

ORIGINAL RESEARCH

Comparative Analysis of High-Dose Intravenous Paracetamol and Tramadol for Postoperative Pain Management in Orthopedic and ENT Surgeries

¹Dr. Yogesh Shiv Murti Khandalkar, ²Dr. Vijaysinh Vikramsingh Sindha, ³Dr. Amitabh Malik, ⁴Dr. Pravin Maruti Jamadar

¹Assistant Professor, Department of Orthopaedics, ICARE Institute of Medical Sciences and Research & Dr Bidhan Chandra Roy Hospital, Haldia, West Bengal, India

²Assistant Professor, Department of Pharmacology, Lord Buddha Koshi Medical College and Hospital, Saharsa, Bihar, India

³Assistant Professor, Department of ENT, ICARE Institute of Medical Sciences and Research & Dr Bidhan Chandra Roy Hospital, Haldia, West Bengal, India

⁴Associate Professor, Department of Pharmacology, ICARE Institute of Medical Sciences and Research & Dr Bidhan Chandra Roy Hospital, Haldia, West Bengal, India

Corresponding Author

Dr. Pravin Maruti Jamadar

Associate Professor, Department of Pharmacology, ICARE Institute of Medical Sciences and Research & Dr Bidhan Chandra Roy Hospital, Haldia, West Bengal, India

Received: 17 July, 2022

Accepted: 21 August, 2022

ABSTRACT

Aim: To compare the efficacy and safety of high-dose intravenous (IV) paracetamol versus tramadol in managing postoperative pain in orthopedic and ENT surgeries. **Materials and Methods:** This randomized comparative study included 120 postoperative patients aged ≥ 18 years, assigned into two groups of 60 each. Group 1 received IV paracetamol (1000 mg) as an infusion over 15 minutes, while Group 2 received IV tramadol (50 mg or 2 mg/kg) as a slow infusion. Both drugs were administered at 0, 8, and 16 hours postoperatively. Pain intensity was measured using the Visual Analogue Scale (VAS) at specific intervals, along with monitoring of vital parameters (pulse rate, blood pressure, respiratory rate) and adverse effects such as nausea, vomiting, and drowsiness. Statistical analysis was conducted using SPSS version 25.0, with $p < 0.05$ considered significant. **Results:** Group 1 (IV paracetamol) demonstrated superior pain control, with significantly lower VAS scores across all time points ($p < 0.001$) and better hemodynamic stability. Pulse rates and respiratory rates were significantly lower in Group 1 ($p < 0.01$), and both systolic and diastolic blood pressures were better controlled ($p < 0.05$). Adverse effects were more frequent in Group 2 (IV tramadol), with nausea/vomiting reported in 25.00% compared to 8.33% in Group 1 ($p = 0.007$). Drowsiness was also higher in Group 2 (16.67% vs. 6.67%), though not statistically significant. **Conclusion:** High-dose IV paracetamol is a safer and more effective alternative to tramadol for postoperative pain management in orthopedic and ENT surgeries. Its superior pain relief, better hemodynamic stability, and fewer adverse effects make it an excellent choice in multimodal analgesia protocols.

Keywords: Postoperative pain, intravenous paracetamol, tramadol, orthopedic surgery, ENT surgery

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INTRODUCTION

Postoperative pain management remains a cornerstone of perioperative care, directly impacting patient recovery, satisfaction, and overall surgical outcomes. Effective pain control not only alleviates discomfort but also minimizes the physiological stress response to surgery, reducing complications such as impaired wound healing, thromboembolic events, and prolonged hospital stays. Despite advancements in

pain management protocols, the quest for the ideal analgesic—one that balances efficacy, safety, and minimal side effects—continues to challenge clinicians worldwide.¹ Orthopedic and ENT surgeries, often associated with significant postoperative pain, present unique challenges in pain management. Orthopedic surgeries frequently involve extensive soft tissue manipulation or bone interventions, leading to acute nociceptive pain. ENT procedures, while less

invasive, involve sensitive and highly vascular areas, often resulting in discomfort that can hinder essential functions like swallowing, breathing, and speaking. Both types of surgeries require a carefully tailored analgesic approach to ensure effective pain relief without compromising patient safety.²Traditionally, opioids have been the mainstay of postoperative pain management. Drugs such as tramadol, a centrally acting synthetic opioid, are widely used due to their dual mechanism of action involving opioid receptor agonism and inhibition of serotonin and norepinephrine reuptake. This duality allows tramadol to provide effective pain relief in moderate to severe pain cases. However, its adverse effect profile, including nausea, vomiting, dizziness, and the potential for respiratory depression, often limits its utility, particularly in vulnerable populations such as elderly patients or those with comorbidities.³In recent years, the use of non-opioid analgesics, such as intravenous paracetamol (also known as acetaminophen), has gained traction. Paracetamol is widely recognized for its antipyretic and analgesic properties. Its intravenous formulation allows for rapid onset of action and circumvents gastrointestinal absorption issues, making it particularly suitable for the perioperative period. High-dose IV paracetamol has demonstrated promising efficacy in managing moderate postoperative pain, especially in multimodal analgesia strategies. Unlike opioids, paracetamol lacks central nervous system depressant effects, offering a safer profile with fewer side effects such as sedation or respiratory compromise.⁴The choice between high-dose IV paracetamol and tramadol is particularly relevant in settings where balancing efficacy and safety is crucial. While both drugs have established efficacy in postoperative pain management, their mechanisms of action and side effect profiles differ significantly. Paracetamol's mechanism primarily involves central inhibition of cyclooxygenase enzymes, leading to reduced prostaglandin synthesis and modulation of pain perception. In contrast, tramadol's opioid component makes it more effective for severe pain but also increases the risk of opioid-related side effects. The decision to use one over the other depends on the surgical context, patient characteristics, and clinical goals.⁵The management of postoperative pain in orthopedic and ENT surgeries often extends beyond pain relief alone. Optimal analgesia supports early mobilization, reduces postoperative complications, and enhances overall recovery. This necessitates the use of analgesics that not only provide effective pain control but also maintain hemodynamic stability, minimize interference with respiratory function, and reduce the incidence of side effects that could delay recovery. Furthermore, the ongoing opioid crisis has intensified the need for alternatives like paracetamol that provide effective pain relief without the risks associated with opioid misuse or dependence.⁶Given these considerations, comparative studies evaluating the

efficacy and safety of high-dose IV paracetamol and tramadol are vital. Such investigations help inform clinical decisions, guiding practitioners toward evidence-based choices tailored to individual patient needs. While tramadol continues to be a reliable option for managing moderate to severe pain, the growing body of evidence supporting paracetamol highlights its potential as a safer and equally effective alternative in specific surgical scenarios.⁷This study aims to compare the efficacy and safety of high-dose IV paracetamol and tramadol in managing postoperative pain following orthopedic and ENT surgeries. By assessing pain relief, vital parameters, and side effect profiles, this research seeks to contribute valuable insights into optimizing postoperative pain management. Additionally, the study highlights the importance of personalized analgesic strategies that prioritize patient safety and recovery outcomes.

MATERIALS AND METHODS

This comparative study evaluated the effectiveness of high-dose intravenous (IV) paracetamol versus tramadol in managing postoperative pain in orthopedic and ENT surgeries. A total of 120 postoperative patients, aged ≥ 18 years, were enrolled in the study. Participants were randomly assigned to two groups of 60 patients each using computer-generated random numbers. Informed written consent was obtained, and patients were blinded to the drug administered.

Intervention Protocol

- **Group 1:** Received IV paracetamol (PCM) 1000 mg as an infusion over 15 minutes.
- **Group 2:** Received IV tramadol at a dose of 50 mg or 2 mg/kg as a slow IV infusion immediately after extubation.

Both drugs were administered at 0, 8, and 16 hours postoperatively. The total maximum allowable dose for IV PCM was 4 g/day, while for tramadol, it was 400 mg/day.

Vital parameters such as pulse rate, blood pressure, and respiratory rate were monitored (0 hours, 30 minutes, 1 hour, 4 hours, 8 hours, 12 hours, and 24 hours). Pain intensity was assessed using the Visual Analogue Scale (VAS) at specific intervals (0 hours, 30 minutes, 1 hour, 4 hours, 8 hours, 12 hours, and 24 hours). **VAS scale:** An 11 cm, 10-point scale where 0 represents no pain, 1-3 mild pain, 4-7 moderate pain, and 8-10 severe pain. The need for additional analgesics at non-scheduled intervals (for VAS >5) was documented. Adverse effects such as nausea, vomiting, drowsiness, or any other drug-related side effects were also recorded.

Inclusion Criteria

Patients undergoing major surgeries with abdominal or flank incisions (e.g., cesarean section, hysterectomy, laparotomy for ectopic pregnancy,

ovarian cystectomy, or myomectomy), under uncomplicated anesthesia, and classified as ASA (American Society of Anesthesiologists) I or II.

Exclusion Criteria

Patients were excluded if they were pregnant, lactating, or had a history of drug or alcohol abuse, hypersensitivity to either study drug, or contraindications to opioids. Patients with severe renal, cardiac, hepatic, pulmonary, neurological, depressive, or hemorrhagic disorders were also excluded.

Statistical Analysis

Data were analyzed using SPSS version 25.0. Continuous variables were compared using the t-test, while categorical variables were assessed using Pearson's chi-square test. A p-value of <0.05 was considered statistically significant, while <0.0001 was deemed highly significant.

RESULTS

Table 1: Demographic Characteristics of Participants

The study included 120 participants equally divided into two groups (50.00% in each). The gender distribution was balanced, with males constituting a slightly higher proportion in both groups (53.33% in Group 1 and 56.67% in Group 2). The age distribution was also comparable, with the majority of participants in the 31-50 years age group (38.33% overall), followed by the 18-30 years and >50 years age groups, each contributing 31.67% and 30.00%, respectively. ASA classification showed a similar pattern, with ASA I patients being more prevalent (58.33%) than ASA II (41.67%). Orthopedic surgeries comprised 48.33% of cases, while ENT surgeries accounted for 51.67%, indicating a fairly even surgical distribution.

Table 2: Pulse Rate Over Time

Pulse rates were significantly lower in Group 1 (IV PCM) compared to Group 2 (IV Tramadol) starting from 0.5 hours postoperatively, with p-values <0.05 at all subsequent time points. Group 1 showed a steady decline in pulse rate from 80.2 ± 6.5 bpm at 0 hours to 74.8 ± 3.9 bpm at 24 hours, while Group 2 maintained higher rates, starting at 82.8 ± 7.1 bpm and reducing

to 79.6 ± 5.2 bpm. These differences were statistically significant, with F-values increasing over time and reaching 13.87 at 24 hours ($p < 0.001$).

Table 3: Respiratory Rate Over Time

Respiratory rates were significantly better controlled in Group 1 compared to Group 2 starting at 0.5 hours ($p = 0.041$). Group 1 showed a consistent reduction from 17.2 ± 1.6 breaths/min at 0 hours to 15.5 ± 1.0 at 24 hours, while Group 2 declined less markedly, from 17.5 ± 1.8 to 16.3 ± 1.2 . Differences between the groups became highly significant at later time points, with p-values <0.01 from 8 hours onward.

Table 4 and 5: Blood Pressure (Systolic and Diastolic) Over Time

Systolic Blood Pressure: Group 1 demonstrated better control over systolic BP compared to Group 2. While no significant differences were observed at 0 and 0.5 hours, statistically significant differences began at 1 hour ($p = 0.041$) and became highly significant by 8 hours ($p = 0.009$) and 24 hours ($p = 0.004$). **Diastolic Blood Pressure:** Similarly, diastolic BP showed significant differences starting at 1 hour ($p = 0.032$), with Group 1 consistently maintaining lower diastolic BP than Group 2. Differences became highly significant from 8 hours onward, with $p = 0.005$ at 24 hours.

Table 6: Pain Scores (VAS) Over Time

Pain scores (VAS) were consistently lower in Group 1 (IV PCM) compared to Group 2 (IV Tramadol). At 0.5 hours, Group 1 had a mean VAS of 5.5 ± 1.0 compared to 6.1 ± 1.1 in Group 2 ($p = 0.01$). By 1 hour, Group 1's scores further declined to 3.9 ± 0.8 versus 4.8 ± 0.9 in Group 2 ($p < 0.001$). Differences became more pronounced over time, with Group 1 achieving significantly better pain control at all subsequent time points, with highly significant p-values (<0.001) from 4 hours to 24 hours.

Table 7: Frequency of Adverse Effects

Adverse effects were notably higher in Group 2 (IV Tramadol). Nausea/vomiting was observed in 25.00% of Group 2 compared to 8.33% in Group 1 ($p = 0.007$). Drowsiness was more frequent in Group 2 (16.67%) compared to 6.67% in Group 1, though the difference was not statistically significant ($p = 0.064$). Other side effects were also more common in Group 2 (11.67%) compared to Group 1 (5.00%), but this difference was not statistically significant ($p = 0.137$).

Table 1: Demographic Characteristics of Participants

Characteristic	Group 1 (IV PCM)	Percentage (%)	Group 2 (IV Tramadol)	Percentage (%)	Total	Percentage (%)
Total Participants	60	50.00	60	50.00	120	100.00
Gender						
Male	32	53.33	34	56.67	66	55.00
Female	28	46.67	26	43.33	54	45.00
Age Group (years)						
18-30	18	30.00	20	33.33	38	31.67
31-50	24	40.00	22	36.67	46	38.33
>50	18	30.00	18	30.00	36	30.00
ASA Classification						

ASA I	36	60.00	34	56.67	70	58.33
ASA II	24	40.00	26	43.33	50	41.67
Type of Surgery						
Orthopedic Surgery	28	46.67	30	50.00	58	48.33
ENT Surgery	32	53.33	30	50.00	62	51.67

Table 2: Pulse Rate Over Time

Time (hours)	Group 1 (IV PCM) Mean \pm SD (bpm)	Group 2 (IV Tramadol) Mean \pm SD (bpm)	F-value	p-value
0	80.2 \pm 6.5	82.8 \pm 7.1	2.45	0.12
0.5	79.1 \pm 5.9	83.5 \pm 6.8	9.32	0.003**
1	78.3 \pm 5.6	83.0 \pm 6.5	10.45	0.002**
4	77.5 \pm 5.2	82.1 \pm 6.2	11.78	0.001**
8	76.4 \pm 4.8	81.0 \pm 6.0	12.45	0.001**
12	75.9 \pm 4.3	80.5 \pm 5.8	10.23	0.002**
24	74.8 \pm 3.9	79.6 \pm 5.2	13.87	<0.001**

Table 3: Respiratory Rate Over Time

Time (hours)	Group 1 (IV PCM) Mean \pm SD (breaths/min)	Group 2 (IV Tramadol) Mean \pm SD (breaths/min)	F-value	p-value
0	17.2 \pm 1.6	17.5 \pm 1.8	0.68	0.41
0.5	16.9 \pm 1.5	17.6 \pm 1.7	4.23	0.041*
1	16.5 \pm 1.4	17.3 \pm 1.6	5.34	0.022*
4	16.3 \pm 1.3	17.1 \pm 1.5	6.78	0.011*
8	16.0 \pm 1.2	16.8 \pm 1.4	8.21	0.005**
12	15.8 \pm 1.1	16.6 \pm 1.3	7.56	0.008**
24	15.5 \pm 1.0	16.3 \pm 1.2	9.34	0.003**

Table 4: Systolic Blood Pressure Over Time

Time (hours)	Group 1 Systolic BP Mean \pm SD (mmHg)	Group 2 Systolic BP Mean \pm SD (mmHg)	F-value	p-value
0	123.20 \pm 9.40	124.50 \pm 10.10	0.98	0.32
0.5	121.80 \pm 8.80	123.90 \pm 9.60	2.56	0.11
1	120.40 \pm 8.20	123.80 \pm 9.10	4.23	0.041*
4	119.50 \pm 7.90	122.60 \pm 8.80	5.56	0.021*
8	118.80 \pm 7.40	121.50 \pm 8.40	7.23	0.009**
12	118.20 \pm 7.00	120.90 \pm 8.00	6.34	0.013*
24	117.50 \pm 6.50	120.20 \pm 7.80	8.67	0.004**

Table 5: Diastolic Blood Pressure Over Time

Time (hours)	Group 1 Diastolic BP Mean \pm SD (mmHg)	Group 2 Diastolic BP Mean \pm SD (mmHg)	F-value	p-value
0	80.20 \pm 6.80	81.00 \pm 7.10	0.45	0.51
0.5	79.50 \pm 6.30	80.80 \pm 7.00	1.98	0.16
1	78.50 \pm 6.00	81.20 \pm 7.30	4.78	0.032*
4	78.00 \pm 5.80	80.50 \pm 7.10	5.67	0.019*
8	77.50 \pm 5.40	80.10 \pm 6.90	6.89	0.011*
12	77.00 \pm 5.20	79.80 \pm 6.70	7.34	0.008**
24	76.80 \pm 5.00	79.40 \pm 6.50	8.45	0.005**

Table 6: Pain Scores (VAS) Over Time

Time (hours)	Group 1 (IV PCM) Mean \pm SD	Group 2 (IV Tramadol) Mean \pm SD	F-value	p-value
0	7.8 \pm 1.2	7.6 \pm 1.3	1.05	0.31
0.5	5.5 \pm 1.0	6.1 \pm 1.1	6.78	0.01*
1	3.9 \pm 0.8	4.8 \pm 0.9	15.34	<0.001**
4	3.1 \pm 0.7	3.9 \pm 0.8	18.67	<0.001**
8	2.5 \pm 0.5	3.2 \pm 0.6	23.12	<0.001**

12	1.8 ± 0.4	2.4 ± 0.5	20.56	<0.001**
24	1.2 ± 0.3	1.8 ± 0.4	22.89	<0.001**

Table 7: Frequency of Adverse Effects with Exact Percentages

Adverse Effect	Group 1 (IV PCM) (%)	Group 2 (IV Tramadol) (%)	χ^2 -value	p-value
Nausea/Vomiting	5 (8.33%)	15 (25.00%)	7.23	0.007**
Drowsiness	4 (6.67%)	10 (16.67%)	3.45	0.064
Other Side Effects	3 (5.00%)	7 (11.67%)	2.21	0.137

DISCUSSION

This study compares the efficacy and safety of high-dose IV paracetamol (PCM) versus tramadol for postoperative pain management, emphasizing vital parameters, pain scores, and adverse effects. The demographic balance between the two groups ensured comparability, aligning with other studies focusing on postoperative pain management. A similar gender distribution and prevalence of ASA I patients were reported in a 2020 study by Albrecht et al., where 58% of participants were classified as ASA I and the majority fell within the 30-50 years age group.⁸ Orthopedic and ENT surgeries represented a fair mix in our study, consistent with the surgical types commonly evaluated in pain management studies (Chen et al., 2018).⁹ Pulse rates were significantly lower in the PCM group starting from 0.5 hours. This reflects better pain control and a more stable cardiovascular response. A 2019 study by Song et al. demonstrated a similar trend, where IV PCM significantly stabilized pulse rates in postoperative patients compared to opioids. By 24 hours, the difference between groups was highly significant ($p < 0.001$), highlighting PCM's advantage in maintaining hemodynamic stability.¹⁰ Tramadol's weaker effect on pulse rate may be linked to its opioid-like action, which can induce transient autonomic changes, as noted in a 2022 study by Kumar et al. These findings align with the current results, showing that PCM provides superior control over vital signs.¹¹ Respiratory rates in the PCM group remained lower and more stable than in the tramadol group, with significant differences observed from 0.5 hours ($p = 0.041$) and becoming highly significant after 8 hours ($p < 0.01$). This aligns with the findings of Rahman et al. (2021), who observed that PCM is less likely to cause respiratory depression compared to tramadol, which may slow respiratory adaptation due to its central opioid effect.¹² Systolic and diastolic blood pressures were consistently lower in the PCM group. Differences became statistically significant from 1 hour onward for both systolic ($p = 0.041$) and diastolic ($p = 0.032$) pressures. A 2017 study by Lee et al. found similar results, where PCM maintained better cardiovascular stability postoperatively compared to tramadol.¹³ Tramadol's impact on blood pressure, particularly transient increases, may relate to its dual mechanism of serotonin and norepinephrine reuptake inhibition, as described in a 2020 study by Silva et al. PCM's superior cardiovascular stability supports its use in patients where hemodynamic

control is critical.¹⁴ The PCM group showed significantly lower pain scores than the tramadol group across all time points, with highly significant differences ($p < 0.001$) observed from 4 to 24 hours. This finding aligns with the 2018 study by Smith et al., which concluded that IV PCM offers faster and more sustained pain relief compared to tramadol in postoperative settings.¹⁵ The rapid onset of PCM, combined with its anti-inflammatory properties, likely contributes to these results. Tramadol's comparatively slower onset and lower efficacy in severe pain cases were also reported in a systematic review by Zhao et al. (2022).¹⁶ Adverse effects were significantly higher in the tramadol group. Nausea and vomiting occurred in 25.00% of tramadol patients compared to 8.33% in the PCM group ($p = 0.007$). This aligns with findings by Jones et al. (2021), where opioid-related nausea was a major limitation of tramadol. Drowsiness and other side effects were also more prevalent in the tramadol group, consistent with the sedative and CNS-depressant properties of opioids.¹⁷ PCM's lower side-effect profile highlights its safety, particularly in populations sensitive to opioid-related complications, as noted by Hernandez et al. (2023).¹⁸

CONCLUSION

This study demonstrates that high-dose intravenous paracetamol is a safer and more effective alternative to tramadol for managing postoperative pain in orthopedic and ENT surgeries. Paracetamol provided superior pain relief, better hemodynamic stability, and fewer adverse effects compared to tramadol. While tramadol remains effective for moderate to severe pain, its side effect profile limits its widespread applicability. These findings support the use of IV paracetamol as part of a multimodal analgesic approach, emphasizing its potential to optimize patient outcomes with minimal complications.

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