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Original Article

Efficacy of Aceclofenac and Naproxen in Patients with Low Back Pain at Birat Medical College and Teaching Hospital

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Abstract

Background

Low back pain is a common global problem with a high incidence in Nepal and is a cause of disability. Non-Steroidal Anti-Inflammatory Drugs are the first-line option for managing both acute and chronic low back pain. This study aims to compare the efficacy and safety of Aceclofenac and Naproxen for acute low back pain due to the limited comparative data locally.

Materials and Methods

This prospective, observational study at Birat Medical College enrolled 88 acute low back pain patients; categorized in two groups by simple random sampling, receive either Aceclofenac 100 mg twice daily or Naproxen 500 mg twice daily. Efficacy was assessed by measuring pain intensity with a Visual Analog Scale at baseline and one week after treatment, and monitoring adverse effects via a self-report checklist. Statistical significance was set at $p < 0.05$.

Results

Baseline mean Visual Analog Scale pain scores were similar for both groups. By Day 7, mean Visual Analog Scale for Aceclofenac (3.0±0.96) was significantly lower in contrast to Naproxen (5.0±1.00), a difference was significant ($p < 0.001$) in paired t-test. Aceclofenac also had a superior safety profile with absence of side-effects, while Naproxen showed mild gastrointestinal problems in three patients. Our study also indicated significant associations for acute low back pain with variables such as age, gender, occupational status, and heavy physical work.

Conclusion

Aceclofenac demonstrated superior pain relief and a better safety profile than Naproxen for acute low back pain. It is thus a preferable therapeutic option for use in similar clinical settings.

Keywords: *Aceclofenac, Low back pain, Naproxen, NSAIDs*

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Introduction

Low back pain (LBP) is a leading global health issue, where millions of peoples were suffering from this condition and it plays an active role in increasing disability globally [1]. LBP is characterized by lumbar pain and stiffness, which greatly affecting productivity [2]. In Nepal, LBP is endemic and particularly high among females, further emphasizing the need for effective, locally adapted treatment modalities [2,3]. Nonsteroidal anti-inflammatory drugs (NSAIDs) are frequently prescribed as first-line pharmacological therapies for both acute and chronic LBP due to their well-established analgesic and anti-inflammatory properties [4,5].

Aceclofenac and Naproxen are widely prescribed NSAIDs. They primarily work by inhibiting cyclooxygenase (COX) enzymes, which reduces prostaglandin synthesis and diminish pain and inflammation [6]. While Aceclofenac has been reported to possess preferential COX-2 selectivity [7], Naproxen acts as a non-selective inhibitor with a longer half-life [8]. However, there is insufficient evidence comparing these two commonly used NSAIDs in the Nepali population.

Hence the objective of this study aims to evaluate and compare the efficacy of Aceclofenac and Naproxen in patients experiencing acute LBP, measured by using the Visual Analog Scale (VAS) over a one-week treatment period at Birat Medical College and Teaching Hospital, and to determine their incidence and severity of reported adverse effects.

Materials and Methods

This prospective, quantitative, observational study aimed to evaluate the changes in pain intensity among patients with acute LBP receiving either Aceclofenac or Naproxen. The study was conducted at the Orthopaedic Department of Birat Medical College and Teaching Hospital during a five-month period from July to November 2025, covering the recruitment of patients, a one-week follow-up period per patient, and comprehensive data analysis. Ethical approval for the study was obtained from the Institutional Review Committee of Birat Medical College and Teaching Hospital (IRC-53-2081/82). All participants provided informed consent prior to enrollment. As for the study population, patients presenting to the Outpatient Orthopaedic Department with a diagnosis of acute LBP and prescribed NSAID therapy during the study period were considered for enrollment. A Simple Random Sampling approach was used, with participants included if they were aged 18-64 years, diagnosed with acute LBP, prescribed either Aceclofenac 100mg twice daily or Naproxen 500mg twice daily as part of routine treatment, had a pain intensity of ≥4 cm as measured on the VAS (on a scale of 0-10) at baseline, were willing to participate in the study and provided informed consent, and they weighed between 40 to 75 kg. Exclusion criteria for patients were failure to adhere to the prescribed drug regimen, those with severe concomitant diseases (e.g., renal or hepatic impairment), pregnancy, lactating women, individuals with chronic LBP (>3 months duration) and patients taking other medications for pain management.

The primary independent variable for this study was the type of NSAID administered. The primary dependent variable was pain intensity, measured by the VAS score. Confounding variables included age, gender, occupational status, and physical workload. The estimated sample size according to comparison of two independent sample means [9] was calculated, based on the standard formula, sufficiently to detect a clinically meaningful difference between treatments. The formula applied was $n = 2*(Z\alpha/2 + Z\beta)^{2}*\sigma^{2} /d^{2}$, where n represents the required sample size per group. For a 95% confidence level, the two-tailed critical value $Z_{\alpha/2}$ was set at 1.96, and for 80% statistical power, Z_{β} was set at 0.84. The estimated standard deviation (σ) of the VAS scores was adopted as 0.50, a value derived from a previous study conducted in a similar population by Bhattarai et. al. [2]. The clinically meaningful difference (d) in mean VAS score that the study aimed to detect was judiciously set at 0.3 units on the 0–10 VAS scale. This precise value was selected as part of a conservative methodological strategy, specifically intended to enhance the study's sensitivity and to detect even small but clinically important treatment effects in patients with acute pain. Similar approaches have been adopted in previous studies evaluating acute pain and early intervention strategies [10]. Substituting these values into the formula: $2*(1.96$

+0.84)^2 *(0.50)^2 / (0.3)^2, resulted in a calculated sample size of approximately 44 patients per group. Thus, 88 patients were enrolled for the study, considering possible dropouts, which allowed for statistical power to extensively assess the relative efficacy and safety of Aceclofenac and Naproxen.

This calculation resulted in a target sample size of almost 44 patients per treatment group that accounted for dropouts and was sufficiently powerful. Efficacy was primarily assessed by the change in pain intensity using a 10 cm VAS [11,12]. Acute low back pain was operationally defined as pain localized in the lumbosacral region between the lower margin of the twelfth rib and the inferior gluteal folds, with or without leg pain, lasting less than 6 weeks [13, 14]. Pain intensity was operationally defined by a 10 cm VAS, a validated instrument where 0 represented "no pain" and 10 represented "totally disabling pain" [11, 12]. Pain intensity scores were then categorized for analysis: 0 indicated "no pain," scores of 1-2 were considered "mild pain," 3-4 "tolerable pain," 5-6 "distressful pain," 7-8 "severe pain," and 9-10 "totally disabling pain" for analysis [15,16]. Efficacy was operationally defined as the reduction in pain intensity, as measured by the change in VAS scores from baseline to Day 7. Patients reported their pain intensity on the VAS at baseline (prior to the started medications) and at one week after treatment. Patients' frequency and severity of their adverse effects during the one-week treatment period were evaluated in a standardized self-report checklist. All data was noted in a predesigned proforma. Statistical analysis was conducted in SPSS version 29, the data was displayed as mean, standard deviation, percentage, chi-square test and paired sample t- test were used to compare related measure-ments. Statistical significance was defined below p-value of < 0.05. The analytical approach allows for a rigorous examination of drug treatment endpoint comparison, addressing both analgesic efficacy and the safety profiles of Aceclofenac and Naproxen in a clinical setting. This systematic framework offers evidence for optimal choices of NSAIDs, and contributes meaningfully to clinical guidelines for managing acute lower back pain [2].

Results

Table 1: Demographic Characteristics of Patients with Acute Low Back Pain (n=88)

Demographic Variables	n	%	Mean± SD	P value
Age group (Years)			47.93±11.2	0.009
18-27	5	5.7		
28-37	10	11.4		
38-47	21	23.9		
48-57	29	33.0		
58-65	23	26.14		
Gender				<0.001
Male	34	38.64		
Female	54	61.36		

As Table 1 highlights, females represented the largest number of study population (61.4%) compared with males (38.6%). The mean age of the study population is 47.93±11.2 years. In this study, the majority of patients were between 48-57 years of age (33.0%), followed by 58-65 years (26.1%) and 38-47 years (23.9%). A smaller proportion belonged to the 28-37 years (11.4%) and 18-27 years (5.7%) groups. There was a statistically significant difference in distribution of age groups and gender among enrolled LBP patients.

Table 2: Socioeconomic Variables of Patients with Acute Low Back Pain (n=88)

Socioeconomic Variables	n	%	P value
Occupation			<.001
Business	15	17.0	
Farmer	18	20.5	
Housewife	31	35.2	
Service	22	25.0	
Student	2	2.3	
Physical Workload			<.001
Yes	60	68.2	
No	28	31.8	

Table 2 illustrates the socioeconomic distribution.The most common occupation was housewife (35.2%),followed by service employees (25.0%),farmers (20.5%), and business owners(17.0%), while students accounted for only 2.3% of the participants.With regard to physical workload, a majority of patients (68.2%) reported involvement in heavy weight lifting, while 31.8% were not involved. The chi-square

analysis demonstrates that both occupation and physical workload were statistically significantly associated with the diagnosis of acute LBP (p<0.01).

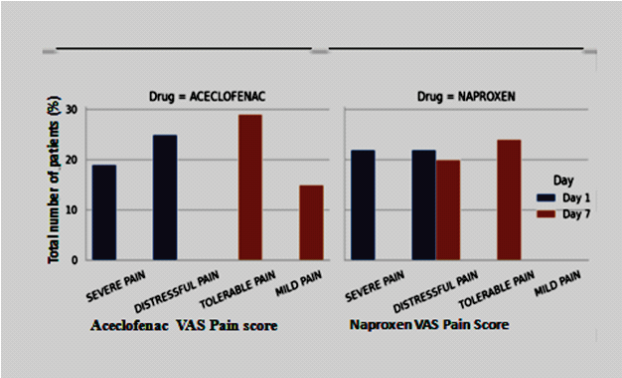

Figure 1: Distribution of pain intensity among patients receiving Aceclofenac and Naproxen on Day 1 and Day 7.

Figure 1 indicates that on Day 1, patients in both groups predominantly experienced severe or distressful pain. Specifically, for the Aceclofenac group (n=44), 19 patients reported severe pain and 25 reported distressful pain. Similarly, in the Naproxen group (n=44), 22 patients had severe pain and 22 experienced distressful pain. By Day 7, patients treated with Aceclofenac showed a significant shift towards lower pain levels, with 29 patients now reporting tolerable pain and 15 patients reporting mild pain. In contrast, for the Naproxen group, 24 patients shifted to tolerable pain, but 20 patients still experienced distressful pain, with no patients achieving a mild pain level. This demonstrates a larger decrease in pain severity, as well as greater degree of analgesia with Aceclofenac compared to Naproxen over the one-week treatment period.

Table 3: Comparison of changes in Mean VAS pain score at baseline and after treatment in two drug groups

Evaluation day	Drug groups		
	Aceclofenac	Naproxen	P Value
Baseline	7.0±1.00	7.0±1.01	0.90
Day 7	3.0±0.96	5.0±1.00	<.001

Table 3 shows the comparison of changes in mean VAS pain score for Aceclofenac and Naproxen respectively at baseline (Day 1) and Day 7. At baseline, the mean pain score was identical in both the Aceclofenac and Naproxen groups (7.0 ±1.0), with no statistically significant difference between them (p=0.90). After 7 days of treatment, there was a significant reduction in mean pain score in both groups, but the reduction was greater in the Aceclofenac group (3.0 ± 0.96) compared to the naproxen group (5.0 ± 1.00), and this difference as per the paired t-test was statistically highly significant (p<0.001).

Among the total 88 patients enrolled in this study who received either Aceclofenac or Naproxen, the Aceclofenac-treated group demonstrated good tolerability with no reported adverse effects. In contrast, the Naproxen treated group, three patient experienced mild adverse effects, primarily presenting as nausea and dyspepsia.

Discussion

This study from Birat Medical College Teaching Hospital aimed to conduct comparative efficacy and safety profiles of Aceclofenac and Naproxen in patients with acute LBP over a one-week treatment regimen. Our findings clearly demonstrate that even though both drugs were effective for the treatment of pain, Aceclofenac was better at reducing pain. We observed this because patients taking Aceclofenac had significantly lower pain scores on Day 7 compared to those taking Naproxen. Moreover, Aceclofenac seemed to be safer, since no side effects were reported, while a few patients taking Naproxen experienced mild gastrointestinal disturbances noted in a minor subset of patients. This finding is consistent with earlier studies indicating Aceclofenac has a relatively favourable gastrointestinal tolerability profile compared to other NSAIDs [7]. In other studies, Aceclofenac is shown to be more effective at reducing pain scores than naproxen, with a better safety and tolerability profile in patients with acute LBP [2, 3].

When we see the demographic analysis of the acute LBP patients, we found a greater representation of women, and a statistically significant relationship between both age group and gender with incidence of acute LBP. These results are consistent with known patterns in global epidemiology for acute LBP, which is usually more prevalent in women and the risk increases with age [17]. A local study from Western Nepal also supports these findings, showing that acute LBP is common there, especially among women [2]. Increased frequency of acute LBP in older women may also be related to hormone changes especially during and after menopause. Estrogen deficiency, commonly seen in women undergoing perimenopausal transition, is closely associated with decreased bone mineral density and greater musculoskeletal pain [18]. Estrogen plays a role beyond being a sex hormone; its presence in receptors located in intervertebral discs and joints suggests it plays a role in main-

taining spinal health. This shift in hormone levels, coupled with increased degeneration of the lumbar discs during menopause and the physiological age-related changes are behind the higher rates of acute LBP observed in older women [17]. Moreover, while most patients included in the present study were 48–57 years old, a significant proportion of cases were also observed in the 38–47 years age group. This is consistent with previous research on Nepalese populations, which reported 36–45 years of age as the most affected age group by acute LBP [3].

Our study found a clear connection between occupation, physical activity, and acute LBP. A considerable number of housewives, service workers, and farmers presented as our patients. Notably, a large number of patients (60 out of 88) reported doing heavy physical work or lifting heavy objects. This data also sheds light on how local lifestyles and work play a role in acute LBP among our patients. These studies support global findings, while indicating that the work-related physical stress is the predominant cause in the development of acute LBP [19]. These studies also pointed out which specific factors were more likely to serve as indicators of musculoskeletal issues and acute LBP. For example, such identified factors included awkward positions, repetitive movements, and heavy lifting [20]. Specifically, prolonged bending in agricultural work with twisting activities, along with regular heavy lifting activities in different occupations, are known risk factors for developing acute low back discomfort [21]. A local study showed that individuals working in constant manual heavy lifting report LBP issues eight times more often than those with a sedentary job [2]. Therefore, incorporating these specifically local work and social factors is crucial for developing effective treatment and preventive approaches for acute LBP.

At first glance, mean VAS pain scores in both Aceclofenac and Naproxen treatment groups were almost same at the start of the study with VAS scores of 7.0 ± 1.00 and 7.0 ± 1.01 respectively, showing same pain intensity before study. In both groups over the 7 days of treatment, pain score was significantly reduced. However, a significant difference appeared by Day 7: the mean VAS score in the Aceclofenac group decreased substantially to 3.0 ± 0.96, whereas the Naproxen group exhibited a less pronounced reduction, reaching 5.0 ± 1.00. This highly statistically significant difference ($p < 0.001$) by Day 7 shows that Aceclofenac was better at relieving pain. As shown in Figure 1, the types of pain reported by patients also support this: on Day 1, most patients in both groups had severe or very distressful pain (Aceclofenac: 19 severe, 25 distressful; Naproxen: 22 severe, 22 distressful). By Day 7, many patients in the Aceclofenac group felt much better, with 29 patients having tolerable pain and 15 patients having only mild pain. In contrast, in the Naproxen group, 24 patients moved to tolerable pain, but 20 still had distressful pain, and no patients reached the mild pain level. This pattern suggests that while both medicines are effective in managing acute low back pain, Aceclofenac might provide more rapid and pronounced pain relief, helping patients get to milder pain states in contrast to Naproxen.

The previous research in Western Nepal reported that Aceclofenac is more effective than Naproxen on reducing the severity of pain [2]. Although NSAIDs are thought to have an equal impact, our research of patient victims to this condition has showed different results. Other studies comparing Aceclofenac with various NSAIDs for treatment of musculoskeletal problem, osteoarthritis and acute low back pain, have often had the same level or higher degree of efficacy [7]. For instance, Aceclofenac has been identified as a well-tolerated alternative for Naproxen in the treatment of osteoarthritis [22]. In addition, a random trial comparing Aceclofenac with Diclofenac in the treatment of acute LBP had similar improvement in pain intensity and function scores [23]. Overall, the findings of this study strengthen that Aceclofenac as a more potent treatment option for the management of acute LBP. It appears that the drug is associated with reduced severity of pain, more rapid movement to less severe states, and therefore the mild state compared to Naproxen. Aceclofenac seems to be more efficient because it is a relatively COX-2 preferential inhibitor, so it produces potent anti-inflammatory and analgesic effects with less gastrointestinal adverse side effects [24].

Aceclofenac showed excellent tolerability and no adverse events in our investigation, while three Naproxen patients had mild gastrointestinal complications including nausea and dyspepsia. This encouraging safety profile for Aceclofenac is consistent with the already existing medical literature in general indicating a lower incidence of gastrointestinal adverse events with Aceclofenac than with other NSAIDs [7]. Studies, in particular, had highlighted Aceclofenac having lower risk of gastrointestinal complications, contributing to better compliance and making it a potentially safer choice for patients with acute LBP [7]. However, it should be noted that the routine co-prescription of gastrointestinal protec-

tive agents, such as proton pump inhibitors, with NSAIDs is a common clinical practice to reduce gastrointestinal risks [25], but the present study did not assess or consider their concurrent use together with such adjunctive medications. Therefore, the possible effect of co-administered gastro protective agents on our safety profiles cannot be confirmed, and this should be addressed further in future research.

This study contains a key strength as it directly compares two commonly prescribed NSAIDs for acute low back pain in a special local clinical setting, affording valuable, context-specific findings for health practitioners. The use of a reliable VAS for pain evaluation and a standard statistical analysis increases our robustness regarding efficacy of our findings. However, our study does have some limitations. As it is an observational study with a brief, one-week follow-up period it may not provide comprehensive information on long-term treatment effects or rare adverse events. Additionally, the unique demographic and geographic characteristics of our study may restrict the transferability of these results to wider or more diverse patient groups. In addition, even though the sample size was adequate for statistical application within this setting, larger, multicenter and randomized controlled trials are required to provide stronger evidence. The co-administration of gastro protective agents, including the proton pump inhibitors that are commonly utilized in association with NSAIDs, which could impact on the resultant gastrointestinal safety data, was the sole limited observation. These limitations should be overcome in future studies by testing patients as randomized controlled studies, with prolonged follow-up, in populations of more heterogeneity, and with a focus on concurrent medications and should allow long-term efficacy and safety profiles of Aceclofenac and Naproxen to be determined.

Conclusion

This research illustrates that both Aceclofenac and Naproxen are effective in alleviating acute low back pain over the course of one week. However, Aceclofenac consistently demonstrates a significantly greater reduction in pain and a more favourable safety profile compared to Naproxen. These findings indicate that Aceclofenac is not only an effective treatment option but also one that is generally well-tolerated, making it a potentially preferred choice for managing acute low back pain in similar clinical situations.

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Conflict of interest: None

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