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Efficacy and Safety of Etoricoxib in Patients with Lower Limb Degenerative Arthritis: A Prospective Observational Study at a Tertiary Care Centre in India

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ABSTRACT

Background: Lower limb degenerative arthritis is a major cause of chronic pain and functional limitation, particularly in older adults. Although non-pharmacological measures remain central to management, many patients continue to require short-term analgesic therapy. This study evaluated the efficacy and safety of etoricoxib in patients with lower limb degenerative arthritis.

Methods: This prospective, observational, single-arm study enrolled 98 patients with lower limb degenerative arthritis at a tertiary care center in India. All patients received etoricoxib 60 mg twice daily for 4 weeks along with physical therapy, followed by physical therapy alone up to 8 weeks. Pain intensity was assessed using the Visual Analog Scale (VAS), and functional status using the Lower Extremity Functional Scale (LEFS), at baseline, week 4, and week 8. Safety was evaluated by monitoring adverse drug reactions (ADRs) and assessing causality using the World Health Organization–Uppsala Monitoring Centre (WHO–UMC) system.

Results: Median VAS score decreased from 6.0 (IQR 6.0–7.0) at baseline to 5.0 (4.0–5.0) at week 4 and 5.0 (4.25–6.0) at week 8 ($p<0.001$). Mean LEFS score improved from 39.03 ± 7.87 at baseline to 50.15 ± 7.86 at week 4 and 55.02 ± 7.40 at week 8, with significant improvement at all pairwise comparisons ($p<0.001$). ADRs were reported in 21.4% of patients; the most common were headache and dyspepsia/epigastric discomfort. Most ADRs were mild to moderate, and all recovered.

Conclusion: Etoricoxib was associated with significant short-term pain reduction and progressive functional improvement, with an acceptable safety profile, in patients with lower limb degenerative arthritis.

Keywords: Etoricoxib; lower limb degenerative arthritis; osteoarthritis; Visual Analog Scale; Lower Extremity Functional Scale; adverse drug reactions.

INTRODUCTION

Lower limb degenerative arthritis, most commonly presenting as osteoarthritis of weight-bearing joints, is a major cause of chronic pain, mobility restriction, and disability worldwide [1]. It is now recognized as a whole-joint disorder involving cartilage, subchondral bone, synovium, and periarticular structures rather than an isolated cartilage disease [2]. In India, the burden is substantial and continues to rise with population ageing, occupational joint stress, and increasing chronic disease burden [3].

Current management emphasizes non-pharmacological measures such as exercise, rehabilitation, and weight reduction, but many patients continue to experience persistent symptoms requiring pharmacological treatment [4]. Nonsteroidal anti-

inflammatory drugs remain an important option for symptomatic relief, and selective cyclooxygenase-2 inhibitors such as etoricoxib are widely used because they provide effective analgesia with improved gastrointestinal tolerability compared with non-selective agents [5]. Clinical trials have demonstrated that etoricoxib improves pain and physical function in osteoarthritis [6], and real-world evidence has also supported its effectiveness in routine practice [7].

Despite its widespread use, there is limited short-format real-world evidence from Indian tertiary-care settings evaluating pain, function, and safety together in the same cohort. The present study was therefore undertaken to evaluate the efficacy and safety of etoricoxib in patients with lower limb degenerative arthritis by assessing changes in pain intensity and functional status over time, along with structured monitoring of adverse drug reactions.

MATERIALS AND METHODS

This prospective, observational, single-arm study was conducted at Dr. Ram Manohar Lohia Institute of Medical Sciences, Lucknow, in collaboration between the Departments of Pharmacology and Orthopaedics, after approval from the Institutional Ethics Committee (IEC No. 85/24). Patients attending the Orthopaedics outpatient department with lower limb degenerative arthritis were screened for eligibility and enrolled after written informed consent. Eligible participants were aged 50–70 years, of either sex, and had unilateral or bilateral degenerative arthritis involving the lower limb. Patients with limb deformity, inflammatory arthritis, life-threatening comorbid illness, bleeding or coagulation disorders, or malnutrition were excluded. A total of 98 patients were enrolled by purposive sampling. Baseline evaluation included age, sex, height, weight, body mass index (BMI), and comorbidities. Pain intensity was assessed using the Visual Analog Scale (VAS) [8], and functional status using the Lower Extremity Functional Scale (LEFS) [9]. All patients received etoricoxib 60 mg twice daily with physical therapy for 4 weeks, followed by physical therapy alone for a further 4 weeks. Follow-up assessments were performed at week 4 and week 8. Adverse drug reactions (ADRs) were monitored throughout the study and causality was assessed using the WHO–UMC system [10]. Continuous variables were expressed as mean ± SD or median (IQR), and categorical variables as frequency and percentage. VAS scores were analyzed using the Friedman test with Wilcoxon signed-rank post-hoc comparisons, while LEFS scores were analyzed using paired t-tests. A p value <0.05 was considered statistically significant.

RESULTS

Baseline characteristics

A total of 98 patients were included in the final analysis. Females comprised 60.2% of the study population. The median age was 55.0 (IQR 52.0–60.0) years, and mean BMI was 26.81 ± 3.41 kg/m². Hypertension was the most common comorbidity, followed by diabetes mellitus and thyroid disorder. These findings indicate that the study population largely represented middle-aged to older adults with symptomatic lower limb degenerative arthritis and relevant cardiometabolic comorbidity burden.

Table 1. Baseline characteristics of the study population (N = 98)

Variable	Overall
Female sex, n (%)	59 (60.2)
Male sex, n (%)	39 (39.8)
Age, median (IQR), years	55.0 (52.0–60.0)
BMI, mean ± SD, kg/m²	26.81 ± 3.41
Hypertension, n (%)	43 (43.9)
Diabetes mellitus, n (%)	19 (19.4)
Thyroid disorder, n (%)	11 (11.2)

Efficacy outcomes

Pain intensity showed significant improvement over time. Median VAS score decreased from 6.0 (IQR 6.0–7.0) at baseline to 5.0 (4.0–5.0) at week 4 and remained 5.0 (4.25–6.0) at week 8. Friedman test showed a significant difference across the three time points ($\chi^2 = 168.20$, df = 2, $p<0.001$). On pairwise comparison, pain decreased significantly from baseline to week 4 and from baseline to week 8 (both $p<0.001$), while a small but significant worsening was observed between week 4 and week 8 ($p<0.01$).

Functional status improved progressively throughout follow-up. Mean LEFS score increased from 39.03 ± 7.87 at baseline to 50.15 ± 7.86 at week 4 and 55.02 ± 7.40 at week 8. Pairwise analysis showed significant improvement from baseline to week 4 (mean difference 11.12; t = 49.37; $p<0.001$), baseline to week 8 (mean difference 15.99; t = 54.54; $p<0.001$), and week 4 to week 8 (mean difference 4.87; t = 29.03; $p<0.001$).

Table 2. Main efficacy outcomes over follow-up (N = 98)

Outcome	Baseline	Week 4	Week 8	Statistical test / pairwise comparison

VAS, median (IQR)	6.0 (6.0–7.0)	5.0 (4.0–5.0)	5.0 (4.25–6.0)	Friedman $\chi^2 = 168.20$, df = 2, $p<0.001$; baseline vs week 4 $p<0.001$; baseline vs week 8 $p<0.001$; week 4 vs week 8 $p<0.01$
LEFS, mean ± SD	39.03 ± 7.87	50.15 ± 7.86	55.02 ± 7.40	Baseline vs week 4: mean difference 11.12, t = 49.37, $p<0.001$; baseline vs week 8: mean difference 15.99, t = 54.54, $p<0.001$; week 4 vs week 8: mean difference 4.87, t = 29.03, $p<0.001$

Safety

ADRs were reported in 21 of 98 patients (21.4%). The most frequent ADRs were headache and dyspepsia/epigastric discomfort, with 7 cases each. Other less frequent events included raised blood pressure (3 cases), pedal edema (2 cases), nausea (1 case), and diarrhoea (1 case). Most ADRs were mild or moderate in severity. On WHO–UMC assessment, 10 ADRs were classified as probable/likely, 7 as possible, 2 as certain, and 2 as unlikely. All reported ADRs recovered, and no long-term sequelae were observed.

DISCUSSION

The present study showed that etoricoxib was associated with significant improvement in both pain intensity and functional status in patients with lower limb degenerative arthritis. VAS scores decreased significantly by week 4 and remained lower than baseline at week 8, while LEFS scores improved progressively across all follow-up points. These findings are consistent with randomized trials showing that etoricoxib provides effective symptomatic relief in osteoarthritis and improves physical function in routine clinical use [11,12].

An important finding in the present study was the pattern observed after drug discontinuation. Although a small worsening in pain was seen between week 4 and week 8, VAS scores remained significantly better than baseline, and functional improvement continued during this period. This suggests that early analgesic control with etoricoxib may help patients participate more effectively in continued physical therapy, thereby supporting longer-term functional recovery. Such an interpretation is clinically plausible within current osteoarthritis management strategies, which emphasize multimodal treatment and the central role of exercise and rehabilitation [4,13].

The improvement in LEFS scores is particularly relevant because functional recovery is a major treatment goal in degenerative joint disease. In the present study, function improved not only during active etoricoxib treatment but also during the subsequent rehabilitation-only phase, indicating that symptom control and physical therapy may have acted synergistically. This finding is in line with previous studies showing improvement in physical function and quality of life with etoricoxib in osteoarthritis, including older patient populations and short-term interventional settings [14,15].

With regard to safety, ADRs were observed in 21.4% of patients, and the overall tolerability profile was acceptable. The most frequent events were headache and dyspepsia/epigastric discomfort, most reactions were mild to moderate, and all recovered without long-term sequelae. This pattern is broadly compatible with the known safety profile of etoricoxib, particularly its gastrointestinal tolerability profile when used appropriately [16]. The use of WHO–UMC causality assessment added methodological strength to safety evaluation [10]. The study should, however, be interpreted in light of its limitations, including single-arm design, modest sample size, single-center setting, and short follow-up. Overall, the findings support the pragmatic use of etoricoxib for short-term symptom control as part of a combined pharmacological and rehabilitation-based approach.

CONCLUSION

In this prospective single-arm study, etoricoxib was associated with significant short-term reduction in pain and progressive improvement in functional status in patients with lower limb degenerative arthritis. Pain relief achieved during the first 4 weeks remained better than baseline at week 8, while functional improvement continued even after drug discontinuation during ongoing physical therapy. Adverse drug reactions were observed in a minority of patients, were largely mild to moderate, and all recovered without long-term sequelae. Overall, these findings support the pragmatic use of etoricoxib as part of a combined pharmacological and rehabilitation-based approach for short-term symptomatic management in selected patients with lower limb degenerative arthritis.

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