

## An Evaluation of the Effectiveness and Safety of Diclofenac and Lornoxicam as Postoperative Analgesics following Mastoidectomy Surgery

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### Abstract

**Background:** Postoperative discomfort is brought on by the surgical trauma that occurs during the manipulation of tissues. Lornoxicam is a nonselective NSAID with analgesic and anti-inflammatory properties. It acts more quickly than other oxicams and has a shorter half-life. Diclofenac sodium, a cyclooxygenase inhibitor, has long been used to manage postoperative pain. The active metabolite of the drug accumulates in the inflamed tissue and maintains a greater plasma concentration for several hours by acting as an analgesic. The current study compares the effectiveness and safety of diclofenac and lornoxicam for the treatment of postoperative pain following mastoidectomy surgery.

**Methods:** Eighty patients who underwent mastoidectomy surgery and were randomly assigned to two parallel groups participated in this prospective single-blinded trial at Nalanda Medical College and Hospital from December 2021 to November 2022. Group A was given an intramuscular injection of lornoxicam 8 mg three days in a succession, while group B was given an injection of diclofenac 75 mg. The major indicator was postoperative pain, which was measured using the Visual Analogue Scale and Wong Bakers Scale. The rescue medication used was a 300 mg intramuscular injection of paracetamol. The secondary parameters include the frequency and length of usage of rescue medication by the patients in each trial group. During each follow-up appointment, the doctor made a note of any adverse events that the patient had reported or that he or she had personally witnessed.

**Results:** When comparing the lornoxicam group to the diclofenac group, the primary efficacy parameter consistently showed a significant reduction in postoperative pain (p value 0.05). Three (7.5%) patients in the lornoxicam group required rescue medication, compared to 11 (27.5%) in the diclofenac group. In comparison to the lornoxicam group, the diclofenac group had a considerably greater percentage of patients who required rescue medication. The average time spent utilising rescue medication was 7.09±3.36 hours for the diclofenac group and 7.33±2.21 hours for the lornoxicam group. Renal and liver function markers' preoperative and postoperative levels did not substantially change from one another. There were no noteworthy adverse effects in any of the two groups.

**Conclusion:** Based on the results of our study, we draw the conclusion that lornoxicam 8 mg intramuscular injection is a more potent and well-tolerated analgesic than diclofenac 75 mg intramuscular injection for the management of postoperative pain following mastoidectomy surgery.

**Keywords:** Postoperative pain, Lornoxicam, Diclofenac, Mastoidectomy surgery.

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## Introduction

Any kind of surgery comes with a postoperative period of pain. The type of operation and the degree of postoperative pain are associated, and pain treatment is a crucial part of postoperative patient care. The surgical trauma that occurs during tissue manipulation is what causes postoperative discomfort[1]. Mastoidectomy surgery continuously distresses the patient, which slows down healing and impacts the patient's result. Lack of early pain relief triggers the immune system's stress response, which delays wound healing and lengthens hospital stays[2]. Early and successful postoperative pain management can shorten hospital stays by facilitating early ambulation, which in turn reduces problems associated to postoperative pain [3].

Drugs used to treat postoperative pain must be efficient, safe, and have few side effects[1]. Opioids are the standard treatment for postoperative pain following surgery, but they have a number of side effects, including respiratory depression, nausea, vomiting, and constipation. Non-steroidal anti-inflammatory medications (NSAIDs), on the other hand, are utilised in the postoperative pain treatment to prevent the negative effects linked to the opioids [5]. The benefits of NSAIDs include their ability to act locally without causing harmful central effects or cognitive impairments [6]. NSAIDs have anti-inflammatory, analgesic, and antipyretic properties that make them useful painkillers [7].

Strong analgesic and anti-inflammatory NSAID lornoxicam is a member of the oxycam family and has superior tolerance

than other NSAIDs. It has been shown to be useful in treating rheumatoid arthritis and post-operative pain, and its analgesic activity is comparable to that of opioids[4]. Similar to piroxicam in terms of pharmacokinetics and pharmacodynamics, lornoxicam is equally effective in treating post-major surgery pain as morphine, pethidine, and tramadol[5]. Lornoxicam begins to work more quickly and has a shorter half-life than other oxycams [1]. Lornoxicam has been used successfully to treat postoperative pain and has a better safety profile than diclofenac in terms of renal and hepatic function tests[8].

Diclofenac sodium, a cyclooxygenase inhibitor, has long been used to manage postoperative pain. As it accumulates in the inflamed tissue, its active metabolite continues to have higher plasma concentrations while acting as an analgesic for several hours[9]. There aren't many clinical research comparing lornoxicam with diclofenac for the management of postoperative pain. Determining the efficiency and safety of lornoxicam and diclofenac in the treatment of acute postoperative pain following mastoidectomy surgery was the objective of the current investigation.

## Material and Methods

Present prospective single-blinded, randomized study was conducted at Nalanda Medical College and Hospital, Patna, Bihar from December 2021 to November 2022.

80 patients in total (40 in the lornoxicam group and 40 in the diclofenac group). The study included sex-either patients undergoing mastoidectomy surgery who were older than

18 and younger than 70. Patients with a history of substance abuse, liver or kidney disease, liver or kidney disease-related medications, bleeding diathesis in the past, lactating mothers, drug hypersensitivity, bronchial asthma, hypertension, diabetes mellitus, peptic ulcer disease, and seizures. The participants were then included based on inclusion and exclusion criteria after the screening. These examinations included complete blood count, bleeding and clotting time, random blood sugar, blood urea, serum creatinine, and liver function tests.

With the aid of a computer-generated random table, individuals were divided into two groups (group A and group B) after enrolment. The postoperative patients in Group A received an intramuscular injection of lornoxicam 8 mg twice daily for three days and Group B: Following surgery, participants in this group received 75 mg of injection diclofenac twice day for three days.

All trial participants in both groups received their first dose of the analgesic immediately following the skin closure, and subsequent doses were administered every 12 hours for the next three days.

Blood samples were obtained before surgery and on the third postoperative day. Haemoglobin, the total blood count, the differential count, the erythrocyte sedimentation rate, the platelet count, the bleeding and clotting times, and the random blood sugar levels were all measured as hemodynamic parameters. In addition, liver function tests that measure alanine transaminase (ALT), aspartate transaminase (AST), and alkaline phosphatase as well as

direct, indirect, and total bilirubin are evaluated. Renal function tests and the levels of blood urea and serum creatinine were assessed.

The statistical software SPSS (Statistical Package for the Social Sciences) version 11 was used to conduct the statistical analysis.

Both groups initial characteristics were tabulated using frequency tables and descriptive statistics (mean, standard deviation). By using the Pearson chi-square test and the unpaired student 't' test, they were matched. At 1, 3, 6, 12, 24, 48, and 72 hours into the study, student unpaired 't' tests were used to compare the two groups' major parameters. The Pearson chi-square method was used to determine the percentage of patients who required rescue medication and their relationship to the two groups. The mean and standard deviation of the time to take rescue medication were also computed. The negative effects were expressed as a percentage, and the relationship between the two groups was examined using Pearson chi-square. When comparing two groups in two-tailed situations, p values below 0.05 ( $p < 0.05$ ) were considered significant.

### Results

The mean age in the lornoxicam group was 28.42 years, while it was 29.72 years in the diclofenac group. In both categories, there were 19% and 21% of male and female patients, respectively. The mean weight of the two groups was similar, with no discernible difference between them; the group using lornoxicam weighed 65.52 kg, while the group taking diclofenac weighed 64.52 kg. Both groups initial characteristics were similar ( $p > 0.05$ ) (table 1).

**Table1: Baseline characteristics of both groups**

Baseline Parameters		Inj. Lornoxicam group A n = 40	Inj. Diclofenac group B n=40	p value
Age yrs (mean/SD)		29.72 ± 9.21	28.42 ± 7.54	0.492
Gender n (%)	Male	19 (47.5%)	19 (47.5%)	
	Female	21 (52.5%)	21 (52.5%)	
Weight (Kgs)(mean/SD)		65.52 ± 5.12	64.52 ± 5.79	0.416
Duration of Surgery(min ) (mean/SD)		91.12 ± 12.88	88.50 ± 10.07	0.313
Hb (%) (mean/SD)		13.56 ± 1.47	13.6 ± 1.35	0.9
WBC (cells/cumm) (mean/SD)		8490 ± 1274.16	8112.5 ± 1294	0.192
Platelet count (lakhs/cumm) (mean/SD)		2.93 ± 0.65	2.77 ± 0.63	0.26
Blood sugar (gms%) (mean/SD)		92.07 ± 9.09	93.45 ± 9.72	0.516

The baseline characteristics of both groups are displayed in Table 1. Both groups initial characteristics were comparable ( $p>0.05$ ).

**Table 2: Vas pain response rates of both groups**

VAS	Inj. Lornoxicam group A			Inj. Diclofenac group B			p value
	MEAN ± SD			MEAN ± SD			
VAS 1	2.42	±	0.87	5.62	±	1.16	< 0.0001*
VAS 3	1.9	±	0.81	5.17	±	0.98	< 0.0001*
VAS 6	1.7	±	0.88	5.17	±	1.39	< 0.0001*
VAS 12	1.72	±	0.98	5.07	±	1.28	< 0.0001*
VAS 24	1.77	±	0.91	4.35	±	1.02	< 0.0001*
VAS 48	1.1	±	0.84	3.85	±	0.97	< 0.0001*
VAS 72	0.47	±	0.75	2.65	±	1.16	< 0.0001*

\* p value <0.05, statistically significant

- The visual analogue scale score comparison of the effectiveness of diclofenac and lornoxicam is shown in Table 2.
- When compared to diclofenac, lornoxicam significantly reduced postoperative pain at 1 hour, 3 hours, 6 hours, 12 hours, 24 hours, 48 hours, and 72 hours. ( $p<0.0001$ ).

**Table 3: WBS pain response rates of both groups**

VAS	Inj. Lornoxicam group A			Inj. Diclofenac group B			p value
	MEAN ± SD			MEAN ± SD			
VAS 1	2.42	±	0.87	5.62	±	1.16	< 0.0001*
VAS 3	1.9	±	0.81	5.17	±	0.98	< 0.0001*
VAS 6	1.7	±	0.88	5.17	±	1.39	< 0.0001*
VAS 12	1.72	±	0.98	5.07	±	1.28	< 0.0001*
VAS 24	1.77	±	0.91	4.35	±	1.02	< 0.0001*
VAS 48	1.1	±	0.84	3.85	±	0.97	< 0.0001*
VAS 72	0.47	±	0.75	2.65	±	1.16	< 0.0001*

\* p value <0.05, statistically significant

- Table 3 compares the effectiveness of Lornoxicam and Diclofenac based on the Wong Bakers pain scale score.
- When compared to diclofenac, lornoxicam significantly reduced postoperative pain at 1 hour, 3 hours, 6 hours, 12 hours, 24 hours, 48 hours, and 72 hours. ( $p < 0.0001$ )

**Table 4: Proportion of patients required rescue medication of both groups.**

Groups	Rescue Medication Required		p value
	Yes	No	
Group A	3(7.5%)	37(92.5%)	0.019*
Group B	11(27.5%)	29(72.5%)	

\* p value  $< 0.05$ , statistically significant

- Table 4 displays the percentage of patients in both research groups who needed rescue medication.
- Three patients in trial group A (lornoxicam) and eleven patients in study group B (diclofenac) needed rescue medication.
- It was statistically significant that more patients in the diclofenac group needed rescue medication than those in the lornoxicam group.

**Table 5: Time to use rescue medication of both groups.**

Groups	Number of Patients	Time to use Rescue Medication (HRS)		
		MEAN $\pm$ S.D.		
Group A	3(7.5%)	7.33	$\pm$	2.51
Group B	11(27.5%)	7.09	$\pm$	3.36

- The average time to utilise rescue medication is displayed in Table 5
- The median time to administer a rescue medication was  $7.33 \pm 2.21$  hours after the initial dosage in the lornoxicam group.
- The average amount of time needed to utilise rescue medication in the diclofenac group was  $7.09 \pm 3.36$ .

**Table 6: Renal and liver function parameters of lornoxicam group.**

Parameters	Pre-Operative Mean $\pm$ SD	Post-Operative Mean $\pm$ SD	P-Value
Serum Creatinine mg/dl	$0.76 \pm 0.07$	$0.77 \pm 0.08$	0.279
Blood Urea mg/dl	$25.02 \pm 2.06$	$25 \pm 2.14$	0.959
ALT U/L	$28.67 \pm 2.67$	$29.35 \pm 2.55$	0.202
AST U/L	$22.60 \pm 2.12$	$22.47 \pm 2.89$	0.835
ALKP U/L	$49.25 \pm 1.80$	$49.90 \pm 1.82$	0.128
Total Bilirubin U/L	$0.71 \pm 0.6$	$0.72 \pm 0.6$	0.881
Total Protein U/L	$6.86 \pm 0.45$	$6.84 \pm 0.34$	0.757

The renal function test, including blood urea and serum creatinine in study patients of the lornoxicam group, showed no significant difference between the preoperative and postoperative values. Table 6 illustrates the Renal and Liver function test of the lornoxicam group.

**Table 7: Renal and liver function parameters of diclofenac group**

Parameters	Pre-Operative Mean $\pm$ SD	Post-Operative Mean $\pm$ SD	P-Value
Serum Creatinine mg/dl	$0.77 \pm 0.10$	$0.78 \pm 0.10$	0.706

Blood Urea mg/dl	24.5 ± 2.17	24.67 ± 1.71	0.594
ALT U/L	28.62 ± 2.24	28.52 ± 2.33	0.851
AST U/L	22.17 ± 2.53	21.47 ± 2.57	0.248
ALKP U/L	50.47 ± 1.50	50.15 ± 4.09	0.668
Total BilirubinU/L	0.73 ± 0.21	0.77 ± 0.29	0.244
Total ProteinU/L	7.02 ± 0.26	7.05 ± 0.19	0.573

- There was no significant difference between the preoperative and postoperative results of the renal and liver function test in the diclofenac group of the study population. Table 7 displays the Renal and Liver function parameters of the diclofenac group.

### Adverse Effects

Each patient in each group finished the study. Both medications were accepted nicely. In the two groups, there were no significant adverse effects. The common negative effects noted are included in the table below.

**Table 8: Number of patients with specific adverse reaction**

ADR	GROUP A n / (%)	GROUP B n / (%)
Nausea	2 (5)	7 (17.5)
Vomiting	-	1 (2.5)
Epigastric pain	-	7 (17.5)
Dizziness	2 (5)	-
Constipation	-	1 (2.5)
Drowsiness	1 (2.5)	-

- In the diclofenac group, Table 8 reveals that 7 (17.5%) patients experienced nausea and epigastric discomfort, while 1 (2.5%) patient experienced vomiting and constipation.
- One (2.5%) patient and two (5%) patients in the lornoxicam group experienced sleepiness.

### Discussion

Anesthesiologists and surgeons are very concerned with effective postoperative pain management[10]. Despite significant advancements in our understanding of post-operative pain pathophysiology, about 80% of surgical patients have mild to severe post-operative pain [9].

Mastoidectomy is one of the most common surgical operations carried out under local anaesthesia in the department of otorhinolaryngology. Diclofenac is the NSAID that is used the most frequently to treat postoperative pain, and it is known to increase the risk of side effects include stomach pain, dyspepsia, heartburn,

gastrointestinal ulcers, and diarrhoea[11]. When compared to other members of its class, lornoxicam is an NSAID with lower gastrointestinal toxicity and the high therapeutic potency of oxicams[1]. Therefore, the current study is being conducted to contrast lornoxicam with diclofenac. When oral administration is not an option or when immediate analgesia is necessary following surgery, the parenteral route of administration is the preferred method[3]. In this investigation, it is preferred to administer the analgesic intramuscularly.

Lornoxicam has been shown to be equally effective in preventing and treating post-operative pain as morphine, meperidine, and tramadol[8]. Both diclofenac and lornoxicam have been used to manage post-operative pain following a range of surgical procedures. These drugs can be used alone or in conjunction with other drugs, and different rescue drugs can be utilised in different studies[9].

In the present study, which analyses patients using the two drugs, there is no statistically significant difference between the mean age of the patients in the diclofenac group and the lornoxicam group. The median age is consistent with findings from a different study by Geethbhandari et al.[12]. In the current study, male patients made up 19 (47.5%) and female patients made up 21 (52.5%), with an equal distribution of each sex between groups A and B. This demonstrated that more female patients than male patients got mastoidectomy surgery during the time of our study. This was comparable to another study on mastoidectomy patients that Daewook et al. conducted[13]. With no discernible difference between the two trial groups, the mean weights of the patients in both groups were  $65.52 \pm 5.12$  kg and  $64.52 \pm 5.79$  kg for lornoxicam and diclofenac, respectively. The average weight was consistent with research by Daewook et al. [13].

Participants in the current experiment who received lornoxicam for acute postoperative pain after mastoidectomy surgery experienced a statistically significant ( $p$  value  $< 0.0001$ , tables 2 and 3) decline in VAS score and WBS score throughout the course of the study as compared to those who received diclofenac. Six hours after the first dose of lornoxicam and twelve hours after the first dose of diclofenac, the pain was at its lowest point in the first twelve hours. This illustrated the earlier onset of action of the drug lornoxicam. Sudip et al. carried a comparable

studies, comparing the effectiveness and safety of lornoxicam versus tramadol as analgesics after head and neck surgery, and discovered that lornoxicam had an early onset of action [1].

They have been used to assess the efficacy of pain therapy for acute postoperative pain since VAS and WBS are reliable at characterising pain severity[3]. Lornoxicam and diclofenac were evaluated in a study by Galanivarsha et al. on patients experiencing acute postoperative pain after spinal surgery, and the findings revealed that lornoxicam had a considerably stronger analgesic effect than diclofenac at 30 min and 300 min[9]. When lornoxicam and diclofenac were compared for efficacy and safety in arthritic knee patients, Vishalkumar et al. found that lornoxicam considerably reduced pain more than diclofenac[14]. There aren't many research comparing the effectiveness and safety of lornoxicam with diclofenac, which is similar to our study.

Sushila godara et al. concluded that both drugs are similarly effective and safe for the treatment of acute renal colic in their trial comparing lornoxicam and diclofenac, with the added benefit of lornoxicam being more effective in the early stages[15].

Compared to 3 (7.5%) patients who took lornoxicam and 11 (27.5%) patients who took diclofenac, a total of 14 (17.5%) patients in the current study required paracetamol as a rescue medication (table 4). Patients in both groups required rescue analgesics following the study drug's initial dose, although the total amount of rescue analgesic drug consumption was lower in the lornoxicam group compared to the diclofenac group. In a study by Sudip et al.[1], lornoxicam was similarly utilised as a rescue drug less frequently. The difference showed that lornoxicam was more effective than diclofenac ( $p < 0.019$ , table 4).

It took the lornoxicam group five hours and the diclofenac group three hours after the first dosage of the study drug to administer the first rescue medication (table 5), demonstrating that the diclofenac group administered the rescue medication earlier. Comparable research was done by Girija et al., who compared tramadol and lornoxicam as postoperative treatments for patients having elective gynaecological surgery.

The results revealed a significant difference in the duration of time required to take rescue medication between the two groups. When compared to the tramadol group, the time it took to use the first rescue analgesic was longer in the lornoxicam group ( $194.96 \pm 103.94$  min) than in the tramadol group ( $159.44 \pm 70.4$  min), and the amount of rescue analgesic used was lower in the lornoxicam group ( $63.6 \pm 17.8$ ). [16].

No patients left the current study as a result of negative side effects. Totalling 5 (12.5%) patients in the lornoxicam group and 16 (40%) patients in the diclofenac group, a total of 21 (26.25%) patients in both groups experienced side effects. Significantly more patients in the diclofenac group experienced adverse reactions ( $p < 0.005$ , table 6), demonstrating the superior safety and tolerability of lornoxicam in comparison to diclofenac.

In comparison to the lornoxicam group, the diclofenac group reported higher nausea and epigastric pain (table 7). In contrast to the lornoxicam group, which included only 2 patients, the diclofenac group had 7 (17.5%) patients who reported experiencing nausea and epigastric pain. This was supported by Nagendra et al. in their study, "Efficacy of Aceclofenac and Diclofenac for the Relief of Postoperative Pain after Third Molar Surgery," which showed that diclofenac was more unpleasant to take than aceclofenac in terms of nausea and epigastric pain[11]. In the lornoxicam group, drowsiness and

dizziness were observed in 2 (5%), 1 (2.5%), and no patients in the diclofenac group, respectively.

One of the potential side effects of mastoidectomy surgery is the dizziness that was observed in the lornoxicam group [17]. Lornoxicam had a high level of tolerance and minimal gastrointestinal effects, as demonstrated by Galani Varsha et al.[9]. Lornoxicam 16 mg/day shown much less gastrointestinal toxicity than naproxen 1000 mg/day in a separate comparison experiment with healthy subjects, which was supported endoscopically[18]. In the current study, neither group's baseline values for blood urea, serum creatinine, or liver function markers like AST, ALT, alkaline phosphatase, total protein, and total bilirubin significantly changed after 72 hours. Comparable to this investigation was one by Turhan Togrul et al. [3]

It was not able to comment on the nephrotoxicity and hepatotoxicity of these medications because the renal function parameters and liver function parameters in the current study were only investigated for a short length of time (72 hours). However, the variance between trials may be due to variations in lornoxicam dosing regimens and surgical approaches.

A few recent placebo-controlled and comparative clinical research carried out in India[18] have shown the efficacy of lornoxicam as an analgesic following surgery. The aforementioned results show that in terms of effectiveness and tolerability, lornoxicam 8 mg twice day is a more effective analgesic than diclofenac 75 mg twice daily for the management of postoperative pain following mastoidectomy surgery under local anaesthesia. Both research populations exhibited satisfactory compliance.

## Conclusion



Based on the results of our study, we draw the conclusion that lornoxicam 8 mg intramuscular injection is a more potent and well-tolerated analgesic than diclofenac 75 mg intramuscular injection for the management of postoperative pain following mastoidectomy surgery.

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