

Post Operative Pain Control in Inguinal Hernia Repair: Comparison of Tramadol Versus Bupivacaine in Local Wound Infiltration: A Randomized Controlled Trial

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Background: Post-operative pain control is a key factor in surgery. It greatly increases patient satisfaction, and influences the hospital stay period.

Local wound infiltration has often been used to control postoperative pain following hernia surgery, with the use of the conventional local anesthetics like Lidocaine or Bupivacaine. The use of Tramadol for local wound infiltration is new and not yet practised in Rwanda. The aim of this study was to compare the postoperative pain control effects and cost effectiveness of Tramadol versus Bupivacaine in wound infiltration following inguinal hernia repair.

Methods: This was a randomized controlled trial conducted between September 2015 and February 2016. Randomization was done using a sealed envelope containing the name of drug to be used for local wound infiltrations following inguinal hernia repair.

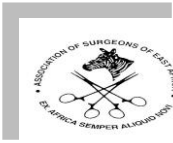
Results: A total of 52 patients were enrolled equally in the two study groups. Only one female patient enrolled in the study. Tramadol was found to be superior to Bupivacaine in providing postoperative pain control. ($P=0.000$). Pain free period was 4.7 ± 1.3 hours in Bupivacaine group while it was more than 12 hours in Tramadol group. Additional analgesia request in both groups was significantly different, in favor of Tramadol. ($P=0.000$). No complications reported in both groups. Bupivacaine was found to be 5 times more expensive than Tramadol.

Conclusion: Wound infiltration with Tramadol after open inguinal hernia repair offers a superior and prolonged pain control compared to Bupivacaine. The need of additional analgesics is very low after Tramadol wound infiltration compared to Bupivacaine used in the same conditions. In addition, Tramadol is cheaper making its use cost affordable

Key words: Postoperative pain, Wound infiltration, Tramadol, Bupivacaine/ macaine.

Introduction

Maximizing Postoperative pain control in inguinal hernia repair is essential, in order to facilitate earlier patient discharge from hospital. Inadequate analgesia during the



postoperative period may have short or long term consequences ¹. Benefits from local infiltration in the wound before closing the skin post hernia repair with Bupivacaine have been proved to be efficient in order to decrease opioids demands subcutaneously, intramuscularly or via intravenously ^{2,3}.

The local anesthetic effects of opioids have been demonstrated both in clinical and animal models ³. Even if Tramadol is a weak opioid, it has proved to be effective in pain control if used as local infiltration in the surgical wound before closing the skin ⁵. It has a selective anesthetic effect on N receptors of peripheral nerves ^{3,5}. Studies have shown that it has a longer postoperative pain control effect and less side effects compared to Bupivacaine when used as local wound infiltration ^{3, 6, 7, 8}.

Hernia repairs are among the commonest operations carried out by in general surgeons in Rwanda. Currently, the patients are hospitalized for 2-3 days postoperatively; it is believed that inadequate pain control is a contributing factor for the prolonged hospital stay. By maximizing postoperative pain control, inguinal hernia repair can be done as a day case.

Patients and Methods

This randomized controlled trial was conducted between September 2015 and February 2016. All patients who met the inclusion criteria (adult patients on appointment for elective inguinal hernia repair) and accepted to participate in the study were enrolled. Randomization was done using sealed envelopes containing the name of drug was to be used for infiltration (Tramadol or Bupivacaine). Both the patient and the researcher were blinded. Only the anesthesiologist knew the drug given as he/ she was the one to prepare it and to hand it to the surgeon, ready for infiltration.

The study was conducted in two Rwandan referral hospitals. The University teaching hospital of Butare (CHUB) in Southern province, a public referral hospital with 4 running theaters used for both elective and emergency surgeries in general surgery, orthopedics, ENT and gynecology. It has 509 beds, the surgical department occupying 26% of them. The second hospital was Rwanda military Hospital (RMH), a referral hospital located in Kigali city; it has 4 theater rooms, used for orthopedics, general surgery, gynecology, plastic surgery, urology and ENT. It currently treats 80% civilian and 20% military patients. It offers secondary and tertiary level health care services but its new strategic direction focuses on referral and teaching activities. Adult patients confirmed to have inguinal hernia that needed elective surgery (herniorrhaphy or hernioplasty) and accepted to consent for the study, were enrolled.

In the previous almost similar study⁷, the proportion of those who had not experienced pain necessitating analgesia in group A which had received Tramadol local wound infiltration post herniorrhaphy was 4/30 while in the group B which received Bupivacaine as local wound infiltration were 0/30. In this study, the sample size was calculated to be 50. But it was further increased by 5% to account for anticipated contingencies such as non-response or recording error; so it included 52 participants with 26 in each group. Randomization was

done using a sealed envelope containing the kind of drug, prepared by the researcher then given to the surgeon.

Data analysis

Analyzed variables included age, ASA classification, types of inguinal hernia, pain free period, pain severity, drug cost, and complications. The data were entered and analyzed using SPSS 16.0. Numerical variables were presented as means plus standard deviations and student "t" test was used to compare the means between two groups. All the data were calculated on 95% confidence interval. A P value <0.05 was considered as statistically significant level for all comparisons.

Results

The study was carried out from September 2015 till February 2016. It included 51 males and one female. Their ages were ranging between 16 years and 85 years. The mean age was 43.5 ± 20.5 years in the group received Bupivacaine (group B); and 41 ± 18 years in group which received Tramadol (group T). Both groups were comparable with respect to age. The study patients were mainly male (51/52), despite cumulative enrollment. This was probably due to the fact that inguinal hernias are more common in men. The inguinal hernias in this study were indirect (43 or 82%), while 9 or 18% were direct. Most of the patients in this study were in the ASA1 category (88%), while the rest were in ASA2 category. Generally, no drug side effects were observed in during this study.

We didn't calculate the mean of starting requesting adjuvant analgesia in the group with Tramadol as there was single patient who received adjuvant analgesia in that group in the study period.

Table 2. Pain severity in 2 groups at every Visit (V)

		V0	V1	V2	V3	V4	V5	V6
Bupivacaine	No pain	26	12	7	2	2	1	
	Mild		14	14	10	3	0	
	Moderate			3	6	3	1	
	Severe			2	3	6	1	
	Total	26	26	26	21	12	3	1
Tramadol	No	23	22	23	22	22	24	24
	Mild	3	4	2	3	3	1	1
	Moderate							
	Severe			1				
	Total	26	26	26	25	25	25	25

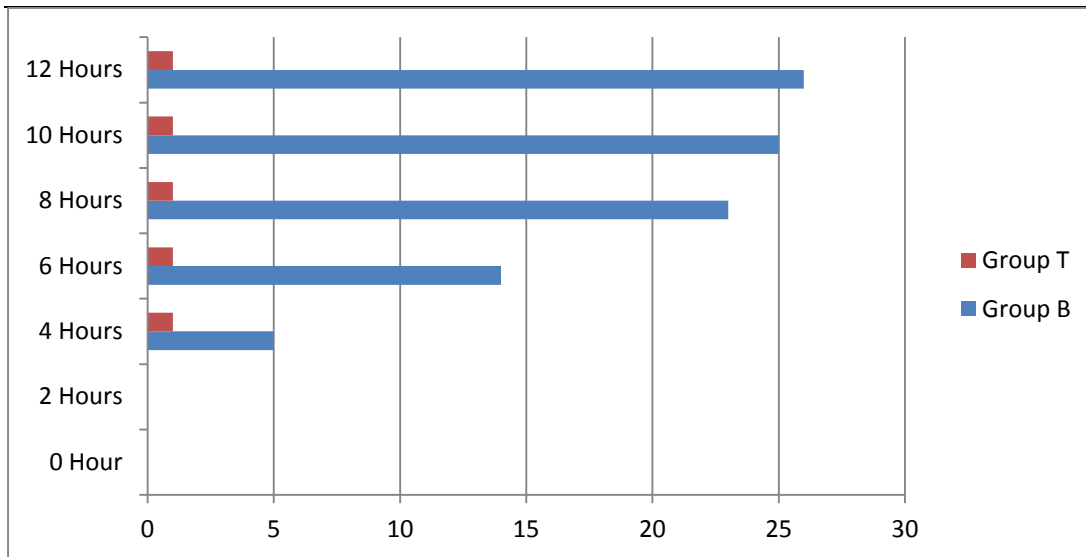


Figure 1. Adjuvant analgesia demand in both Groups

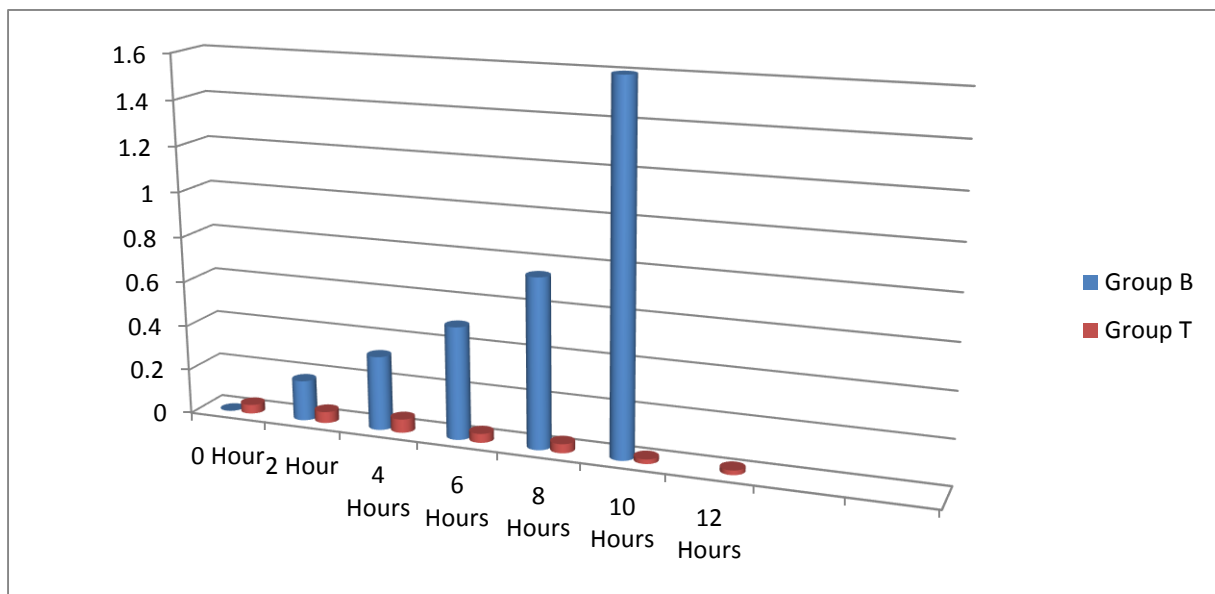


Figure 2. Post Hernia VDS Pain Score Mean After Every Two Hours in Each Group

Figure 2 shows how the pain was fluctuating in both groups. In the group which received Bupivacaine the pain was significantly increasing with time while in the group which received Tramadol the pain was not significant and was decreasing with time.

The sig (2- tailed) value is 0.000. This value is less than 0.05. Because of this, we concluded that there is a statistically significant difference between the mean of patients who received Tramadol and the mean of patients who received Bupivacaine in rescuing adjuvant analgesia. Since our group Statistics box revealed that the mean of tolerable pain in group received Tramadol was greater than the mean for tolerable pain the group which received Bupivacaine.

Table 3. Comparison of Means of Time to Rescue the First Analgesia

Independent Samples Test										
		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
Start request ing analgesics	Equal variances assumed	1.032	.315	16.262	50	.000	6.885	.423	6.034	.7735
	Equal variances not assumed			16.262	44.899	.000	6.885	.423	6.032	.7737

Cost of the Drugs

In the hospital pharmacy, we found that the cost of Tramadol 100mg was 400 Rwanda francs (0.52USD) whereas the cost of Bupivacaine 0.5% 20ml was 4300 Rwandan francs (5.6USD), Diclofenac IM vial of 75mg was 100 Rwandan Francs (0.13 USD) whereas the price of Paracetamol tablets of 500mg was 100 Rwandan francs (0.13USD), 10 tablets.

This means that the patients in the group received Tramadol with local wound infiltration paid 400 Rwandan francs (0.52USD) in 12 hours for pain medications, for each patient, whereas the patients in the group received Bupivacaine the one who received Bupivacaine and Diclofenac IM paid 4400 Rwandan francs (5.73USD), the same as the one who received Paracetamol tablets.

Discussion

Given an increasing trend of day case surgery and early hospital discharge, role of pain relief via local wound infiltration is increasingly becoming common^{1, 2, 11}. In this study, local wound infiltration with Tramadol before closing the skin after inguinal hernia repair, provided a significant postoperative pain relief when compared to Bupivacaine (onset of postoperative pain requiring adjuvant analgesics was more than 12 hours vs 4.7 ± 1.23 hours for Tramadol and Bupivacaine respectively) ($P=0.000$). Afaq Iqbal Malik et al found that when Tramadol used locally post inguinal hernia repair, at 2mg/kg body weight the mean time for requiring adjuvant analgesic was 11.6 hours, while when Bupivacaine used as local wound infiltration at 0.25% 10cc the mean time for requiring adjuvant analgesics was 8.2 hours⁶.

Furthermore, the study done by Abdullah M Kaki et al from the Department of Anaesthesia, Faculty of Medicine, King Abdulaziz University Hospital, Jeddah, Saudi Arabia in 2008, found that Tramadol used locally at 1mg/kg total body weight diluted in normal saline post inguinal hernia repair, the first adjuvant analgesia requirement was 6.6 ± 0.99 hours, while in the group which received Marcaine 0.25% 10cc the mean time to rescue the first adjuvant analgesia was 3.7 ± 0.74 hours⁷. Demiraran et al. also made a study comparing post hernia local wound infiltration with Tramadol and Bupivacaine and showed that the pain score was high in the group received Bupivacaine than in the group received Tramadol ($P < 0.005$), Average time to first analgesic requirement was significantly longer in group T (6.72 ± 4.09 h after herniotomy than both group I (4.49 ± 3.9 h) and group B (6.04 ± 3.7 h) ($P < 0.05$)²³

Hernia repair with either tension free (Lichtenstein procedure) or herniorrhaphy (using modified Bassini technique) were used equally. The choice of the technique was based on surgeon's preference but also on the availability of prolene mesh. It may be thought that the variety of surgical techniques could have caused bias and influence regarding postoperative pain. However, the analysis did not shown any difference. Operators were either consultant general surgeons or senior residents in general surgery. This constitutes one of our study limitations as multiple operators with different level of expertise have been involved.

The severity of self reported pain was high in the group which received Bupivacaine compared to the group which received Tramadol ($P = 0.000$) (Figure 2). In the study done by Abdllah M. Kaki et al there was a significant difference between the two groups in the recorded visual analog pain scale rating high in group with Bupivacaine ($P < 0.05$). In the study done by Bahanur C. et al revealed that the severity of pain was high in the group which received L Bupivacaine compared to the group which received Tramadol⁸.

Side effects also have been evaluated in our study; we evaluated nausea, vomiting, bradycardia and hypotension, no single side effect recorded in the 2 groups. Bahnur C et al, in their study comparing Tramadol and Bupivacaine used as local wound infiltration they were monitoring side effects of each drug(nausea, vomiting, cardiovascular), no side effect found in their study⁸.

In the study done by M.E. Ausems et al, evaluating side effects of Bupivacaine used locally there were no side effect related to the local wound infiltration with Bupivacaine^[24].

In this study the cost of all products the patients consumed along our study period has been evaluated, we found that the group received Tramadol paid 10 times low for analgesia as one vial of Tramadol was 0.52USD, whereas the group received Bupivacaine one vial 20ml was 5.6 USD plus additional analgesics received to control pain better.

Conclusion

Wound infiltration with Tramadol after open inguinal hernia repair offers a superior and prolonged pain control compared to Bupivacaine. The need of additional analgesics is very



low after Tramadol wound infiltration compared to Bupivacaine used in the same conditions. In addition, Tramadol is cheaper making its use cost affordable

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