

Comparison of Intravenous Ibuprofen and Paracetamol for Postoperative Pain Relief in Functional Endoscopic Sinus Surgeries: A Randomised Controlled Study

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ABSTRACT

Introduction: Functional Endoscopic Sinus Surgery (FESS) is widely performed for chronic rhinosinusitis and sinonasal disorders. Despite being minimally invasive, it can cause moderate to severe postoperative pain, necessitating effective analgesia with minimal opioid use.

Aim: To compare the efficacy of intravenous (i.v.) ibuprofen and i.v. paracetamol for postoperative pain management in patients undergoing FESS.

Materials and Methods: This double-blind, randomised, controlled study was conducted at SRM Medical College Hospital and Research Centre in Chennai, Tamil Nadu, India done from 15th November 2024 and 2nd February 2025. It included 100 adult patients undergoing elective FESS under general anaesthesia. Patients were divided into two groups (n=50 each) to receive either i.v. ibuprofen (400 mg) (group I) or i.v. paracetamol (1 g) (group P), 30 minutes before the end of surgery. Postoperative pain intensity was assessed using the Visual Analogue Scale (VAS)

score at 0, 4, 8, 12, 16, 20, and 24 hours. Secondary outcomes included total rescue opioid (i.v. tramadol) consumption, rescue analgesia requirement. Results were considered significant if 'p' was less than 0.05 (two-tailed). The analysis was done using IBM Statistical Package for Social Sciences (SPSS) version 21.0.

Results: The baseline characteristics of groups I and P were comparable, with no significant differences observed across age (p-value=0.956), gender distribution (p-value=0.229), and weight (p-value=0.651). The ibuprofen group had significantly lower Non Steroidal Anti-Inflammatory Drugs (NSAIDs) requirements at 4, 8, 16, and 20 hours postoperatively (p-value <0.0001). Only 8% of patients in the ibuprofen group required rescue analgesia compared with 36% in the paracetamol group (p-value=0.001).

Conclusion: The i.v. ibuprofen provides superior early postoperative analgesia compared to i.v. paracetamol in FESS patients, with reduced need for rescue opioids and better patient satisfaction, makes it a valuable choice in opioid-sparing pain management protocols.

Keywords: Analgesia, Pain management, Patient satisfaction, Rhinosinusitis

INTRODUCTION

The FESS is commonly performed to treat chronic rhinosinusitis and various other sinonasal conditions. It is a go-to procedure for addressing persistent issues in the nasal and sinus regions. Although the technique is minimally invasive, it still requires handling and clearing sensitive mucosal tissues inside the nasal cavity and sinuses. Patients often experience moderate to severe pain after the procedure [1]. This postoperative discomfort not only delays ambulation and discharge but also adversely affects patient satisfaction and overall recovery outcomes [2]. Despite technological advances in surgical techniques, effective postoperative pain management remains a cornerstone of perioperative care in FESS to enhance recovery and reduce morbidity.

Traditionally, opioids have been the main method for managing pain after surgery. However, they are known to cause many side-effects, such as drowsiness, impaired consciousness, nausea, vomiting, breathing difficulties, and the risk of getting addicted, posing considerable limitations in modern clinical settings [3,4]. These drawbacks have prompted a paradigm shift toward multimodal analgesia strategies, incorporating non opioid analgesics to minimise opioid use without compromising pain relief. Consequently, paracetamol (acetaminophen) and NSAIDs like ibuprofen are now more commonly used because they can reduce the need for opioids and work well in many types of surgeries [5].

The i.v. ibuprofen, a Cyclooxygenase (COX) inhibitor, exerts analgesic effects primarily by inhibiting prostaglandin synthesis at the peripheral and central levels. Its anti-inflammatory action

offers a dual advantage in surgeries such as FESS, where tissue inflammation is an inherent component of the postoperative course [6]. On the other hand, i.v. paracetamol is widely valued for its central analgesic effect and favourable safety profile, making it particularly suitable for patients with contraindications to NSAIDs [7]. Both agents are routinely used in postoperative settings; however, their comparative efficacy, specifically in FESS —a procedure with distinct pain characteristics —remains inadequately explored. The current literature highlights the analgesic utility of both drugs in diverse surgical populations. For instance, Abdelbaser I et al., demonstrated that i.v. ibuprofen improved postoperative pain scores in paediatric cardiac surgery [8], while Martínez G et al., showed paracetamol's efficacy in managing orthodontic pain [9]. The absence of robust empirical analyses in this specific surgical domain constitutes a crucial gap in evidence-based perioperative care. This study mainly aimed to compare how well i.v. ibuprofen and paracetamol work for pain relief in patients having FESS. The primary outcome of the study was the postoperative pain intensity in patients who underwent FESS. The secondary objectives were to assess the rescue analgesia requirement and patient satisfaction.

MATERIALS AND METHODS

This double-blind, randomised, controlled study was conducted at SRM Medical College Hospital and Research Centre in Chennai, Tamil Nadu, India done from 15th November 2024 and 2nd February 2025. The study was conducted with adherence to ethical standards, as evidenced by the approval obtained from the Hospital Ethics Committee (Ethics Clearance Number: SRMIEC-

ST0724-1424) and registered in the Clinical Trials Registry of India (CTRI/2024/11/076335). Informed written consent was obtained from all participants before their study enrolment.

Sample size calculation: The sample size was calculated with reference to the study by Alshehri AA [10], considering the VAS score as the primary objective. The following formula was used:

$$\{n \geq [Z_{1-\alpha/2} + Z_{1-\beta}]^2 \times (\sigma_1^2 + \sigma_2^2) \div (\mu_1 - \mu_2)^2\}$$

By substituting the values from Alshehri AA study [11],

$$n = (2.58 + 1.64)^2 (1.292 + 0.932);$$

$$n = 17.8084 (1.6641 + 0.8649);$$

$$n = 17.8084 \times 2.529 / 0.9409$$

$$n = 45.0374 / 0.9409;$$

$$n = 47.86;$$

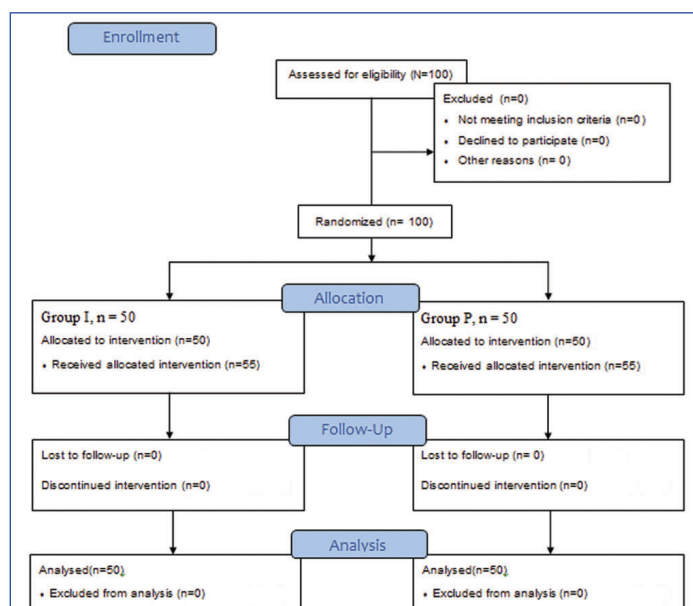
$$n_1 = 48; n_2 = 48;$$

Total sample size, N=100

Inclusion criteria: The study included 100 adult patients aged 18-60 years who were scheduled to undergo elective FESS under general anaesthesia. They also needed to have an American Society of Anaesthesiologists (ASA) physical status of I or II and be able to comprehend the Numeric Rating Scale (NRS) for pain.

Exclusion criteria: Patients were excluded if they had a known allergy to NSAIDs or paracetamol, a history of peptic ulcer disease, hepatic or renal impairment, asthma, or a coagulation disorder. Additionally, patients on chronic analgesic therapy or with a history of substance abuse were excluded.

Randomisation was achieved using a computer-generated random allocation sequence, with allocation concealment maintained through Sequentially Numbered Opaque Sealed Envelopes (SNOSE) [Table/Fig-1]. The study was double-blind, meaning that both the patients and the anaesthesiologist checking the recovery did not know which group the patients were in. The study medication was prepared by a pharmacy worker who did not participate in data collection.



[Table/Fig-1]: Consolidated Standards of Reporting Trials (CONSORT) flow diagram

Group I (i.v. ibuprofen group) received 400 mg of i.v. ibuprofen, and group P (i.v. paracetamol group) received 1 gm of i.v. paracetamol. The paracetamol group was taken as the control group. Both drugs were administered as slow i.v. infusions 15 minutes before the anticipated end of surgery. All patients were monitored intraoperatively using standard non invasive parameters, including Electrocardiogram (ECG), Non Invasive Blood Pressure (NIBP), and % oxygen saturation (SpO₂). General anaesthesia was administered using standard protocols. No other NSAIDs or paracetamol were administered during the surgery.

After surgery, the patients were monitored in the Post-Anaesthesia Care Unit (PACU). Pain was measured using the VAS at 0, 4, 8, 12, 16, 20 and 24 hours. If the VAS score was ≥ 4 , the assigned i.v. pain medicine was administered again, with an 8 hour waiting time between doses. The i.v. tramadol (1.5 mg/kg) was used as a backup if more pain relief was needed. The primary outcome measures included postoperative pain intensity, VAS 0-10, at multiple intervals. Secondary outcomes included tramadol use, rescue analgesia requirement and patient satisfaction, which was assessed using a 5-point Likert scale.

STATISTICAL ANALYSIS

Data are presented as Mean $\pm$ Standard Deviation (SD) for continuous variables and as frequencies (percentages) for categories. The Mann-Whitney U test was used to compare continuous data, and Pearson's Chi-square test was used for categorical data. Results were considered significant if 'p' was less than 0.05 (two-tailed). The analysis was done using IBM SPSS version 21.0.

RESULTS

A total of 100 patients were randomly divided into two groups: group I, n=50 and group P, n=50. All patients who participated completed the study and were included in the final analysis.

The baseline characteristics of groups I and P were comparable, with no significant differences observed across age (p-value=0.956), gender distribution (p-value=0.229), weight (p-value=0.651), Systolic Blood Pressure (SBP) (p-value=0.128), Diastolic Blood Pressure (DBP) (p-value=0.068), or Pulse Rate (PR) (p-value=0.344). Both groups had 100% SpO₂; thus, there was no significant difference [Table/Fig-2].

Characteristics	Group I (Mean $\pm$ SD)	Group-P (Mean $\pm$ SD)	p-value
Age (in years)	33.60 $\pm$ 5.94	34.14 $\pm$ 8.34	0.956
Gender n (%)	Female 26 (52.0%)	20 (40.0%)	0.229
	Male 24 (48.0%)	30 (60.0%)	
Weight (in kg)	66.78 $\pm$ 10.43	65.62 $\pm$ 10.25	0.651
SBP (mmHg)	112.80 $\pm$ 11.26	116.60 $\pm$ 12.55	0.128
DBP (mmHg)	71.00 $\pm$ 9.74	74.60 $\pm$ 9.94	0.068
PR (bpm)	79.28 $\pm$ 10.93	77.42 $\pm$ 8.81	0.344
SPO ₂ n (%)	50 (100.0%)	50 (100.0%)	NA

[Table/Fig-2]: Baseline demographic and clinical characteristics.

Age and gender are expressed in Pearson's Chi-square test; Other parameters are measured in the Mann-Whitney U test *beats per minute (bpm)

Group I (ibuprofen) patients needed significantly fewer additional NSAID doses than group P (paracetamol) at 4, 8, 16, 20, and 24 hours postoperative (p-value <0.0001), with 0% needing extra doses at 4, 16, and 20 hours vs 36-50% in group P. At eight hours, only 4% in group I required more, compared to 56% in group P. No significant difference was observed at 12 and 24 hours [Table/Fig-3].

While surgical procedure types (p-value=0.42) and Mallampati grades (p-value=0.498) were comparable between groups, group I had a significantly shorter duration of surgery (1.70 $\pm$ 0.54 h) than group

Amount of NSAIDs used	Group I n (%)	Group P n (%)	p-value
4 h	No 50 (100.0%)	32 (64.0%)	<0.0001
	Yes 0	18 (36.0%)	
8 h	No 48 (96.0%)	22 (44.0%)	<0.0001
	Yes 2 (4.0%)	28 (56.0%)	
12 h	No 37 (74.0%)	31 (62.0%)	0.198
	Yes 13 (26.0%)	19 (38.0%)	
16 h	No 50 (100.0%)	25 (50.0%)	<0.0001
	yes 0	25 (50.0%)	
20 h	No 50 (100.0%)	27 (54.0%)	<0.0001
	Yes 0	23 (46.0%)	

24 h	No	24 (48.0%)	27 (54.0%)	0.548
	Yes	26 (52.0%)	23 (46.0%)	

[Table/Fig-3]: Comparative analysis of NSAID requirements at various postoperative intervals.

P (2.00±0.76 h; p-value=0.046). Furthermore, a highly significant difference was observed in rescue analgesia requirements, with 92.0% of group I patients needing no additional analgesia, in stark contrast to only 64.0% in group P (p-value=0.001) [Table/Fig-4].

Characteristics		Group I n (%)	Group P n (%)	p-value
Procedure	FESS	20 (40.0%)	24 (48.0%)	0.42
	Septoplasty with FESS	30 (60.0%)	26 (52.0%)	
MPC Grade	1	15 (30.0%)	20 (40.0%)	0.498
	2	26 (52.0%)	24 (48.0%)	
	3	9 (18.0%)	6 (12.0%)	
Duration of surgery (Mean±SD)		1.70±0.54	2.00±0.76	0.046
Rescue analgesia		46 (92.0%)	32 (64.0%)	0.001

[Table/Fig-4]: Intraoperative characteristics and rescue analgesia requirements.

Baseline VAS pain scores were identical in both groups (0.00±0.00). However, group I (ibuprofen) reported significantly lower pain scores at 4, 8, 16, and 20 hours postoperative compared to group P (paracetamol), with the most notable differences at four and eight hours (p-value <0.0001). No significant differences were seen at 12 and 24 hours [Table/Fig-5]. Patients in group I experienced more effective or longer-lasting postoperative pain control compared with those in group P, as evidenced by their markedly lower requirement for additional analgesics. This supports the superior analgesic efficacy of the intervention used in group I.

VAS	Groups		p-value
	Group I	Group P	
	(Mean±SD)	(Mean±SD)	
0 h	0	0	n/a
4 h	1.32±0.71	2.64±1.32	<0.0001
8 h	1.22±1.02	3.18±1.76	<0.0001
12 h	2.54±1.42	2.30±1.78	0.457
16 h	1.60±0.97	2.88±1.81	<0.0001
20 h	1.94±0.89	2.70±1.93	0.013
24 h	3.60±1.43	3.44±1.54	0.591

[Table/Fig-5]: VAS score analysis between both groups.

Patient satisfaction scores were significantly higher in group I (4.58±0.50) compared with group P (2.92±0.72), and the difference was highly significant (p-value <0.0001), indicating superior satisfaction among patients in group I [Table/Fig-6].

	Groups		p-value
	Group I	Group P	
	(Mean±SD)	(Mean±SD)	
Patient satisfaction score	4.58±0.50	2.92±0.72	<0.0001

[Table/Fig-6]: Patient satisfaction score between both groups.

DISCUSSION

The primary outcome, postoperative pain intensity measured using the VAS score at fixed intervals, revealed that ibuprofen led to consistently low pain scores and delayed rescue analgesic need during the first 24 hour. By the 8th postoperative hour, only 4% of patients in the ibuprofen group required an additional analgesic compared to 56% in the paracetamol group. These differences were significant at multiple time points (4, 8, 16, and 20 h). Akbas S et al., found persistently reduced VAS scores with ibuprofen (p-value <0.001) but no significant difference with paracetamol relative to

control (p-value=0.394) [12]. In this study, the better pain relief with ibuprofen soon after surgery agrees with the results of Çelik EC et al., who found that patients having septorhinoplasty had lower VAS pain scores and used less opioids in the first 12 hours when given i.v. ibuprofen compared to i.v. paracetamol [11]. In contrast, Alshehri AA reported that both paracetamol and ibuprofen reduced VAS scores at all times compared with control (p-value <0.05), though ibuprofen retained a significant advantage at the 1st and 6th postoperative hours [10]. Collectively, these findings highlight ibuprofen's superior analgesic efficacy, particularly in the immediate postoperative phase.

In the present study, intravenous ibuprofen resulted in a significant reduction in total morphine consumption compared with both paracetamol and control groups, underscoring its superior opioid-sparing potential in the early postoperative period. This observation is consistent with the findings of Akbas S et al., who reported markedly lower morphine requirements in patients receiving ibuprofen compared with those given paracetamol or placebo (p-value <0.001) [12]. Such concordance across studies reinforces the role of NSAIDs as valuable components of multimodal analgesic regimens for FESS.

The superior analgesic profile observed with ibuprofen in our study also underscores the importance of pre-emptive administration in optimising postoperative pain control. Supporting this concept, Koteswara CM and Sheetal D demonstrated that pre-emptive intravenous paracetamol produced more effective postoperative analgesia than intraoperative dosing in FESS patients, although ibuprofen was not evaluated in their trial [13]. When considered alongside the current data, these results suggest that both agent selection and timing of administration are critical determinants of analgesic effectiveness, with NSAIDs offering an additional advantage when used pre-emptively.

The present study results are consistent with a broader evidence base of the study by Calim M et al., which demonstrated that i.v. ibuprofen significantly reduced tramadol consumption and pain scores compared to paracetamol in patients undergoing arthroscopic shoulder surgery [14]. Similarly, Ucar M et al., showed that in percutaneous nephrolithotomy, i.v. ibuprofen led to significantly lower opioid consumption than i.v. paracetamol [15]. Similarly, A meta-analysis by Abushanab D and Al-Badriyeh D reported that combinations of high-dose regimens of ibuprofen and paracetamol effectively reduced pain and opioid use in acute postoperative settings, with favourable safety profiles [16]. This study reported the superiority of ibuprofen during the early postoperative period. In contrast, the study by Björnsson GA et al., reported that taking ibuprofen 600 mg four times a day for three days does not give any better results than the usual paracetamol 1000 mg four times a day for reducing swelling and pain after third molar surgery [17].

This study findings stated that there are significant differences in pain between the two groups at certain intervals but in contrast, the study by Rahim MR et al., reported, the efficacy of intravenous paracetamol combined with ibuprofen or ketorolac in reducing postoperative pain and Neutrophil-Lymphocyte Ratio (NLR) after FESS in 40 patients, finding no significant differences between the two combinations [18]. This study is one of the few to provide a direct head-to-head comparison of i.v. ibuprofen and paracetamol, specifically in FESS patients. Future research should expand on our findings through multicentre trials with larger sample sizes. Evaluating long-term pain outcomes, exploring inflammatory markers, and studying combination regimens of ibuprofen and paracetamol could further optimise multimodal pain strategies for FESS. Investigations comparing newer NSAIDs or COX-2 inhibitors with paracetamol may offer refined insights into balancing efficacy and safety.

Limitation(s)

The present study was a single-centre study conducted in South India; this may limit how well the results apply to other groups of people and healthcare settings in the future. Additionally, the follow-up period for assessing outcomes was limited to 24 hours, precluding the evaluation of long-term pain management and patient recovery.

CONCLUSION(S)

Both ibuprofen and paracetamol work well to control pain after surgery in patients who have undergone FESS. However, intravenous ibuprofen demonstrates superior analgesic efficacy, particularly in the early postoperative period, with significantly reduced rescue analgesic requirements and improved patient comfort. Given its greater opioid-sparing effect and sustained pain control, intravenous ibuprofen may be the preferred non opioid analgesic for perioperative FESS pain management, especially in cases where minimising opioid use is clinically advantageous.

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