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Original Article

Effectiveness of physiotherapy in comparative assessment of pain and quality of life in patients with mild knee osteoarthritis receiving non-steroidal anti-inflammatory drug therapy

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ABSTRACT

Objectives: Knee osteoarthritis (OA) is a common degenerative joint disorder affecting the elderly population and is characterized by pain, stiffness, and progressive decline in physical function and quality of life. Although non steroidal anti-inflammatory drugs (NSAIDs) are widely prescribed for symptomatic relief, the role of physiotherapy as an adjuvant to pharmacological management in early-stage OA remains under explored. The present study aimed to evaluate and compare the effectiveness of NSAID monotherapy versus a combination of NSAIDs and physiotherapy in reducing pain and improving functional outcomes among individuals diagnosed with mild knee OA. **Methods:** This randomised, open-label, comparative, prospective, parallel-group studyenrolled 110 participants aged 40 to 70 years with clinically confirmed mild knee OA. Participants were randomly allocated into two equal groups (n=55 each). Group N received Aceclofenac 100mg twice daily for 5 days, while Group P received the same regimen plus a standardised 21-day physiotherapy program. Clinical assessments were performed at baseline, day 7, day 14 and day 21. Primary outcome measures included change in pain intensity using the Visual Analog Scale (VAS) and changes in total and subscale scores of theWestern Ontario and McMaster Universities Arthritis Index (WOMAC). Secondary outcomes included the Global Assessment of Response to Therapy (GART) completed independently by participants and clinicians. Adverse events, if any, were documented at each visit. **Results:** All 110 enrolled participants completed the study. Baseline demographic and clinical characteristics were comparable between groups (p>0.05).Both groups demonstrated a significant reduction in VAS and WOMAC scores from baseline to day 21 (p < 0.001), but improvements were consistently greater in Group P (p<0.001). By Day 21, mean VAS scores reduced to 3.03±0.82 in Group P compared to 4.96±0.79 in Group N, and WOMAC scores decreased to 33.40±6.45 in Group P compared to 44.58±7.42 in Group N. Significant improvements were also observed in WOMAC sub-domains (pain, stiffness and physical function) favouring Group P at all evaluation points (p<0.001). GART revealed that a higher proportion of participants and clinicians rated outcomes as “very good” or “excellent” in Group P compared to Group N. No serious adverse events occurred, though NSAID-related discomfort, such as epigastric discomfort, nausea, and vomiting,was reported. **Conclusion:** Physiotherapy as an adjuvant to NSAID therapy results in superior pain relief, functional improvement, and mobility enhancement compared with NSAID therapy alone in patients with mild knee OA. These findings support incorporating structured physiotherapy into routine management for optimal clinical outcomes.

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Introduction

Osteoarthritis (OA) is a major cause of disability among the elderly worldwide, with a higher prevalence among women.[1]

Although OA may affect multiple joints including the hips, spine, shoulder and hands; the knee remains the most frequently affected site.[2] In India, the reported prevalence of knee OA among older adults is approximately 47%, emphasising its substantial public health burden.[3]

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Beyond physical limitations, OA can negatively influence sleep, psychological wellbeing, productivity, daily functioning and even long-term mortality risk.[4] The primary goals of OA management are to reduce pain and inflammation and to improve physical function through a combination of pharmacological and non-pharmacological treatment strategies. [5]Current therapeutic approaches include lifestyle modification, pharmacotherapy, and surgical intervention when conservative measures fail.[6,7] Non-pharmacological strategies such as weight reduction, structured exercise, and physiotherapy form the cornerstone of early OA management.[8] Pharmacological agents, particularly nonsteroidal anti-inflammatory drugs (NSAIDs) and opioids, remain standard options for pain relief.[9] The present pharmacological methods are mostly intended for symptomatic relief but do not stop the progression of OA. Furthermore, prolonged use-especially of NSAIDs-can lead to gastrointestinal adverse effects, reducing long term adherence and tolerabilility. [10]

Knee OA is among the most common chronic joint disorders, resulting in pain, stiffness and functional impairment. Physiotherapy represents a key non-invasive therapeutic modality that encompasses exercise therapy, manual therapy and electro-therapy techniques.[11] It is widely recommended in international clinical guidelines as a core non-pharmacological intervention, either alone or in combination with pharmacological treatment.[8,12] Physiotherapy has been shown to effectively reduce pain, enhance mobility and improve quality of life (QOL) among individuals with knee OA, while being cost-effective and associated with minimal adverse effects. [13]

There are very few studies highlighting the combined effectiveness of NSAIDs and physiotherapy, particularly in patients with mild knee OA. Previous studies have primarily focused on each intervention in isolation. [14,5] A comprehensive comparative assessment is crucial to determine if integrating physiotherapy as an adjuvant therapy provides superior outcomes in terms of pain reduction and quality of life improvement. The primary objective of the study was to assess and compare the effectiveness of adjunctive physiotherapy in reducing pain among patients with mild knee OA receiving NSAID therapy, while the secondary objective was to assess and compare its effectiveness in improving QOL among these same patients. Our findings will provide valuable insights into the optimal integrated management of mild knee OA and may help lessen the long-term reliance on NSAIDs, thus improving patient-centred outcomes.

Materials and methods

Design and subject selection

This was a randomised, open-label, comparative, parallel-group, prospective study conducted over 21 days. Participants had knee pain but were not under active medical supervision for the condition. The study adhered to the principles of the Declaration of Helsinki (2024 revision) and International Conference on Harmonization—Good Clinical Practice (ICH-GCP)guidelines. Approval was obtained from the Institutional Ethics Committee, and the trial was registered with the Clinical Trials Registry–India. Written informed consent was obtained from all participants.

Participants were recruited from the Orthopaedics Outpatient Department of a tertiary care hospital. The following inclusion criteria were applied: (1) Subjects of either gender aged 40–70 years with symptomatic idiopathic bilateral knee OA at least 3 months duration; (2) Subjects with radiological evidence of Kellgren-Lawrence(KL) Grade -1 or 2 OA of knee joints (mild OA)[15]; (3) Subjects with morning stiffness lasting< 30 minutes with detectable crepitus on motion; (4) Subjects who have the ability to perform physiotherapy exercises;and (5) Subjects' willingness to comply with study procedures and provide informed consent.

The exclusion criteria included: (1) Subjects with history of surgery or acute trauma to the knee joint within the preceding 6 months;(2) Subjects with history of underlying inflammatory arthropathies or severe rheumatoid arthritis;(3) Subjects having known hypersensitivity to NSAIDs;(4) Subjects with neurological, musculoskeletal or spinal disorders affecting lower limb function; (5) Pregnancy, lactation or planned pregnancy and (6) Subjects with history of gastrointestinal bleeding, peptic ulcer disease,cardiovascular disease, psychiatric illness, bronchial asthma, pseudogout, severe osteoporosis or abnormal hepatic or renal function. The participants were recruited between July 2025 and September 2025.

Sample size calculation

Using previous data reported by Mohammed, et al,[9] a sample size of 110 participants (55 per group) was calculated to detect a mean VAS difference of 0.98 at the end of one month, with an effect size of 0.564, 80 % power, 5%alpha error, and an estimated 10% dropout rate.

Randomisation

A total of 110 eligible participants were randomly allocated in a 1:1 ratio using a simple random allocation sequence without stratification. Group N (n=55) received Aceclofenac 100mg twice daily for 5 days, while Group P (n=55) received the same medication regimen along with standardized physiotherapy for 21 days.

Assessments

Baseline assessment included demographic details, complete medical and drug history, adverse event history, laboratory investigations, comprehensive physical and bilateral knee radiographs graded using the KL system. Outcome measures included the Visual Analog ScaleVAS[16] and Western Ontario and McMaster Universities Arthritis Index (WOMAC) [17]. These were assessed at baseline, Day 7, Day 14 and Day 21. Global Assessment of Response to Therapy (GART)[18] was evaluated by participants and clinicians at Day 21.

VAS was measured on a validated 10-cm scale (0=no pain; 10=worst imaginable pain) using standardized instructions. The WOMAC questionnaire included 24 items across pain (0-20), stiffness (0-8), and physical function (0-68) domains, using a 5-point Likert scale (0 = none to 4 = extreme). A reduction in total WOMAC score indicated improved quality of life. GART was scored on a 5-point Likert scale (0 = poor to 4= excellent) independently by participants and clinicians. All adverse events were documented throughout follow-up.

Primary end points

The primary endpoints were changes in VAS and WOMAC total and sub scale scores from baseline to Day 7, Day 14, and Day 21. The secondary endpoint was the GART score assessed on Day 21.

Statistical analysis

Data were entered into Microsoft Excel and analysed using standard statistical methods. Descriptive statistics (mean±SD, frequency, and percentages) summarised baseline characteristics. Repeated measures analysis of variance (ANOVA) assessed changes across time within and between groups. This was followed by Bonferroni post-hoc analysis for pair-wise comparisons to identify significant within group changes and an unpaired t-test for between group comparisons at each specific time points. GART, being an ordinal outcome measure, was analysed using the Mann–Whitney U test to compare participant and clinician ratings between the two treatment groups.

All comparisons were reported with 95% confidence intervals (CI). This analysis followed the intention-to-treat principle. A p-value <0.05 was considered statistically significant.

Results

Participant characteristics

A total of 123 individuals were screened, of whom 110 participants met the eligibility criteria and were randomised into two groups (Figure 1). Fifty-five participants were allocated to the NSAIDs only group (Group N) and fifty-five to the NSAIDs plus physiotherapy group (Group P). All participants received the allocated intervention, completed the 21-day study period, and were included in the final analysis.

Baseline demographic and clinical characteristics are summarised in Table 1. Both groups were comparable in terms of age, gender distribution, and duration of knee OA. The mean age was 58.62 ± 6.06 years in Group N and 58.11 ± 6.29 years in Group P. The majority of participants in both groups were females (70.9% in Group N and 69.1% in Group P). The mean duration of OA symptoms varied slightly between the groups (1.34 ± 0.69 years in Group N vs. 2.19 ± 0.97 years in Group P), but remained within the mild OA range.

Efficacy endpoints

1.Primary Outcomes:

Pain Severity (VAS)

Both treatment groups demonstrated statistically significant reductions in pain scores over the study duration; however, the magnitude of improvement was greater in Group P at all follow-up points beyond baseline. As shown in Table 2, VAS scores decreased from 7.04 ± 0.76 at baseline to 4.96 ± 0.79 by Day 21 in Group N, whereas Group P demonstrated a greater reduction from 6.85 ± 0.91 to 3.03 ± 0.82 during the same period. The between-group difference was statistically significant beginning at Day 7 ($p < 0.001$) and increased progressively, with the largest difference observed on Day 21 (mean difference = −1.93; 95% CI: −2.23 to −1.63; $p < 0.001$). The large effect sizes across all follow-up intervals confirm the clinical relevance of physiotherapy as an adjunct treatment.

Functional Status and Quality of Life (WOMAC Scores)

A similar trend was observed for WOMAC total scores. Both groups showed significant within-group improvement from baseline to Day 21; however, Group P achieved greater functional gains (Table 2). By Day 21, the mean WOMAC score decreased from 53.64 ± 5.59 to 33.40 ± 6.45 in Group P, compared with a reduction from 54.55 ± 5.42 to 44.58 ± 7.42 in Group N. The between-group difference was statistically significant from Day 7 onward ($p < 0.001$), with the maximum difference recorded at Day 21 (mean difference = −11.18; effect size = −1.97).

Subscale analysis (Table 3) further demonstrated superior results in Group P. Improvements in pain, stiffness, and physical function scores were significantly greater in Group P beginning at Day 7 and continued to widen over time. By Day 21, Group P showed markedly lower pain scores (7.00 ± 1.33 vs. 9.00 ± 1.36), reduced stiffness (2.78 ± 0.57 vs. 3.64 ± 0.68), and better physical function (23.40 ± 4.03 vs. 30.47 ± 4.78), all with $p < 0.001$.

2. Secondary Outcome:

Global Assessment of Response to Therapy (GART)

The GART findings corroborated the primary outcomes (Table 4). No participant rated their response as poor. In Group N, the majority reported a good response (56.3%), while Group P demonstrated superior treatment satisfaction, with most participants rating their outcome as very good (47.2%) or excellent (32.7%). Clinician assessments mirrored participant responses, with excellent ratings predominating in Group P (49.0%) compared to Group N (9.0%).

Safety and Tolerability

Aceclofenac was generally well tolerated. Mild adverse effects reported included epigastric discomfort (10%), nausea (6.4%), and vomiting (2.7%). No serious adverse events occurred, and no participants discontinued treatment due to adverse effects.

Table 1: Baseline demographic and clinical characteristics of study participants

Characteristics	Group N (NSAIDs only) (n=55)	Group P (NSAIDs + Physiotherapy) (n=55)
Age (years)	58.62±6.06*	58.11±6.29*
Gender		
Male n (%)	16 (29.1%)	17 (30.9%)
Female n (%)	39 (70.9%)	38 (69.1%)
Duration of OA (years)	1.34±0.69*	2.19±0.97*

**Data are presented as mean ± SD*
SD: Standard deviation

Table 2: Statistical Analysis of VAS and WOMAC Scores

Outcome measure	Group N* (n=55)	Group P* (n=55)	Mean difference [95% CI]	Effect size [95% CI]	p-value
VAS Score					
Baseline	7.04±0.76	6.85±0.91	0.04[−0.21,0.28]	0.06 [−0.32,0.43]	0.774
Day 7	6.57±0.61‡	5.53±1.05‡	−1.04[−1.36,−0.72]	−1.21[−1.61, −0.80]	<0.001†
Day 14	5.91±0.74‡	4.29±0.81‡	−1.62[−1.98,−1.26]	−1.67[−2.10, −1.24]	<0.001†
Day 21	4.96±0.79‡	3.03±0.82‡	−1.93[−2.23,−1.63]	−2.39 [−2.88, −1.90]	<0.001†
WOMAC Total score					
Baseline	54.55±5.42	53.64±5.59	−0.31[−2.18,1.56]	−0.06[−0.44, 0.31]	0.747
Day 7	49.75±6.55‡	45.16±6.84‡	−4.59[−6.41,−2.77]	−0.94 [−1.33, −0.55]	<0.001†
Day 14	46.36±6.94‡	38.31±6.36‡	−8.05[−9.95,−6.15]	−1.57 [−2.00, −1.15]	<0.001†
Day 21	44.58±7.42‡	33.40±6.45‡	−11.18[−13.29,−9.07]	−1.97 [−2.42, −1.51]	<0.001†

**Results are expressed as mean ± SD*
†P value<0.001 shows significant difference between the groups at each timeline
‡P value <0.001 shows significant reduction in VAS and WOMAC scores within the group from the baseline at each timeline

Table 3: Comparison of subscales of WOMAC betweenthe groups at all evaluation points

	Group P* (n=55)	Group N* (n=55)	p-value (between groups)
Pain subscale			
Baseline	11.27±0.97	11.38±1.22	0.613
Day 7	9.42±1.08	10.36±1.28	0.002
Day 14	7.96±1.26	9.60±1.30	<0.001
Day 21	7.00±1.33	9.00±1.36	<0.001
Stiffness subscale			
Baseline	4.49±0.54	4.51±0.54	0.860
Day 7	3.78±0.53	4.15±0.49	<0.001
Day 14	3.16±0.63	3.84±0.60	<0.001
Day 21	2.78±0.57	3.64±0.68	<0.001
Physical function subscale			
Baseline	38.44±3.21	38.55±3.87	0.872
Day 7	32.15±3.77	35.31±4.29	<0.001
Day 14	27.18±3.96	32.78±4.53	<0.001
Day 21	23.40±4.03	30.47±4.78	<0.001

*Results are expressed as mean ± SD

Table 4: Global Assessment of Response to Therapy (GART)

	Group N (n=55) n(%)	Group P (n=55) n (%)
Participant response		
Poor (0)	0 (0%)	0 (0%)
Fair (1)	9 (16.3%)	3 (5.4%)
Good (2)	31 (56.3%)	8 (14.5%)
Very Good (3)	9 (16.3%)	26 (47.2%)
Excellent (4)	6 (10.9%)	18 (32.7%)
Clinician response		
Poor(0)	0 (0%)	0 (0%)
Fair (1)	1 (1.8%)	0 (0%)
Good (2)	30 (54.5)	4 (7.2%)
Very Good (3)	19 (34.5)	24 (43.6%)
Excellent (4)	5 (9.0%)	27 (49.0%)

Discussion

The present study compared the clinical effectiveness of NSAID monotherapy with a combination of NSAIDs and physiotherapy in individuals with mild knee osteoarthritis over a 21-day treatment period. The findings demonstrated that while both treatment approaches resulted in significant reductions in pain and improvements in function, the addition of physiotherapy produced markedly superior clinical outcomes across all assessment domains, including pain intensity, joint stiffness, functional capacity, and patient-reported treatment satisfaction.

A study by Vaishali Saini et al. (2024), reported that combining pharmaceutical and physical therapy interventions provides the best outcomes for chronic conditions.[19] Similarly, Bennell et al. (2014) reported that structured exercise interventions resulted in meaningful improvements in pain, stiffness, and physical function among individuals with mild-to-moderate knee OA.[20] J. Thorlund et al. (2020), demonstrated an 18.1% reduction in analgesic use following an 8-week supervised exercise program, with 52% of participants either discontinuing analgesics or switching to lower-risk alternatives.[21]

The findings of our study are further supported byWaleed Medhat et al. (2024), who demonstrated that a 12-week comprehensive physiotherapy program—consisting of exercises, manual therapy, and education—produced substantial improvements in WOMAC pain, function, muscle strength, and quality of life. Although our study employed a shorter and more focused physiotherapy protocol, both studies show consistent patterns of symptomatic relief, suggesting that even brief physiotherapy interventions can deliver meaningful clinical benefits.[22]

Physiotherapy as an adjunct modality is further supported by the global recommendations from the Osteoarthritis Research Society International (OARSI) and the American College of Rheumatology (ACR), which strongly recommend exercise and weight-bearing physical therapy as first-line therapy before pharmacological agents.[23,24]

In contrast, studies evaluating NSAIDs alone have shown only short-term benefits, often limited by adverse gastrointestinal outcomes with continuous use.[25,26] This aligns with our findings where, although NSAID monotherapy produced improvement, the magnitude was noticeably lower than when physiotherapy was included. The improvement in patient satisfaction, reflected through GART scores, supports previously published evidence that multimodal therapy improves subjective treatment experience and functional confidence more than medication alone. Josune Martín et al. (2012), found patients receiving an interdisciplinary treatment reported greater satisfaction compared to standard pharmacological care.[27]

Overall, the convergence of evidence from prior studies and the present findings suggests that early implementation of physiotherapy—when combined with NSAIDs—provides superior clinical benefit in pain control, gait improvement, stiffness reduction, and overall quality of life compared to NSAID monotherapy.

This study has several strengths, including a randomized design, standardized physiotherapy protocol, high participant retention, and the use of validated outcome measures. However, some limitations should be acknowledged. The study duration was relatively short (21 days), and longer follow-up is needed to determine whether improvements persist beyond the treatment period. Additionally, the study focused exclusively on mild OA; future research should assess whether similar benefits apply to moderate or advanced disease cases.

Conclusion

Overall, the study provides strong evidence that physiotherapy, when used as an adjunct to NSAID therapy, offers superior clinical benefits compared to NSAID monotherapy in patients with mild knee OA. Combination therapy resulted in greater pain relief, reduced stiffness, improved function, and higher patient satisfaction. These findings support the early integration of physiotherapy into standard clinical management pathways to optimize outcomes and reduce long-term reliance on pharmacological interventions.

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