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Original Research Article

Clinical Efficacy and Safety of Diacerein Compared With Aceclofenac in Knee Osteoarthritis: A Prospective Hospital-Based Study

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Abstract

Background: Knee osteoarthritis (OA) is one of the most common degenerative joint disorders causing chronic pain, stiffness, and functional disability. While non-steroidal anti-inflammatory drugs (NSAIDs) such as Aceclofenac provide rapid symptomatic relief, they do not modify disease progression. Diacerein, an interleukin-1β inhibitor, has demonstrated disease-modifying potential with sustained symptomatic benefits.

Objectives: To compare the clinical efficacy and safety of Diacerein and Aceclofenac in patients with knee osteoarthritis using the Visual Analogue Scale (VAS) and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).

Methods: A total of 246 patients with radiologically confirmed Kellgren–Lawrence grade II or III knee OA were enrolled and allocated into two equal groups (n=123 each). Group A received Diacerein 50 mg twice daily, while Group B received Aceclofenac 100 mg twice daily for eight weeks. Patients were assessed at baseline and after 2, 4, 8, and 10 weeks using VAS and WOMAC scores.

Results: Both treatments produced significant reductions in pain and improvement in functional status over the study period. Aceclofenac demonstrated a faster onset of action, with significantly lower VAS and WOMAC scores at 2, 4, and 8 weeks ($p<0.05$). However, at the 10-week follow-up after treatment discontinuation, the Diacerein group exhibited lower VAS scores, indicating a sustained carry-over effect. WOMAC scores also suggested prolonged functional improvement with Diacerein after cessation of therapy.

Conclusion: Both Diacerein and Aceclofenac were effective and well tolerated in the management of knee osteoarthritis. Aceclofenac provided superior early symptomatic relief, whereas Diacerein demonstrated sustained post-treatment benefits, suggesting a disease-modifying carry-over effect.

Keywords: Knee osteoarthritis; Diacerein; Aceclofenac; WOMAC; Visual Analogue Scale; Non-steroidal anti-inflammatory drug.

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Introduction

Osteoarthritis (OA) is a progressive, multifactorial degenerative disorder characterized by destruction of articular cartilage, subchondral sclerosis associated with synovial changes. [1] Osteoarthritis is the most prevalent musculoskeletal disease and the most severe joint disorder with a prevalence of 22-30% in India. [2] Knee osteoarthritis is much more prevalent in India than the Western countries and it is the most common cause for joint dysfunction. There is a multifactorial cause for OA. Age, female sex, obesity, physical labor, occupational knee bending, family history, joint damage, and vitamin-D deficiency are significant risk factors for osteoarthritis. Though use of NSAIDs provide the symptomatic relief they do not play role in the reversal of basic pathology of osteoarthritis instead they may flare up the disease processes like degeneration of cartilage, inhibition of chondroitin synthesis and suppression of proteoglycan synthesis by chondrocyte. [3] Among NSAIDs, Aceclofenac has been established as a safe and effective medicine due to its superior selectivity for COX-2 inhibition. [4] Since the inflammation in knee OA is primarily due to the

presence of the cytokine interleukin-1β (IL-1β), Diacerein, an anthraquinone derivative inhibits IL-1β and has been shown to significantly decrease the symptoms by proving remission in pathological process. [5,6]

Diacerein is anthraquinone derivative that inhibits IL-1β and its signalling pathway. By delaying all biological process commencing in OA, it has been demonstrated to have an anti-catabolic and pro-anabolic effect on OA tissues. Diacerein is proven to be equally effective analgesic as compared to Aceclofenac in the patient of OA knee.

Aceclofenac is a non-steroidal anti-inflammatory drug (NSAID) commonly used to treat knee osteoarthritis. It works by inhibiting the cyclo-oxygenase (COX) enzymes, particularly COX-2, which is involved in the production of inflammatory mediators like prostaglandins. [7] Aceclofenac is known for its good tolerability and lower incidence of gastrointestinal side effects compared to other NSAIDs, making it a preferred option for long-term management of osteoarthritis.

Since the majority of population in eastern Uttar Pradesh belong to middle to lower middle-class family and has farming as its main occupation. The incidence rate of knee OA is found to be on higher side. Hence, to provide relief from pain and to reduce the disease progression along with minimum side effects, we did a comparative study of Diacerein with Aceclofenac to show its safety and efficacy in the population of eastern Uttar Pradesh.

Material & Methods

Study Design and Settings: This prospective, comparative, and observational study was carried out at Government Medical College and Super Facility Hospital, Azamgarh, in the Department of Pharmacology in collaboration with the Department of Orthopedics. The objective was to evaluate and compare the efficacy and safety of Diacerein and Aceclofenac in patients with knee osteoarthritis.

Study Duration: 18 months (July 2023 to December 2024)

Study Population & Sample Size: A total of 246 patients (123 patients in each group) diagnosed with knee osteoarthritis (OA) were recruited from the Outpatient Department (OPD) of Orthopedics at the hospital.

Inclusion & Exclusion Criteria: Symptomatic Patients between 40 to 70 years of age who fits in the criteria of the American College of Rheumatology for OA knee with a radiologic score of II / III on the Kellgren/Lawrence grading for OA Knee and willing to participate were included in the study. However Patients with a history of surgery around the knee or hip joint or with a history of previous intra-articular injection in the past 3 months or Patient with a history of oral treatment with a symptomatic slow-acting OA drug within 4 months prior to the start of the study were excluded from the study.

Intervention and Study Procedure: Patients who met the inclusion criteria were selected for the study after signing the written informed consent and randomly assigned to one of the two treatment groups.

Group A received Diacerein & Group B received Aceclofenac

Before prescribing the drugs thorough history, physical examination was done and data on demographic details, clinical symptoms, co-morbid conditions, and other baseline characteristics were also collected. After the initial evaluation the patients were followed up to evaluate the efficacy and safety of the treatments at 2 weeks, 4 weeks, 8 weeks and at 10 weeks in hospital.

Both the groups were treated with respective drugs for duration of 8 weeks. Detailed information regarding the drug, including dosage, frequency, and duration, was recorded in a Case Record Form (CRF). In Group A Diacerein 50 mg twice a day, orally was given for 8 weeks. In Group B Aceclofenac 100 mg twice a day, orally was given for 8 weeks.

All enrolled patients were monitored for compliance, adverse drug reactions (ADR), and other clinical outcomes. During the study period, adverse drug reactions were carefully monitored and reported to the ADR Monitoring Centre using the Red Form. Each patient's compliance with therapy was assessed through pill counts and patient history.

Outcome Measures: The primary objective was to compare the efficacy of Diacerein and Aceclofenac in alleviating the symptoms of knee osteoarthritis, including pain, stiffness, and functional impairment. The efficacy was measured by using Western Ontario and McMaster Universities Arthritis Index (WOMAC) which has three sub-score for pain, stiffness and physical function and visual analogue scale (VAS) for pain. Both scores were evaluated on the first day of treatment followed by at 2 weeks, 4 weeks, and 8 weeks. After stopping the therapy, WOMAC and VAS score were evaluated again at 10 weeks to see the carryover effects of the drugs.

Statistical Analysis: Data were recorded in an MS Excel spreadsheet for analysis using Statistical Package for Social Sciences (SPSS) version 26.0. Categorical variables were presented in terms of number and percentage (%), while continuous

variables were expressed as mean ± SD and median. A p-value ≤ 0.05 was considered statistically significant.

Results

The study included 246 patients, with 123 in both Diacerein group and Aceclofenac group. Group A received Diacerein & Group B received Aceclofenac.

Table 1: Distribution of the studied patients based on age

Age group	Group- Diacerein (n=123)	Group- Aceclofenac (n=123)	p-value
≤40 year	15 (12.2%)	12 (9.8%)	0.397
41-50 year	39 (31.7%)	38 (30.9%)	
51-60 year	32 (26.0%)	42 (34.1%)	
61-70 year	34 (27.6%)	25 (20.3%)	
>70 year	3 (2.4%)	6 (4.9%)	
Mean±SD	53.93±9.7	54.44±8.9	0.673

In the Diacerein group, the majority of patients (31.7%) were aged 41-50 years while in the Aceclofenac group, the majority of patients (34.1%) were aged 51-60 years.

Table 2: Distribution of the studied patients based on clinical symptoms

Clinical Symptoms	Group- Diacerein (n=123)	Group- Aceclofenac (n=123)	p-value
Pain	115 (93.5%)	110 (89.4%)	0.335
Pain, Swelling	6 (4.9%)	7 (5.7%)	
Pain, Stiffness	2 (1.6%)	6 (4.9%)	

The majority of patients in both the Diacerein and Aceclofenac groups experienced pain, with 115 (93.5%) in the Diacerein group and 110 (89.4%) in the Aceclofenac group. There was statistically non-significant difference between clinical symptoms & both groups (P>0.05).

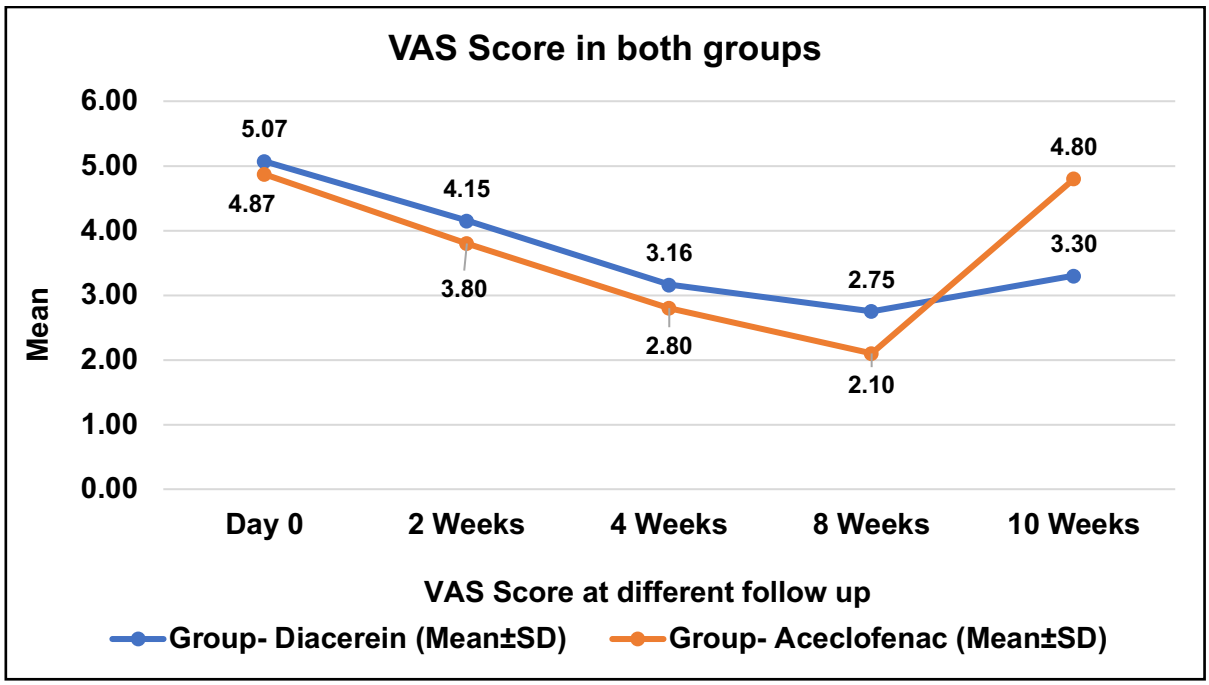

Figure 1: Distribution of the studied patients based on VAS Score

On Day 0, the difference in VAS scores were non-significant (P>0.05). However, significant differences were observed at 2 weeks, 4 weeks, 8 weeks and 10 weeks (P<0.05), with the Aceclofenac group generally showing lower pain scores compared to the Diacerein group, except at 10 weeks, where the Diacerein group had a lower score.

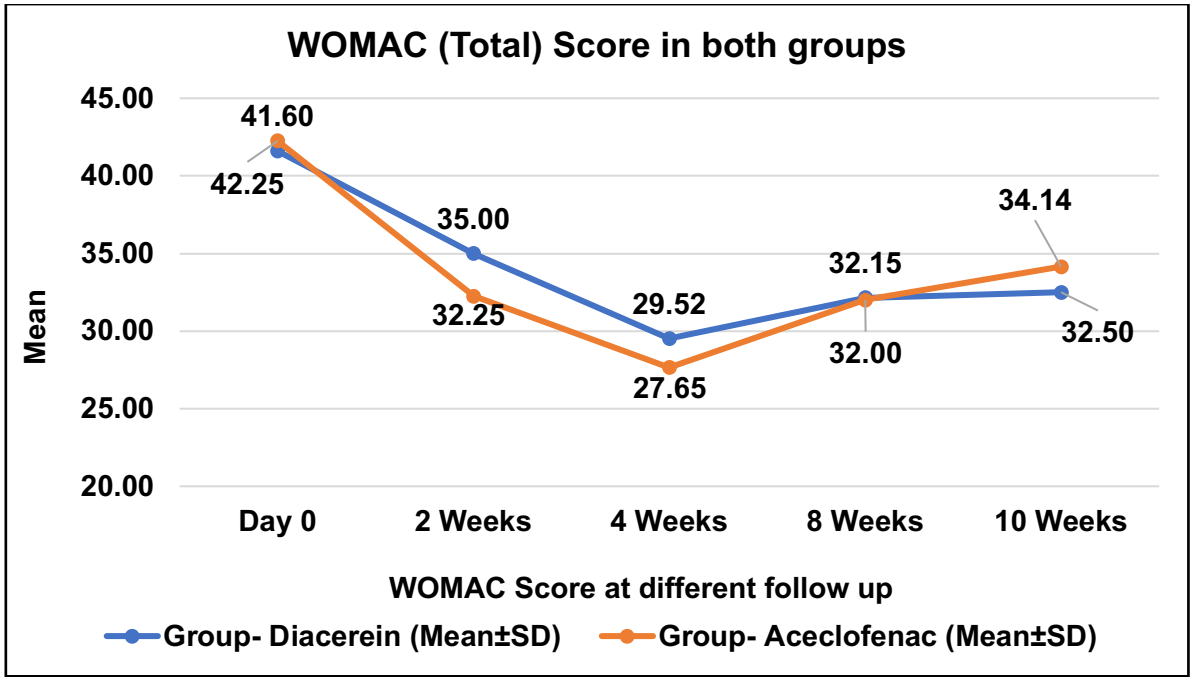

Figure 2: WOMAC score in two groups at baseline and different follow-up days

The WOMAC scores between two groups: Diacerein and Aceclofenac, over different follow-up days, it was observed that while both treatments are effective, Aceclofenac may provide more significant improvements in physical function and overall WOMAC scores in the earlier weeks.

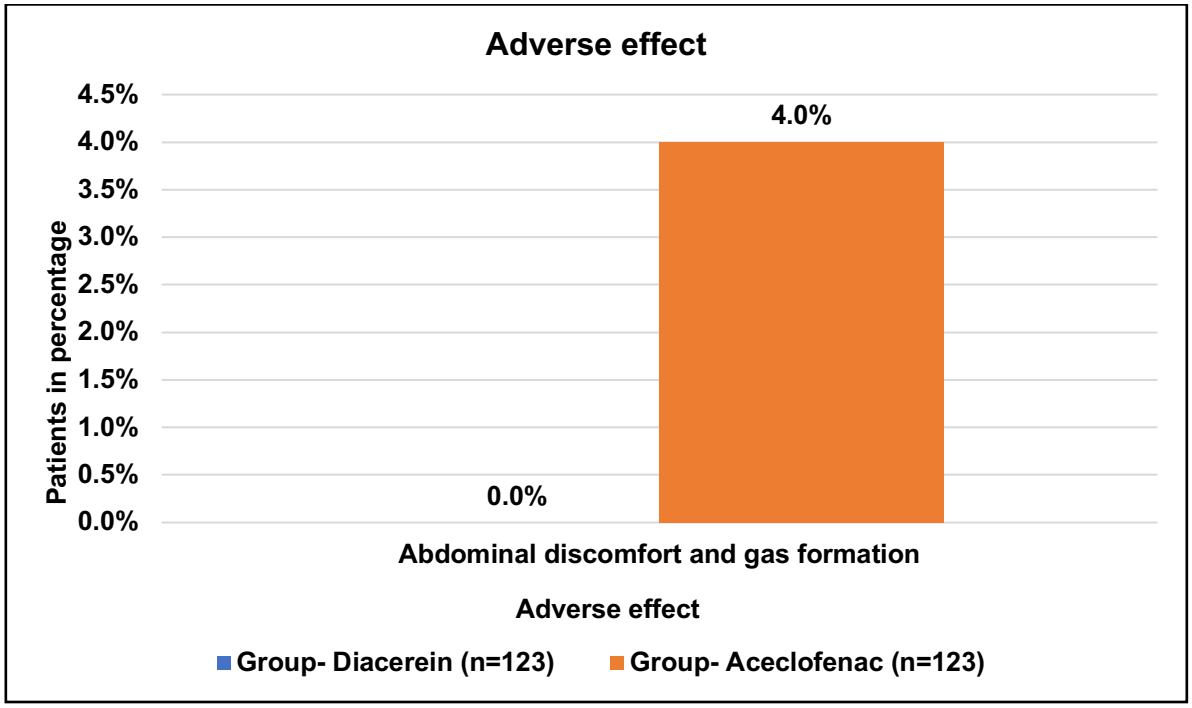

Figure 3: Adverse effects in both groups

Only 5 (4.0%) patients had the adverse effect in the Aceclofenac group**.**

Discussion

In the current study, the majority of patients in both the Diacerein and Aceclofenac groups experienced pain, with 115 (93.5%) participants in the Diacerein group and 110 (89.4%) in the Aceclofenac group. Additionally, 6 patients (4.9%) in the Diacerein group and 7 patients (5.7%) in the Aceclofenac group reported pain and swelling. Pain and stiffness were observed in 2 patients (1.6%) in the Diacerein group and 6 patients (4.9%) in the Aceclofenac group but the difference was

insignificant (p>0.05). Our findings were similar to the findings of Gupta N and Datta S [8] who reported that there was no notable variation in the number of participants reporting knee swelling across the different treatment groups. Pelletier JP et al [9] reported that joint swelling and effusion were in 21.6% and 23.8% cases of the Diacerein and Celecoxib groups respectively (p>0.05). Joint pain is the dominant symptom of OA. [**Error! Bookmark not defined.**]

In the present study, On Day 0, the difference in scores was non-significant (P>0.05). However, significant differences were observed at 2 weeks, 4 weeks, 8 weeks, and 10 weeks (P<0.05), with the Aceclofenac group generally showing lower pain scores compared to the Diacerein group, except at 10 weeks where the Diacerein group had a lower score.

Diacerein and Aceclofenac, over different follow-up days, it was observed that while both treatments are effective, Aceclofenac may provide more significant improvements in physical function and overall WOMAC scores in the earlier weeks. Our findings were in concordance with the findings of Sharma S et al [10] who reported that the VAS score difference between the two groups at baseline was 0.6mm (7.05 ± 0.94 in the Diacerein group and 6.4 ± 0.94 in Aceclofenac group) whereas at the end of one month, it was 1.1 mm (4.2±0.76 in Diacerein group and 3.15±0.93 in Aceclofenac group). At 45 days the difference in VAS score between the two groups is not significant (p>0.05). At the end of 1 month treatment period, the reduction of the VAS and WOMAC scores was better in Aceclofenac group. However, there was a decrease of VAS and WOMAC scores by 40.04% and 32.78% in the Diacerein group at the end of 1 month suggesting the efficacy of Diacerein as well. Palvelka K et al [11] control trial shows a reduction of WOMAC score by 18.86% in his study in the Diacerein group and Singh K et al [12] studies show a reduction of VAS score by 32.97% and WOMAC score by 15.04% at 3 weeks in Diacerein group in his study.

In within-group analysis, the increase in VAS and WOMAC scores are comparatively lower in the Diacerein group when compared at 45 days which signifies the carryover effect of Diacerein which has been also shown in other studies. As Aceclofenac is an established treatment given safety and efficacy in this study it has been used as a control to evaluate the efficacy of Diacerein as reported by Patel PB et al. [13]

The present study's finding that Aceclofenac may provide more significant improvements in the earlier weeks is consistent with a study by Gossec L et al [14], which found that Aceclofenac had a faster onset of action compared to Diacerein in patients with osteoarthritis. The present study's finding that Diacerein had a lower pain score at 10 weeks is consistent with a study by Dieppe P et al [15], which found that Diacerein had a sustained effect on pain reduction in patients with osteoarthritis.

Recommendations

1. Future studies should aim to recruit larger sample sizes from multiple centers to increase the generalizability of the findings.
2. Future studies should consider longer follow-up periods to capture the long-term effects of the treatments.

Limitations

1. The study's sample size may not be large enough to detect all potential differences and rare adverse events between the two groups. A larger sample size would increase the statistical power and reliability of the results.
2. The study duration was only 10 weeks, which may not be sufficient to capture the long-term effects of the treatments.

Conclusion

In conclusion, the choice between Diacerein and Aceclofenac for treating knee osteoarthritis should be guided by the patient's specific needs, with consideration of the balance between immediate efficacy and the potential for adverse effects.

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