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Intravenous Paracetamol vs Intravenous Tramadol for Post-Laparoscopic Cholecystectomy Pain: A Randomized Double-Blind Trial

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ABSTRACT

Background: Post-operative pain management is crucial for patient comfort and recovery following laparoscopic cholecystectomy. This study aimed to compare the analgesic efficacy and safety of intravenous (IV) paracetamol and IV tramadol for post-operative pain relief in patients undergoing this procedure.

Methods: The present study was conducted in the Government General Hospital, Rangaraya Medical College, Kakinada, in collaboration with the General Surgery and Anesthesia department. A total of 80 patients between 18-60 years of age, scheduled for laparoscopic cholecystectomy, were randomly allocated to two groups of 40 each. Group A received 1g of paracetamol intravenously in 100 ml solution, and Group B received 100 mg of tramadol intravenously in 100 ml normal saline, with both groups receiving infusions at 0, 8, 16, and 24 hours. Pain intensity was assessed using a 10-point Visual Analogue Scale (VAS).

Results: During postoperative follow-up, Pain was significantly lower in the paracetamol group compared to the tramadol group. Furthermore, the incidence of adverse effects was higher in the tramadol group.

Conclusion: Administering multiple doses of IV Paracetamol was found to be effective in reducing postoperative pain in laparoscopic cholecystectomy compared to IV Tramadol. The Paracetamol group showed fewer side effects than Tramadol.

Key-words: Laparoscopic cholecystectomy, Post-operative pain, Intravenous paracetamol, Intravenous tramadol, Randomized controlled trial, Analgesia

INTRODUCTION

Laparoscopic cholecystectomy is a minimally invasive procedure commonly performed for gallstone disease. It causes less injury to the body than open surgery and allows faster recovery with reduced postoperative pain [1]. Acute postoperative pain is a common complaint after elective laparoscopic surgeries; if left untreated, it can prolong hospital stays and lead to severe morbidity.

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Though laparoscopic techniques reduce overall tissue trauma, significant pain persists in the immediate postoperative period due to peritoneal stretching, diaphragmatic irritation, and residual pneumoperitoneum [2].

Pain following laparoscopic cholecystectomy is typically managed using a combination of opioids, NSAIDs, and other analgesics. However, opioid-related side effects, such as nausea, vomiting, dizziness, and sedation, limit their routine use. NSAIDs, while effective, are contraindicated in patients with peptic ulcers or renal dysfunction. Paracetamol (acetaminophen) is often the first-line analgesic due to its favorable safety profile—it does not inhibit platelet function and is safe in patients with asthma or gastrointestinal risks [3,4]. Its analgesic

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action is thought to involve central inhibition of COX enzymes, particularly COX-2, though precise mechanisms remain under study [5].

Paracetamol is predominantly metabolized in the liver and has minimal gastrointestinal or cardiovascular side effects. On the other hand, tramadol is a centrally acting synthetic opioid of the aminocyclohexanol class. It provides analgesia via weak μ-opioid receptor agonism and inhibition of norepinephrine and serotonin reuptake, making it suitable for moderate to severe pain [6].

Despite the common use of these agents, comparative studies evaluating their efficacy and safety in postoperative laparoscopic cholecystectomy are limited. This study aims to compare intravenous paracetamol and intravenous tramadol in terms of their analgesic efficacy and adverse effect profile during the first 24 hours postoperatively.

MATERIALS AND METHODS

Research design- The present study was conducted in the Government General Hospital, Rangaraya Medical College, Kakinada, India, in collaboration with the General Surgery and Anesthesia department. 80 patients between 18-60 years of age, scheduled for laparoscopic cholecystectomy were randomly allocated to two groups of 40 each. Group A received 1g of paracetamol intravenously in 100 ml solution, and Group B received 100 mg of tramadol intravenously in 100 ml normal saline, with both groups receiving infusions at 0, 8, 16, and 24 hours. Pain intensity was assessed using a 10-point Visual Analogue Scale (VAS).

Methodology- The present study is a randomized, prospective, double-blind, and comparative study conducted for 1 year from August 2021 to July 2022 in the Government General Hospital, Rangaraya Medical College, Kakinada, India, in collaboration with the General Surgery and Anesthesia Department. 80 patients between 18-60 years of age, scheduled for laparoscopic cholecystectomy, were randomly allocated to two groups of 40 each. Group A received 1g of paracetamol intravenously in 100 ml solution, and Group B received 100 mg of tramadol intravenously in 100 ml normal saline, with both groups receiving infusions at 0, 8, 16, and 24 hours.

Inclusion criteria

- Patients of ASA physical states stage I and II.
- Age between 18 – 60 yrs.
- BMI < 40 kg/m2.
- Patients posted for elective laparoscopic cholecystectomy.

Exclusion criteria

- Emergency cholecystectomy
- If the surgery required conversion to open cholecystectomy
- Known hypersensitive to Paracetamol/tramadol
- BMI > 40 kg/m^2 and History of chronic pain
- Daily intake of analgesics or steroids within two weeks of surgery
- Pregnant and lactating women
- Patients with ASA status greater than 2
- Alcohol /drug addiction
- Patients with immunocompromised and Autoimmune diseases
- Hepatic, Renal, Cardiovascular disease

Statistical analysis- At the end of the study, blinding was disclosed. The data were expressed as Mean±SD. Results were analyzed within the group and between 2 groups using paired and unpaired T-test with the help of SPSS software (version 20). The analysis was started when the last patient completed the total study period. the p-value of<0.05 was considered statistically significant.

Ethical approval- The study has been approved by the Institutional Ethics Committee of the hospital.

RESULTS

A total of 107 patients were screened for the study.80 patients were enrolled. Ultimately, we analysed 77 (38 paracetamol, 39 tramadol) after excluding three due to surgical complications. Patients received either intravenous paracetamol (1g) or tramadol (100mg) at 8-, 16-, and 24 hours post-surgery, with pain levels assessed via VAS and VRS at those time points, ranging from 0 (no pain) to 10 (worst pain).

Baseline demographic characteristics- 39 out of 38 patients in group A 22 were males, and 16 were females. Out of 39 patients in group B, 18 were males, and 21 were females (Table 2). In the present study, most of the patients were males, which constitutes 52%.

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Post-operative pain scores from baseline (0 hrs) to 8 hrs, 16 hrs, and 24 hrs in Group A and Group B were calculated with the help of the Visual Analogue Scale, and the Verbal rating scale was calculated using the paired t-test. In group A (Paracetamol), the mean VAS pain score at 0 hrs was 7.63±0.85, and the mean VRS pain score at 0 hrs was 7.68±0.70. In group B, the mean VAS pain score at 0 hrs was 7.97±0.78 & the mean VRS pain score at 0 hrs was 7.97±0.71. On applying a paired t-test for both the groups, a significant difference was seen in the reduction of postoperative pain from baseline (0 hrs) to 8 hrs, 16 hrs, and 24 hrs. Within the groups, it was statistically significant with a p-value (Table 1).

Table 1: Reduction in pain score within group A using a paired t-test

Study group	Assessment scale 0hrs, 8hrs, 16hrs, 24 hrs	Mean difference± SD	SE of difference	p-value	95% confidence interval	
					Upper limit	Lower limit
A	VAS score 0 hrs to 8hrs	1.5±0.11	0.098	<0.0001	1.30	1.70
A	VAS score 0 hrs to 16hrs	2.95±0.15	0.125	<0.0001	2.69	3.20
A	VAS score 0 hrs to 24 hrs	5.0±0.18	0.146	<0.0001	4.70	5.30
A	VRS score 0 hrs to 8hrs	2.0±0.17	0.125	<0.0001	1.75	2.25
A	VRS score 0 hrs to 16hrs	3.21±0.01	0.156	<0.0001	2.89	3.53
A	VRS score 0 hrs to 24hrs	4.87±0.01	0.165	<0.0001	4.53	5.20

On applying paired t-test for both the groups, a significant difference was seen in the reduction of postoperative pain from baseline (0 hrs) to 8 hrs, 16 hrs, and 24 hrs. Within the groups, which was statistically significant with a p-value (Table 2).

Table 2: Reduction in pain score within group B using a paired t-test

Study group	Assessment scale 0hrs, 8hrs, 16hrs, 24 hrs	Mean difference± SD	SE of difference	p-value	95% confidence interval	
					Upper limit	Lower limit
B	VAS score 0 hrs to 8hrs	1.31±0.08	0.091	<0.0001	1.12	1.49
B	VAS score 0 hrs to 16hrs	2.92±0.06	0.129	<0.0001	2.66	3.08
B	VAS score 0 hrs to 24 hrs	4.72±0.06	0.151	<0.0001	4.41	5.02
B	VRS score 0 hrs to 8hrs	1.59±0.04	0.126	<0.0001	1.34	1.84
B	VRS score 0 hrs to 16hrs	2.92±0.01	0.134	<0.0001	2.65	3.20
B	VRS score 0 hrs to 24hrs	4.85±0.30	0.125	<0.0001	4.59	5.10

Post-operative Pain scores were measured with VAS and VRS between Group A and Group B. On applying an unpaired t-test, $p<0.05$ was observed between the 2 groups, showing a statistically significant difference in the reduction of postoperative pain (Table 3 & 4).

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Table 3: VAS score between group A and B using an unpaired t-test

Follow up hours	Group A Mean±SD	Group B Mean±SD	p-value	95% confidence interval	
8 hrs	6.13±0.04	6.67±0.04	0.0017	-0.86	-0.21
16 hrs	4.68±0.02	5.05±0.02	0.0268	-0.69	-0.04
24 hrs	2.63±0.05	3.26±0.05	0.0002	-0.94	-0.31

Table 4: VRS score between group A and B using an unpaired t-test

Follow up hours	Group A Mean±SD	Group B Mean±SD	p-value	95% confidence interval	
8 hrs	5.68±0.30	6.38±0.30	0.0002	-1.05	-0.35
16 hrs	4.47±0.03	5.05±0.03	0.0006	-0.90	-0.26
24 hrs	2.87±0.25	3.13±0.25	0.0417	-0.51	-0.01

In group A, among 4 patients who presented with side effects, 4 patients (100%) were encountered with gastric irritation as the most common side effect. In group B, among ten patients who presented with side effects, 8 patients (60%) encountered nausea, six patients presented with vomiting, one patient presented with dizziness and the remaining one patient presented with sedation (Table 5).

Table 5: Safety profile of two intervention groups

Adverse Events	Group A	Group B
Gastric irritation	4	0
Nausea	0	8
Vomiting	0	6
Dizziness	0	1
Sedation	0	1
Headache	0	0

DISCUSSION

Several studies have encouraged the use of NSAIDs and opioids as standard modalities for postoperative pain relief following laparoscopic cholecystectomy. Despite the preemptive use of analgesics, a substantial number of patients continue to report significant pain even after 24 hours post-surgery. This persistent discomfort is primarily due to factors such as diaphragmatic irritation from residual CO_2, surgical trauma, and visceral pain components that are inadequately addressed by monotherapy [7,8].

Our study aimed to assess the effectiveness of intravenous paracetamol and intravenous tramadol when administered at 8-hour intervals for 24 hours postoperatively. The results demonstrated that both agents significantly reduced pain scores, as assessed by VAS and VRS. However, the paracetamol group consistently showed greater pain reduction at all time intervals compared to the tramadol group, with fewer side effects.

This observation aligns with previous findings by Bandey *et al.,* who noted that IV paracetamol provided better postoperative analgesia with minimal adverse effects compared to tramadol in patients undergoing laparoscopic surgeries [9]. Similarly, studies by Jawad and Jebur [10], and El-Radaideh *et al.* confirmed the superior

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or comparable efficacy of paracetamol with improved safety profiles [11].

Although tramadol is pharmacologically considered more potent due to its dual mechanism—μ-opioid receptor agonism and monoaminergic activity—its higher incidence of side effects such as nausea, vomiting, dizziness, and sedation can limit its use [12]. This was observed in our study, where the tramadol group experienced more adverse events, aligning with outcomes reported by Hoogewijs *et al.* and Ghamry *et al.* [13,14].

The enhanced tolerability of paracetamol, alongside its opioid-sparing effect, supports its inclusion in multimodal analgesic regimens. Our findings are consistent with those of Rastogi *et al*., who found that IV paracetamol significantly reduced postoperative analgesic consumption and improved patient comfort in laparoscopic procedures [8].

Furthermore, adopting a multimodal approach aligns with Enhanced Recovery After Surgery (ERAS) protocols, which emphasise minimising opioid use while achieving effective analgesia and faster recovery [15].

However, limitations of our study include a short follow-up period restricted to 24 hours and a lack of data on delayed or chronic postoperative pain. Long-term comparative studies with larger sample sizes and additional parameters such as patient satisfaction, mobilization, and discharge timing would be beneficial. Future studies could also explore the efficacy of combining paracetamol with other non-opioid analgesics or adjuncts to enhance analgesia while minimizing side effects.

CONCLUSIONS

We conclude that administering multiple intravenous doses of paracetamol provided more effective postoperative pain relief for patients after laparoscopic cholecystectomy when compared to multiple intravenous doses of tramadol. Furthermore, paracetamol was associated with a more favourable safety profile, exhibiting fewer adverse effects than tramadol in this patient group. The results advocate for a potential re-evaluation of current postoperative pain management protocols for laparoscopic cholecystectomy, suggesting that intravenous paracetamol could be positioned as a preferred first-line analgesic over intravenous tramadol, particularly when considering both efficacy and patient tolerability. Further research into optimal dosing schedules and the potential synergistic effects of intravenous paracetamol with other non-opioid analgesics in a multimodal approach would be valuable.

CONTRIBUTION OF AUTHORS

Research concept- Vineela Ganta**,** Ekta Padma Priya
Research design- Vineela Ganta, Krishna Sai Attili
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