

Evaluation of Tramadol Wound Infiltration and Ropivacaine for Postoperative Analgesia in Children Undergoing Inguinal Herniotomy.

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Abstract

BACKGROUND: Recent studies have demonstrated that children experience a similar severity of post operative pain as adults.

OBJECTIVE: To study the advantage of tramadol wound infiltration over ropivacaine for post-operative pain relief in children following inguinal herniotomy.

METHODS: In this prospective single blinded randomized controlled study, 75 children aged between 1-7 year undergoing elective repair of unilateral inguinal hernia were randomly divided into three groups of 25 each Group A Tramadol wound infiltration with 2mg/kg tramadol in 0.2 ml/kg saline Group B Ropivacaine a wound infiltration 0.2 ml/kg Group C tramadol 2 mg/kg intramuscularly twenty minutes before end of surgery. Children were assessed post anesthesia for pain score.

CONCLUSION: Wound infiltration with tramadol is a good choice for post operative analgesia in children undergoing inguinal herniotomy.

Keywords: Tramadol, Post-operative analgesia, Ropivacaine, herniotomy.

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I. Introduction

International Association for study of Pain defined pain as an “unpleasant sensation & an emotionally charged experience associated with actual or potential tissue damage or described in terms of such damage. Recent clinical studies have demonstrated that children experience a similar severity of post operative pain as adults and that even preterm infants demonstrate alterations in heart rate, blood pressure and oxygen saturation in response to pain. The subjectivity and multidimensional nature of pain requires clinicians to approach pain assessment using a combination of child’s verbal report in conjunction with observation and psychological measures. The optimal methods to achieve analgesia after inguinal hernia repair in children are not clear. Techniques include: administration of opioids, NSAIDs, peripheral nerve blocks, caudal block and wound infiltration with local agents. Studies have shown that instillation of local anesthetics into a wound provides post-operative pain relief following hernia repair which is as effective as that provided by a post-operative caudal block. Several clinical studies have shown that Tramadol might have peripheral local anesthetic like properties. Various observations of behavior techniques are useful for pain assessment in children as Facies Score, Modified Children’s Hospital of Eastern Ontario Pain Scale (m- CHEOPS), Visual analogue scale, Observer pain scale etc. In children, anesthetist can assess child’s mood on a scale of 1 to 5 in the anesthesia room immediately before induction as Mood Grades (Cheerful Apprehensive & Cooperative, Tearful and cooperative, Uncooperative, Terrified and virtually un-manageable).

II. Methods

The prospective single blinded randomized controlled study looking at the advantage of tramadol wound infiltration and ropivacaine post operative pain relief in children aged 1-7 years following inguinal herniotomy included 75 children who were divided randomly into 3 groups of 25 each as group A (Tramadol) in whom wound infiltration with 2 mg/kg tramadol in 0.2ml/Kg saline was done by the surgeon, Group B in whom wound infiltration with 0.2ml/kg Ropivacaine by the surgeon and Group C (Tramadol i/m) 2mg/kg tamadol injected intra muscular 20 minutes before the end of surgery. A standardized anaesthesia technique was carried out in all the patients with mandatory monitoring. Before the end of surgery, local infiltration into the region of surgical incision was performed by the surgeon. Children were reversed, extubated and assessed in Post

Anesthesia Care Unit by nurses who were unaware of the group assignment. Pulse rate, respiratory rate and pain score were assessed using FACIES pain score.

Patients with pain score > 4 received 20mg/kg paracetamol rectally. Children were discharged from Post Anesthesia Care unit when they achieved recovery score of 10. The frequency of vomiting, pruritus, local allergic reaction and analgesic used were also recorded. The pain scores at 1, 4, 8, 12 and 24 hours were noted. Age, weight, duration of Surgery, duration of GA, First analgesic requirement and average pain scores were compared with ANOVA (one way analysis of variance). All data were collected and comparison between groups was expressed as arithmetic mean (mean ± SD) and analyzed using standard statistical tests and inferences were drawn accordingly.

III. Results

The mean age (years) of patients was 3.4 ± 1.4 , 3.7 ± 1.1 and 3.9 ± 1.4 in groups A, B, C respectively (Table 1). The weights of all children ranged from 8-24Kg, the average weight (mean ± S.D.) in Kg was 15.8 ± 3.1 , 15.2 ± 2.9 , and 16.3 ± 3.1 in groups A, B, C respectively, being statistically insignificant on comparison. ($p = 0.421$).

	Max	Min	Mean ± S.D	p value(inter group)			
Age (years)	A	7	1	3.4 ± 1.4	A&B	0.430	0.364(not significant)
	B	6	1	3.7 ± 1.1	A&C	0.158	
	C	7	2	3.9 ± 1.4	B&C	0.528	
Weight (kg)	A	22	10	15.8 ± 3.1	A&B	0.453	0.42(not significant)
	B	20	8	15.2 ± 2.9	A&C	0.573	
	C	24	11	16.3 ± 3.1	B&C	0.100	

TABLE 1. Distribution of Age & Weight

Mean Respiratory Rate (breaths/min); At 1 hour it was 22.0 ± 8.2 , $27.5 \pm$ and 26.6 ± 3.1 in groups A, B and C respectively Intergroup comparison revealed a statistically significant ($p = 0.00$) difference in respiratory rates between groups A and B but not significant between groups B and C. Similarly at 4,8,12 and 24 hour intervals the respiratory rates recorded were 20.2 ± 2.0 , 28.3 ± 4.0 and 27.5 ± 2.7 at 4 hour, 20.5 ± 2.7 , 25.8 ± 3.5 , and 25.3 ± 3.2 at 8 hour, 19.6 ± 2.5 , 26.7 ± 1.6 and 24.3 ± 3.4 at 12 hour and 19.3 ± 1.6 , 26.1 ± 3.9 , 27.2 ± 4.0 at 24 hour interval in groups A, B and C respectively. The statistical difference was significant ($P = 0.000$) when groups A & B and A & C were compared at these intervals but insignificant ($p = 0.376$, 0.596 , 0.012 , 0.852) when compared between Groups B and C at 4,8,12 and 24 hour intervals respectively (Fig. 1).

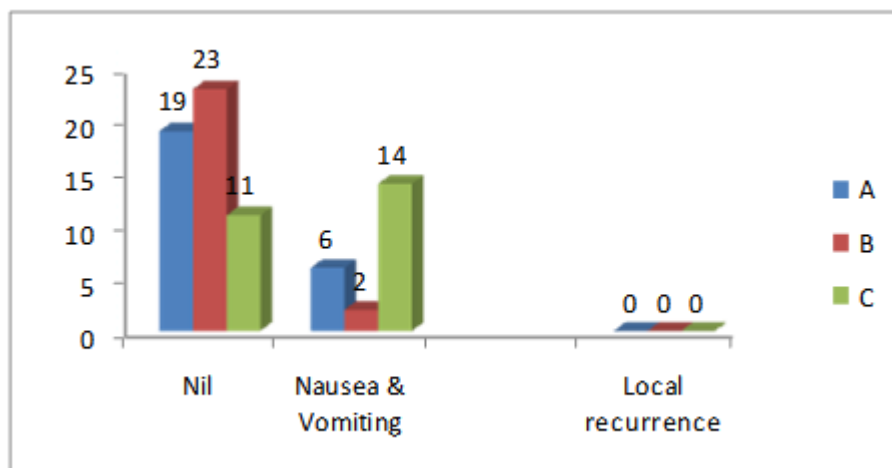


FIGURE 1: Graph showing postoperative complications in the three groups

Mean Pulse Rate: Pulse rate (beats/min) shared almost a similar trend as respiratory rate at different study stages. At 1 hour postoperatively the rate was at its minimum in group A (97.7 ± 8.8) compared to group B (110.4 ± 10.7) and group C (110.8 ± 11.1), showing a statistically significant ($p = 0.000$) difference between Group A & B, but non-significant between B & C ($p = 0.912$). Similarly the recorded pulse rates were 95.5 ± 5.0 , 111.6 ± 11.6 and 111.1 ± 11.4 at 4 hours; 94.6 ± 6.2 , 107.2 ± 10.3 and 108.0 ± 8.6 at 8 hours and 92.8 ± 5.1 , 106.2 ± 9.2 and 106 ± 8.6 bpm at 12 hour interval in groups A, B & C respectively

The statistical difference was significant ($p = 0.000$) when groups A & B and A & C were compared at these intervals but insignificant ($p = 0.852$, 0.767 , 0.760) when compared between Groups B and C. The pulse rates at 24 hour interval were 91.6 ± 4.2 , 105.1 ± 10.2 and 110.8 ± 9.2 showing a significant difference between

A & B ($p=0.000$) and A&C ($p=0.000$) and between B & C (0.021).

Pain SCORE: As shown in figure 2, the pain score at 1 hour post operatively was minimum in group A (1.4 ± 0.3) compared to group B (4.7 ± 0.3) and Group C (6.1 ± 0.4), the difference being significant between Groups A & B (0.000), A&C (0.000), and B & C (0.005). On comparing the pain score at 4 hours, it was lowest in group A (2.0 ± 0.2), B (5.8 ± 0.3) and C (6.6 ± 0.4) being significant ($p=0.000$) between A & B and A&C, but insignificant between B & C ($p=0.061$), significant difference ($p=0.000$) between A & B and A&C and between A&C ($p=0.001$) were observed between the groups at 8 hour interval with values of $1.9 \pm 0.2, 5.7 \pm 0.3$ and 7.1 ± 0.3 in groups A, B and C respectively Scores at 12 hour were $2.4 \pm 0.3, 6.2 \pm 0.3$ and 6.7 ± 0.3 in A B and C respectively, being significant ($p=0.000$) between A & B and A&C only. Comparing pain score at 24 hour showed lowest values in group A (2.2 ± 0.3), then group B (6.2 ± 0.3) and group C (7.2 ± 0.4) with significant

($p=0.000$) difference between A & B and A&C only.

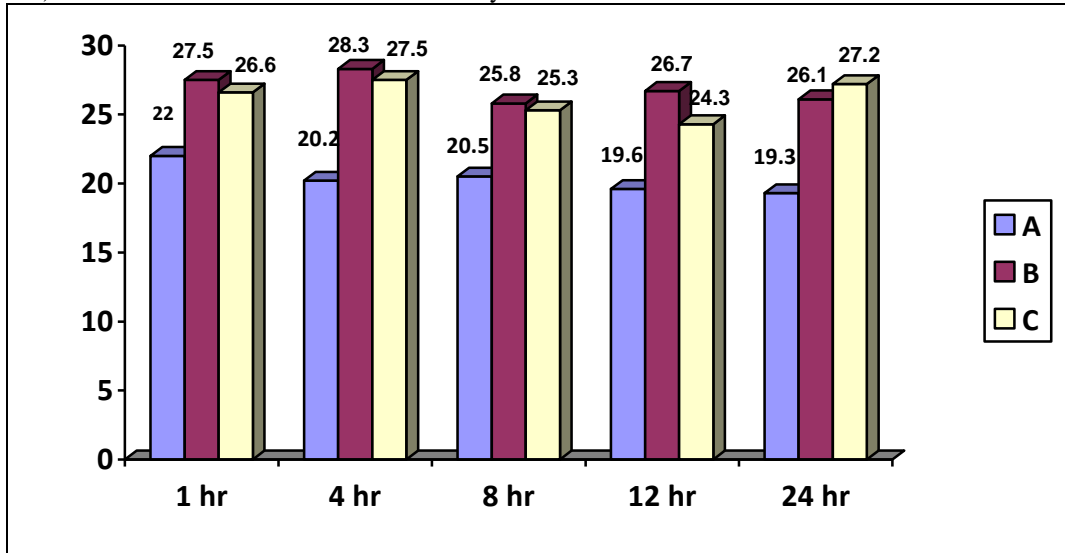


FIGURE 2: Graph showing distribution of mean respiratory rates between three groups

Post OPERATIVE COMPLICATIONS: 6 (24%) children in group A, 2 (8%) in group B and 14 (56%) children in group C had nausea/vomiting. No child had any local reaction. Comparing the postoperative complications among all 3 groups A & B, A & C and B & C, no significant variation ($p > 0.05$) was observed. Overall 53 (70.6%) children in our study did not develop any postoperative complication. (Fig. 3)

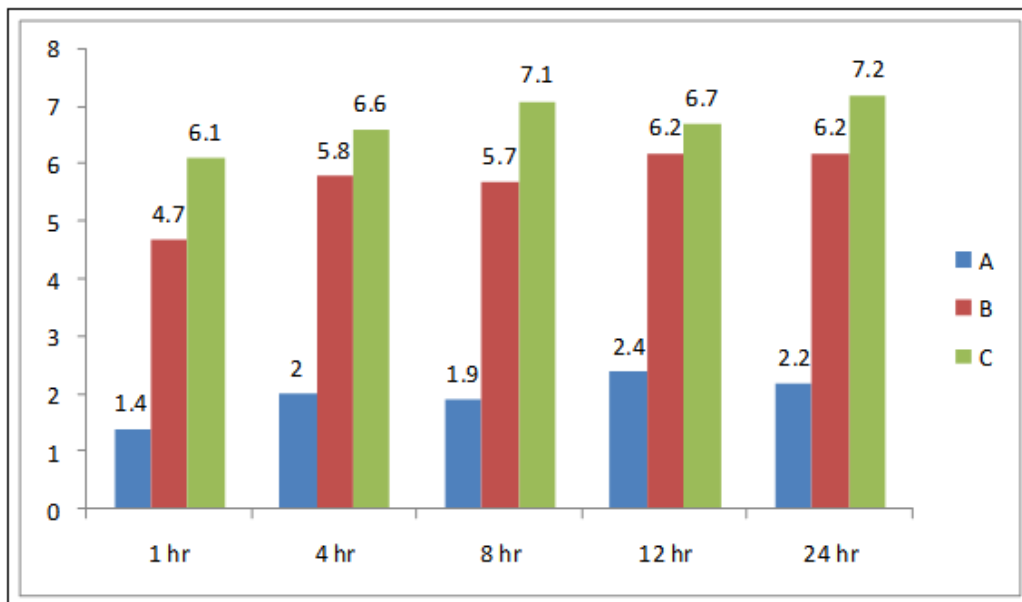


FIGURE 3: Graph showing distribution of mean pain score between three groups

Post operative Analgesia requirement

In the first hour, inter group comparison revealed statistically significant difference ($p = 0.049$) of analgesic requirement between A&C, but insignificant between groups A & B and B & C. Further comparison revealed significant differences in fourth hour between A & B (0.001), and A&C (0.032); at eight hour between A & B (0.049), at 12th hour between groups A & B (0.049) and group B & C (0.020). At 24 hours postoperatively, none of the children in any of the three groups required any form of rescue analgesic. The overall requirement of rescue analgesia was lowest in Group A. However, the difference was statistically significant at fourth hour ($p = 0.003$) and 12 hour ($p = 0.005$).

IV. Discussion

Acute pain is one of the most common experiences a child will have as a result of injury, illness or medical procedures. The pediatric experience of acute pain involves the interaction of physiological, psychological, behavioral, developmental and situational factors. Recent clinical studies have demonstrated that children experience a similar severity of post operative pain as adults and that even preterm infants demonstrate alterations in heart rate, blood pressure and oxygen saturation in response to pain.

Currently available post operative pain management modalities for children are oral preparations, rectal preparations, parenteral preparations & regional blocks. Studies have shown that instillation of local anesthetic into a wound provides postoperative pain relief following hernia repair which is as effective as that provided by a post-operative caudal block.

The effect of infiltration is short lived but may be increased by the insertion of catheter into or near the wound. Opioids provide good pain relief particularly in severe pain. However their use is restricted because of potential side effect. Nevertheless the use of local anesthetic agents may also avoid many of the potential problems associated with opioids. Various observations of behavior techniques useful for pain assessment in children include: FACIES SCORE - Smiley test (Facial expression of pain score), suitable for pre-school children, where child is asked to select from a series of pictures of facial expression ranging from laughter to crying & choose the one that depicts how he or she feels now⁷ Others include m-CHEOPS (Modified Children's Hospital of Eastern Ontario Pain Scale), Visual Analogue Scale, Observer Pain Scale etc.

Tramadol is a typical centrally acting opioid producing antinociceptive and analgesic effects through spinal and supraspinal sites. However, several clinical studies have shown that it might have peripheral local anesthetic type properties. Ropivacaine is an amino-amide local anesthetic used since 1963 for infiltration, peripheral nerve blocks and neuraxial blocks.

The aim of the present study was to compare the post operative analgesic effect of surgical wound infiltration of tramadol 2mg/kg body weight with wound infiltration of 0.2% Ropivacaine 2m/kg body weight 2mg/kg body weight, in children undergoing inguinal herniotomy.

The physical characteristics, age and weight were comparable in all the three groups ($p > 0.05$). In the present study, pain scores were evaluated using the FACIES pain score, and respiratory rate as well as the pulse rate were evaluated for the first hour in the post anesthesia care unit and for the next 24 hours in the pediatric surgery ward. At 1,4, and 8 hour time intervals, the comparative parameters of mean pain score, respiratory rate and pulse rate were statistically significant between group A & B and groups A&C ($p = 0.001$).

Intergroup comparison revealed a statistically significant difference ($P = 0.000$) between groups A & B and A & C at 12 hour, as regards mean pain score, respiratory rate and pulse rate. At 24 hour, mean pain score, respiratory rate and pulse rate was lowest in group A and, the difference was found to be statistically significant between the groups. The overall requirement of rescue analgesia in the form of paracetamol 20mg/kg body weight rectally was lowest in group A However the difference between the three groups was statistically significant only at the fourth hour ($p = 0.003$) and 12 hours ($P = 0.005$) postoperatively. No significant postoperative complication was found in any of the three groups. Study by Hanife Altunkaya demonstrated that tramadol infiltration has local anesthetic action and that rescue analgesic need was minimal with the use of tramadol. Gereketal¹⁰ in his study showed that subcutaneous tramadol infiltration can provide effective analgesia and may have anti-inflammatory effects. Studies by Kargi *et al* and Pang WW *et al* were similar to findings in our study with regards to quality and duration of analgesia by tramadol. The difference between some studies is with regards to local reaction. In our study none of the children had any local reaction at the surgical site. Our study showed that analgesic effect was longest in the tramadol infiltration group.

In conclusion, postoperative analgesia was significantly prolonged and fewer analgesics were required after wound infiltration with tramadol hence demonstrating that tramadol is a good choice for postoperative analgesia in children undergoing inguinal herniotomy.

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