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OPTIMIZING POSTOPERATIVE ANALGESIA: A RANDOMIZED COMPARISON OF INTRAVENOUS IBUPROFEN AND PARACETAMOL IN ABDOMINAL STOMA CLOSURE

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Abstract

Background: Postoperative pain is a common challenge following abdominal stoma closure surgeries. This study aimed to compare the analgesic efficacy of intravenous (IV) ibuprofen with IV paracetamol in adult patients undergoing these surgeries under subarachnoid block.

Materials and Methods: A total of 132 patients were randomly allocated into two groups: Group I (n=66) received IV ibuprofen (20mg/kg) every 6 hours, and Group P (n=66) received IV paracetamol (15mg/kg) every 6 hours. Data collected included age, gender, anthropometric parameters, duration of surgery, Visual Analog Scale (VAS) scores at rest and during movement at various time intervals (0, 1, 2, 6, 12, 18, 24 hours), and any adverse effects. Rescue analgesia (IV tramadol 1mg/kg) was administered if the VAS score exceeded 40mm.

Results: Postoperative VAS scores at rest showed no statistically significant difference between the two groups throughout the observed intervals. For VAS scores on movement, Group I showed significantly lower scores at 0 hours and 6 hours compared to Group P (p=0.019 and p=0.016, respectively), though this difference was not considered clinically significant. While 21 patients in Group I and 34 patients in Group P required rescue tramadol, indicating a statistically significant difference in the incidence of rescue analgesia (p=0.022), the mean dosage of tramadol consumed was also statistically significantly lower in Group I (24.2 ± 37.2 mg) compared to Group P (39.4 ± 41.4 mg) (p=0.029). Adverse effects were observed in 11 patients (16.7%) in Group I and 4 patients (6%) in Group P, with no statistically significant difference between groups.

Conclusions: The analgesic efficacy of IV ibuprofen was found to be equivalent to IV paracetamol

in terms of VAS scores but demonstrated a statistically significant reduction in the incidence and mean dosage of rescue analgesia compared to IV paracetamol in adult patients undergoing abdominal stoma closure surgeries under subarachnoid block. Both agents showed comparable adverse effects. These findings suggest a potential advantage of IV ibuprofen in reducing opioid requirements.

Key words: Intravenous ibuprofen, Intravenous paracetamol, abdominal stoma closure surgery, VAS scores.

Introduction

Effective management of postoperative pain is a critical component of patient care, directly influencing recovery trajectories, patient satisfaction, and the incidence of complications. Acute pain following surgical procedures, particularly abdominal and thoracic interventions, can lead to significant morbidity, including impaired respiratory function and delayed ambulation [1]. National surveys indicate that a substantial majority of surgical patients, often exceeding 80%, report experiencing postoperative pain, with a high proportion describing it as moderate to extreme in severity [2,3]. Uncontrolled acute pain is associated with increased morbidity, functional impairment, delayed recovery, prolonged opioid use, and higher healthcare costs [2]. Comprehensive pain control is thus paramount for facilitating rapid recovery, reducing hospital stays, and mitigating risks such as deep vein thrombosis and pulmonary complications [4].

The complex neurophysiological mechanisms underlying postoperative pain necessitate a multimodal analgesic approach to achieve synergistic pain relief [5,6]. Historically, opioids have been a cornerstone of postoperative pain management for moderate to severe pain. However, their widespread use is increasingly scrutinized due to a spectrum of dose-dependent adverse effects, including respiratory depression, sedation, nausea, vomiting, constipation, pruritus, ileus, and urinary retention, which can impede recovery and prolong hospitalization [7,8]. Furthermore, concerns regarding opioid-induced hyperalgesia and the potential for prolonged opioid use underscore the need for effective non-opioid alternatives [9].

In response to these challenges, non-opioid analgesics, such as paracetamol and non-steroidal anti-inflammatory drugs (NSAIDs) like ibuprofen, have gained prominence as integral components of multimodal pain regimens [10,11,12]. NSAIDs exert their analgesic effects primarily through peripheral mechanisms by inhibiting prostaglandin synthesis, offering pain relief without the central nervous system side effects associated with opioids. They provide effective analgesia, often comparable to opioids, while avoiding issues of accumulation, addiction, tolerance, or physical dependence [13,12]. Their inclusion in multimodal strategies has been shown to reduce opioid consumption, decrease opioid-related adverse events, and potentially shorten hospital stays [6,14].

While the efficacy of intravenous ibuprofen and paracetamol has been extensively studied in various surgical contexts, including laparoscopic and orthopedic procedures, there remains a paucity of comparative literature specifically addressing their use in open abdominal stoma closure surgeries performed under subarachnoid block. This study aims to bridge this knowledge gap by rigorously comparing the analgesic efficacy and safety profiles of intravenous ibuprofen and intravenous paracetamol in this distinct patient population and surgical setting.

Materials and Methods

This randomized controlled trial was conducted in a tertiary care hospital after obtaining approval from the institutional ethical committee and securing written informed consent from all participants. The sample size of 132 patients was determined based on a previous study using G*Power software v3.0 [11]. Patients were allocated into two groups through computerized randomization.

Study Groups and Intervention:

- **Group I (Ibuprofen):** Sixty-six (66) patients received intravenous ibuprofen at a dose of 20 mg/kg.
- Group P (Paracetamol): Sixty-six (66) patients received intravenous paracetamol at a dose of 15

mg/kg.
Both drugs were administered every 6th hour.

Inclusion and Exclusion Criteria:

- **Inclusion Criteria:** Patients aged between 18 and 70 years of either gender, with American Society of Anesthesiologists (ASA) physical status class I/II, undergoing elective single-site abdominal stoma closure surgery under subarachnoid block.
- **Exclusion Criteria:** Patients who had used NSAIDs within 12 hours prior to the first planned dose, those with pre-existing dependence on narcotics or receiving chronic opioid treatment, patients on oral anticoagulants, lithium, ACE inhibitors, furosemide, or aspirin, and individuals with a known history of anemia, asthma, heart failure, pregnancy, peptic ulcer, bleeding diathesis, or liver and kidney diseases, or hypersensitivity to ibuprofen or paracetamol.

Preoperative and Intraoperative Management:

All eligible patients underwent a pre-anesthetic evaluation according to departmental protocol. Patients were instructed on the self-assessment of pain using the Visual Analog Scale (VAS), where 0 indicated "no pain" and 10 indicated "worst pain". NPO (nil per os) guidelines of 6 hours for solids were strictly followed. Pre-medication included oral alprazolam 0.25 mg the night before surgery, and oral ranitidine 150 mg and metoclopramide 10 mg two hours prior to surgery.

Upon arrival in the operating room, standard monitors (ECG leads, NIBP, pulse oximeter, SpO2) were attached. An 18 G intravenous cannula was secured in the non-dominant hand. Patients were preloaded with 500 ml of Ringer Lactate as per hospital protocol. Under aseptic precautions, a lumbar subarachnoid block was performed in the best palpable space in a sitting position, using 2.8 ml of Inj. Bupivacaine 0.5% (H) and 10 mcg (0.2ml) of Inj. Fentanyl, after confirming free flow of cerebrospinal fluid (CSF). Patients were then positioned supine, and the level of anesthesia was continuously monitored. Surgery commenced once adequate anesthesia, confirmed up to T6 level, was achieved. Standard routine intraoperative monitoring was maintained throughout the surgical procedure.

Postoperative Analgesia and Data Collection:

Thirty minutes before the anticipated end of surgery, patients received their assigned study drug. Group I received 20 mg/kg of IV ibuprofen diluted in 250 ml, while Group P received 15 mg/kg of IV paracetamol, both infused over a 30-minute period. The same dose was repeated every 6 hours according to the assigned group.

Demographic data and duration of surgery were recorded. Pain intensity was assessed by patient self-assessment using a 0-100 mm horizontal VAS scale, anchored by "NO PAIN" (0 mm) and "MOST POSSIBLE PAIN" (100 mm). Patients marked the point on the line that represented their current pain perception. Pain was categorized as mild (10-40 mm), moderate (41-60 mm), or severe (61-100 mm). VAS scores were recorded at rest and during movement (induced by coughing and deep breathing) at several time points: 0 hours (15 minutes after shifting to post-anesthesia care unit), 1, 2, 6, 12, 18, and 24 hours.

If a patient's VAS score exceeded 40 mm at any assessment time point, a dose of rescue analgesic, Inj. Tramadol 1 mg/kg intravenously, was administered. If pain persisted within 20 minutes, an additional 0.5 mg/kg of Inj. Tramadol was given. The total cumulative dose of tramadol consumed over 24 hours was recorded for each group. Any adverse effects such as nausea, vomiting, or allergic reactions were noted and managed according to hospital protocol.

Statistical Analysis:

Results were presented as frequencies, percentages, and mean ± standard deviation (SD). The Chi-square test was employed for comparing categorical variables between the groups. One-way analysis of variance (ANOVA) was used to compare continuous variables across time periods. A p-value of <0.05 was considered statistically significant. All statistical analyses were performed using BlueSky Statistics Version 10.

Results

A total of 132 patients successfully completed the study and were included in the final analysis. Demographic characteristics, including age, height, weight, BMI, sex, ASA physical status, and total duration of surgery, were comparable between the two groups, with no statistically significant differences observed (p-values ranging from 0.065 to 0.853) (Table 1).

Figure 1: CONSORT Flow Diagram

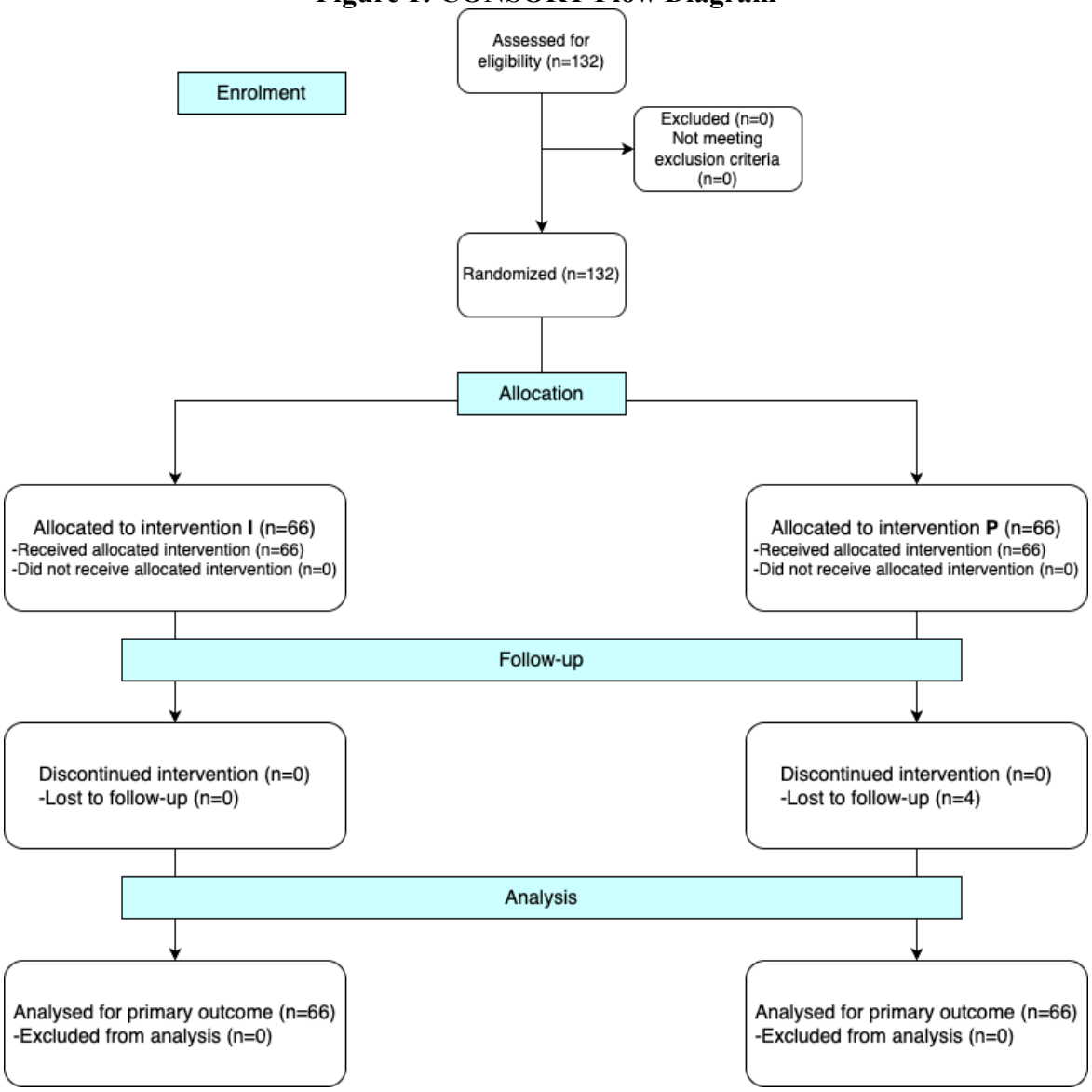

Table 1: Comparison of Age, Height, Weight, BMI, Sex & ASA-PS between Group I (Ibuprofen) and Group P (Paracetamol)

Variable	**Group I (n=66)** Mean±SD	**Group P (n=66)** Mean±SD	**p-value**
Age (yrs)	30.7±8.7	30.2±9.1	0.748†
Height (cm)	164.9±8.7	165.2±8.2	0.853†
Weight (kg)	66.3±7.9	68.7±6.5	0.065†
BMI (kg/m^2)	24.6±3.9	25.3±3.2	0.253†
Total Duration of Surgery (minutes)	107.1±20.4	105.9±20.2	0.732†
	Group I (n=66) n(%)	**Group P (n=66)** n(%)	**p-value**

Sex Male Female	 32 (48.5%) 34 (51.5%)	 37 (56.1%) 29 (43.9%)	 0.384[#]
ASA I II	 57 (86.4%) 9 (13.6%)	 59 (89.4%) 7 (10.6%)	 0.594[#]
[†] Test applied: Independent t-test [#] Test applied: Chi-squared test			

VAS Scores at Rest: The mean VAS scores at rest for both Group I (Ibuprofen) and Group P (Paracetamol) are presented in Table 3 and Figure 2. At TP0 (15 minutes post-surgery), the mean VAS score at rest was 16.4 ± 5.4 mm for Group I and 17.1 ± 6 mm for Group P, with no statistically significant difference (p=0.518). Throughout subsequent time intervals (TP1, TP2, TP6, TP12, TP18, TP24), the mean VAS scores at rest remained comparable between the two groups, with no statistically significant differences observed. Although not statistically significant, the mean VAS score at rest in Group I was consistently lower than in Group P at all observation points.

Figure 2: Mean Postoperative VAS at Rest by Treatment Group

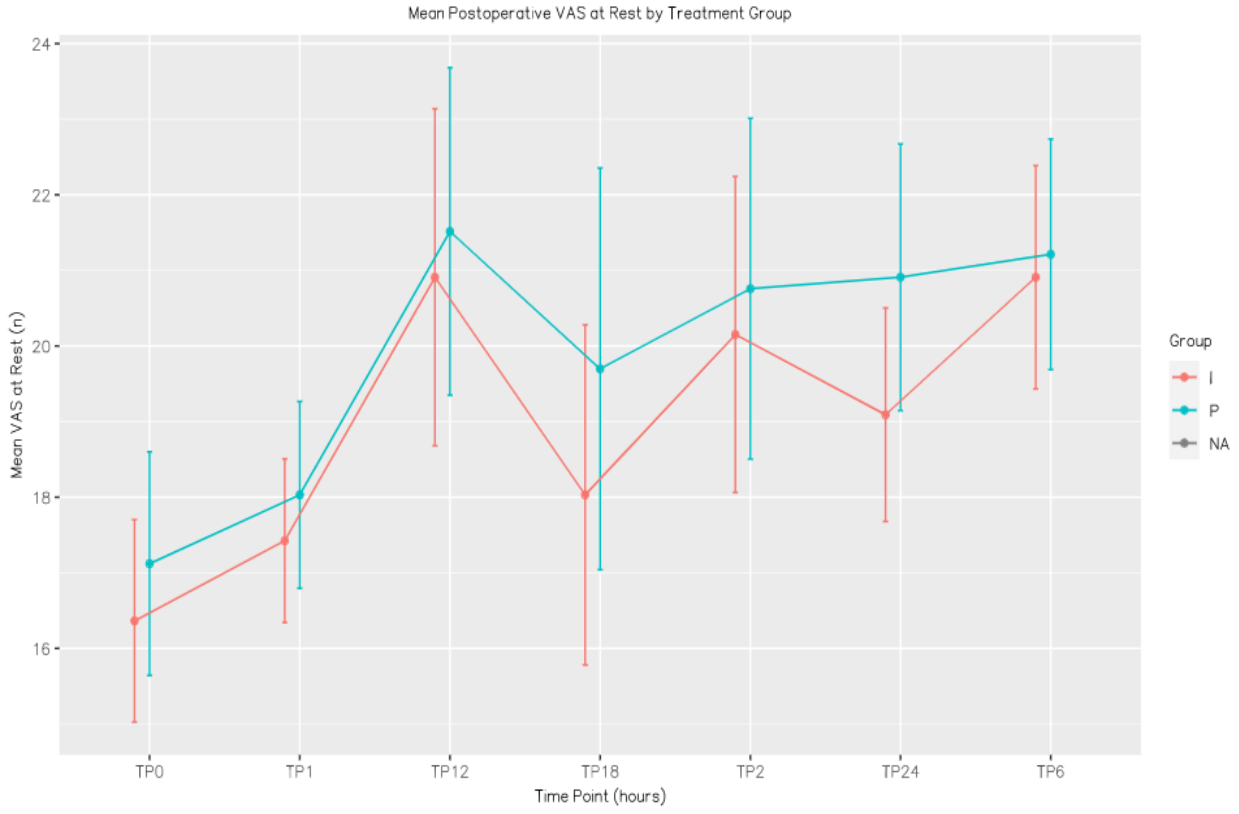

Table 3: Comparison of VAS at rest between Group I (Ibuprofen) and Group P (Paracetamol)				
VAS on Movement at time point	**χ^2**	**df**	**p**	**ε^2**
0 hours (TP0)	0.418	1	0.518	0.00319
1 hour (TP1)	0.392	1	0.531	0.00299
2 hours (TP2)	0.116	1	0.733	0.000889
6 hours (TP6)	0.204	1	0.651	0.00156
12 hours(TP12)	0.262	1	0.609	0.00200
18 hours(TP18)	0.499	1	0.480	0.00381
24 hours(TP24)	2.079	1	0.149	0.01587
Test applied: Kruskal-Wallis				

VAS Scores on Movement: The mean VAS scores on movement for both groups at different time intervals are detailed in Table 2 and Figure 3. At TP0, the mean VAS score on movement was 18.6 ± 5.2 mm for Group I and 21.1 ± 6.6 mm for Group P, showing a statistically significant difference (p=0.019). Similarly, at TP6, the mean VAS score on movement was 27.3 ± 6.2 mm for Group I and 31.1 ± 9.6 mm for Group P, which also demonstrated a statistically significant difference (p=0.016). However, despite statistical significance at these points, no clinical difference was observed between the groups. At other time points (TP1, TP2, TP12, TP18, TP24), no statistically significant difference was found between the two groups regarding VAS scores on movement.

Figure 3: Mean Postoperative VAS on Movement by Treatment Group

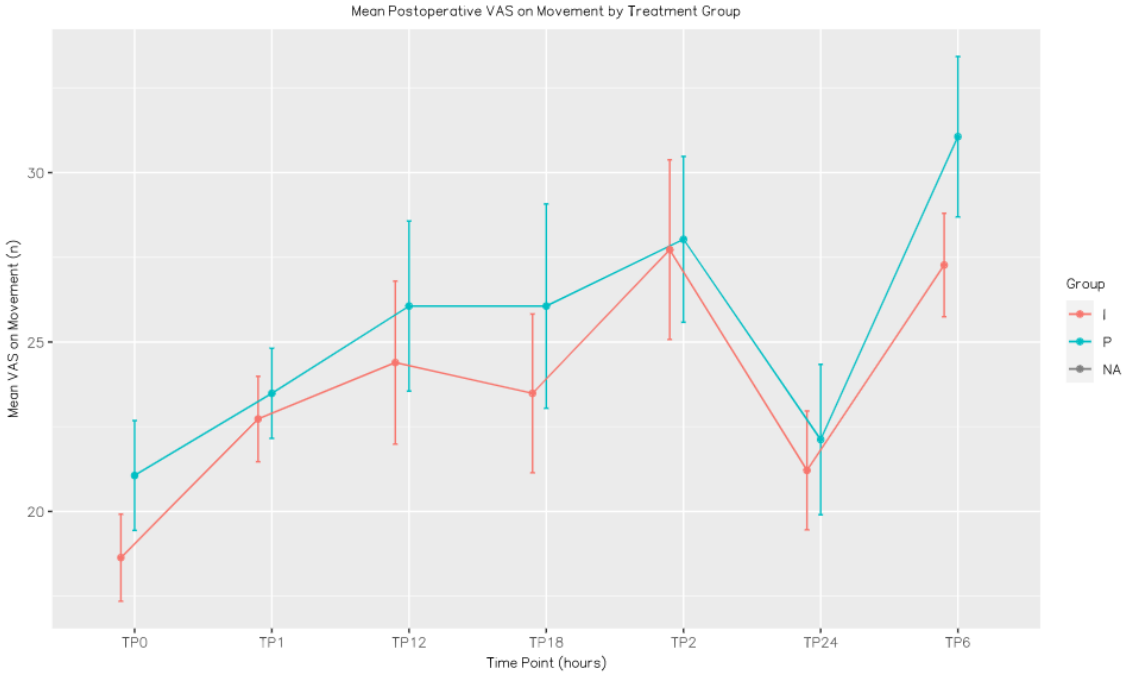

Table 2: Comparison of VAS on movement between Group I (Ibuprofen) and Group P (Paracetamol)				
VAS on Movement at time point	**χ^2**	**df**	**p**	**ε^2**
0 hours (TP0)	5.495	1	0.019*	0.04195
1 hour (TP1)	0.745	1	0.388	0.00569
2 hours (TP2)	0.250	1	0.617	0.00191
6 hours (TP6)	5.819	1	0.016*	0.04442
12 hours(TP12)	1.374	1	0.241	0.01049
18 hours(TP18)	1.388	1	0.239	0.01059
24 hours(TP24)	0.229	1	0.632	0.00175
Test applied: Kruskal-Wallis *p<0.05 is considered significant				

Rescue Analgesia Requirement (Tramadol): The incidence and total dosage of rescue analgesia (tramadol) requirement over 24 hours is presented in Table 4. Out of 66 patients in Group I, 21 (31.8%) required tramadol, while in Group P, 34 (51.5%) required tramadol. This difference in the number of patients requiring rescue analgesia was statistically significant (p=0.022). Furthermore, the mean dosage of tramadol required was 24.2 ± 37.2 mg for Group I and 39.4 ± 41.4 mg for Group P. This difference in mean dosage was also statistically significant (p=0.029). Overall, 77 out of 132 patients (58.3%) required rescue analgesia during the 24-hour postoperative observation

period.

Figure 4: Boxplot of Total Tramadol Consumed by Treatment Group

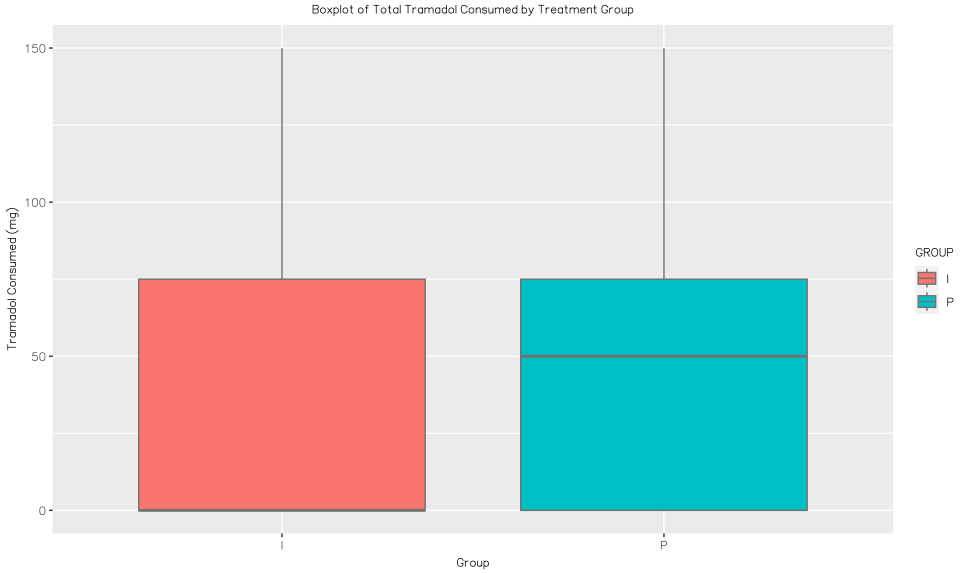

Table 4: Rescue Analgesia (Tramadol) requirement					
Variable	**Group I (n=66)** Mean±SD	**Group P (n=66)** Mean±SD	**p-value**	**Cohen's D**	**-**
Tramadol Requirement (mg)	24.2±37.2	39.4±41.4	0.029†	0.385	-
	Group I (n=66) n (%)	**Group P (n=66)** n (%)	**p-value**	**Odds Ratio**	**Cramer's V**
Tramadol given Yes No	 21 (31.8%) 45 (68.2%)	 34 (51.5%) 32 (48.5%)	 0.022#	 0.439	 0.200
† Test applied: Independent t-test # Test applied: Chi-squared test					

Adverse Effects: The comparison of adverse effects between the two groups is shown in Table 5. In Group I, 11 patients (16.6%) experienced adverse effects, primarily nausea, vomiting, or abdominal pain. In Group P, 4 patients (6.1%) reported adverse effects. Specifically, 5 patients in Group I and 2 in Group P reported nausea and vomiting (p=0.244), while 6 patients in Group I and 2 in Group P reported retrosternal burning sensation and epigastric pain (p=0.145). The data showed no statistically significant difference in the incidence of adverse effects between the two groups. All reported adverse effects were treated according to hospital protocol (e.g., IV ondansetron for nausea/vomiting, IV pantoprazole for gastritis pain).

Table: 5 Incidence of Adverse effects (Nausea/Vomiting and Retrosternal burning sensation/Epigastric Pain)			
Incidence	**Group I (n =66)n(%)**	**Group P (n=66) n(%)**	**p- value**
Nausea/Vomiting	5 (7.6%)	2 (3%)	0.244
Retrosternal burning sensation/Epigastric pain	6 (9.1%)	2 (3%)	0.145
Total	11 (16.7%)	4 (6%)	0.548
Test applied: Chi-squared test			

Discussion

Effective postoperative pain management is paramount for patient recovery and overall surgical outcomes. This study investigated the comparative efficacy and safety of intravenous ibuprofen and paracetamol as components of a multimodal analgesic regimen following abdominal stoma closure surgeries performed under subarachnoid block. Our findings indicate that both agents provide comparable analgesia in terms of VAS scores, but intravenous ibuprofen demonstrated a statistically significant reduction in the need for rescue analgesia.

The demographic and surgical characteristics were well-matched between the two treatment arms, ensuring the internal validity of our comparisons. This foundational similarity allows for a confident interpretation of the observed analgesic and safety profiles.

Regarding pain intensity, our results demonstrated that mean Visual Analog Scale (VAS) scores at rest remained consistently below 40 mm in both groups throughout the 24-hour postoperative period, signifying mild pain. Crucially, no statistically significant differences were observed in VAS scores at rest between the ibuprofen and paracetamol groups at any time point. This suggests that for pain experienced at rest, both intravenous ibuprofen and paracetamol offer equivalent analgesic efficacy in this patient population.

However, a more nuanced picture emerged when assessing pain during movement. While the mean VAS scores on movement were statistically lower in the ibuprofen group at 0 hours (immediately post-surgery) and 6 hours, it is important to note that these differences were not deemed clinically significant. This implies that despite statistical significance, the magnitude of pain reduction achieved by ibuprofen over paracetamol at these specific time points may not translate into a perceptible clinical benefit for the patient. At all other time intervals, VAS scores on movement were comparable between the groups. These findings align with some existing literature [13,14] which reported similar overall VAS scores between ibuprofen and paracetamol groups, although their contexts (laparoscopic cholecystectomy and sleeve gastrectomy under general anesthesia) differ from our open surgical setting under subarachnoid block. Conversely, a study on bariatric surgery [11] observed statistically significant lower VAS scores on movement with intravenous ibuprofen, suggesting a potentially greater immediate postoperative analgesic benefit in their specific surgical model. The discrepancy may be attributable to differences in surgical invasiveness (open vs. laparoscopic) and anesthetic techniques, which influence the pain experience.

The requirement for rescue analgesia provides an objective measure of analgesic effectiveness. Our study found a statistically significant difference in the incidence of rescue tramadol administration, with fewer patients in the ibuprofen group requiring supplemental analgesia compared to the paracetamol group (31.8% vs. 51.5%, p=0.022). Furthermore, the mean dosage of tramadol consumed was also statistically significantly lower in the ibuprofen group (24.2 ± 37.2 mg) compared to the paracetamol group (39.4 ± 41.4 mg) (p=0.029). This suggests that intravenous ibuprofen may offer a more effective analgesic profile, leading to a reduced need for breakthrough pain medication and lower overall opioid consumption. This finding contrasts with some studies, such as one in arthroscopic knee surgery [15], where opioid consumption was comparable between ibuprofen and ketorolac groups. The observed reduction in opioid requirement with ibuprofen in our study highlights its potential role in opioid-sparing strategies, which is a significant clinical goal in modern pain management.

Regarding safety, the incidence of adverse effects, including nausea, vomiting, and gastrointestinal discomfort (retrosternal burning sensation and epigastric pain), was low in both groups and did not differ statistically. While numerically higher rates of nausea/vomiting and gastritis symptoms were observed in the ibuprofen group, these differences were not significant, suggesting a comparable safety profile for both drugs at the administered doses. This finding is generally consistent with other studies on these agents [11,13,14], although variations in surgical procedures can influence the baseline incidence of adverse events. Importantly, no severe adverse events or instances of gastrointestinal bleeding were observed.

A key strength of our study lies in its focus on open abdominal stoma closure surgeries under

subarachnoid block, a context less frequently explored in comparative analgesic trials involving intravenous ibuprofen and paracetamol. This contributes valuable data to the understanding of non-opioid analgesia in a specific surgical population.

Limitations:

Despite these contributions, our study has several limitations. The use of subarachnoid block, while providing excellent intraoperative analgesia, may have masked some initial differences in postoperative pain profiles that might be more evident with general anesthesia. The mean duration of surgery (approximately 105 minutes) could also influence the overall pain experience and analgesic requirements. Furthermore, the absence of local anesthetic infiltration at the incision line post-surgery might have affected early postoperative pain scores. Finally, the reliance on bolus tramadol injections rather than a patient-controlled analgesia (PCA) pump for rescue analgesia may introduce variability in the assessment of total analgesic consumption and patient-driven pain control. Future studies incorporating PCA and assessing long-term outcomes, such as chronic pain incidence, would provide further insights.

Conclusion

This randomized comparative study demonstrates that while intravenous ibuprofen and intravenous paracetamol offer equivalent analgesic efficacy for postoperative pain management in adult patients undergoing abdominal stoma closure surgeries under subarachnoid block in terms of VAS scores, IV ibuprofen significantly reduced the incidence and mean dosage of rescue tramadol. Both agents effectively maintain pain at mild levels and exhibit comparable safety profiles. These findings suggest that intravenous ibuprofen may offer a more favorable profile in reducing opioid requirements in this surgical population, supporting its robust role as an effective non-opioid option in multimodal pain management strategies.

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