Postoperative Pain Relief Following Inguinal Hernioplasty: A Randomized Controlled Trial Comparing Intravenous Ketorolac and Tramadol

Abstract

Background: Postoperative pain management is critical for recovery following inguinal hernioplasty. Tramadol, a commonly used opioid analgesic, is associated with side effects such as nausea, vomiting, and delayed bowel function. Ketorolac, a non-steroidal anti-inflammatory drug (NSAID), offers a potential alternative with fewer adverse effects. This study aimed to compare the analgesic efficacy and safety of intravenous ketorolac versus tramadol in patients undergoing elective open inguinal hernioplasty.

Methods: In this prospective, randomized, double-blinded trial, 60 adult patients undergoing elective open inguinal hernioplasty under spinal anaesthesia were assigned to two groups: Group K received ketorolac 30 mg IV every 8 hours, and Group T received tramadol 50 mg IV every 8 hours. Pain was assessed using the Visual Analog Scale (VAS) at 2, 6, 12, and 24 hours postoperatively. Secondary outcomes included time to rescue analgesia, ambulation, and first flatus.

Results: The ketorolac group had significantly lower VAS scores at all time points ($p < 0.05$), required less rescue analgesia, and showed faster recovery, with earlier ambulation and bowel function return. Postoperative Hemodynamic stability was maintained in both groups.

Conclusion: Intravenous ketorolac provides superior analgesia and enhanced recovery compared to tramadol, making it an effective opioid-sparing option for postoperative pain management in inguinal hernioplasty.

Key words: Inguinal hernioplasty, ketorolac, tramadol, randomized controlled trial, Visual Analog Scale, recovery outcomes.

Introduction

Inguinal hernia repair is a common and standardized surgical procedure globally, but postoperative pain management continues to pose a challenge in enhancing early recovery and patient satisfaction [1]. Despite advancements in surgical techniques such as tension-free mesh repair, postoperative pain remains a major concern, often leading to delayed recovery, prolonged hospital stay, and reduced patient satisfaction [2].

Opioids have long been the cornerstone of postoperative pain management. Among them, tramadol is frequently used due to its dual mechanism: binding to μ-opioid receptors and inhibiting norepinephrine and serotonin reuptake [3]. While tramadol offers a favourable safety profile with minimal respiratory depression, its use is still associated with side effects such as nausea, vomiting, sedation, and delayed bowel function recovery [4].

To minimize opioid-related adverse effects, non-steroidal anti-inflammatory drugs (NSAIDs) such as ketorolac have been widely adopted as alternatives or adjuncts in pain protocols. Ketorolac exerts its analgesic effect by inhibiting COX enzymes, thereby reducing

prostaglandin synthesis [5]. Studies suggest that ketorolac not only reduces opioid requirements but also enhances early ambulation and recovery [6,7].

Recent randomized controlled trials comparing ketorolac and tramadol in hernia surgeries have shown mixed results: some highlight tramadol's prolonged analgesic effect [8], while others support ketorolac for superior pain control and fewer side effects [1,6]. Given the increasing concern over opioid use and the need for safer, equally effective alternatives, our study aims to compare the efficacy and safety of intravenous ketorolac versus intravenous tramadol in patients undergoing elective open inguinal hernioplasty.

Materials and Methods

This was a prospective, randomized, double-blinded controlled clinical trial conducted at Park Hospital, Faridabad, from March 2023 to April 2025. The trial aimed to evaluate and compare the postoperative analgesic efficacy of intravenous ketorolac versus intravenous tramadol in patients undergoing elective inguinal hernioplasty. Ethical Approval for the study protocol was granted by the Institutional Review Board. Written informed consent was obtained from all participants prior to inclusion.

Inclusion Criteria

- Adult patients aged 18–65 years
- American Society of Anaesthesiologists (ASA) physical status I or II
- Scheduled for unilateral, elective open inguinal hernioplasty using mesh under spinal anaesthesia

Exclusion Criteria

- Known allergy to NSAIDs or opioids
- Chronic pain or long-term analgesic use
- Bleeding disorders or renal impairment
- History of peptic ulcer disease, asthma, or GI bleeding
- Pregnant or lactating women

Sample Size

The sample size was calculated based on prior studies using a standard deviation of pain scores of 1.5 and a difference of 1.0 in VAS considered clinically significant. With a power of 80% and a significance level of 0.05, a minimum of 30 patients per group was required. A total of 60 patients were enrolled and randomized equally.

Randomization and blinding patients were randomly allocated using a computer-generated table into:

- Group K (Ketorolac group): received 30 mg of intravenous ketorolac every 8 hours

- Group T (Tramadol group): received 50 mg of intravenous tramadol every 8 hours

Study drugs were prepared in identical syringes by a pharmacist not involved in patient care. Both patients and outcome assessors were blinded to the treatment allocation.

Surgical and Anaesthetic Technique

All procedures were performed under spinal anaesthesia using 3 ml of 0.5% hyperbaric bupivacaine. Standard intraoperative monitoring was applied. All surgeries followed the Lichtenstein tension-free mesh repair technique and were performed by experienced surgeons.

Post operative Pain Assessment

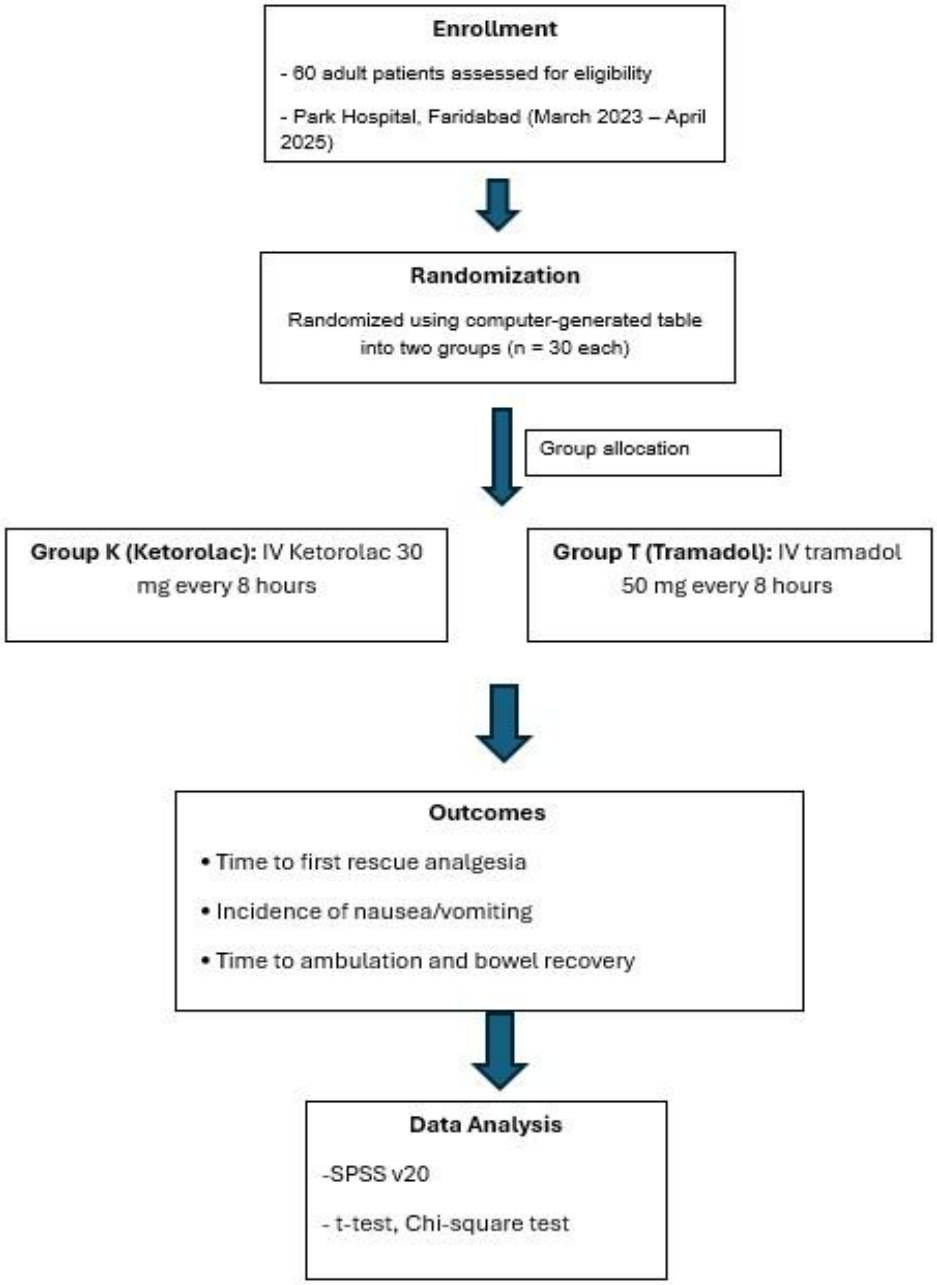
Pain intensity was assessed using the Visual Analog Scale (VAS) at 2, 6, 12, and 24 **hours** postoperatively. Rescue analgesia (IV nalbuphine 5 mg) was administered if the VAS score exceeded 5.

Secondary Outcomes

- Time to first request for rescue analgesia
- Incidence of nausea and vomiting
- Time to ambulation
- Time to first flatus passage

Statistical Analysis

All data were analysed using SPSS version 20. Continuous variables were expressed as mean ± standard error and analysed using independent t-tests. Categorical data were analysed using the chi-square test. A p-value < 0.05 was considered statistically significant.



Flowchart 1: Study Design and Methods Flowchart

Results

Table 1: Demographic and Baseline Characteristics of Patients in Both Groups (n = 60)

Variable	Group K (n = 30)	Group T (n = 30)	p-value
Age (years)	44.8 ± 10.2	46.1 ± 11.5	0.53
Gender (M/F)	27 / 3	26 / 4	0.68
Weight (kg)	65.2 ± 8.9	66.7 ± 9.3	0.47
ASA Grade I / II	22 / 8	23 / 7	0.78
Duration of Surgery (min)	58.3 ± 6.2	57.6 ± 5.9	0.64

Note: All p-values > 0.05, indicating no significant differences between the two groups in age, gender, weight, ASA classification, or surgical duration.

Table 2: Comparison of Postoperative VAS Pain Scores Between Groups

Time After Surgery	Group K (Mean ± SD)	Group T (Mean ± SD)	p-value
2 hours	3.6 ± 0.9	4.8 ± 1.0	0.001**
6 hours	2.9 ± 1.0	4.3 ± 1.1	0.0005**
12 hours	2.2 ± 0.8	3.6 ± 1.0	0.0003**
24 hours	1.5 ± 0.6	2.9 ± 0.9	0.0001**

Note: All p-values < 0.05, confirming statistically significant.

Table 3: Rescue Analgesia and Recovery Outcomes Between Groups

Parameter	Group K (Mean ± SD)	Group T (Mean ± SD)	p-value
Time to First Rescue Analgesia (hrs)	9.8 ± 2.1	6.2 ± 1.8	0.0001**
Number of Patients Requiring Rescue Analgesia	5 (16.7%)	18 (60.0%)	0.0004**
Time to Ambulation (hrs)	5 (16.7%)	13.4 ± 2.3	0.002**
Time to First Flatus Passage (hrs)	12.8 ± 2.6	17.6 ± 3.0	0.0002**

Note: All p-values < 0.05, confirming statistically significant.

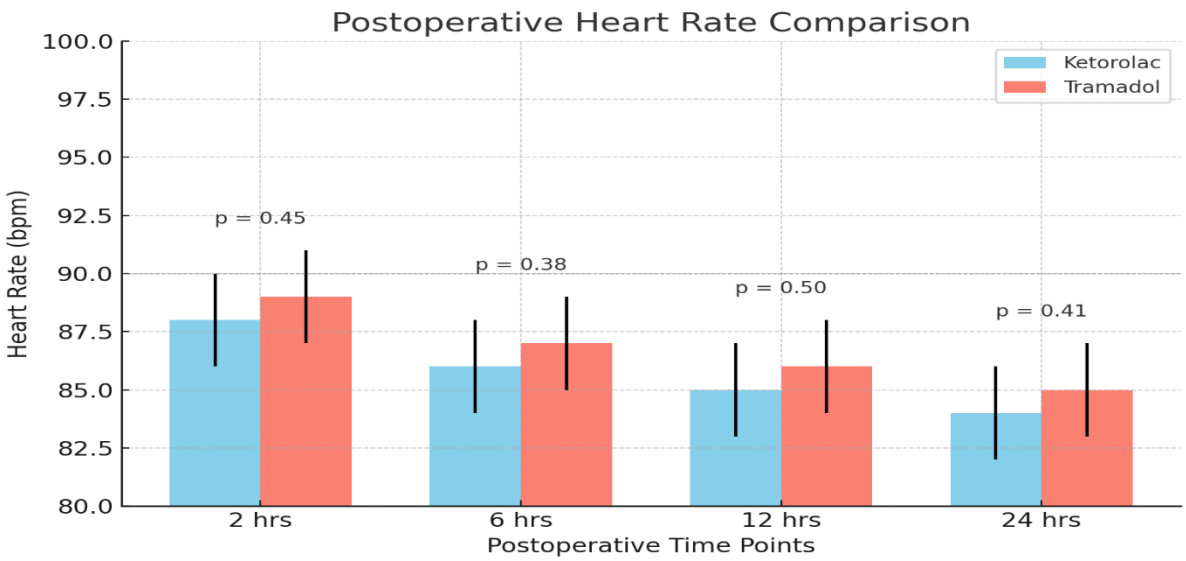


Figure 1: Postoperative Heart Rate Comparison Between Ketorolac and Tramadol Groups

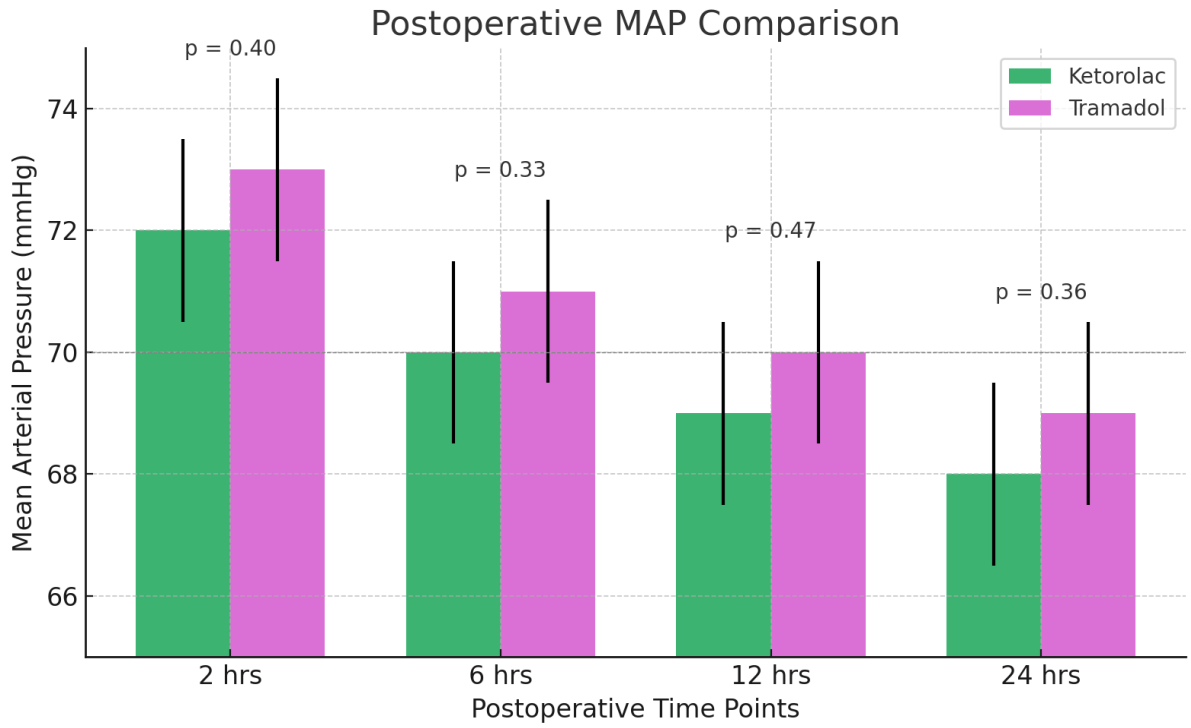


Figure 2: Postoperative Mean arterial pressure Between Ketorolac and Tramadol Groups

Results:

The demographic profiles and baseline characteristics of patients in both groups were comparable (Table 1). The mean age of patients in the Ketorolac group (Group K) was 44.8 ± 10.2 years, while it was 46.1 ± 11.5 years in the Tramadol group (Group T), with no statistically significant difference ($p = 0.53$). The gender distribution showed a male predominance in both groups, with 27 males and 3 females in Group K, and 26 males and 4 females in Group T ($p = 0.68$).

The average body weight was 65.2 ± 8.9 kg in Group K and 66.7 ± 9.3 kg in Group T ($p = 0.47$). ASA physical status distribution was similar, with Group K having 22 patients in ASA I and 8 in ASA II, while Group T had 23 in ASA I and 7 in ASA II ($p = 0.78$). The mean duration of surgery was also comparable between the two groups—58.3 ± 6.2 minutes in Group K and 57.6 ± 5.9 minutes in Group T ($p = 0.64$). None of the variables showed statistically significant differences, indicating that the groups were well matched at baseline.

Postoperative pain scores, measured using the Visual Analog Scale (VAS) at 2, 6, 12, and 24 hours after surgery, are summarized in Table 2. Patients in the Ketorolac group reported consistently and significantly lower VAS scores than those in the Tramadol group at all recorded time points.

At 2 hours, the mean VAS score in the Ketorolac group was 3.6 ± 0.9, compared to 4.8 ± 1.0 in the Tramadol group (p = 0.001). At 6 hours, the Ketorolac group had a mean score of 2.9 ± 1.0, while the Tramadol group reported 4.3 ± 1.1 (p = 0.0005).

At 12 hours postoperatively, pain scores further declined to 2.2 ± 0.8 in the Ketorolac group and 3.6 ± 1.0 in the Tramadol group (p = 0.0003). By 24 hours, patients receiving Ketorolac recorded a mean VAS of 1.5 ± 0.6, whereas those receiving Tramadol had a mean score of 2.9 ± 0.9 (p = 0.0001).

These statistically significant differences, detailed in Table 2, demonstrate the superior analgesic efficacy of intravenous ketorolac over tramadol in the postoperative period following inguinal hernioplasty

A comparative analysis of rescue analgesia requirements and postoperative recovery parameters between the two groups is detailed in Table 3. The results show that patients receiving ketorolac had significantly better postoperative outcomes compared to those receiving tramadol.

The time to first request for rescue analgesia was significantly longer in the Ketorolac group (9.8 ± 2.1 hours) than in the Tramadol group (6.2 ± 1.8 hours, p = 0.0001). Furthermore, only 5 patients (16.7%) in the Ketorolac group required rescue analgesia, compared to 18 patients (60.0%) in the Tramadol group (p = 0.0004), underscoring the superior analgesic profile of ketorolac.

In terms of recovery, the time to ambulation was considerably shorter in the Ketorolac group (5.0 ± 1.2 hours) than in the Tramadol group (13.4 ± 2.3 hours, p = 0.002). Similarly, the time to first passage of flatus was significantly earlier with ketorolac (12.8 ± 2.6 hours) compared to tramadol (17.6 ± 3.0 hours, p = 0.0002).

Postoperative hemodynamic parameters were also monitored (Figures 1 and 2). Although Group K demonstrated slightly more stable postoperative heart rate and MAP trends compared to Group T, the graphical analysis shows no statistically significant differences between the two groups in these hemodynamic parameters.

Results and Discussion

Postoperative pain management is a critical aspect of recovery after inguinal hernioplasty. Although opioids such as tramadol are frequently used due to their dual mechanism of action—μ-opioid receptor agonism and inhibition of norepinephrine and serotonin reuptake—they are associated with several adverse effects including nausea, vomiting, and delayed bowel recovery [9,10]. To overcome these limitations, non-steroidal anti-inflammatory drugs (NSAIDs) like ketorolac have been increasingly used as alternatives or adjuncts in multimodal analgesic regimens [11,12].

This study evaluated the postoperative analgesic efficacy of ketorolac compared to the weak opioid tramadol following open inguinal hernia repair. The demographic characteristics of both groups were comparable, with no statistically significant differences in age, gender distribution, body weight, ASA physical status, or duration of surgery. This ensured that

baseline variables were well matched, allowing for an unbiased comparison of analgesic outcomes. Similar methodological rigor in group matching has been emphasized in previous randomized trials, such as the study by Ahmed et al., which also reported balanced demographic profiles when comparing ketorolac and tramadol in inguinal hernia repair patients (1).

Postoperative pain scores, as assessed using the Visual Analog Scale (VAS), were significantly lower in the ketorolac group at all measured time intervals—2, 6, 12, and 24 hours—compared to the tramadol group (table 2). These findings indicate a superior analgesic effect of intravenous ketorolac in the immediate postoperative period following open inguinal hernia repair. These findings are consistent with a study comparing intravenous ketorolac with high-dose rectal acetaminophen (35 mg/kg) in pediatric tonsillectomy patients found that ketorolac (1 mg/kg) was no more effective for pain control and was associated with an increased need for hemostatic measures during surgery (13).In contrast, Bugada et al. found no significant difference in VAS scores between the two drugs, indicating that clinical context and patient population may influence analgesic outcomes (7).

Beyond superior pain relief, the ketorolac group exhibited a significantly reduced need for rescue analgesia alongside enhanced recovery outcomes (Table 3). Patients mobilized earlier and experienced a faster return of bowel function—key milestones in postoperative recovery that contribute to shorter hospital stays and improved patient satisfaction. These findings underscore the dual benefit of ketorolac in not only controlling pain effectively but also accelerating functional recovery. Similar findings were reported by Bugada et al., where these side effects were more in the tramadol group but not statistically significant (7). Conversely, nausea and postoperative ileus are well-documented adverse effects associated with opioid use, and these were notably evident in our patient cohort, highlighting the impact of tramadol on delayed gastrointestinal recovery (14,15,16).

The postoperative hemodynamic parameters—specifically heart rate and mean arterial pressure (MAP)—remained stable and comparable between the ketorolac and tramadol groups, as depicted in Figures 1 and 2. No statistically significant fluctuations were observed at any measured time point, suggesting that both analgesics maintain cardiovascular stability when monitored after surgery. Similarly, McEvoy et al. (1996) and Pavy et al. (2001) also support the conclusion that ketorolac and tramadol are hemodynamically safe options when used at recommended doses [17,18]. These results reinforce the cardiovascular safety of both agents, indicating that the choice of analgesic can be more appropriately guided by analgesic efficacy and side effect profile rather than concerns over postoperative hemodynamic changes.

Conclusion

This randomized controlled trial demonstrated that intravenous ketorolac provides superior postoperative analgesia compared to tramadol in patients undergoing elective open inguinal hernioplasty. Patients in the ketorolac group reported lower pain scores, required less rescue analgesia, and achieved faster recovery milestones such as earlier ambulation and return of bowel function. Both drugs maintained stable postoperative hemodynamics, confirming their

safety. Given its effectiveness and favorable side-effect profile, ketorolac represents a valuable opioid-sparing option in postoperative pain management. Further large-scale studies are recommended to validate these findings across diverse patient populations.

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