

Prospective Randomized Controlled Research Comparing Intravenous IBUPROFEN and Intravenous KETOROLAC for Acute Post-operative Pain in Patients Undergoing Abdominal Surgery

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Abstract

Introduction: Recovery is greatly impacted by acute post-operative pain, which also affects patient outcomes and comfort. Non-steroidal anti-inflammatory drugs (NSAIDs), which lower opioid usage and improve pain management, are essential parts of multimodal pain therapy. By obstructing enzymes cyclooxygenase (COX)-1 and COX-2, NSAIDs like ibuprofen and ketorolac provide analgesia by blocking the synthesis of pain-related prostaglandins. Both drugs are commonly used intravenously, but limited studies have compared their efficacy in surgical settings. This prospective randomized study aims to evaluate the efficacy, safety, and tolerability of intravenous (IV) ibuprofen versus IV ketorolac in managing acute post-operative pain in abdominal surgery patients. **Methods:** The prospective randomized controlled trial took place at a tertiary hospital using 60 patients who were to undergo abdominal surgery, divided equally into two Groups A and B, receiving IV ketorolac and ibuprofen respectively, administered 6-hourly. Variables measured included heart rate, mean arterial blood pressure, visual analogue scale (VAS) score, opioid usage in the first 24 h post-surgery, time to ambulate, and time to request first analgesic. **Results:** The Ibuprofen group presented lesser 24 h opioid requirement compared with Ketorolac group, with a mean of 44.0 ± 23.31 mg and 108.0 ± 14.68 mg, respectively, with $P < 0.01$. Relatively lower VAS scores, inclusive of patients in both rest as well as movement was observed in group B. The overall VAS scores at rest in Group A and B, respectively, are 4.23 ± 1.23 and 3.37 ± 1.18 with $P = 0.007$, whereas the overall VAS scores during movement are 4.66 ± 1.25 and 3.61 ± 1.13 with $P = 0.01$. The time to ambulate is significantly lower in Group B, and only 20% patients woke up during the night due to pain. Group B took a longer time to request the first analgesic dose (344.0 ± 89.53 min) compared with group A (162.40 ± 59.13), with $P < 0.01$. The patients in Group B also showed more hemodynamic stability than patients in Group A. **Conclusion:** As found from the results gathered from this research study, the use of IV ibuprofen is more effective than IV ketorolac in terms of providing analgesia following abdominal surgery because pain reduction is more significant, along with lower doses of opioid medications for 24 h post-surgery.

Key words: Abdominal surgeries, ibuprofen, ketorolac, post-operative pain

INTRODUCTION

Acute post-operative pain is one of the crucial aspects while evaluating wound healing process intensity. Moreover, acute pain may influence the quality of the rehabilitation period in general.^[1] The topic of pain and the necessity for managing it is one of the issues of public health care that has gained significant attention from the World Health

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Received: 16-05-2026

Revised: 22-06-2026

Accepted: 29-06-2026

Organization. Pain after surgery can be associated with various clinical considerations related to the post-recovery and post-operative hospital stay period. Given the ongoing opioid epidemic in the United States, it becomes crucial to use non-opioids in perioperative management.^[2]

The Non-steroidal anti-inflammatory drugs (NSAIDs) are used as an essential component of multimodal pain management due to its properties of reduction of the necessary dosage of opioid and prevention of their side effects, as well as providing adequate analgesia.^[1] The proper way of managing pain is using a few types of modalities combined together. In this case, it is possible to obtain a maximal analgesia with minimum drug dosages and no negative interaction of various drugs on each other and on the overall condition of a patient. As for the classification of painkillers, they can include opioid, NSAIDs, paracetamol, local anesthetics, and α 2-adrenergic agonists.^[3] Some drugs, for example, ketorolac or ibuprofen, can be prescribed in case of post-operative pain.^[4] In 2009, the Food and Drug Administration gave permission to use IV ibuprofen (Caldolor), which was developed by Cumberland Pharmaceuticals Inc., based in Nashville, Tennessee. Intravenous (IV) ibuprofen offers another drug option for physicians to choose. The drug is not dangerous for elderly people since it does not require dose modification.^[5]

NSAIDs can serve as an alternative to opioids in the treatment of acute post-operative pain. Their major advantage is an inhibition of cyclooxygenase (COX)-1 and COX-2 enzymes activity and synthesis of prostaglandins. Furthermore, ibuprofen in oral and IV forms also blocks cytokine production by neutrophils. Recently, new research findings have shown a possible role of elevated endocannabinoids levels in the analgesic effect of NSAIDs.^[3,6] Ketorolac and ibuprofen are among the most commonly used NSAIDs as they are present in an injectable form and can be effectively used for perioperative purposes. Even though ketorolac and ibuprofen have been widely used in pain management programs, there is no consensus as far as the efficacy of either medication is concerned when they are used on patients who have undergone surgery.^[7]

Even though IV ibuprofen and ketorolac have been widely used in clinical practice, there is definitely a need for solid research to provide reliable evidence on the comparison of their effectiveness. It is necessary to find out which of them gives greater analgesic effects, has a shorter time to act, and produces fewer opioids. Furthermore, it is important to clarify which medicine makes patients more satisfied and ensures their better recovery.

Objectives

Primary objective

- To compare post-operative efficacy of drugs by assessing static and dynamic visual analogue scale (VAS) scores in the first 24 h.

Secondary objectives

- To assess the duration of pain relief by knowing the time of the first rescue analgesic provided in post-operative period
- To assess the amount of opioid consumption in post-operative period.

METHODS

Study design

This research aimed to compare the safety, effectiveness, and tolerance levels of ibuprofen and ketorolac when administered through IV means to assess their efficacy in providing analgesic action in acute post-operative pain among patients undergoing elective abdominal surgery from January 2025 to June 2025.

Study population

Adult patients (20–70 years) undergoing elective abdominal surgery at Saveetha Medical College.

Sample size

A total of 60 participants who met the defined inclusion and exclusion criteria were enrolled consecutively during the study period and subsequently randomized, 30 to each group.

Inclusion criteria

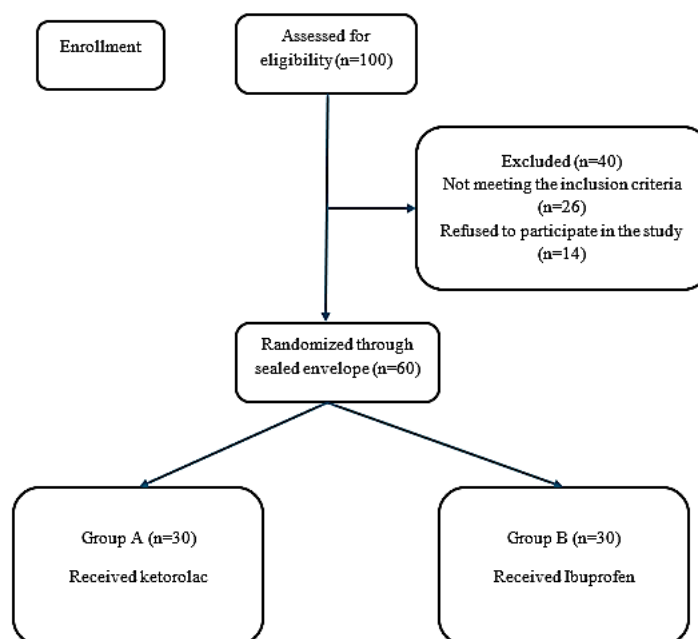
- Subjects who are enrolled in the study through signed informed consents
- Subjects scheduled for elective abdominal surgery with general anesthesia
- Subjects whose ASA classification is grade I and grade II
- Subjects within age 18 to 60 years old.

Exclusion criteria

- Pediatric patients
- Patients allergic to study medications
- Patients with deranged renal function test.
- Patients under American Society of Anesthesiologists (ASA) 3 and ASA 4.

Sampling method

After approval from the IRB and Ethical Committee Clearance, patients posted for elective surgeries are to be included in the study after written and informed consent. They will be randomly assigned to receive IV Ibuprofen preoperatively in Group B before giving General Anesthesia, whereas in Group A IV Ketorolac is given before giving General



Anesthesia. Group allocation is done by randomly allocated sealed envelope method. The attending anesthesiologist is unaware of group allocation.^[2]

Methods

The demographic characteristics, such as age, weight, and height, of the patients were recorded. The patients were moved to the operation theatre for the connection of the monitoring machines to the patient and recording of pre-anesthesia pain score by VAS. Peripheral IV access was made, and initiation of IV fluids was carried out. In accordance with the proper pre-oxygenation, ibuprofen (400 mg) and ketorolac (30 mg) were administered intravenously depending on the specific groups the subjects belonged to. General anesthesia was initiated using Fentanyl (2 µg/kg IV), Propofol (2 mg/kg IV) and Atracurium (0.5 mg/kg IV). Maintenance of anesthesia was ensured using oxygen and nitrous oxide in the ratio of 1:1 with isoflurane/sevoflurane and atracurium as required.^[2]

Data collection

Demographic data (age, sex, body weight), along with surgical duration, were recorded. Measurement of heart rate (per minute) and mean arterial pressure (MAP) (mmHg) was carried out at 1, 3, 6, 12, 18, and 24 h postoperatively. Pain intensity was measured using VAS for resting and moving conditions at each time interval. Whenever patients registered four or more on the VAS scale, a bolus dose of Tramadol (50 mg) was administered.

Data analysis and interpretation

All the data collected was analyzed using a Microsoft Excel spreadsheet (Microsoft Excel). After validating the data, the

Excel file consisting of all data was uploaded on Statistical Package for the Social Sciences (SPSS) version 24 software.

Statistical analysis

The statistical analysis of data was done using SPSS version 24. All continuous data were presented in Mean $\pm$ Standard deviation format, while all categorical data were presented in percentages of frequency distribution. For analysis of categorical data, Chi-square test was applied, while the independent sample *t*-test was employed for continuous data.

RESULTS

Figure 1 shows that majority of the study participants belong to the age group of 30–40 years with a mean age of 34.6 ± 1.2 years, followed by the age group 20–30 years with a mean age of 27.2 ± 1.3 years. In comparison, the majority of people in Group A are of 20–30 years age group, whereas it is 30–40 years in the other group, with a mean age of 32.3 ± 2.7 and 34.4 ± 3.2 years in Groups A and B, respectively.

Figure 2 shows that majority of the study participants are females undergoing abdominal hysterectomy due to uterine fibroids. In males, the cause for surgery is open cholecystectomies. About 43% among all the participants are males, whereas 57% are females.

Figure 3 shows that around 50% of patients are overweight with a mean body mass index (BMI) of 27.3 ± 2.4 kg/m², followed by normal weight with a mean BMI of 22 ± 8.1 kg/m². Group A has more participants who are overweight compared with Group B.

In Figure 4, we can see that 33 and 30% as well as 27 and 33% of A and B group participants had their surgeries completed within 30 and 30–40 min range, respectively. Overall, only 3 out of 60 participants had surgeries for more than 60 min.

The baseline heart rate was noted to be 90.4 ± 3.08 in Group A, whereas 91.0 ± 2.19 in Group B ($P = 0.668$) [Table 1]. The baseline heart rate decreased in both groups at 1 h mark. The heart rate increased steadily in Group A, but in Group B, it shows slight increase at 3 h and 6 h followed by a decrease at 12 h, 18 h and 24 h. In comparison, there is a

significant difference in heart rates between both the groups with significant P -values at 1 h, 3 h, 6 h, 12 h, 18 h, and 24 h.

The MAP at baseline was noted to be 97.60 ± 4.15 mmHg in Group A, whereas 94.20 ± 5.67 mmHg in Group B with ($P = 0.326$) [Table 2]. The baseline MAP decreased in both groups at 1 h mark. The MAP increased at 3 h and 6 h, followed by a decrease at 12 h, 18 h and 24 h in both groups. However, there is a significant difference of MAP values in Group B compared with Group A, with significant P -values at 1 h, 3 h, 6 h, 12 h, 18 h, and 24 h.

VAS at rest increased in the 1st 6 h postoperatively and then decreased until 24 h [Table 3]. The VAS score in Group B is significantly less when compared with Group A. The overall VAS score of Group A is 4.23 ± 1.23 , which is higher when compared with the 3.37 ± 1.18 score of Group B, with a significant $P = 0.007$.

VAS (movement) increased in the 1st 6 h postoperatively and then decreased until 24 h [Table 4]. The VAS score in Group B is significantly less when compared with Group A, showing a similar trend to VAS at rest. The overall VAS score (movement) of Group A is 4.66 ± 1.25 , which is also higher when compared with Group B, with a score of 3.61 ± 1.13 and statistically significant ($P = 0.012$).

The total opioid requirement (in mg) in the first day post-surgery is notably higher in Group A (108.0 ± 14.68) with Ketorolac compared to Group B (44.0 ± 23.31) with Ibuprofen [Table 5]. The participants of Group A requested the first analgesic dose within 3 h post-operative, compared with Group B, who did not request until after 6 h post-operative with significant P -values. The ambulatory time of Group B is also less when compared with Group A.

DISCUSSION

Pain management is very critical during the recovery process following surgery, and it should be multi-modal to help minimize opioid usage and the negative effects that come with them.^[6] NSAIDs like ibuprofen are some of the adjuvants that are used in pain control due to the benefits they offer in terms of inflammation.^[7] Unlike ketorolac, the

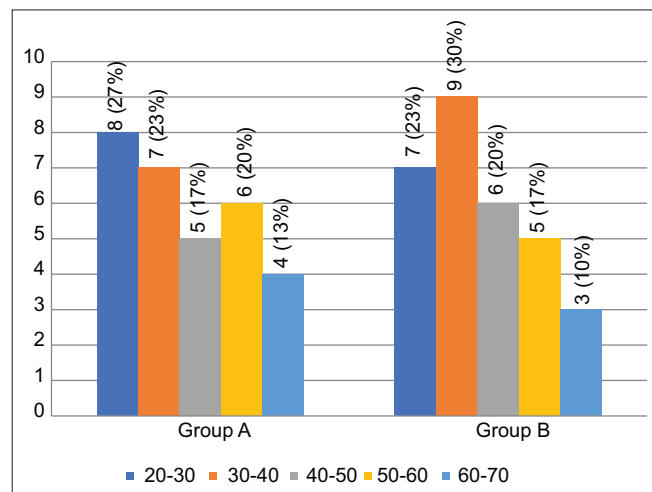


Figure 1: Age distribution of the study

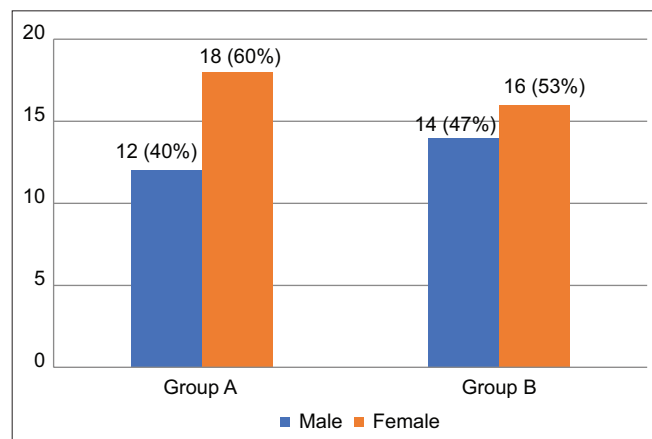


Figure 2: Gender distribution of the study

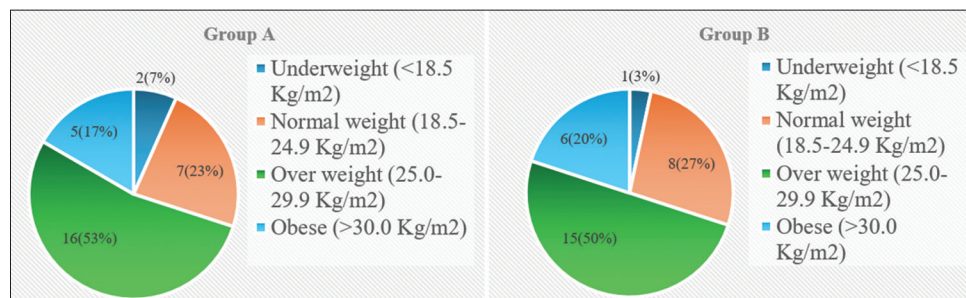


Figure 3: Body mass index distribution of the study

Table 1: Comparative assessment of heart rate (beats/min) in the two groups

Heart rate (beats/min)	Group A	Group B	t-test	P
Baseline value immediately after extubation	90.4±3.08	91.0±2.19	0.34	0.668
1 h	83.76±2.05	67.40±4.14	6.7	0.003*
3 h	84.40±3.93	71.40±4.55	6.5	0.002*
6 h	95.40±4.39	89.16±2.14	7.16	0.0001*
12 h	98.00±3.08	83.72±3.65	10.4	0.001*
18 h	98.64±4.07	79.72±2.88	9.66	0.001*
24 h	99.40±4.69	77.52±2.22	4.86	0.0032*

*Statistically significant at $P \leq 0.05$ **Table 2:** Comparison of MAP (mmHg) in the two groups

Mean arterial blood pressure MAP (mmHg)	Group A	Group B	t-test	P
Baseline value immediately after extubation	97.60±4.15	94.20±5.67	0.895	0.326
1 h	87.60±4.58	72.00±4.18	4.23	0.002*
3 h	91.66±5.5	79.60±3.58	4.98	0.003*
6 h	103.50±4.43	86.28±3.22	6.23	0.0001*
12 h	100.36±4.74	83.72±3.46	6.7	0.002*
18 h	99.66±4.58	82.67±3.54	6.52	0.001*
24 h	98.54±4.95	81.56±3.55	5.05	0.001*

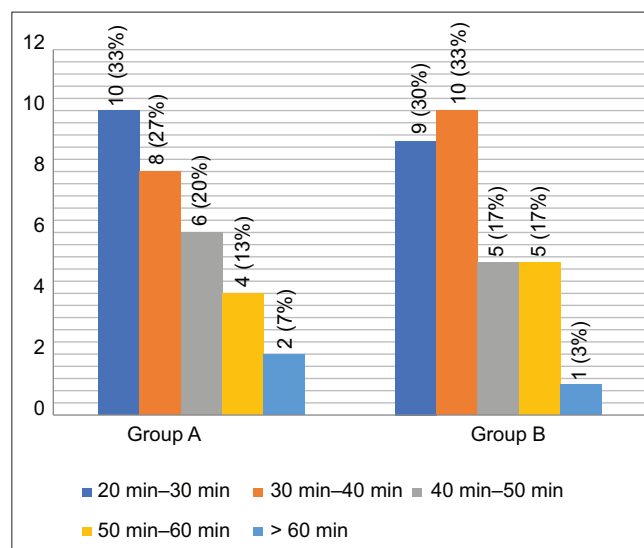
MAP: Mean arterial pressure. *Statistically significant at $P \leq 0.05$ **Table 3:** Comparison of VAS at rest in the two studied groups at different periods and the overall VAS (rest)

VAS (rest)	Group A	Group B	t-test	P
1 h	2.82±0.44	1.24±0.45	2.02	0.013*
3 h	3.12±0.48	2.2±0.40	1.72	0.034*
6 h	5.76±0.31	3.76±0.55	2.83	0.006*
12 h	4.94±0.79	3.52±0.41	3.35	0.004*
18 h	4.20±0.05	3.26±0.7	3.68	0.001*
24 h	4.0±0.0	2.96±0.35	3.55	0.01*
Overall VAS (rest)	4.23±1.23	3.37±1.18	2.65	0.007*

VAS: Visual Analog Scale. *Statistically significant at $P \leq 0.05$

administration of ibuprofen through the IV route is less likely to result in gastric complications since there is balanced COX inhibition.^[8,9]

The results of the present study correlate well with those identified by Uribe *et al.*, as it is clear that analgesic properties provided by IV ibuprofen were superior compared to those provided by ketorolac because of lower VAS scores after knee arthroscopy.^[10] Similar results can be found in the current study, in which patients receiving IV ibuprofen experienced consistently lower levels of pain, whether during rest or motion periods in all post-operative days.^[11] This effect might be related to anti-inflammatory actions of this drug due to the blocking of both COX-1 and COX-2 enzymes to the same extent, resulting in decreased production of prostaglandins.

**Figure 4:** Duration of surgery

Another advantage of ibuprofen is related to its action on the process of sensitization pathways.

Moreover, the present findings are consistent with those described by Daungsupawong and Wiwanitkit, who emphasized the positive impact of IV ibuprofen on providing enhanced post-operative pain management and decreased need for analgesics.^[12] The results serve as further proof of the notion that, besides being a potent pain reliever, ibuprofen can be utilized for sparing opioids, which is one of the major goals of modern multimodal analgesia approaches. As shown

Table 4: Comparison of VAS in movement in the two studied groups at different periods and the overall VAS

VAS (movement)	Group A	Group B	t-test	P
1 h	3.12±0.56	1.58±0.61	3.42	0.001*
3 h	3.24±0.97	2.06±0.67	3.18	0.003*
6 h	5.66±0.40	3.56±0.65	2.76	0.01*
12 h	4.60±0.40	3.32±0.54	2.98	0.01*
18 h	4.25±0.64	3.16±0.21	2.51	0.015*
24 h	4.06±0.38	2.49±0.46	3.85	0.014*
Overall VAS (movement)	4.66±1.25	3.61±1.13	2.48	0.012*

VAS: Visual Analog Scale. *Statistically significant at $P \leq 0.05$

Table 5: Comparison between the two studied groups on post-operative recovery outcomes between groups

Post-operative recovery outcome	Group A	Group B	test	P
Opioid requirement during the first 24 h after surgery (mg)	108.0±14.68	44.0±23.31	T=6.4	0.002*
Nocturnal awakening due to pain, n (%)			$\chi^2=22.6$	<0.001*
Yes	22 (73.33)	6 (20)		
No	8 (26.66)	24 (80)		
Time to ambulate (min)	214.0±65.64	94.40±41.0	T=9.12	0.001*
Time to first analgesic dose (min)	162.40±59.13	344.0±89.53	T=8.54	0.001*

*Statistically significant at $P \leq 0.05$

in the present work, this effect was achieved by means of decreased opioid use, delayed administration of supplemental pain medications, and decreased night-time wakefulness in the ibuprofen group. Based on the consistency between the present research and existing literature, it can be concluded that IV ibuprofen demonstrates superiority over ketorolac in improving recovery outcomes and reducing side effects associated with opioids.^[13-15]

The study by Singla *et al.* was a multi-center randomized double-blind controlled study on 800 mg IV ibuprofen post 6 h for orthopedic surgery, and it showed that fewer opiates were used. This is important because the fewer opiates used means that it is critical to administer IV ibuprofen since the negative consequences arise from the use of opiates.^[16-21]

Moreover, Kroll *et al.* state that in a multi-centered, randomized, and double-blind study, the use of IV Ibuprofen causes a substantial rise in rescue analgesic duration after surgery in abdominal hysterectomies compared with the control group. Moreover, it can be observed from the above-mentioned study that the rescue analgesic period in Group B (Ibuprofen) was substantially higher than that of Group A (Ketorolac).^[22-25] This study indicates that pre-operative administration of IV Ibuprofen (400 mg) before abdominal surgery results in significantly lower pain scores and morphine intake.

Limitations

The limitations of the above study include that it was carried out in one hospital, involving only a few subjects. Moreover,

individuals have varying tolerances for pain; thus, it is not possible to make generalizations.

CONCLUSION

Summing up the results of the research mentioned above, it is possible to note that the results of the randomized controlled trial demonstrate that IV ibuprofen is significantly more effective than IV ketorolac concerning post-operative pain after abdominal surgery. Indeed, the administration of ibuprofen resulted in lower pain ratings on VAS, lower usage of opioids within 24 h after the surgery, delayed need for additional analgesia, higher mobilization, and fewer awakenings at night due to pain. In addition to that, the application of ibuprofen ensured more stable hemodynamic indicators. It is thus possible to say that the application of IV ibuprofen in multimodal analgesia is significantly more favorable because of lower demands for opioids.

AUTHORS' CONTRIBUTIONS

Dr. B. Bharathi and Dr. R. Lakshmi: Conceptualization, literature review, writing, editing, and Dr. K. Chanthini, Dr. Ajay Pujala and Dr. Sivakumar Bandaru revision of the manuscript.

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Source of Support: Nil. **Conflicts of Interest:** None declared.