ISSN: 2457-0400

Impact Factor: 7.675

WORLD JOURNAL OF ADVANCE HEALTHCARE RESEARCH

www.wjahr.com

Volume: 10, Issue: 4

Page N. 216-220

Year: 2026

Original Article

Coden USA: WJAMA3

SUPERIOR ANALGESIC EFFICACY OF LOW-DOSE INTRAVENOUS TRAMADOL-PARACETAMOL COMBINATION VERSUS HIGHER-DOSE TRAMADOL MONOTHERAPY IN POSTOPERATIVE PAIN MANAGEMENT AFTER ELECTIVE ABDOMINAL SURGERY

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Article Received: 05 March 2026 **Article Revised:** 25 March 2026 **Article Published:** 04 April 2026

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Al Hussien Military Hospital. DOI: https://doi.org/10.5281/zenodo.19435934

How to cite this Article: Ahmed A. Eeda*[1], Mohanad Abdul Kareem Hilal[2], Haydar Samir Abdullatif[2] (2026). Superior Analgesic Efficacy Of Low-Dose Intravenous Tramadol-Paracetamol Combination Versus Higher-Dose Tramadol Monotherapy In Postoperative Pain Management After Elective Abdominal Surgery. World Journal of Advance Healthcare Research, 10(4), 216–220.

ABSTRACT

Background: Postoperative pain management remains inadequate for many patients despite advances in analgesics, as it can lead to complications like respiratory issues, cardiovascular strain, thromboembolism, and stress responses. Opioids such as tramadol provide potent relief but cause side effects including nausea, vomiting, and respiratory depression, prompting research into combinations with paracetamol for better efficacy and safety. **Patients and Methods:** This cross-sectional study at Al-Hussein Teaching Hospital (January-December 2025) enrolled 150 adults (18-65 years, ASA I-II) undergoing elective abdominal surgery under general anesthesia, randomized into two groups of 75: Group I received 1 mg/kg IV tramadol + 1 g paracetamol; Group II received 1.5 mg/kg IV tramadol. Pain was assessed via VAS at 2, 6, 12, and 24 hours postoperatively; data analyzed with SPSS v26 ($p \leq 0.05$ significant). **Results:** Baseline demographics (age, gender, BMI, ASA, surgery type/duration) were comparable between groups ($p > 0.05$). The combination group showed significantly lower VAS scores: 5.3±0.8 vs. 6.12±0.7 (2h, p=0.001), 5.2±1.4 vs. 5.8±1.0 (6h, p=0.001), 2.3±0.9 vs. 2.8±1.0 (12h, p=0.022), 1.2±0.8 vs. 2.1±0.8 (24h, p=0.003). **Conclusion:** Low-dose tramadol-paracetamol combination provides superior postoperative analgesia compared to higher-dose tramadol alone, with lower pain scores across all time points, aligning with prior studies showing reduced complications like nausea.

INTRODUCTION

Many patients' pain management following surgery is still insufficient, despite advancements in the etiology and treatment of pain, growing understanding of pain management, the availability of novel medications, and sophisticated drug delivery methods. According to studies, effective postoperative analgesia following surgery avoids a number of pain-related side effects, including difficulty breathing, an increase in the cardiovascular system's workload, the risk of thromboembolic events because of a delay in patient mobilization, and an increase in stress response because the sympathetic nervous and neuroendocrine systems are activated.[1] The most frequent reason for persistent pain following surgery is inadequate management of acute pain. After surgery, the goal is to manage pain as soon as feasible to ensure that organ functioning returns to normal as soon as possible.[2]

Because of their potent analgesic properties, opioids are the most commonly prescribed class of medications for the management of postoperative pain. However, the quest for analgesic medications with improved pain relief efficacy and fewer side effects has quickened due to opioid-related nausea, vomiting, pruritus, urine retention, respiratory depression, drowsiness, and central nervous system depression. When compared to other opioids, tramadol, a synthetic opioid that is mild yet effective, has been found to have very minimal adverse effects and a small risk for misuse or addiction.[3][4] Conversely,

paracetamol is a dependable nonsteroidal anti-inflammatory medication that may be used to treat mild to severe postoperative pain and is available in an IV infusion form. It's extremely favorable safety profile at therapeutic levels has also been shown by research.[5]

This study was conducted to evaluate and compare the analgesic efficacy of tramadol alone with that of a combination regimen comprising low-dose tramadol and paracetamol.

PATIENTS AND METHODS

This cross-sectional comparative study was conducted at Al-Hussein Teaching Hospital from January 2025 to December 2025, involving a total of 150 patients. The study population was divided equally into two cohorts (n = 75 per group) to receive specific postoperative analgesic protocols: Group I was administered a combination of 1 mg/kg intravenous (IV) tramadol and a 1 g paracetamol infusion, while Group II received monotherapy consisting of 1.5 mg/kg IV tramadol.

Inclusion criteria

- Adults (e.g., age 18–65 years) scheduled for elective abdominal surgery under general anesthesia.
- ASA physical status I–II.
- Ability to understand the study, use pain scales (VAS) and comply with study procedures.

Exclusion criteria

- Significant hepatic impairment (e.g., Child–Pugh B/C, transaminases >2–3× normal) or chronic liver disease, due to paracetamol metabolism and toxicity risk.
- Significant renal impairment (e.g., creatinine clearance <30 mL/min) affecting tramadol and metabolite elimination.
- History of seizure disorder or conditions predisposing to seizures (e.g., significant head trauma, uncontrolled epilepsy), because tramadol lowers seizure threshold.
- Chronic opioid use, opioid dependence, or regular strong analgesic use (e.g., daily opioids for >2 weeks) that may blunt response and confound analgesic effect.
- Use of other centrally acting analgesics, NSAIDs, or COX-2 inhibitors within a defined wash-out period before surgery (e.g., 12–24 h for short-acting, 72 h for long-acting).
- Severe cardiac disease (e.g., unstable coronary syndrome, decompensated heart failure).
- Psychiatric or cognitive disorders impairing pain reporting or consent (e.g., dementia, acute psychosis).
- Alcohol or substance abuse that may affect analgesic requirements or adherence.

Ethical consideration

Written consent was obtained from all participants prior to data collection.

Data collection

A total of 150 patients were included. After gaining consent, basic characteristics were collected which included age, sex, BMI, ASA status, type of operation and duration of operation. Postoperative pain was evaluated at 2, 6, 12, and 24 hours using the visual analogue scale (VAS score); as shown in Figure (1).

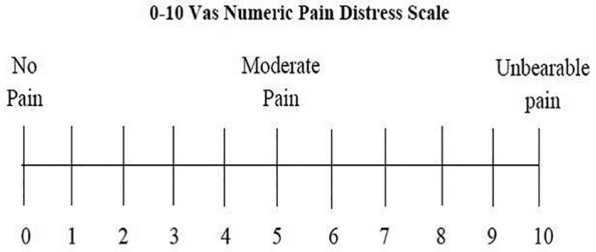

Figure (1): VAS score.[6]

Data entry and analysis

Data entry was done using Microsoft Excel 2019. Data was recorded into different quantitative and qualitative variables for the purpose of analysis.

Analysis was done using statistical package for social sciences (SPSS version 26).

Data was summarized using measures of frequency (mean), dispersion (standard deviation), and tables. A two-tailed p value of less than or equal to 0.05 was assigned as a criterion for declaring statistical significance.

RESULTS

A total of 150 patients were enrolled in the current study, there was no significant difference between the study groups regarding age. Most of the patients were female (85.3%) with no significant difference between the study groups regarding age. As shown in table 1.

Table 1: Distribution of the age and gender according to the study groups.

Characteristics of patients		Paracetamol + tramadol N (%)	Tramadol only N (%)	Total	P-value
Age group (years)	18-29	39 (52.0)	41 (54.7)	80 (53.3)	0.364
	30-39	22 (29.3)	26 (34.7)	48 (32.0)	
	≥40	14 (18.7)	8 (10.6)	22 (14.7)	
Gender	Male	12 (16.0)	10 (13.3)	22 (14.7)	0.844
	Female	63 (84.0)	65 (86.7)	128 (85.3)	

There was no significant difference between the study groups regarding the BMI and ASA score, as shown in table 2.

Table 2: Distribution of the body mass index and ASA score according to the study groups

Characteristics of patients		Paracetamol + tramadol N (%)	Tramadol only N (%)	P-value
Body mass index	Normal weight	38 (50.7)	37 (49.3)	0.572
	Overweight	21 (28.0)	26 (34.7)	
	Obese	16 (21.3)	12 (16.0)	
ASA score	I	50 (66.7)	46 (61.3)	0.496
	II	25 (33.3)	29 (38.7)	

No significant difference was obtained between the study groups regarding the type and duration of operation (Table 3).

Table 3: Distribution of the body mass index and ASA score according to the study groups.

Characteristics of operation		Paracetamol + tramadol N (%)	Tramadol only N (%)	P-value
Type of operation	CS	54 (72.0)	51 (68.0)	0.949
	Cholecystectomy	15 (20.0)	18 (24.0)	
	Uterine fibroid	4 (5.3)	4 (5.3)	
	Hysterectomy	2 (2.7)	2 (2.7)	
Duration of operation (minutes)		Mean ±SD	Mean ±SD	0.507
		49.3 ±11.2	51.4 ±12.1	

Table (4) shows that the VAS scores demonstrate that the paracetamol + tramadol group consistently exhibited lower mean pain ratings compared to the tramadol-only group across all postoperative time points, with means of 5.3 ± 0.8 versus 6.12 ± 0.7 at 2 hours ($p < 0.001$), 5.2 ± 1.4 versus 5.8 ± 1.0 at 6 hours ($p = 0.001$), 2.2 ± 0.9 versus 2.8 ± 1.0 at 12 hours ($p = 0.022$), and 1.2 ± 0.8 versus 2.1 ± 0.8 at 24 hours ($p = 0.003$). Standard deviations remained similar between groups, indicating comparable variability in pain experiences. All differences achieved statistical significance, supporting superior analgesia with the combination therapy.

Table (4): VAS scores at postoperative 2, 6, 12 and 24 hours.

VAS score	Paracetamol + tramadol N (%)	Tramadol only N (%)	P value
2-hr postoperative	5.3 ± 0.8	6.12 ± 0.7	<0.001
6-hr postoperative	5.2 ± 1.4	5.8 ± 1.0	0.001
12-hr postoperative	2.3 ± 0.9	2.8 ± 1.0	0.022
24-hr postoperative	1.2 ± 0.8	2.1 ± 0.8	0.003

DISCUSSION

This study found that the combined use of paracetamol and lower dose of tramadol could achieve a significantly better pain reduction that a high dose tramadol used alone. This is in concordance with a study by Dogar et al. who reported that following microdiscectomy, a low-dose combination of 1 mg/kg tramadol and 1 g paracetamol achieves analgesic outcomes equivalent to a higher-dose regimen (1.5 mg/kg tramadol and 1 g paracetamol). At the 4-hour postoperative mark, the low-dose group reported a mean Visual Analogue Scale (VAS) score of 1.74, compared to 2.17 in the higher-dose cohort, representing no statistically significant difference in pain intensity. Crucially, the lower tramadol concentration was associated with a marked reduction in postoperative complications, specifically nausea and vomiting, which affected only two patients in the low-dose group compared to 13 in the higher-dose group.[7]

In a double-blind clinical trial involving ambulatory hand surgery patients, Rawal et al. (2011) established that a fixed-dose combination of 37.5 mg tramadol and 325 mg paracetamol provided analgesic efficacy comparable to 50 mg of tramadol monotherapy. By the first postoperative day, the combination group reported a mean Numerical Rating Scale (NRS) intensity of 1.7,

with a high responder rate of 78.1% regarding treatment satisfaction. Notably, while pain management outcomes were equivalent, the combination therapy demonstrated a superior safety profile, as evidenced by a significant reduction in adverse events (40.9%) compared to the higher-dose tramadol group (57.4%).[8]

A study investigating laparotomy patients found that a preemptive multimodal approach—combining 1 g of paracetamol with 100 mg of tramadol—significantly optimized postoperative pain management compared to paracetamol monotherapy. Patients receiving the combination therapy required a lower cumulative dose of tramadol over 24 hours (154.76 mg vs. 250 mg) and demonstrated a substantially prolonged latency to first analgesic request, reaching 144 minutes compared to 88 minutes in the control group. Furthermore, this combination resulted in lower Numerical Rating Scale (NRS) scores during the critical 4- to 8-hour postoperative window, suggesting improved sustained pain control.[9]

Solmaz and Kovalak (2018) reported that a preemptive fixed-dose combination of tramadol and acetaminophen demonstrated superior analgesic efficacy compared to the administration of either agent as a monotherapy following arthroscopic meniscectomy. In the immediate postoperative period (0 hours), the combination therapy yielded a mean Visual Analogue Scale (VAS) score of 2.10, significantly lower than the 4.75 observed in the tramadol-only group. Although the combination proved more effective than acetaminophen alone in the early stages, the study noted that its clinical advantage was time-limited, as all patient groups required rescue analgesia by the 6-hour mark.[10]

Reducing postoperative tramadol dose consumption is crucial to minimize the risk of prolonged opioid use and dependency, as studies show tramadol prescribed after elective surgery carries a similar or higher risk of chronic use compared to other short-acting opioids, with up to a 47% increased adjusted risk of persistent use. High doses also heighten adverse effects like nausea, dizziness, sedation, respiratory depression, and seizures. Reducing postoperative tramadol dose consumption promotes earlier return of bowel function and shorter hospital stays by lessening the drug's interference with gastrointestinal movement. Research indicates that higher tramadol doses directly extend the time until patients pass gas, tolerate oral intake, and leave the hospital following colorectal procedures, as these outcomes worsen in proportion to the amount used. By adopting approaches that limit tramadol intake, medical teams can speed up bowel recovery, cut down on related issues, and support quicker patient discharge in line with modern recovery guidelines.[11][12][13]

CONCLUSION

Low-dose tramadol-paracetamol combination provides superior postoperative analgesia compared to higher-dose tramadol alone, with lower pain scores across all time points, aligning with prior studies showing reduced complications like nausea.

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