

Comparative Evaluation of IV Paracetamol and IV Tramadol for Postoperative Pain Management Following Infraumbilical Surgeries

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Abstract:

Background: Effective postoperative analgesia is a cornerstone of enhanced recovery following surgery. Infraumbilical procedures are associated with significant postoperative discomfort, necessitating the use of safe and effective analgesics. Intravenous (IV) paracetamol and IV tramadol are commonly employed analgesics with distinct mechanisms of action and side effect profiles. This study aimed to compare the efficacy and safety of IV paracetamol and IV tramadol in providing postoperative pain relief in patients undergoing infraumbilical surgeries.

Methods: This prospective, randomized, comparative study was conducted on 120 adult patients undergoing elective infraumbilical surgeries under spinal anesthesia at Katihar Medical College, Al-Karim University, Bihar. Patients were randomly allocated into two groups: Group P received IV paracetamol 1 g every 6 hours, and Group T received IV tramadol 100 mg every 6 hours. Pain scores were assessed using the Visual Analogue Scale (VAS) at 1, 2, 4, 6, and 8 hours postoperatively. Additional analgesic requirements, vital parameters, and adverse effects such as nausea, vomiting, and sedation were also recorded.

Results: Both groups achieved adequate pain control; however, Group P exhibited significantly lower VAS scores at 4 and 6 hours postoperatively. Group T had a higher incidence of nausea and vomiting (28.3%) compared to Group P (8.3%). Sedation scores were also higher in the tramadol group. The requirement for rescue analgesia was comparable in both groups, though slightly lower in Group P.

Conclusion: IV paracetamol was found to be as effective as IV tramadol in managing postoperative pain following infraumbilical surgery, with the added advantages of fewer side effects and better patient tolerance. It may be considered a preferable alternative for postoperative analgesia in similar clinical settings.

Keywords: Intravenous Paracetamol, Intravenous Tramadol, Postoperative Analgesia, Infraumbilical Surgery, Visual Analogue Scale, Pain Management, Side Effects, Spinal Anesthesia.

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Introduction

Postoperative pain management is a critical aspect of recovery following surgery. Effective analgesia is essential not only for patient comfort but also for promoting early mobilization, reducing complications such as deep vein thrombosis and pneumonia, and enhancing overall recovery [1]. Infraumbilical surgeries, which include a wide range of procedures such as hernia repairs, appendectomies, and gynecological surgeries, are commonly performed under spinal anesthesia. Although spinal anesthesia provides excellent intraoperative analgesia, it often leaves patients with significant postoperative pain, particularly in the first few hours after surgery [2].

The management of postoperative pain has evolved over the years, with an increasing focus on multimodal analgesia, which combines different drugs acting at various points along the pain

pathway. Among the commonly used analgesics, intravenous (IV) paracetamol and IV tramadol have gained attention due to their effectiveness and relative safety profiles [3]. IV paracetamol, a centrally acting analgesic, is well known for its ability to reduce pain and fever with minimal side effects. It works primarily by inhibiting the cyclooxygenase (COX) enzyme in the central nervous system, thus reducing prostaglandin synthesis, which plays a key role in pain and inflammation [4].

On the other hand, IV tramadol is a synthetic opioid analgesic that has a dual mechanism of action. It acts both as a weak μ -opioid receptor agonist and as an inhibitor of the reuptake of serotonin and norepinephrine [5]. This makes tramadol effective in managing moderate to severe pain, though it is often associated with side effects such as nausea,

vomiting, and sedation, especially when administered in higher doses.

Both of these agents have demonstrated efficacy in postoperative pain management; however, their comparative effectiveness and side effect profiles remain unclear [6]. In particular, the potential advantages of using IV paracetamol over IV tramadol in terms of reduced side effects such as nausea, vomiting, and sedation need further exploration, especially in the context of infraumbilical surgeries, which typically result in moderate pain [7].

This study aims to compare the efficacy of IV paracetamol and IV tramadol for postoperative pain relief in patients undergoing infraumbilical surgeries. Specifically, we will evaluate pain intensity using the Visual Analogue Scale (VAS), the need for additional analgesics, and the occurrence of any side effects such as nausea, vomiting, and sedation.

By providing evidence on the comparative effectiveness of these two commonly used analgesics, the study seeks to contribute valuable insights that could inform postoperative pain management strategies in clinical practice, particularly in resource-constrained settings like ours.

Methods

This prospective, randomized, comparative study was conducted in the Department of Anaesthesiology at Katihar Medical College, Al-Karim University, Katihar, Bihar, India, over a period of one year. The study aimed to compare the efficacy and safety of intravenous (IV) paracetamol and IV tramadol for postoperative analgesia in patients undergoing infraumbilical surgeries under spinal anesthesia.

Study Population and Inclusion Criteria: A total of 120 adult patients (aged 18-60 years) scheduled for elective infraumbilical surgeries, including hernia repair, appendectomy, and gynecological procedures, were enrolled in the study. Patients were included if they met the following criteria: ASA physical status I or II, no history of allergy to paracetamol or tramadol, and no contraindications to the use of these analgesics. Patients with a history of chronic pain management, opioid dependence, or known gastrointestinal disorders were excluded from the study.

Randomization and Grouping: Patients were randomly assigned to one of two groups using computer-generated random numbers. Group P (n=60) received IV paracetamol 1 g every 6 hours for 24 hours postoperatively, while Group T (n=60) received IV tramadol 100 mg every 6 hours for 24 hours postoperatively. Both medications were

administered by the nursing staff, who were blinded to the treatment allocation. The primary outcome measure was the Visual Analogue Scale (VAS) score for pain at various time points postoperatively. Secondary outcome measures included the need for rescue analgesia, incidence of side effects such as nausea, vomiting, and sedation, and vital signs (blood pressure, heart rate, and respiratory rate).

Preoperative and Intraoperative Management:

All patients were premedicated with oral lorazepam 1 mg the night before surgery and received standard monitoring (ECG, non-invasive blood pressure, pulse oximetry) during surgery. All surgeries were performed under spinal anesthesia with 0.5% bupivacaine heavy (3.6 mL) administered in the L3-L4 interspace. After surgery, patients were transferred to the post-anesthesia care unit (PACU) and closely monitored for 2 hours, after which they were shifted to the surgical ward.

Pain Assessment and Data Collection:

Postoperative pain was assessed using the Visual Analogue Scale (VAS), which ranged from 0 (no pain) to 10 (worst pain imaginable). VAS scores were recorded at 1, 2, 4, 6, and 8 hours postoperatively. The need for rescue analgesia, defined as the administration of additional analgesic agents (e.g., IV morphine), was recorded. Adverse effects such as nausea, vomiting, and sedation were also monitored and documented. Sedation was assessed using the Ramsay Sedation Scale, which ranges from 1 (anxious, agitated) to 6 (deep coma).

Statistical Analysis: The data collected were entered into a computer database and analyzed using SPSS software (version 25). Descriptive statistics were used to summarize the demographic characteristics and outcome measures. Continuous variables were compared using the Student's t-test or Mann-Whitney U test, as appropriate. Categorical variables were compared using the Chi-square test or Fisher's exact test. A p-value of less than 0.05 was considered statistically significant. The sample size was calculated to detect a significant difference in VAS scores between the two groups, assuming a power of 80% and a significance level of 0.05.

Results

A total of 120 patients were enrolled and completed the study, with 60 patients in each group. Both groups were comparable in terms of age, sex, and type of infraumbilical surgeries. Postoperative pain was assessed at multiple intervals, and the IV paracetamol group showed better pain control at 4, 6, and 8 hours postoperatively. Moreover, the paracetamol group experienced fewer side effects such as nausea, vomiting, and sedation. The requirement for rescue analgesia was slightly higher in the tramadol group, though not statistically significant.

Table 1: Demographic Distribution of Patients

Parameter	Group P (Paracetamol)	Group T (Tramadol)	p-value
Mean Age (years)	38.7 ± 9.4	39.2 ± 10.1	0.76
Male (%)	36 (60%)	35 (58.3%)	0.85
Female (%)	24 (40%)	25 (41.7%)	0.85

Table 2: Preoperative Vital Parameters

Parameter	Group P (Paracetamol)	Group T (Tramadol)	p-value
Systolic BP (mmHg)	122 ± 6	124 ± 7	0.14
Diastolic BP (mmHg)	78 ± 5	79 ± 6	0.32
Heart Rate (beats/min)	77 ± 8	76 ± 7	0.47
Respiratory Rate (/min)	16 ± 2	16 ± 2	0.89

Table 3: Mean Visual Analogue Scale (VAS) Scores

Time Post-op (hrs)	Group P (Paracetamol)	Group T (Tramadol)	p-value
1	4.5 ± 1.1	4.8 ± 1.3	0.18
2	4.1 ± 1.0	4.5 ± 1.2	0.09
4	3.2 ± 1.1	4.3 ± 1.4	0.001
6	2.9 ± 0.9	4.0 ± 1.2	<0.001
8	2.6 ± 0.8	3.2 ± 1.0	0.004

Table 4: Rescue Analgesia Requirement

Group	Patients Requiring Rescue Analgesia	Percentage (%)	p-value
Group P (Paracetamol)	9	15.0%	
Group T (Tramadol)	13	21.7%	0.34

Table 5: Time to First Rescue Analgesia (hours)

Group	Mean Time ± SD	p-value
Group P (Paracetamol)	6.8 ± 1.2	
Group T (Tramadol)	5.7 ± 1.4	0.003

Table 6: Incidence of Side Effects

Side Effect	Group P (Paracetamol)	Group T (Tramadol)	p-value
Nausea	4 (6.7%)	14 (23.3%)	0.01
Vomiting	3 (5.0%)	11 (18.3%)	0.02
Sedation (RSS ≥ 3)	2 (3.3%)	9 (15.0%)	0.03

Table 7: Postoperative Hemodynamic Stability (at 4 hours)

Parameter	Group P (Paracetamol)	Group T (Tramadol)	p-value
Systolic BP (mmHg)	118 ± 7	120 ± 6	0.12
Diastolic BP (mmHg)	76 ± 5	77 ± 6	0.28
Heart Rate (beats/min)	74 ± 6	76 ± 7	0.11

Table 8: Ramsay Sedation Score at 2 Hours

Sedation Score	Group P (Paracetamol)	Group T (Tramadol)
Score 2	55 (91.7%)	48 (80.0%)
Score 3	5 (8.3%)	10 (16.7%)
Score 4	0 (0%)	2 (3.3%)

Table 9: Patient Satisfaction Score (1–5 Scale)

Satisfaction Score	Group P (Paracetamol)	Group T (Tramadol)
5 (Highly Satisfied)	30 (50.0%)	22 (36.7%)
4	21 (35.0%)	20 (33.3%)
3	7 (11.7%)	12 (20.0%)
≤2	2 (3.3%)	6 (10.0%)

Table 10: Duration of Postoperative Hospital Stay

Duration (Days)	Group P (Paracetamol)	Group T (Tramadol)
≤2 Days	51 (85.0%)	49 (81.7%)
>2 Days	9 (15.0%)	11 (18.3%)

Discussion

Postoperative pain management is critical to patient recovery, particularly in infraumbilical surgeries, where effective analgesia promotes early ambulation, reduces hospital stay, and enhances patient satisfaction [8]. This study compared the analgesic efficacy and side effect profile of two commonly used intravenous agents—paracetamol and tramadol—administered as monotherapy in the postoperative period.

The demographic and baseline clinical variables were statistically similar between the two groups, ensuring valid comparisons [9]. The findings of this study indicate that IV paracetamol provided significantly better pain relief at several key postoperative time points—particularly at 4, 6, and 8 hours—compared to IV tramadol. These results align with existing literature suggesting that paracetamol's central COX inhibition and indirect action on serotonergic pathways make it effective for moderate postoperative pain without the typical opioid-related side effects.

A key observation was the lower requirement for rescue analgesia in the paracetamol group, although the difference was not statistically significant. More importantly, the time to first rescue analgesia was longer in the paracetamol group, suggesting a more sustained analgesic effect [10]. This indicates that IV paracetamol may reduce the frequency of additional dosing, thereby improving overall patient comfort and reducing workload for healthcare staff.

One of the most notable advantages of IV paracetamol observed in the study was the significantly lower incidence of side effects, including nausea, vomiting, and sedation [11]. These are common concerns with opioid-based analgesia like tramadol, often resulting in poor patient tolerance and delayed recovery. The higher Ramsay sedation scores in the tramadol group corroborate this concern, potentially leading to prolonged postoperative drowsiness and reduced early mobilization [12].

Furthermore, patient satisfaction scores were higher in the paracetamol group, demonstrating a favorable perception of its analgesic efficacy and tolerability [14,15]. Although both groups had similar lengths of hospital stay, it is worth noting that early and effective pain relief, as achieved with paracetamol, can be instrumental in enhanced recovery protocols and day-care surgical pathways [16,17].

Our findings are consistent with several previous studies. For example, Bektas et al. (2010) and

Apfelbaum et al. (2003) have shown that IV paracetamol is effective in managing moderate pain and reducing opioid consumption when used as a part of multimodal analgesia. However, unlike those studies, we explored paracetamol as monotherapy, giving clear insight into its standalone efficacy compared to tramadol.

Despite its advantages, paracetamol has a ceiling effect, beyond which dose escalation does not produce additional analgesic benefit. On the other hand, tramadol, being a centrally acting opioid, can offer stronger pain relief in severe cases, though at the cost of a higher side-effect burden.

Limitations of this study include the lack of long-term follow-up, which might have offered insights into chronic pain development or delayed side effects. Additionally, we did not evaluate combinations of both drugs, which might reflect real-world practice where multimodal analgesia is increasingly preferred.

Conclusion

This prospective comparative study demonstrates that intravenous paracetamol is a safer and more effective alternative to intravenous tramadol for postoperative analgesia in patients undergoing infraumbilical surgeries. Paracetamol provided comparable, and in some time intervals superior, pain relief with significantly fewer side effects, such as nausea, vomiting, and sedation.

Although both drugs were effective in controlling postoperative pain, paracetamol showed a longer duration to first rescue analgesia, lower incidence of opioid-related complications, and higher patient satisfaction. These findings support the preferential use of IV paracetamol as a primary analgesic in moderate postoperative pain scenarios, especially where patient comfort and early recovery are prioritized.

Further studies involving multimodal regimens and longer follow-up may strengthen the evidence and help develop more tailored postoperative pain protocols.

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