.57±2.67).

Patients in tramadol alone group (A) recorded higher incidence of postoperative nausea and vomiting (7 patients) than Ropivacaine alone group (4 patients) and the combination group (only 1 patient) . However, the difference was statistically insignificant ($P>0.5$) . None of the patients in either group had any local reaction .

V. Conclusion

In conclusion, we observed that wound infiltration of tramadol as an adjuvant to Ropivacaine improves the quality and duration of postoperative analgesia compared to Ropivacaine alone in children undergoing inguinal hernia repair and undescended testis surgery, and that the requirement for rescue analgesic was lower.

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