

Original Article



Comparison of Tramadol Versus Bupivacaine as Local Anesthetic in Pain Control in Inguinal Hernia Surgery

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Author's Contribution

^{1,3,4}Substantial contributions to the conception or design of the work, acquisition, analysis, or interpretation of data for the work,²Drafting the work or revising it critically for important intellectual content,- ⁵Active participation in active methodology, critical review, ⁶Final approval of the version to be published

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ABSTRACT

Objective: To compare the outcomes of local infiltration of tramadol versus bupivacaine for postoperative pain control and time to mobilize patients out of bed with less intravenous analgesia consumption in inguinal hernia surgery.

Methodology: This randomized controlled trial was conducted at the Department of General Surgery, Pakistan Institute of Medical Sciences (PIMS), Islamabad September 2018 to August 2019. A total of 122 patients who were randomly allocated to either Group A (tramadol) or Group B (bupivacaine). Data on postoperative pain scores (VAS at 3, 6, 12, 24 hours), time to first analgesia, and time to mobilization were collected using a structured proforma and analyzed with SPSS version 26.

Results: In the bupivacaine group, mean age was 34 ± 9 years; in the tramadol group, 31 ± 8 years. At 24 hours post-surgery, mean pain score was 5.2 ± 1 in bupivacaine and 2.7 ± 0.5 in tramadol. Tramadol showed significantly lower mean pain at 3rd, 6th, 12th, and 24th hours ($p < 0.001$). Time to first analgesia was 10 ± 7 hours in bupivacaine and 13.5 ± 5.6 hours in tramadol, indicating a statistically longer duration for tramadol ($p < 0.05$). Mobilization time was 9 ± 4 hours in bupivacaine and 6 ± 4.5 hours in tramadol, with tramadol showing significantly lower time to mobilize ($p < 0.001$).

Conclusion: Tramadol local infiltration is effective in reducing pain, delaying analgesia need, and promoting earlier mobilization compared to bupivacaine. Consideration of tramadol at wound closure for inguinal hernia repair may enhance outcomes and patient satisfaction.

Key Words: Analgesia, Inguinal hernia, Local infiltration, Visual Analogue Score, pain.

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Introduction

The surgical correction of inguinal hernias ranks as the second most prevalent procedure within the field of general surgery.¹ In the United States alone, approximately 800,000 inguinal hernia surgeries are performed each year, contributing to a staggering 20 million such procedures conducted globally.¹⁻³ General, local anaesthetic infiltration or regional anaesthesia, anyone of them can be used to perform inguinal hernia surgery.⁴ Regardless of the specific method of anesthesia chosen, it is crucial to focus on addressing both the prevention and management of postoperative pain.⁴ Inguinal hernia repair is consistently identified with continuous post-op misery and pain which

delayed the recovery and lengthen the duration of stay in the hospital.⁵ Inguinal herniorrhaphy is one of the frequent surgical procedures. Pain and gastrointestinal motility after surgery is a chief complaint that can defer early mobilization, hence delaying the discharge from hospital.⁶

It is because of insufficient treatment of post-op pain and considered as a vital obligation of a surgeon to manage pain after surgery, effectively. Acute post-operative pain is a unique and versatile physiologic response to injury. Generally, the management of pain after surgery is not done on priority basis in many centers. Accordingly, patients in the past acknowledged pain as a mandatory piece of the post-surgical experience. Due to the

advancement in knowledge regarding the disease transmission and pain pathophysiology, the surgeons are more focused on alleviating pain to enhance the quality of care and prevent post-surgical morbidity and mortality. A perfect postoperative pain-relieving agent ought to be safe with insignificant side effects, easily accessible and provide fast relief from discomfort. Non steroid anti-inflammatory drugs (NSAID) are commonly used on surgical floor but their pain-relieving power isn't sufficient to manage postoperative pain in many patients.⁷

Traditionally, postoperative analgesia is maintained by using opioids despite having side effects like rash, nausea, vomiting and addictions with regular use. Their drug cost is another downside in their utilization.⁷ Sufficient analgesia can be provided by using Inguinal local anesthesia with almost none adverse effects systemically, if technique is proper. It is reasonable, quite simple to perform and exceptionally safe. This method can be utilized during and after operation in order to control pain. Inguinal local infiltration is studied by many researchers with various local anesthetic agents such as ropivacaine, bupivacaine, lignocaine and currently tramadol. Early discharge from hospital and significant analgesic effect is observed in all conducted studies.^{8,9} Studies have likewise demonstrated prolong analgesic effect with the use of inguinal local infiltration along with decline in the usage of systemic analgesia after surgery.¹⁰ The satisfaction of patient was also substantial. Research on a global scale continues to investigate inguinal hernia wound infiltration with local anesthesia as an effective and alternative technique for postoperative pain management. This approach offers advantages both for the patients, who experience less postoperative pain, and for hospitals, which can reduce the usage of analgesia and expedite discharges. This study aimed to provide an effective post-operative analgesia solution that is not only economical and safe but also minimizes the patient's postoperative discomfort.

Methodology

This Randomized Controlled Trail was done at department of General Surgery, Pakistan Institute of Medical Science (PIMS)/SZABMU, Islamabad. The study was done during a period of one year from September 2018 to 31 August 2019. Ethical approval was obtained from the hospital's ethics committee prior to the study. All adult patients of both genders who underwent elective inguinal hernia surgery under spinal anesthesia and had an ASA Physical Status Classification of I or II, were included. All the patients with sensitivity to any of the study drug, patients

with co-morbid, diabetes and BMI above 36kg/m², patients with recurrent inguinal hernia, patients with chronic pain and on daily use of CNS medications and patients with contraindications to spinal anesthesia were excluded. All the patients were operated on elective operative list. Written consent was obtained from all patients who underwent inguinal mesh repair to include them in the study. The consent process involved a detailed explanation of the procedure, its associated benefits, and the potential risks. Data collection was conducted in the ward using a well-structured proforma. The proforma included assessments of pain scores at 3, 6, 12, and 24 hours using the Visual Analog Scale (VAS). Additionally, the proforma contained the personal profile of each patient. Randomization of patients into two groups, Group A (tramadol) and Group B (bupivacaine), was achieved using a lottery method. The tramadol dose administered was 2 mg/kg, while 0.25% bupivacaine was given at a dose of 0.2 mg/kg in the current study. Outcomes was compared in terms of the time of administration of the first analgesia and the time it took for the patients to mobilize out of bed at 3-, 6-, 12-, and 24-hours post

Results

Overall, the mean age of cases was 32.70 ± 8.51 years. The mean age of cases in Bupivacaine group was 34.13 ± 8.96 years and in Tramadol group was 31.28 ± 7.85 years, $t\text{-test} = 1.870$, $P\text{-value} = 0.064$. At 3 hours, the mean pain score in the Bupivacaine group was 8.39 ± 0.59 , while in the Tramadol group, it was 6.28 ± 0.71 . Similarly, at 6 hours, the mean pain score in the Bupivacaine group was 7.89 ± 0.88 , and in the Tramadol group, it was 4.92 ± 0.97 . At the 12th hour, the mean pain score in the Bupivacaine group was 6.10 ± 0.89 , and in the Tramadol group, it was 3.15 ± 0.77 . Finally, at the 24th hour, the mean pain score in the Bupivacaine group was 5.21 ± 1.05 , and in the Tramadol group, it was 2.72 ± 0.55 . Statistical analysis revealed that the mean pain scores in the Tramadol group were significantly lower compared to the Bupivacaine group at 3rd, 6th, 12th, and 24th hours, ($p < 0.001$). Table I

At the 3rd, 6th, 12th, and 24th-hour assessments, it was observed that the severity of pain was significantly lower in the Tramadol group compared to the Bupivacaine group, ($p < 0.01$). Table II

In the Bupivacaine group, 9 (14.8%) cases required their first dose of analgesia within 1-3 hours, 12 (19.7%) within 4-6 hours, 21 (34.4%) within 7-12 hours, and 19 (31.3%) within 13-24 hours. In the Tramadol group, 4 (6.6%) cases required their first analgesia dose within 1-3 hours, 7

(11.5%) within 4-6 hours, 10 (16.4%) within 7-12 hours, and 40 (65.6%) within 13-24 hours. Table III

Table I: Mean Comparison of pain at 3, 6, 12 and 24 hours in both study groups. (n=122)

| Pain | Study groups | VAS | | t-test | p-value |
|-------------|--------------|------|------|--------|----------|
| | | Mean | SD | | |
| At 3 hours | Bupivacaine | 8.39 | 0.59 | 17.947 | <0.001** |
| | Tramadol | 6.28 | 0.71 | | |
| | Total | 7.34 | 1.24 | | |
| At 6 hours | Bupivacaine | 7.89 | 0.88 | 17.706 | <0.001** |
| | Tramadol | 4.92 | 0.97 | | |
| | Total | 6.40 | 1.75 | | |
| At 12 hours | Bupivacaine | 6.10 | 0.89 | 19.585 | <0.001** |
| | Tramadol | 3.15 | 0.77 | | |
| | Total | 4.62 | 1.70 | | |
| At 24 hours | Bupivacaine | 5.21 | 1.05 | 16.400 | <0.001** |
| | Tramadol | 2.72 | 0.55 | | |
| | Total | 3.97 | 1.50 | | |

In the Bupivacaine group, the mean time to mobilize out of bed was 8.90 ± 4 hours, while in the Tramadol group, it was 5.80 ± 4.54 hours. Mean time to mobilize out of bed was significantly shorter in Tramadol group compared to the Bupivacaine group, (p=0.001). Table IV

Discussion

Post-operative pain management and the time required to mobilize patients are critical aspects of recovery in inguinal hernia surgery. Inguinal hernia repair is a common surgical procedure, and how effectively post-operative pain is managed can significantly impact patient comfort and the speed of their return to daily activities. This intricate interplay between post-operative pain management and timely mobilization underscores the importance of exploring and optimizing the techniques and agents used in inguinal hernia surgery.

In our research, we observed that local wound infiltration with Tramadol, when used before wound closure in hernia

Table II: Comparison of pain severity at 3 hours in both study groups. (n=122)

| | | Study groups | | Chi-square | p-value |
|------------------|----------|--------------|-----------|------------|---------|
| | | Bupivacaine | Tramadol | | |
| Pain at 3 hours | Moderate | 0(0%) | 37(60.7%) | 53.106 | <0.001 |
| | Severe | 61(100%) | 24(39.3%) | | |
| Pain at 6 hours | Mild | 0(0%) | 5(8.2%) | 1.18 | <0.001 |
| | Moderate | 1(1.6%) | 56(91.8%) | | |
| | Severe | 60(98.4%) | 0(0%) | | |
| Pain at 12 hours | Mild | 0(0%) | 38(62.3%) | 66.48 | <0.001 |
| | Moderate | 35(57.4%) | 23(37.7%) | | |
| | Severe | 26(42.6%) | 0(0%) | | |
| Pain at 24 hours | Mild | 1(1.6%) | 58(95.1%) | 1.67 | <0.001 |
| | Moderate | 55(90.2%) | 3(4.9%) | | |
| | Severe | 5(8.2%) | 0(0%) | | |

Table III: Comparison of time of first analgesia on demand in both study groups. (n=122)

| | | Study groups | | Chi-square | p-value |
|--|-------|--------------|-----------|------------|---------|
| | | Bupivacaine | Tramadol | | |
| <i>Time of first Analgesia on demand (hours)</i> | 1-3 | 9(14.8%) | 4(6.6%) | 14.61 | 0.002 |
| | 4-6 | 12(19.7%) | 7(11.5%) | | |
| | 7-12 | 21(34.4%) | 10(16.4%) | | |
| | 13-24 | 19(31.3%) | 40(65.6%) | | |
| <i>Total</i> | | 61(100%) | 61(100%) | | |

Table IV: Mean comparison of time to mobilize out of bed in both study groups. (n=122)

| Study groups | Time to mobilize out of bed (hours) | | | |
|--------------|-------------------------------------|------|---------|---------|
| | Mean | SD | Minimum | Maximum |
| Bupivacaine | 8.90 | 4.00 | 14.00 | 24.00 |
| Tramadol | 5.80 | 4.54 | 4.00 | 14.00 |
| Total | 7.35 | 4.53 | 4.00 | 24.00 |

repair, significantly improved postoperative analgesia compared to Bupivacaine. The mean time to the onset of pain or the average time for the first requested analgesia in the Tramadol group was 13.5 hours, whereas in the Bupivacaine group, it was 10.7 hours. Similarly, a local study done by Afaq et al with same doses, they had found mean post operative pain relief for Tramadol and

Bupivacaine 11.6 and 8.2 hours respectively.¹¹ However, Dahal GR et al.¹² observed that when Tramadol was used for local infiltration, it was equally effective as Bupivacaine in providing postoperative pain relief for pediatric patients undergoing herniotomy.¹² On a similar note, HAIDER SA et al.¹³ found consistent observations. In their study involving pre-incisional infiltration anesthesia for children undergoing inguinal herniorrhaphy, Tramadol demonstrated equivalent analgesic efficacy to Bupivacaine and reduced the need for additional analgesics.¹³ These varying findings may be attributed to factors such as patient populations, dosages, or other methodological differences. Tramadol is a viable option for achieving effective postoperative analgesia through local infiltration.¹³ While Niyirera et al. had done a study on east Africa population they had detailed that Tramadol relieved pain for more than 12 hours while Bupivacaine relieved pain for 4.7 hours. Furthermore, they found Tramadol more cost effective and overall decreased intravenous analgesia consumption in this group.¹⁴ It has both analgesic and anti-inflammatory properties when used as local wound infiltration.¹⁵ Jou et al. also investigated Tramadol and found that it acts through a sensory blocking mechanism similar to that of local anesthetics, involving the blocking of voltage-dependent sodium channels.¹⁶

In our study at 24th hour the mean pain in Tramadol group (2mg/kg) was 2.7 ± 0.5 and in Bupivacaine group was 5.2 ± 1.0 . The mean Pain in Tramadol group was statistically less when compared to Bupivacaine group at 6th, 12th and 24th hours, ($p < 0.001$). While Musstafa et al. study on Egyptian population in 2015 found significant difference in VAS at 3rd, 6th and 12th hours with Tramadol (1mg/kg) versus Bupivacaine but no difference after 12 hours. This may be due to dose difference.¹⁷

In this series the mean time to mobilize out of bed in Bupivacaine group was 8.9 ± 4 hours and in Tramadol group was 5.8 ± 4.5 hours. The mean time to mobilize out of bed (hours) was less in T group than B group, P -value < 0.001 . Haider et al and Iqbal et al compared tramadol and bupivacaine as local infiltration after inguinal hernia surgery they found tramadol infiltration results in terms of

pain management and early discharge, in line as in our study for adult population.^{13,18} Furthermore Tramadol is frequently compared with Bupivacaine across different surgical procedures at many medical centers. Sahmeddin et al.¹⁹ conducted a study in Iranian female patients to assess pain control post-cesarean sections, and their findings suggested that Tramadol was superior to Bupivacaine in providing a pain-free interval during the postoperative period. It's important to note that their study focused on female patients following cesarean sections, which differs from our research, which specifically targeted a male adult population post-inguinal hernia surgery. In another study by Bahanur et al.²⁰ the authors monitored potential side effects, such as nausea, vomiting, and cardiovascular toxicity, associated with Tramadol and Bupivacaine. Importantly, neither their study nor ours documented any complications, indicating the safety of Tramadol as a local anesthetic. Our current study was primarily dedicated to assessing pain control, time to the first analgesia request, and the time required for patients to mobilize out of bed following open inguinal hernia repair in male adults. The female and child populations were not included in our evaluation, and we did not investigate potential synergistic effects of other local anesthetics when combined with Tramadol. For a more comprehensive understanding of the topic, further studies are warranted. These studies should aim to document their findings, compare results on the aspects mentioned above, and possibly explore different patient demographics and combinations of local anesthetics to provide a broader perspective on the use of Tramadol in surgical procedures.

Conclusion

Current study concluded that local infiltration with tramadol is an effective approach for reducing pain, delaying the need for analgesia, and facilitating earlier patient mobility when compared to the Bupivacaine group. Therefore, patients undergoing inguinal hernia repair may benefit from tramadol infiltration during wound closure, leading to improved outcomes and increased patient satisfaction.

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