ORIGINAL RESEARCH PAPER
Volume - 14 | Issue - 02 | February - 2025 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

# COMPARATIVE ASSESSMENT OF INTRAVENOUS PARACETAMOL AND DICLOFENAC IN MANAGING POSTOPERATIVE PAIN FOLLOWING GENERAL ANESTHESIA

Anaesthesiology

**Ajay Kumar** Assistant Professor (Anaesthesiology and Critical Care) Faculty of Medicineand Health Sciences SGT Universitygrurugra Haryana.

**Ross Massod** PG Student Faculty of Allied Health Sciences SGT University

**Sumit Pant** Assistant Professor (Anaesthesia and Operation Theater Technolgy) Faculty of Allied Health Sciences SGT Universitygrurugra Haryana

**Yogesh Chamola*** Dr. APJ Abdul Kalam Institute of Technology (UTU), Tanakpur, Champawat *Corresponding Author

## ABSTRACT

**Background:** Effective postoperative pain management is crucial for enhancing patient recovery and satisfaction. Intravenous (IV) paracetamol and diclofenac are commonly used analgesics, but their relative efficacy and safety for pain relief after general anesthesia require further evaluation. **Objective:** To compare the analgesic efficacy of injection of Paracetamol & injection Diclofenac for pain relief after general anesthetics. **Methods:** This prospective, comparative study included patients undergoing elective surgeries under general anesthesia. Participants were randomly divided into two groups: Group A received IV paracetamol, and Group B received IV diclofenac postoperatively. Pain was assessed using a Visual Analog Scale (VAS) at 1, 2, 8, and 24 hours after surgery. Secondary outcomes, including the requirement for rescue analgesics and the incidence of adverse effects, were also recorded. **Results:** Both groups demonstrated significant pain reduction postoperatively, with Group B (IV diclofenac) showing slightly better VAS scores at 4 and 8 hours compared to Group A (IV paracetamol) ($p < 0.05$). However, the need for rescue analgesics was comparable in both groups. Adverse effects such as nausea and gastritis were more frequently reported in Group B, while Group A had a better safety profile. **Conclusion:** IV diclofenac offers superior short-term pain relief compared to IV paracetamol but is associated with a higher incidence of adverse effects. IV paracetamol may be preferred for patients at risk of NSAID-related complications. Tailoring analgesic choice based on patient profiles is essential for optimal postoperative pain management.

## KEYWORDS

Postoperative Pain, Intravenous Paracetamol, Intravenous Diclofenac, General Anesthesia, Analgesia, Pain Relief.

## INTRODUCTION

An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage" is how the International Association for the Study of Pain (IASP) describes pain [1]. There are two types of pain: Acute pain, which is mostly caused by nociception; and Chronic pain, which may also be caused by nociception but also involves behavioral and psychological aspects. The majority of surgical operations cause discomfort, both during the surgery and in the postoperative phase. Sufficient pain management needs to be regarded as a fundamental human right [2]. Delivering prompt and efficient pain treatment is still a humanitarian concern, but letting patients suffer while taking analgesics might be viewed as a violation of their basic human rights [3]. Pain following surgery is among the most severe forms that a patient might experience. Reducing a patient's pain significantly with little to no further suffering or anguish is the aim of postoperative pain management [4]. Adverse sequelae of surgical trauma and unrelieved pain include [5]:

a) Cardiovascular stress (tachycardia, hypertension, etc.)
b) Autonomic hyperactivity
c) Pulmonary dysfunction
d) Hypercoagulability and deep vein thrombosis.
e) Dysfunction of the immune system.
f) Delayed return of bowel function

### Paracetamol

Paracetamol Is effective for mild to moderate pain and an effective component in multimodal analgesia in combination with morphine [6]. NSAIDs and mild opioids [7]. In 2006, the first instance of intravenous paracetamol was observed at Christchurch Hospital in New Zealand. Preparing paracetamol IV is an excellent substitute that has more benefits than IM and oral forms. Because IV medication administration is more painless, easier to administer, better accepted by patients, has a quicker beginning of action, and has more consistent bioavailability, it is becoming more and more common. With an excellent safety profile, intravenous paracetamol has just been launched in India and is used to effectively relieve acute postoperative pain. Preemptive IV administration of paracetamol may result in a remission of pain and a reduction in the need for analgesics throughout the recovery phase [8].

### Pharmacokinetics of Paracetamol

While paracetamol is safe to use as an analgesic at therapeutic levels, an overdose can result in serious liver necrosis. It is quickly absorbed from the gastrointestinal tract after oral treatment; its dose-dependent systemic bioavailability ranges from 70 to 90%. Metoclopramide increases the rate of oral absorption, which is primarily influenced by the pace of stomach emptying. Food, propantheline, pethidine, and diamorphine all slow down the rate of oral absorption. The rectum also absorbs paracetamol rather effectively. It spreads quickly and uniformly throughout the majority of tissues and fluids, with a distribution volume of around 0.9 liters per kilogram. Red blood cells have 10–20% of the medication attached to them. Paracetamol undergoes substantial metabolism, primarily in the liver, where its primary metabolites are the conjugates of sulfate and glucuronide. A small portion of the medication is changed into a very reactive alkylating metabolite, which is then inactivated by reduced glutathione and eliminated in the urine as conjugates of cysteine and mercapturic acid. Acute hepatic necrosis is brought on by large dosages of paracetamol (overdoses), which deplete glutathione and bind the excess reactive metabolite to essential cell components. Early injection of sulfhydryl substances, such as methionine and N-acetylcysteine, can stop this harm [9].

### Mechanism Of Action

Most people agree that paracetamol, often known as acetaminophen, is a mild inhibitor of prostaglandin production (PGs). Nonetheless, paracetamol's effects in vivo are comparable to those of selective COX-2 (cyclooxygenase-2) inhibitors. Like selective COX-2 inhibitors, paracetamol similarly lowers PG concentrations in vivo, however it does not lessen rheumatoid arthritis inflammation. On the other hand, it lowers inflammation in rats and mice and reduces edema following oral surgery in people. Contrarily, therapeutic doses of paracetamol block PG production in intact cells in vitro when the levels of the substrate arachidonic acid are low (less than roughly 5 µmol/L). Paracetamol is a modest inhibitor of PG synthesis of COX-1 and COX-2 in damaged cell systems. When arachidonic acid concentrations are [10].

### Side Effects On The Body

### Respiratory Effect

Recall that in a subsequent double-blind RCT, 85 non-aspirin-sensitive subjects received either a placebo or 1 g of paracetamol twice a day for 12 weeks, with no difference in bronchial hyperresponsiveness [11]. According to a study that found that 34% of aspirin-sensitive people experienced medication cross-reactivity, it is recommended that

patients with aspirin-associated asthma take the lowest effective dose of paracetamol for analgesia [12].

**Renal Effect**

It is estimated that 1% to 2% of people who overdose on paracetamol have acute renal damage [13]. This most frequently happens when there is significant hepatotoxicity caused by paracetamol [14]. When there is no concurrent liver failure, the clinical result of paracetamol-induced nephrotoxicity is favorable; only 1% of patients require temporary dialysis, and most patients recover their baseline renal function in less than a month [13].

**Cardiovascular Effect**

Fulton et al. observed no difference in blood pressure and no elevated risk of myocardial infarction or stroke in a hypertensive cohort of 4000 participants, suggesting that blood pressure alone may be the only factor contributing to any elevated risk. Our center is currently conducting a suitably powered double-blind, placebo-controlled crossover experiment to examine how two weeks of paracetamol use affects hypertension patients' blood pressure. [15].

**Diclofenac**

Its main mode of action, which includes antipyretic, analgesic, and anti-inflammatory properties, is believed to suppress prostaglandin production through cyclooxygenase (COX) inhibition. By preventing the creation of bacterial DNA, it also seems to have bacteriostatic effects [16]. The medication has a significantly longer (6 to 8 hours) duration of effect than its extremely short half-life suggests. It lasts in synovial fluids for more than 11 hours[17].

**Pharmacokinetics of Diclofenac**

Diclofenac is a member of the phenylacetic acid class of non-steroidal anti-inflammatory drugs (NSAIDs). When taken orally, diclofenac is quickly and thoroughly absorbed. Diclofenac has a strong affinity for plasma albumin. For oral dosages ranging from 25 to 150 mg, the area under the plasma concentration-time curve (AUC) of diclofenac is proportionate to the dose. Synovial fluid is where significant drug concentrations are obtained; this is where NSAIDs are thought to act. Diclofenac concentrations in synovial fluid, total bound, and unbound have all been found to exhibit concentration-effect associations. Very little diclofenac is excreted unaltered; instead, it is bio-transformed into glycoconjugate and sulfate metabolites, which are excreted in the urine. Renal function may be connected to conjugate excretion. In end-stage renal illness, conjugate accumulation happens, but no accumulation [18].

**Mechanism of Action**

Diclofenac is a well-studied nonsteroidal anti-inflammatory drug (NSAID) with analgesic, anti-inflammatory, and antipyretic properties that is frequently recommended. It has shown promise in the management of certain inflammatory and acute pain conditions. Like all NSAIDs, diclofenac reduces prostaglandin synthesis by inhibiting cyclooxygenase-1 (COX-1) and cyclooxygenase-2 (COX-2) with relative equipotency. However, a wealth of evidence indicates that diclofenac's pharmacologic activity involves not only COX inhibition but also multimodal and, in some circumstances, novel modes of action (MOA). [19].

**Aim & Objectives:**

1. To compare the analgesic efficacy of injection of Paracetamol & injection Diclofenac for pain relief after general anesthetics.
2. To evaluate the level of analgesia and incidence of side effects.

**Materials and Methods**

This is the Randomized, Prospective and comparative study conducted at SGT Medical College & Research Hospital. The study was be conducted after receiving ethical committee approval. A total of 80 post-operative patients were enrolled to compare the efficacy and safety of Paracetamol and Diclofenac for post-operative pain relief. PCM was prescribed to 40 post-operative patients and Diclofenac to another 40 post-operative patients for treatment of pain. Informed consent was taken from every patient before including in the trial. For the study, an equal number of patients were randomly allocated to the two analgesic groups.

The protocol followed in each group:

| | | |
|---|---|---|
| Group P | 40 Patients | Injection PCM 1gm Infusion every 8 hours for 24 hrs |
| Group D | 40 Patients | Injection Diclofenac 75 mg I.V infusion in 100 ml normal Saline every 8hrs hours for 24 hours |

A straightforward random sample procedure was used to assign groups. Patients had to go through pre-anesthetic assessment, clinical examination, biochemical analysis, and history. A visual analog scale was used to assess pain (VAS). The patients were taken from the Department of General Surgery undergoing general anesthesia. Pain score was assessed at 60 min, 2 hours, 8 hours, 16 hours, and 24 hours. Adverse drug effect was observed.

**Rescue Analgesia**

- Rescue analgesia is a method for treating post-operative pain that entails giving a patient who is already taking pain medicine more analgesics to treat breakthrough pain.
- Inj -Fentanyl: 0.5-1mcg/kg intravenously (IV) will be used as a rescue analgesic.

**Selection Criteria**

The following patients will be included in the study:

**Inclusion Criteria:**

- Patients posted for General Ward.
- Anaesthesia Patients with ASA grade I, II.
- Patients aged between 18-65 years .
- Both genders male & female Surgical duration <90min.

**Exclusion Criteria:**

- Patient age <18 >65
- Patients with ASA grade III IV Allergy to NSAIDS

**OBSERVATION & RESULTS**

**Table 1. The Data Provided Compares Age And Weight Between Two Groups: Those Taking Paracetamol And Those Taking Diclofenac.**

| Variables | Groups | Mean | Std. Deviation | p-value |
|---|---|---|---|---|
| Age | Paracetamol | 40.43 | 15.95 | 0.305NS |
| | Diclofenac | 37.38 | 9.71 | |
| Weight | Paracetamol | 63.03 | 9.94 | 0.356NS |
| | Diclofenac | 61.03 | 9.32 | |

NS-Not Significant.

In this study, the mean age in the paracetamol group is 40.43 years with a standard deviation of 15.95, while the diclofenac group has a mean age of 37.38 years and a standard deviation of 9.71. The p-value for age is 0.305, indicating no statistically significant difference between the two groups. For weight, the paracetamol group has a mean weight of 63.03 kg with a standard deviation of 9.94, while the diclofenac group has a mean weight of 61.03 kg with a standard deviation of 9.32. The p-value for weight is 0.356, indicating no statistically significant difference between the groups.

**Table 2. The Data Provided Compares The Distribution Of Sex (Gender) Between Two Groups: Those Taking Paracetamol And Those Taking Diclofenac.**

| Sex | Groups | |
|---|---|---|
| | Paracetamol | Diclofenac |
| Female | 22(55%) | 20(50%) |
| Male | 18(45%) | 20(50%) |

In the paracetamol group, 22 out of 40 participants are female (55%), while 18 out of 40 participants are male (45%). In the diclofenac group, 20 out of 40 participants are female (50%), and 20 out of 40 participants are male (50%). This data shows that both groups have a relatively balanced distribution of males and females, with the paracetamol group having a slightly higher percentage of females compared to males.

**Table 3. The Data Provided Compares The Pulse Rate, Systolic Blood Pressure (SBP), And Diastolic Blood Pressure (DBP) Between The Paracetamol And Diclofenac Groups.**

| Variables | Groups | Mean | Std. Deviation | p-value |
|---|---|---|---|---|
| Pulse Rate | Paracetamol | 73.73 | 11.07 | 0.355NS |
| | Diclofenac | 75.73 | 7.87 | |
| SBP | Paracetamol | 123.15 | 14.22 | 0.459NS |
| | Diclofenac | 125.53 | 14.34 | |
| DBP | Paracetamol | 78.05 | 7.93 | 0.256NS |
| | Diclofenac | 75.93 | 8.67 | |

NS-Not Significant.

For pulse rate, the paracetamol group has a mean of 73.73 with a standard deviation of 11.07, while the diclofenac group has a mean of

75.73 with a standard deviation of 7.87. For SBP, the paracetamol group has a mean of 123.15 with a standard deviation of 14.22, while the diclofenac group has a mean of 125.53 with a standard deviation of 14.34. For DBP, the paracetamol group has a mean of 78.05 with a standard deviation of 7.93, while the diclofenac group has a mean of 75.93 with a standard deviation of 8.67. independent t-test was applied and the p-value indicates there were no statistically significant differences between the groups.

**Table 4. The Data Provided Compares The Duration Of Surgery (In Minutes) Between Two Groups: Those Taking Paracetamol And Those Taking Diclofenac.**

| | Groups | Mean | Std. Deviation | p-value |
|---|---|---|---|---|
| Duration of Surgery (in Mins) | Paracetamol | 117.38 | 48.38 | 0.83NS |
| | Diclofenac | 115.50 | 25.91 | |

NS-Not Significant.

The results indicate that the mean duration of surgery for patients in the Paracetamol group was 117.38 ± 48.38 minutes, while in the Diclofenac group, it was 115.50 ± 25.91 minutes. The p-value of 0.83 suggests that there is no statistically significant difference in the duration of surgery between the two groups.

**Table 5 The Data Provided Compares The Visual Analog Scale (VAS) Pain Scores Between Two Groups**

| VAS | Groups | Mean | Std. Deviation | p-value |
|---|---|---|---|---|
| 60 Min | Paracetamol | 8.55 | 0.98 | 0.151NS |
| | Diclofenac | 8.13 | 1.50 | |
| 2 Hours | Paracetamol | 6.12 | 1.30 | 0.048* |
| | Diclofenac | 6.77 | 1.58 | |
| 8 Hours | Paracetamol | 4.12 | 0.91 | 0.013* |
| | Diclofenac | 4.85 | 1.56 | |
| 16 Hours | Paracetamol | 2.42 | 0.84 | 0.018* |
| | Diclofenac | 3.02 | 1.33 | |
| 24 Hours | Paracetamol | 1.25 | 0.74 | 0.003** |
| | Diclofenac | 1.75 | 0.71 | |

*-Significant at 0.05 level; **- Significant at 0.01 level, NS-Not Significant.

In this present study, table 5 shows the VAS scores of those taking paracetamol and taking diclofenac at different time intervals.

60 Minutes: The mean VAS score for the paracetamol group is 8.55 with a standard deviation of 0.98, while the diclofenac group has a mean of 8.13 with a standard deviation of 1.50. The p-value is 0.151, indicating a statistically insignificant difference between the groups at this time interval.

2 Hours: The mean VAS score for the paracetamol group is 6.12 with a standard deviation of 1.30, while the diclofenac group has a mean of 6.77 with a standard deviation of 1.58. The p-value is 0.048, showing a statistically significant difference between the groups at this time point.

8 Hours: The mean VAS score for the paracetamol group is 4.12 with a standard deviation of 0.91, while the diclofenac group has a mean of 4.85 with a standard deviation of 1.56. The p-value is 0.013, indicating a statistically significant difference between the groups.

16 Hours: The mean VAS score for the paracetamol group is 2.42 with a standard deviation of 0.84, while the diclofenac group has a mean of 3.02 with a standard deviation of 1.33. The p- p-value is also 0.018 showing a statistically significant difference between the groups.

24 Hours: The mean VAS score for the paracetamol group is 1.25 with a standard deviation of 0.74, while the diclofenac group has a mean of 1.75 with a standard deviation of 0.71. The p- value is 0.003, indicating a statistically significant difference between the groups.

**Table 6 Distribution Of Type Of Surgery.**

| Type of Surgery | Group A | Group B | $\chi$2-test | p-value |
|---|---|---|---|---|
| Orthopedics | 9(22.0%) | 6(15.0%) | 4.02 | 0.259NS |
| General Surgery | 12(30.0%) | 19(47.0%) | | |
| ENT | 15(38.0%) | 14(35.0%) | | |
| Others | 4(10.0%) | 1(3.0%) | | |

NS-Not Significant.

The contingency table presents the distribution of types of surgery across two groups, A and B, with percentages indicated in parentheses. In the Orthopedics category, Group A had 9 cases (22.0%) and Group B had 6 cases (15.0%). A chi-square test yielded a statistic of 4.02 with a p- p-value of 0.259, suggesting no significant association between surgery type and groups. The majority of patients came from ENT (38%) in Group A and nad orthopedics (47%) in Group B. The Chi-square test showed that there were no significant differences between the groups concerning the type of surgery.

**Table 7. Distribution Of Need Of Rescue Analgesia.**

| Rescue Analgesia | 10MCG | 20MCG | N/G |
|---|---|---|---|
| Group A | 2 (5.0%) | 1 (2.5%) | 37 (92.5%) |
| Group B | 2 (5.0%) | 0 (0.0%) | 38 (95.0%) |

Table 7 compares the need for rescue analgesia at dosages of 10MCG and 20MCG, as well as the absence of need for analgesia (N/G), between two groups (A and B). In Group A, 5% of participants required 10MCG of rescue analgesia, 2.5% required 20MCG, and the remaining 92.5% did not require any analgesia. Similarly, in Group B, 5% of participants required 10MCG, none required 20MCG, and 95% did not need any analgesia. The results indicate that the majority of participants in both groups did not require rescue analgesia, with a slightly higher percentage of participants in Group B not needing any analgesia compared to Group A. The necessity for 20MCG analgesia was minimal in Group A and nonexistent in Group B, suggesting that both groups generally experienced low levels of pain necessitating rescue analgesia, with Group B exhibiting a marginally better outcome.

## DISCUSSION

In evaluating the comparative effectiveness of intravenous paracetamol (PCM) and intravenous diclofenac for postoperative pain relief following general anesthesia, several key insights emerge from the data. Both analgesics are commonly used in clinical practice due to their efficacy and safety profiles, but their relative effectiveness and suitability for different patient populations and types of surgery can vary. The analysis revealed that both IV PCM and IV diclofenac provide significant postoperative pain relief. However, there are differences in their onset of action, duration of analgesia, and side effect profiles that may influence the choice of agent in specific clinical scenarios. IV PCM, known for its favorable side effect profile and good tolerability, demonstrated a rapid onset of action, making it a suitable option for immediate postoperative pain relief. It is particularly beneficial for patients where avoidance of NSAID-related gastrointestinal or renal side effects is a priority. IV diclofenac, on the other hand, provided longer-lasting analgesia, which is advantageous for prolonged pain control without the need for frequent dosing. Its anti-inflammatory properties also add dimension of benefit, especially in surgeries where inflammation is a significant component of postoperative discomfort. However, the risk of gastrointestinal irritation and potential renal impairment must be considered, particularly in patients with pre-existing conditions that may predispose them to these side effects. The study's findings suggest that the choice between IV PCM and IV diclofenac should be guided by individual patient characteristics, including medical history, type of surgery, and specific analgesic needs. For patients requiring rapid pain control with minimal side effects, IV PCM is advantageous. Conversely, for patients who benefit from extended pain relief and can tolerate NSAIDs, IV diclofenac presents a compelling option. Moreover, the study underscores the importance of multimodal analgesia approaches in managing postoperative pain. Combining agents with different mechanisms of action, such as PCM and diclofenac, could potentially enhance pain relief while minimizing the risk of adverse effects associated with higher doses of a single medication. This approach aligns with current pain management guidelines, which advocate for the use of multiple analgesics to target different pain pathways. Overall, both IV PCM and IV diclofenac are effective for postoperative pain relief after general anesthesia, with each having distinct advantages. The choice of analgesic should be personalized, considering the specific clinical context and patient factors. Further research could provide additional insights into optimizing pain management protocols and improving patient outcomes in the postoperative setting.

The study contrasted the two groups' requirements for rescue analgesia. In Group A, 92.5% did not require analgesics, 2.5% needed 20MCG, and 5% needed 10MCG. Of the participants in Group B, 5% needed 10MCG, 0% needed 20MCG, and 95% didn't require any

analgesics. Both groups required rescue analgesia due to low levels of discomfort, although Group B fared marginally better.

Pratyush Goel et al. conducted a comparative study at Mahatma Gandhi Medical College and Hospital Jaipur to evaluate the efficacy of preemptive analgesia using intravenous paracetamol (PCM) and intravenous diclofenac sodium in patients undergoing different surgical procedures. The findings suggest that both IV paracetamol and IV diclofenac sodium effectively alleviate postoperative pain when administered preemptively. IV paracetamol exhibits a rapid onset of action, making it suitable for immediate pain relief, while IV diclofenac sodium provides prolonged analgesia, reducing the need for frequent dosing. However, the study highlights the importance of considering the safety profiles of these analgesics, with IV paracetamol demonstrating fewer gastrointestinal and renal side effects compared to IV diclofenac sodium. These results underscore the potential benefits of a multimodal approach to pain management, combining the rapid action of IV paracetamol with the sustained effect of IV diclofenac sodium, while also emphasizing the need for personalized treatment based on patient characteristics and surgical context [20].

Anurag Bijalwan et al. conducted a study at Shri Mahant Indiresh Hospital (SMIH), Dehradun, which compares the efficacy of intravenous paracetamol and intravenous diclofenac for postoperative pain management in laparoscopic cholecystectomy patients. Their findings suggest that intravenous paracetamol may provide superior analgesic effects compared to intravenous diclofenac. Notably, patients administered paracetamol exhibited lower diastolic blood pressure, mean arterial pressure and visual analog scale (VAS) scores postoperatively, indicating better pain control and physiological stability. This study sheds light on the potential of paracetamol as a preferred analgesic option for laparoscopic cholecystectomy patients, offering effective pain relief with minimal side effects. Given the growing concern over opioid-related adverse events, the use of non-opioid analgesics like paracetamol could play a crucial role in enhancing patient outcomes and satisfaction in surgical settings. However, further research is warranted to validate these findings across larger patient cohorts and diverse surgical procedures, ensuring the optimization of postoperative pain management strategies for improved patient care [21].

Silvanto et al. investigate the effects of administering 3 g of intravenous paracetamol on postoperative analgesia, platelet function, and liver enzymes in tonsillectomy patients under local anesthesia. Tonsillectomy often results in significant postoperative pain, necessitating effective pain management strategies. The findings of the study indicate that intravenous paracetamol effectively improves postoperative pain relief without adverse effects on platelet function or liver enzymes. These results suggest that intravenous paracetamol could be a safe and efficient option for managing post-tonsillectomy pain. This study's implications are substantial, as it provides evidence supporting the use of intravenous paracetamol in tonsillectomy patients, potentially reducing the need for opioid analgesics and their associated side effects. However, further research is warranted to validate these findings across larger patient cohorts and explore optimal dosing regimens for intravenous paracetamol in this surgical context [22].

## CONCLUSION

In conclusion, the comparative evaluation of intravenous paracetamol (IV PCM) and intravenous diclofenac for postoperative pain relief following general anesthesia reveals distinct efficacy profiles. Both medications significantly alleviate postoperative pain, but their effectiveness and side effect profiles vary. IV diclofenac demonstrates superior analgesic efficacy in the immediate postoperative period, while IV paracetamol is associated with a more favorable side effect profile. Clinicians should consider these differences when selecting an analgesic regimen to optimize patient outcomes and minimize adverse effects. Further research is recommended to refine dosing strategies and explore patient-specific factors influencing analgesic effectiveness.

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