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EFFECTS OF PHONOPHORESIS WITH DICLOFENAC SODIUM AND THERAPEUTIC ULTRASOUND WITH TRADITIONAL PHYSIOTHERAPY IN KNEE OSTEOARTHRITIS

Muhammad Atif Khan
Institutional Affiliation: Department of Rehabilitation & Health Sciences, Nazeer Hussain University. Email: atif.khan@nhu.edu.pk https://orcid.org/0000-0001-6859-9222
Hira Islam
Institutional Affiliation: Al Hamd Institute of Physiotherapy & Health Sciences Email: drhiraislampt@gmail.com https://orcid.org/0000-0001-8250-5827
Muhammad Asif
Institutional Affiliation: Department of Rehabilitation & Health Sciences, Nazeer Hussain University. Email: m.asif@nhu.edu.pk, https://orcid.org/0000-0002-3190-354X
Maryam Liaquat
Institutional Affiliation: Department of Rehabilitation & Health Sciences, Nazeer Hussain University. Email: maryam.liaquat@nhu.edu.pk https://orcid.org/0009-0008-5152-1144
Nigar Begum
Institutional Affiliation: Al Hamd Institute of Physiotherapy & Health Sciences Email: nigarasim@outlook.com, https://orcid.org/0009-0003-9604-5026
Malika
Institutional Affiliation: Al Hamd Institute of Physiotherapy & Health Sciences. Email: malaikakhan429@gmail.com, https://orcid.org/0009-0009-4145-9022

Author Details

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Corresponding E-mails & Authors*:
Muhammad Atif Khan*
atif.khan@nhu.edu.pk

Abstract

Background: Osteoarthritis of the knee is a common painful condition of the knee. The primary treatment for knee osteoarthritis has been conventional physiotherapy but, other types of adjunct therapy including therapeutic ultrasound and phonophoresis are also combined with physiotherapy. ***Objective:*** This study aimed to determine the effects of diclofenac sodium phonophoresis and therapeutic ultrasound with traditional physiotherapy in symptomatic knee osteoarthritis. ***Methods:*** A randomized controlled trial was carried out on 30 males (50-60 years) who had bilaterally confirmed clinically and radiologically, knee osteoarthritis (Kellgren

Lawrence Grade II to IV). They were randomly divided into two groups (n = 15). A ten day (10 sessions) physiotherapy program was given to them. Therapeutic ultrasound was administered to them, while the ones were administered diclofenac sodium phonophoresis. Pain and function was measured pre- and post-intervention with the Visual Analogue Scale (VAS) and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). Data were analyzed in terms of paired and independent samples t-test ($p < 0.05$). In addition, the effect size (Cohen's d) was also calculated. ***Results:*** There was improvement in pain and function in both groups. And the improvement in the VAS score was greater in the phonophoresis group than the ultrasound group ($p < 0.001$) with a large effect size ($d = 1.58$). There was an improvement in the WOMAC scores in both groups, but no difference in the change in the two groups at post treatment ($p = 0.334$). This is a result of a difference in the WOMAC score at baseline. ***Conclusion:*** The effect of diclofenac sodium phonophoresis is more significant than therapeutic ultrasound and traditional physiotherapy in pain reduction of patients with knee osteoarthritis. Both interventions also have improved function but needs to be studied further with larger sample size and longer follow up period to establish these effects.

Keywords: Diclofenac sodium, Phonophoresis, Osteoarthritis, Ultrasound, Knee Osteoarthritis.

Introduction

OA of the knee is a common joint disease and the most common contributor to pain, disability and impairment. It is known to be associated with the ageing population, obesity and sedentary lifestyle, and is a cost to the health-care system (Dell'Isola et al., 2025; Hawker & King, 2022; Gelber, 2024). Signs and symptoms include pain and disability, and decreases quality of life in elderly (Atukorala & Hunter, 2023; Courties et al., 2024).

Osteoarthritis of the knee is a condition involving loss of cartilage and subchondral bone, inflammation and musculoskeletal dysfunction. So, the main focus of treatment is non-pharmacological, multi-disciplinary and to reduce pain and improve function (Bannuru et al., 2019; Bennell et al., 2012). Nonpharmacological approaches are always recommended as the first-line approach for the management of knee osteoarthritis, including physiotherapy such as exercise therapy (Rodríguez-Reyes et al., 2025). It can

increase the mobility of the joint, decrease pain and inflammation and help with the healing process (Bricca et al., 2019; Hsu et al., 2023).

Although physiotherapy treatments work well, they are often complemented with electrotherapeutic treatments. Physiotherapists sometimes use ultrasound, which has been shown to have thermal and non-thermal effects such as improved blood flow, reduced skin and joint stiffness and inflammation (Ebadi et al., 2020; Hou et al., 2025). However, studies on the use of ultrasound are conflicting, with some showing there were no reported benefits when it was used on its own (Ebadi et al., 2020).

The phonopheresis is a non-creative and successful trans-dermal drug delivery for treatment of Knee osteoarthritis. The non-thermal effects of ultrasound (acoustic streaming and cavitation) make the pores on the skin larger, which leads to more penetration of the skin by the drug (Martin-Vega et al. 2022; Yang et al. 2022). A non-steroidal anti-inflammatory drug (NSAID) called diclofenac sodium (NS) has a high anti-inflammatory and pain relieving effect and can be used as one of the drugs in phonophoresis. NSAIDs are recommended to treat OA because of their pain-relieving properties and adverse effects (Derry et al. 2016; eb et al. 2025).

More recently, it has also been shown that phonophoresis generally has greater effect than therapeutic ultrasound because of the mechanical and pharmacological effects of phonophoresis (Samir et al., 2023; Iordan et al., 2023). Likewise, it's been demonstrated the use of pharmaceuticals and devices is beneficial to the results of non-invasive interventions for osteoarthritis (Santos et al., 2024; Fuggle et al., 2025). However, there are many differences in the treatment protocols, outcomes and study design, so it's difficult to say.

Crucially, the effect of these modalities is not often studied as part of a standardised physiotherapy program, so it's hard to determine the effects of the modalities. Given physiotherapy is regarded as the standard care, it's important to assess the effects of adjunct therapies during physiotherapy (Yang et al., 2022; Martin-Vega et al., 2022). Further, there's no randomised studies on the effect of diclofenac phonophoresis versus therapeutic ultrasound (Samir et al, 2023).

We need to find out the effect of the type of adjunct therapies to physiotherapy, especially in low- and middle-income countries where low-invasive and affordable therapies are needed. We need to find out whether diclofenac phonophoresis is better than therapeutic ultrasound as an adjunct to physiotherapy. So this randomised trial to determine the efficacy of diclofenac sodium phonophoresis and therapeutic ultrasound as adjunct to a particular standardised conventional physiotherapy in patients with knee osteoarthritis.

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METHODS

Study Design

This was a six-month prospective parallel group randomized controlled trial (RCT) following the CONSORT guidelines.

Setting

From the physiotherapy unit of National Healthcare Centre, Karachi.

Participants

30 patients with bilateral knee osteoarthritis.

Inclusion Criteria

- Male and female, aged 50-60 years presenting with bilateral knee osteoarthritis diagnosed clinically and radiologically were:
- Pain (50-90 on pain visual analogue scale (VAS))
- WOMAC score between 48–90
- Radiographic degenerative change of the joint - Kellgren-Lawrence II-IV
- Can walk independently

Exclusion Criteria

Participants with:

- Knee injection/ surgery within 12 months
- Other mobility limiting condition
- Any contraindication to ultrasound treatment
- Severe deformity requiring surgery

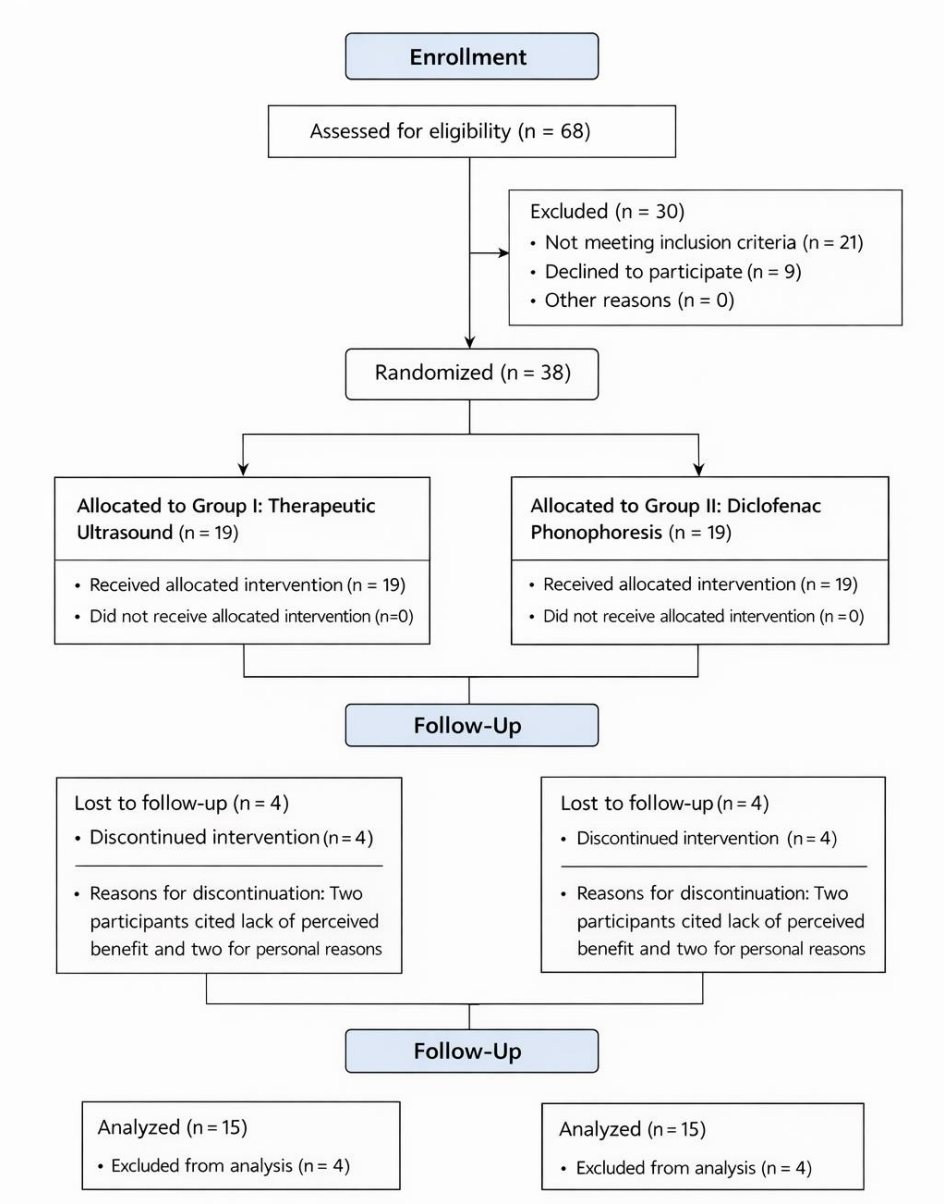
Radiographic Assessment

In this study, radiographs (plain, weight-bearing, anterior-posterior (AP)) were used for the diagnosis of knee OA. The extent of disease was measured by the Kellgren-Lawrence (K-L) grade of osteoarthritis which is a grading system for severity of the disease from I (normal) to IV (severe) which is based on joint space narrowing, osteophyte formation and subchondral sclerosis (hardening of the bone). Patients were included in this study who were diagnosed with Grade II (mild), Grade III (moderate) and Grade IV (severe) osteoarthritis. This was confirmed with a physician prior to the randomization.

Sample Size

In this trial 30 patients (15 for each group) were recruited because of practical and availability of patients during the time of trial. This study was not pre-planned in terms of sample size; therefore, it should be considered as a pilot study. If post hoc sample size calculation with G*Power version 3.1.9.7 are made for independent-samples t-test, two-sided alpha = 0.05, power = 80% and a moderate effect size (d = 0.70), the sample

size should be 30. For a large sample size trial, the drop-out rate should be estimated to be 10%; hence, the sample size should be 38.



Randomization and Allocation Concealment

Simple randomisation was performed to assign participants to the two groups (1:1). Masking of group allocation was performed by recording group allocation in paper and putting them in opaque sealed envelopes prepared by an independent researcher, who was not involved in participant recruitment and data collection.

Blinding

It was not possible to blind therapists or participants. But all outcome assessors were blinded.

INTERVENTIONS

The intervention program (n=30) was conducted with a routine physiotherapist treatment in patients with knee osteoarthritis to reduce pain, improve joint and muscles strengthening and flexibility and enhance the quality of life. The intervention program was physiotherapy (five days per week for two weeks (10 sessions). These were 30-45 minutes in duration, and were tailored to the individual.

Exercises included rehabilitative exercise such as joint mobilization, stretches and/or strengthening exercises. The exercises were performed at a low to moderate intensity (40-60% of maximum voluntary contraction) and the intensity was gradually increased. The exercises were pain-free, and only increased if the patient reported no change in pain or a slight increase in pain (less than 2 points on a Visual Analogue Scale).

The exercise program typically began with a warm up, and then active or active-assisted range of motion exercise to improve the stiffness and lack of movement of the knee joint. These exercises included the heel slide, active knee flexion and extension whilst sitting and passive knee extension with a towel roll. Joint strengthening exercises were primarily aimed at the quadriceps and hamstrings and included isometric contractions of the quadriceps, straight leg raises, quadriceps strengthening (short arc) and hamstring strengthening. Functional strengthening exercises (sit to stand, stepping up and walking) was performed to address issues with activities of daily living. Relaxation exercises (stretching of the lower limbs) were done.

Group I (Therapeutic Ultrasound + Physiotherapy)

This group was treated with therapeutic ultrasound and physiotherapy. The therapeutic ultrasound was used on the knee joint in conjunction with a coupling medium. The continuous mode of ultrasound was used for 5-10 minutes per treatment. The frequency used was either 1 or 3 MHz, depending on the depth of the tissue and intensity was 0.8 to 1.5 W/cm^2 depending on the patient tolerance and the therapist's experience. This was done daily during the treatment. This was a non-invasive method which produced both thermal and non-thermal effects, to reduce pain, enhance blood flow and lengthen the tissue.

Group II (Experimental group: Diclofenac Sodium Phonophoresis + Conventional Physiotherapy)

The group that received the diclofenac sodium phonophoresis received physiotherapy. In the Diclofenac sodium group, the medium employed was a gel of diclofenac sodium

in the ultrasound in order to increase the penetration of the drug. The phonophoresis procedure involved putting a small amount of diclofenac sodium gel (often 1%) (2-4 grams) on the knee joint.

The phonophoresis was provided in continuous mode for 5-10 minutes per day. The frequency used was 1 MHz (deeper tissues) or 3 MHz (superficial tissues) and intensity was 0.8-1.5 W/cm^2 (safe for human use). It was given once per day during physiotherapy. The intervention was thought to increase the area of the effect of the drug on the wound (the skin permeability was increased by the ultrasound) and enhance the anti-inflammatory and analgesic effect of diclofenac sodium without systemic side-effects. The intervention was a combination of the mechanical (ultrasound) and pharmacological (NSAID) effect and was expected to be superior to ultrasound alone.

Progression and Monitoring

The intervention was progressed according to response to the intervention, pain, function and tolerability. Exercise was altered or stopped if there was an increase in symptoms such as pain, swelling or discomfort. The intervention was progressed by a physiotherapist to ensure safety, compliance with intervention and technique.

Outcome Measures

The outcome measures were pain and function. Pain was assessed with the Visual Analogue Scale (VAS); this is a valid, reliable and well-used questionnaire which is a 100 mm line with the words "no pain" and the "worst pain imaginable" at each end of the line and the participant marks the line where they feel their pain is. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) was used to measure function; this is a questionnaire that is only used for people with osteoarthritis and relates to the pain, stiffness and function of the knee.

This outcome measurement was taken twice; prior to the intervention (Day 1) and after the intervention (Day 15). The assessor was masked to treatment to minimise bias.

Statistical Analysis

We used Statistical Package for Social Sciences (SPSS) 23 for the analyses. We used descriptive statistics (mean and standard deviation) to report the baseline measures and demographics. Independent samples t tests were used to compare the groups at baseline (before the intervention).

We used paired t tests to see the effect of the intervention by comparing the change in the outcomes before and after the intervention. Post intervention comparison between two groups was done using independent-samples t-tests. In this two-tail test ($p < 0.05$) was used.

We also calculated the effect sizes to indicate the effect of the intervention. For between-group effects Cohen's d was used to calculate the effect size (small 0.2, moderate 0.5 and large 0.8). Where appropriate eta squared (η^2) was calculated to reflect the percentage of variance accounted for. This was reported along with p-values to determine the effect of the intervention.

RESULTS

A total of 30 patients were recruited and assigned to two groups (therapeutic ultrasound (TUS) group n = 15 and diclofenac sodium phonophoresis (DSPH) group n = 15). There was no drop-out and all the patients were analyzed.

Baseline Characteristics

The baseline characteristics of the participants are given in Table 1. There was no difference in age (56 years vs 55 years) and all were male. There was no difference in the grade of severity of the radiograph (Kellgren-Lawrence Grading) (50% Grade II, 30% Grade III and 20% Grade IV in each group).

There was no difference ($p = 1.000$) in pain (as measured by the Visual Analogue Scale (VAS) (Table 2) at baseline and this suggested the two groups were comparable. But there was a difference ($p < 0.001$) in the Western Ontario and McMaster Universities (WOMAC) score (Table 4) at baseline and there was a functional imbalance.

Pain Outcomes (VAS)

Within-Group Changes

There was improvement in the VAS score in both groups. The mean VAS score of the TUS group decreased from 7.40 ± 1.06 to 4.80 ± 1.70. In the DSPH group, the mean VAS score dropped significantly from 7.40 ± 1.06 to 2.00 ± 1.84.

Between-Group Comparison

At the end of the session the difference between the groups was statistically significant ($p < 0.001$) on the VAS (Table 3) and the DSPH group had a greater decrease in pain. The effect size (Cohen's $d = 1.58$) was large and indicates a large effect of the diclofenac phonophoresis.

The graph (Figure 1A) shows a greater drop in pain over time in the DSPH group compared to the TUS group, which suggests there is an effect.

Functional Outcomes (WOMAC)

Within-Group Changes

Both groups improved in WOMAC. The TUS group improved from 9.93 ± 1.49 to 5.87 ± 0.52, while the DSPH group improved from 4.67 ± 1.29 to 4.00 ± 0.56.

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Between-Group Comparison

There was no significant (p = 0.334) difference between the groups in terms of WOMAC (Table 5). There was a large effect size (Cohen's d = 3.46), indicating a large difference between the groups (but not a significant difference). Both groups showed improvement with less improvement in DSPH group due to low WOMAC at baseline (Figure 1B).

Since the groups were not matched for WOMAC, the difference might have influenced the results. So the effects sizes for WOMAC should be interpreted with caution as they could be due to the differences between the two groups at baseline.

So both groups improved with pain and function when therapeutic ultrasound (US) and diclofenac phonophoresis were added to physiotherapy. However, there was a greater improvement in pain with diclofenac phonophoresis as shown by the large effect size and statistically significant difference. Both groups improved but it is hard to tell if this is meaningful because of the differences at baseline.

Table 1: Demographic Characteristics of Patients with Knee Osteoarthritis

Characteristic	TUS Group (n = 15)	DSPH Group (n = 15)
Age (years)	56 mean age	55 mean age
Radiographic Grade (K–L)		
Grade II	50%	50%
Grade III	30%	30%
Grade IV	20%	20%

TUS = Therapeutic Ultrasound; DSPH = Diclofenac Sodium Phonophoresis

Table 2: ***VAS Pain Scores Between Groups (Pre-Treatment)***

Group	N	Mean ± SD	95% CI	t-value	p-value	Effect Size (d)
TUS	15	7.40 ± 1.06	6.81 – 7.99	0.000	1.000	0.00
DSPH	15	7.40 ± 1.06	6.81 – 7.99			

Table 3: ***VAS Pain Scores Between Groups (Post-Treatment)***

Group	N	Mean ± SD	95% CI	t-value	p-value	Effect Size (d)
TUS	15	4.80 ± 1.70	3.87 – 5.73	10.02	<0.001	**1.58**
DSPH	15	2.00 ± 1.84	1.00 – 3.00			

Table 4: ***WOMAC Scores Between Groups (Pre-Treatment)***

Group	N	Mean ± SD	95% CI	t-value	p-value	Effect Size (d)
TUS	15	9.93 ± 1.49	9.11 – 10.75	18.55	<0.001	**3.79** ⚠
DSPH	15	4.67 ± 1.29	3.96 – 5.38			

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Table 5: *WOMAC Scores Between Groups (Post-Treatment)*

Group	N	Mean ± SD	95% CI	t-value	p-value	Effect Size (d)
TUS	15	5.87 ± 0.52	5.58 – 6.16	1.00	0.334	**3.46**
DSPH	15	4.00 ± 0.56	3.69 – 4.31			

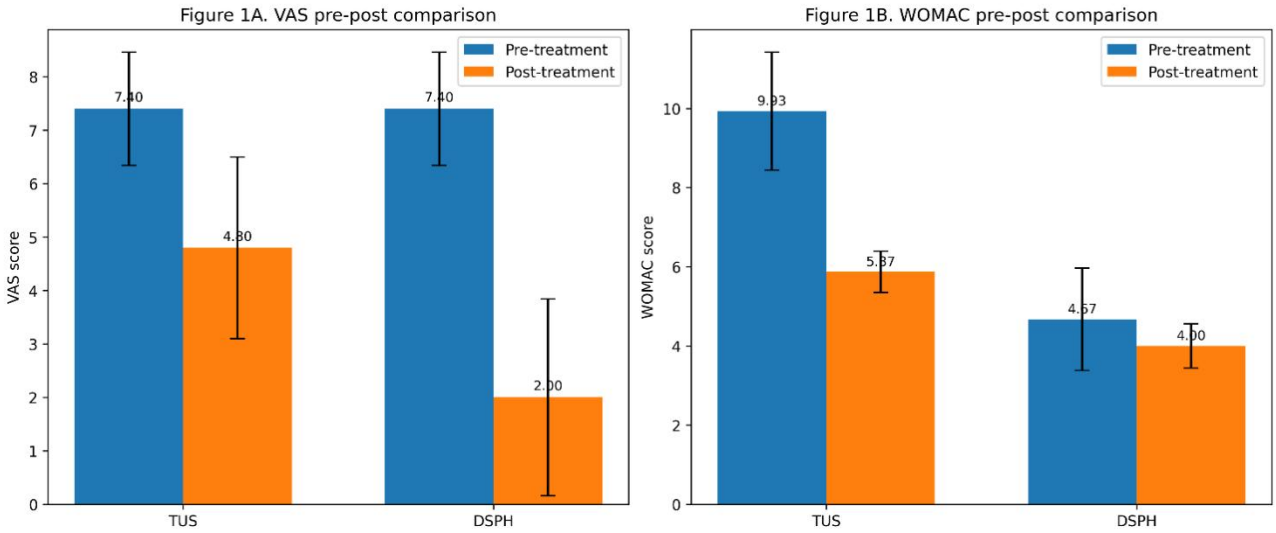

Figure 1: Group Comparison

DISCUSSION

The study aimed to evaluate the effectiveness of therapeutic ultrasound and physio-therapy along with phonophoresis (diclofenac sodium) for knee OA treatment. There was no effect on knee function in either phonophoresis or therapeutic ultrasound, however, pain did decrease with phonophoresis compared to therapeutic ultrasound.

Both Diclofenac phonophoresis and therapeutic ultrasound showed a decrease in pain (VAS), the increase was greater in the phonophoresis group. The reduction in the phonophoresis group was significant but also relevant as the effect size was large. This study is in line with other studies which have compared the pain reduction effect of phonophoresis and therapeutic ultrasound and found phonophoresis is more effective (Samir et al., 2023; Yang et al., 2022; Martin-Vega et al., 2022). This may be due to the combination of the effects of ultrasound (mechanical) and diclofenac (penetration enhancer).

Therapeutic ultrasound was moderate (less pain) compared to the control. Often used in physiotherapy but is the effect unknown? But among other studies, its effectiveness has

been conflicting; ultrasound appears not to be effective when used alone (Ebadi et al., 2020; Hou et al., 2025).

The findings of the present study support this; ultrasound was found to reduce the pain and symptoms, but not as much as phonophoresis and conventional physiotherapy.

With the improvements in function, measured by the WOMAC, both groups showed improvement after treatment. But there were no differences between the groups after treatment, although with large effect sizes. This could have been due to baseline WOMAC scores. The phonophoresis group had a lower mean baseline and this may have affected the group (floor effect). So, the after-effect may be questionable.

The result of this study indicate the need for randomisation of the groups and statistical analysis after taking the difference between the groups, if there is any (Lakens, 2022). But, improvement in both groups suggest conventional physiotherapy treatment such as exercise rehabilitation for the treatment of osteoarthritis (Bannuru et al., 2019; Rodríguez-Reyes et al., 2025; Bricca et al., 2019). To conclude, knee osteoarthritis is prevalent with millions of sufferers with disability and low quality of life (Dell'Isola et al., 2025; Hawker & King, 2022; Gelber 2024). Non-invasive, safe and cost effective treatment is required, especially in low income countries. This study suggests that diclofenac phonophoresis may be a superior adjunct to pain management than therapeutic ultrasound as it has a greater benefit with equal input. In terms of current treatment, osteoarthritis is now treated based on multimodal, personalised strategies including exercise, medications and new technologies (Fuggle et al., 2025; Santos et al., 2024; Chen et al., 2025). Phonophoresis may help these responses and is most likely to be relevant in moderate to severe osteoarthritis.

This study has some limitations. This may have limited generalisability of these results with a small sample size and only males being used and, therefore, this may not be relevant for females. Long-term data extrapolations cannot be made due to the duration and no follow up in interventions. Lastly, there were differences in the treatment protocols and no stratification of disease severity.

In the future, more rigorous randomized controlled trials should be included, with a larger sample size and treatment protocols and longer follow-up. Stratification and individualised protocols should be considered. And multimodal rehabilitation and optimal dose should be explored.

CONCLUSION

Therapeutic ultrasound and diclofenac sodium phonophoresis were effective when combined with standard physiotherapy for pain and function with knee osteoarthritis. But phonophoresis reduced pain significantly and had a large effect. While there was no

significant difference in improvement in function, both groups improved but these results should be considered with caution as there were differences between the two groups at baseline.

Diclofenac phonophoresis may be more beneficial for pain and enhance rehabilitation. Also larger, better quality, longer-term studies are required to confirm these findings and to identify the ideal treatment protocol.

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