

# Oral versus intravenous Paracetamol and Ketorolac in postoperative pain management following laparoscopic cholecystectomy: A prospective comparative study

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## ABSTRACT

**Introduction:** Pain following laparoscopic cholecystectomy is multifactorial and necessitates a multimodal approach for management. Paracetamol and Ketorolac are commonly used as part of a multimodal analgesic regimen postoperatively. This study aimed to compare the efficacy of oral paracetamol and ketorolac with intravenous paracetamol and ketorolac for pain management after laparoscopic cholecystectomy.

**Methods:** A prospective cross-sectional comparative study was conducted on 106 patients who underwent laparoscopic cholecystectomy between August 2022 and July 2023. The patients were divided into two equal groups of 54 each: the OPK group (oral paracetamol and ketorolac) and the IPK group (intravenous paracetamol and ketorolac). The primary outcome was a visual analog scale (VAS) score measured 8 h after the operation and on the first postoperative day at 0800h. The secondary outcome was the amount of tramadol used for rescue analgesia.

**Results:** Most participants were female (67.6%), and the mean age of the population was 44.83±1.27 years. The mean VAS scores measured at 8 hours postoperatively and on the first postoperative day in the OPK and IPK groups were not statistically different (5.85±1.52 vs. 6.24±1.32; p=0.28, and 3.21±1.30 vs. 3.50±1.46; p=0.24, respectively). The mean tramadol required as rescue analgesia was higher in the intravenous group (74.07±39.74 mg) than in the oral group (66.67±38.85 mg); however, the difference was not statistically significant (p=0.33).

**Conclusion:** Our study demonstrated comparable efficacy of oral and IV routes of paracetamol and ketorolac for postoperative pain management following laparoscopic cholecystectomy.

**Keywords:** Intravenous, Ketorolac, Laparoscopic cholecystectomy, Oral, Paracetamol, VAS Score

## INTRODUCTION

Post-laparoscopic cholecystectomy (LC) pain can be effectively controlled via a multimodal approach, including regular use of non-steroidal anti-inflammatory drugs (NSAIDs) and paracetamol and use of short-acting opioids only when other analgesic techniques fail, while avoiding the prophylactic use of postoperative opioids.<sup>1,2</sup>

The usefulness of intravenous paracetamol in post-operative pain control after laparoscopic cholecystectomy is proven.<sup>3</sup> Some studies have also shown the non-inferiority of oral paracetamol compared to intravenous paracetamol in post-LC pain control.<sup>4</sup> Likewise, NSAIDs, including ketorolac, have been proven to be effective for inflammatory pain.<sup>5</sup> Studies have shown that combining paracetamol and ketorolac was more

effective than paracetamol alone.<sup>6, 7</sup>

Regarding the route of administration, the peak plasma concentration of paracetamol was achieved faster with intravenous (IV) administration than with oral (PO) use (15 minutes vs 45-75 minutes). However, up to 89% bioavailability can be achieved with oral administration, and there is no strong evidence that intravenous administration is superior in patients with a functioning alimentary tract who can take oral medications.<sup>8, 9</sup> Likewise, ketorolac has an oral bioavailability of approximately 80% to 100%, achieving a peak plasma level of approximately 30 to 60 min after oral or parenteral administration.<sup>10</sup> In addition, intravenous administration of drugs is associated with higher costs and longer duration of administration, apart from IV cannula-related complications.<sup>9, 11</sup>

The current practice in the study hospital setting is to allow post-LC patients to be fed orally 4-6 h after surgery, to discontinue IV fluids, to administer IV or oral paracetamol and ketorolac as per the surgeon's prescription, and to discharge them on the first postoperative day.<sup>12</sup>

To our knowledge, no study has compared the efficacy of intravenous and oral combinations of Paracetamol and ketorolac for post-LC pain control. The purpose of this study was to compare the efficacy of an oral combination of paracetamol and ketorolac with an intravenous combination of paracetamol and ketorolac in postoperative pain control following laparoscopic cholecystectomy in terms of the visual analog scale (VAS) score and the requirement for rescue analgesia with tramadol.

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## METHODS

This was a hospital-based, prospective, cross-sectional, comparative study conducted in the surgery department of a tertiary care center in the Kathmandu Valley from August 1, 2022, to July 30, 2023, after approval by the institutional review committee.

Patients admitted for laparoscopic cholecystectomy through a routine process, which included clinical history taking, physical examination, preoperative investigations, and fulfilling the inclusion criteria, were enrolled in the study after obtaining written informed consent.

All patients aged  $\geq 18$  years who underwent laparoscopic cholecystectomy and gave consent for the study were included. The exclusion criteria were laparoscopic conversion to open cholecystectomy; known allergies to ketorolac and paracetamol; abnormal liver and renal function tests; platelet count  $< 80,000$ ; history of bleeding disorders, recent gastrointestinal bleeding, active symptomatic peptic ulcer disease, or inflammatory bowel disease; and ongoing use of oral anticoagulants, ACE inhibitors, furosemide, and aspirin.

The sample size was calculated using openepi.com based on mean VAS scores from a similar study ( $22.1 \pm 8.6$  vs.  $17.4 \pm 7.9$ ) with a 95% confidence interval and 80% power, yielding a sample size of 98.<sup>13</sup> Considering a 10% dropout rate, our final sample size was 108. A convenience sampling method was used in this study. Patients were enrolled in one of two study groups, with 54 patients in each: the oral paracetamol and ketorolac (OPK) group and the intravenous paracetamol and ketorolac (IPK) group. Randomization was performed using the sealed-envelope technique.

The patients were oriented on the visual analog scale (VAS) before being taken to the operating theatre. All patients underwent LC under general anesthesia using standard techniques. Intraoperatively, all patients received a 1 g (100 mL) paracetamol infusion over 10-15 minutes. No other specific preoperative or intraoperative protocol was used, and routine surgical practice was observed.

In this study, patients were allowed oral liquids 4 h after completion of the operation, once they were fully conscious, in accordance with our hospital practice. The IV fluid was stopped once the patient tolerated the feeding and was hemodynamically stable. Additionally, 4 hours after the operation, all the patients were administered either intravenous paracetamol 1 g and ketorolac 30 mg or oral paracetamol 1 g and ketorolac 10 mg as per group allocation.<sup>14</sup> Subsequent doses of paracetamol were administered every 6-8 hours, depending on the patient's body weight. The desired dose of paracetamol was 15 mg/kg/dose, which did not exceed 4 g/day. Patients weighing less than 50 kg received PCM 1 g every 8 hours, and all other patients received PCM 1 g for 6 hours. Subsequent doses of ketorolac were repeated every 8 h. The patient, declaring poor control of pain, received on-demand rescue analgesia with IV tramadol 50 mg.

A standard VAS line with zero indicating no pain and 10 indicating the worst pain was used to record postoperative pain (Figure 1). Patients were asked to point to a pain scale based on the severity of their pain. Decimal scores were rounded to the nearest whole number. The first VAS was recorded eight hours after the completion of surgery, and the second VAS the next morning, before the round at 0800 h on the first postoperative day. The VAS was considered 0-4 mild, 5-6 moderate, and 7-10 severe.<sup>15</sup> Tramadol required for rescue analgesia during the first 24 hours following completion of the laparoscopic cholecystectomy was calculated from the prescription chart.

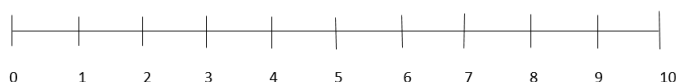


Figure 1: Visual Analogue Scale (VAS)

The study's primary endpoint was mean postoperative pain assessed by VAS at 8 h postoperatively and at 08:00 h on the first postoperative day. The secondary endpoint was the average requirement for tramadol as

rescue analgesia during the first 24 hours postoperatively.

Statistical analyses were performed using Microsoft Excel and EZR version 1.62. All the data were normally distributed. Continuous data are expressed as the mean (standard deviation), and a two-sample t-test was used to conduct a mean comparison. Categorical data are expressed as percentages. The chi-square test was used to compare categorical variables. Statistical significance was set at  $P < 0.05$ .

This study was approved by the institutional review committee of Patan Academy of Health Sciences (IRC-PAHS), Lalitpur, Nepal, on 5 July 2022 (Ref: PSS2207051654). This study is registered with the Research Registry under the unique identifying number (UIN) 10880. The work has been reported in line with the STROCSS (strengthening the reporting of cohort, cross-sectional, and case-control studies in surgery) criteria.<sup>16</sup>

## RESULTS

A total of 108 patients were included in this study. Of these, 73 (67.6%) were female, and 35 (32.4%) were male. The mean age of the study population was  $44.83 \pm 1.27$  years. The mean weight of the participants was 59.82 kilograms. The mean BMI of the participants was  $23.01 \pm 2.73$ , with the minimum and maximum BMIs being 18.07 and 30.86, respectively. The demographic and clinical characteristics of the patients in both groups were similar (Table 1).

Table 1: Demographic and clinical characteristics of the subjects evaluated for the use of OPK vs. IPK in postoperative pain management following laparoscopic cholecystectomy (n=108)

Variables	OPK group	IPK group	P Value
Age, mean (SD), years	44.78 $\pm$ 12.22	44.89 $\pm$ 14.17	0.095**
<b>Gender N (%)</b>			
Males	21 (19.44%)	14 (12.96%)	0.15*
Females	33 (30.56%)	40 (37.04%)	
BMI, mean (SD), kg/m <sup>2</sup>	22.90 $\pm$ 2.88	23.13 $\pm$ 2.58	0.33**
Length of operation, mean (SD), hours	1.17 $\pm$ 0.53	1.14 $\pm$ 0.60	0.86**
Local Anesthesia Infiltration, Number of patients (%)	21 (38.89%)	16 (29.63%)	0.31*
Length of hospital stay, mean (SD), days	1.24 $\pm$ 0.58	1.31 $\pm$ 0.58	0.32**

\*Pearson's Chi-square test \*\* Student's t-test

The mean VAS scores of the intravenous paracetamol and ketorolac groups were slightly higher than those of the oral paracetamol and ketorolac groups at 8 h and on POD1 at 08:00 h postoperatively. However, these measurement differences did not reach statistical significance when compared using Student's t-test. (Table 2)

Table 2: Comparison of mean VAS score between OPK group and IPK group following laparoscopic cholecystectomy comparison of mean VAS score by route of analgesics administration

VAS score	OPK group	IPK group	P value
At 8 hours post-op	5.85 $\pm$ 1.52	6.24 $\pm$ 1.32	0.28**
At 0800 on POD1	3.21 $\pm$ 1.30	3.50 $\pm$ 1.46	0.24**

\*\* Student's t-test

A total of 93 (86.11%) patients required tramadol as rescue analgesia during the first postoperative day. The number of patients requiring tramadol as rescue analgesia and the average amount of tramadol required by patients in both groups were similar. However, the time to the first dose of tramadol rescue was earlier in the OPK group. (Table 3)

**Table 3: Tramadol requirement as rescue analgesia in OPK group and IPK group following laparoscopic cholecystectomy (n=108)**

Tramadol Requirement	OPK group	IPK group	P Value
Number of patients Requiring Tramadol (%)	46 (85.19%)	47 (87.04%)	0.78*
Average amount (mg), Mean $\pm$ SD	66.67 $\pm$ 38.85	74.07 $\pm$ 39.74	0.33**
Time of first dose (post-op hours), Mean $\pm$ SD	1.34 $\pm$ 0.73	2.11 $\pm$ 1.59	0.003**

\*\* Student's t-test

**DISCUSSION**

Pain following laparoscopic cholecystectomy is multifactorial, including incision, carbon dioxide insufflation, and intra-abdominal pressures, necessitating a multimodal pain management approach.<sup>17</sup> Ensuring adequate pain control is of prime importance for patient comfort, timely discharge, and the ability to resume daily activities. Additionally, optimum anesthesia improves postoperative outcomes and reduces overall health care costs.

Based on a 'PROSPECT' review on evidence-based management of pain after laparoscopic cholecystectomy' conducted in 2018, A.W.H. Barazanchi et al. recommended a combination of paracetamol, NSAID, or cyclooxygenase-2 specific inhibitor and local anesthetic infiltration at the surgical site as a fundamental analgesic technique. They recommended the initiation of paracetamol and NSAIDs before or during surgery, along with dexamethasone (Grade A), while utilizing opioids only as rescue analgesia (Grade B). Their recommendations were against the use of gabapentinoids, intraperitoneal local anesthetics, and transversus abdominis plane blocks (Grade D), if basic analgesia could be achieved. Additionally, low-pressure pneumoperitoneum, postprocedural saline lavage, and aspiration of pneumoperitoneum are recommended for pain management (Grade A).<sup>17</sup>

To establish a cost-effective yet adequate analgesia technique, we successfully conducted a prospective comparative observational study of 108 patients undergoing laparoscopic cholecystectomy. In this study, a combination of paracetamol and NSAIDs (Ketorolac) was used routinely in all the cases, with tramadol as a rescue analgesic. Although the route of administration of the analgesics differed by study group, the combined use of paracetamol and ketorolac led to a significant reduction in pain in both the oral and intravenous groups at 8 hours post-operatively and on the first POD.<sup>18</sup> The efficacy of oral and intravenous administration of both analgesics was comparable. This is consistent with the kinetics of ketorolac, which has high oral bioavailability (~80-100%) and predictable elimination, allowing effective analgesia once oral intake can be tolerated.<sup>19</sup> The higher peak plasma level achieved with intravenous paracetamol (30-50  $\mu$ g/mL, 100% bioavailability) compared to oral paracetamol (10-20  $\mu$ g/mL, 70-90% bioavailability), was, however, not reflected in better analgesia in our study since the study protocol was investigating mild to moderate pain.<sup>20, 21</sup> These results are in line with ERAS principles promoting early oral intake and opioid-reducing, multimodal analgesia, indicating that orally administered analgesics may decrease costs, invasiveness, and resource use. The demographic and clinical characteristics of the study population were similar between the two groups. Almost two-thirds of our patients were female, and the mean age was > 40 years. The majority of the patients had normal BMI, identical to the findings of a study done in Nepal in patients with gallstone disease (female: 76%, age (mean $\pm$ SD): 44.51 $\pm$ 14.57 years, and normal BMI in 46.53% patients).<sup>22</sup> This indicated our study population was representative of the local population. In this study, the average length of operation was 1.17 $\pm$ 0.53h for the OPK group and 1.14 $\pm$ 0.60h for the IPK group, with no statistically significant difference between the two groups. It was comparable to the operation length in a similar study, which was 1.10 $\pm$ 0.39 and 1.21 $\pm$ 0.57 for the perioperative oral and intravenous acetaminophen groups, respectively.<sup>23</sup>

In clinical trials assessing pain, it is widely recognized that a clinically significant result should ideally demonstrate either a 2-point decrease on a 10-point scale or a 30% reduction in visual analog scale (VAS) scores.<sup>18</sup>

The severity of the pain following laparoscopic cholecystectomy reduced over time. Most patients in both groups (88.89% in the OPK group and 92.59% in the IPK group) experienced moderate-to-severe pain (moderate to severe) on the day of the operation. Only 6 (11.11%) patients in the OPK group and 4 (7.41%) patients had mild pain/ no pain on the same day. On the first postoperative day, in the morning, most patients in both groups (61.11% in the OPK group and 53.70% in the IPK group) had no or mild pain. In comparison, 21 (38.89%) patients in the OPK and 25 (46.30%) patients in the IPK group reported moderate to severe pain. The observed difference in the number of patients with and without pain between the two groups was not statistically significant.

More than 85% of patients in our study required rescue analgesia. The average amount of tramadol required as rescue analgesia during the first postoperative day or before discharge was higher in the IPK group (74.07 $\pm$ 38.85 mg) than in the OPK group (66.67 $\pm$ 38.85 mg). However, this difference was not statistically significant. This was similar to the findings of another study, in which 75% of the IV and 77% of the oral acetaminophen groups showed no statistically significant difference (p=0.72).<sup>4</sup>

In a retrospective analysis of a single dose of intraoperative IV versus preoperative oral acetaminophen in 579 ambulatory surgical centers, laparoscopic cholecystectomies, the time to the first dose of rescue opioid in the PACU was 21 minutes in the IV paracetamol group and 23 minutes in the oral paracetamol group, with a statistically significant difference of 0.014.<sup>4</sup> However, the clinical significance of two minutes has been questioned. In contrast to this study, patients in our OPK group requested rescue analgesia earlier than those in the IPK group (1.34 $\pm$ 0.73h versus 2.11 $\pm$ 1.59h postoperatively). This was the only statistically significant measurement in this study.

A systematic review by Katherine et al. concluded that the preemptive use of intravenous paracetamol may improve postoperative pain control compared with oral paracetamol. However, we did not use preemptive analgesics.<sup>24</sup> Another systematic review (2020) of randomized controlled trials comparing perioperative intravenous versus oral paracetamol for postoperative pain yielded inconclusive evidence regarding the effect of the route of paracetamol administration on postoperative pain and suggested further studies with larger sample sizes.<sup>25</sup> Despite its quicker onset of action, IV paracetamol's overall pain control has not been proven to be superior to that of the oral form. IV analgesics, including paracetamol, are more expensive than oral formulations.<sup>26</sup>

Similarly, a systematic review demonstrated that the use of intravenous ketorolac resulted in a significant reduction in pain score and opioid consumption in the first 24 hours following laparoscopic cholecystectomy.<sup>27</sup> Studies have also shown that short-term use of oral ketorolac substantially reduced narcotic requirement and post-operative pain scores.<sup>28</sup> However, intravenous administration results in a quicker onset of action than oral consumption.<sup>29</sup>

In conclusion, the combination of paracetamol and ketorolac results in better pain control following laparoscopic cholecystectomy. The efficacy of intravenous and oral administration is comparable. The choice of route of administration depends on several factors, such as the type, severity, and location of the pain, patient preferences, and specific conditions. Additionally, considerations include the speed of analgesic effect, duration of action, ease of use, patient compliance, and cost. These factors play a significant role in determining the most suitable approach to post-LC pain management.<sup>30</sup>

Limitations include the single-center design, a non-blinded (open-label) study with a modest sample size, and reliance on subjective pain scales, which may affect generalizability and introduce variability in pain reporting. Post-LC pain was measured using VAS only twice in the first 24 hours post-operatively, which could have been done more frequently. Patients were not followed up after the first POD.

**CONCLUSION**

The current study demonstrates the comparable efficacy of a combination of paracetamol and ketorolac administered orally and

intravenously in postoperative pain management following laparoscopic cholecystectomy. Further studies involving multiple centers and a larger sample size are suggested in order to draw a conclusion.

## DECLARATION

### Acknowledgements

None

### Author Contributions

AKR reviewed the literature, conceptualized and designed the research; AKR, ASB, SG, DS, KA, and GC did data collection, analysed data, and prepared results; AKR drafted the manuscript; and AKR, SBM, and SP reviewed the manuscript; all the authors approved the final version of the manuscript. All authors agreed to be accountable for all aspects of the research work. Note: AKR, ASB, SG, DS, KA, GC, SBM, and SP are abbreviated names of authors.

### Ethical Approval

This research was approved by the IRC of Patan Academy of Health Sciences with the reference number of PSS2207051654 on 5th July, 2022.

### Consent/Assent

Informed written consent was obtained from all the participants before data collection

### Name of Registry and Registration number

This study is registered with the Research Registry under the unique identifying number (UIN) 10880.

### Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

### Conflicts of Interest

There is no conflict of interest to disclose.

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