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Comparison of the Efficacy of Phonophoresis and Conventional Ultrasound Therapy in Patients with Primary Knee Osteoarthritis

ORIGINAL INVESTIGATION

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ABSTRACT

Objective: To compare the efficacy of phonophoresis (PH) versus ultrasound (US) in patients with primary knee osteoarthritis (OA).

Materials and Methods: Forty patients were divided into two groups as PH and US. Acoustic gel containing no pharmacological agent was applied in the US group, whereas a gel containing 1.16% diclofenac diethylamonium was applied in the PH group for 10 sessions. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain subscale and Visual Analogue Scale (VAS) were used for the assessment of pain. The WOMAC physical function subscale, Lequesne functional index and Stanford Health Assessment Questionnaire (HAQ) were used for the assessment of physical activities. Patients were assessed for a 3 month follow-up period.

Results: In the PH group, painless walking duration improved at all follow-up times except for week 2 ($p<0.05$). Painless walking distance and VAS scores also improved at all follow-up times ($p<0.05$). In the US group, VAS scores during walking and flexion of the knee, WOMAC pain and physical function scores and total WOMAC scores improved significantly at all follow-up times ($p<0.05$).

Conclusion: Both therapeutic modalities were found effective. We suggest neither therapy is superior to the other but PH can improve painless walking duration more successfully than US.

Key words: Knee osteoarthritis, phonophoresis, ultrasound

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INTRODUCTION

Osteoarthritis (OA) is a degenerative disease that causes osteophytic formations, subchondral sclerosis and erosions in the joint cartilage. It can also be associated with biochemical and morphologic changes in the joint capsule. The knee is one of joints most affected by osteoarthritic effects in the human skeleton. Patients with knee OA may have progressive functional disability while walking, standing and climbing. OA principally affects the elderly and causes significant morbidity (1, 2).

Clinicians initially aim at protecting the joint's functions and reducing the pain caused by joint OA. Another important aim is to improve the quality of life, which is affected by this degenerative disease. Although there is no exact cure for OA, recommended approaches for the medical management of knee OA include non-pharmacologic modalities and drug therapy (3). Non steroidal anti-inflammatory drugs (NSAIDs) are generally used for the treatment of OA, but they also have some potential risks for the elderly due to their renal, cardiac and gastrointestinal side effects (4-9). Physical therapy modalities are other methods that can be used in the treatment of OA (3, 10). They are very important in improving physical functions, reducing pain and producing a desired effect in the treatment of edema and inflammation (3, 10-13).

Ultrasound is one of the physical therapy modalities generally used for many musculoskeletal disorders. US converts electrical energy to an acoustic waveform that is converted to heat as it passes through tissues with different resistance compositions (14).

Phonophoresis is the use of ultrasound to enhance percutaneous absorption of a drug (15-18). Phonophoresis provides an advantage as it bypasses the hepatic first-pass metabolism and avoids the side effects in absorption that occur with oral administration (18-20).

The number of clinical trials which compare PH to the other physical therapies is quite limited, which may be explained by the absence of optimizing frequency and the duration of therapy. In some clinical trials, ibuprofen and dexamethasone were used by investigators for phonophoresis in patients with knee OA (21-23). However, we found no trial in our "pubmed" search regarding diclofenac phonophoresis in patients with knee OA.

Cardero et al. (24) indicated the highest transdermal penetration of diclofenac among NSAIDs such as indomethacin, piroxicam, tenoxicam, ketorolac and aceclofenac. Rosim et al. (25) also showed that therapeutic ultrasound administration enhanced the percutaneous absorption of the topical diclofenac gel. According to this, diclofenac seems to be a good candidate for phonophoresis administration.

In this prospective randomised controlled trial, we aimed to compare the efficacy of diclofenac phonophoresis with conventional ultrasound therapy in patients with knee OA at the three-month-follow-up.

MATERIAL and METHODS

Forty patients were randomly assigned to two treatment groups by one of the non-treating authors by drawing an envelope among 40 for each participant which were labeled 'A' (Group I: phonophoresis; 13 woman, 7 men) and 'B' (Group II: ultrasound; 17 women, 3 men). All the patients fulfilled the American College of Rheumatology criteria for knee OA (26) and had Kellgreen and Lawrence (27) scores between II-IV. Patients who had a Visual Analogue Scale (VAS) score over 50 in one of three parameters-i.e walking, flexion of the knee and resting- were included in the trial. On the other hand, patients who had a secondary OA, had received intraarticular or intramuscular corticosteroids or received intaarticular hyaluronic acid injections in the past 3 months, had been on any physical therapy program in the past 6 months and had any systemic disease or abnormal laboratory test results, dermatological problems, skin allergy to NSAIDs and malignant diseases were excluded from the trial.

The Western Ontario and McMasters Universities Osteoarthritis Index (WOMAC) was used to assess pain, stiffness and physical functions (28, 29). WOMAC scores were evaluated on a Likert scale of 0-4, where 0 stood for no pain/limitation, 1 for mild pain/limitation, 2 for moderate pain/limitation and 4 for severe pain/limitation. The patients' WOMAC scores were evaluated at the beginning and end of the trial as well as in the first, second and third months. For the normalization of values among each other, the scores were multiplied by 0.5, 1.25 and 0.147 for pain, stiffness and physical functions, respectively. HAQ scores were also used for the assessment of functional activities. This scale is used for assessing daily activities. Activities are marked between 0-3, where 0 stands for no limitation, 1 for mild limitation, 2 for severe limitation and 3 for complete limitation. All the patients were evaluated according to their HAQ scores, which were recorded.

Pain the patients felt during walking, resting and flexion of the knee was assessed by VAS (VAS 0: No pain, VAS 10: most severe pain). Painless walking duration was measured in minutes whereas painless walking distance was measured in meters and range of flexion by goniometers at the beginning and end of the therapy as well as all the follow-up times.

The State/Trait Anxiety Inventory was used for the assessment of anxiety whereas the Beck Depression Inventory was used for the assessment of depression symptoms.

The patients were asked to rate the treatment efficacy by one of the following: ineffective, poorly effective, effective and very effective. All assessments were repeated at the first, second and third months after the therapy.

A total of 60 patients had been referred to US or PH therapies initially. However, 10 patients refused to participate in the trial for various reasons. In addition, a total of 10 patients were excluded from the trial-3 due to diabetes mellitus, 2 due to a history of intraarticular corticosteroid injection in the past 3 months and 5 due to high sedimentation rates.

The patients were asked about their age, weight, height, level of education, duration of disease, sporting activities and location of the pain in the knee. All the patients underwent physical examination. The patients were also evaluated with their laboratory findings. Complete blood count (CBC), erythrocyte sedimentation rate, C- reactive protein, rheumatoid factor (RF) and routine biochemical tests were performed to rule out other diseases. The patients who were included in the trial had normal laboratory findings.

The use of NSAIDs or other analgesic drugs was not permitted during the study period.

The trial was performed in accordance with the principles stated in the declaration of Helsinki. All the patients were informed about the study design both in verbal and written forms. Each participant gave their written informed consent to the study prior to participation. Patients who fulfilled the ACR knee OA criteria were included in this trial which was conducted in our Clinic of Physical Therapy and Rehabilitation.

Intervention

A physiotherapy program was administrated five times a week for a total of two weeks in 10 sessions. In the US group, an acoustic gel which did not contain any pharmacologic agent was applied to the skin of the knee. In the PH group, gel containing 1.16% diclofenac diethylamonium was applied by an US device to the superomedial, inferomedial and lateral sides of the knee in circular movements. Continuous ultrasonic waves with a frequency of 1 MHz and power of 1.5 W/cm^2 were used in the two groups. US and PH therapies were administered for 10 minutes per session for each knee.

Statistical analysis

We determined the sample size according to the recommendations available at the time of planning the study. To provide 83% capacity for detecting 30% improvement in WOMAC scores at a significance level of 5%, a minimum of 20 patients would be required in each group. Consequently, 40 patients were randomized in the study in order to form diclofenac phonophoresis (PH) and conventional ultrasound (US) groups, each consisting of 20 patients. Data collected were analyzed by using the Statistical Package for the Social Sciences (SPSS 10.0). Results were expressed as mean±standard deviation. Statistical significance was tested using the Two-way analysis of variance for repeated measures of the same group, and student-t test was used for comparisons between the two groups. In addition, the Chi-square test or Fisher's exact test was used for categorical variables when the cell number was small. The level of statistical significance was set at a two-tailed p-value of 0.05.

RESULTS

Characteristics of the patients

A total of 40 patients with primary knee OA (10 men and 30 women) were included in this study. There were 13 women and 7 men at the mean age of 54.55±8.65 in the PH group. On the other hand, there were 17 women and 3 men at a mean age of 55.05±10.08 in the US group. There was no significant difference between the two study groups with respect to demographic data including age, sex, level of education, duration of disease, X-ray scores, location of pain and body mass index (p>0.05) (Table 1). There was also no significant difference between the two groups with respect to clinical parameters at the beginning of the trial (p>0.05) (Table 2).

Clinical changes in the PH group

All the parameters were checked at the beginning of the therapy, in the second week and in the first, second and third months of the therapy.

Fifteen days after the initiation of the therapy (first follow-up), painless walking distance (p=0.033), walking VAS scores (p=0.002), resting VAS scores (p=0.001), flexion of the knee VAS scores (p=0.004), WOMAC physical function scores (p=0.020), total WOMAC scores (p=0.019) and Lequesne Index (p=0.027) scores all improved in relation to the baseline values.

Improvements continued in the first month in painless walking distance (p=0.027), walking VAS scores (p=0.001), resting VAS scores (p=0.001), flexion of the knee VAS scores (p=0.001), WOMAC physical function scores (p=0.005), total WOMAC scores (p=0.008) and Lequesne Index scores (p=0.01). Improvements started to occur in the painless walking duration in the first month (p=0.006). On the other hand, improvements in the WOMAC physical function scores, total WOMAC scores and Lequesne Index scores were not sustained in the second and third months.

Improvements in the painless walking duration (p=0.035), painless walking distance (p=0.02), walking VAS scores (p=0.002), resting VAS scores (p=0.002) and flexion of the knee VAS scores (p=0.005) continued in the PH group in the second month.

In the third month, improvements in the painless walking duration (p=0.034), painless walking distance (p=0.017), walking VAS scores (p=0.03), resting VAS scores (p=0.007) and flexion of the knee VAS scores (p=0.007) were found to be permanent (Table 3).

Table 1. Demographic features of the patients (mean±standard deviation)

		Phonophoresis group	Ultrasound group
Age (year)		54.55±8.65	55.05±10.08
Sex	Woman	13 (65%)	17 (85%)
	Man	7 (35%)	3 (15%)
BMI* (kg/m^2)		29.67±4.21	30.20±3.29
Smoking (year)	Non-smoker	15 (75%)	17 (85)
	0-5 year	0 (0%)	0 (0%)
	5-10 year	0 (0%)	0 (0%)
	10-20 year	0 (0%)	1 (5%)
	>20 year	5 (25%)	2 (10%)
Education	Illiterate	9 (45%)	12 (60%)
	Primary school	5 (25%)	5 (25%)
	Secondary School	3 (15%)	1 (5%)
	High school	1(5%)	1 (5%)
	University	2 (10%)	1 (5%)
Duration of disease (year)		4.50±4.77	4.70±5.31
Location of pain	Lateral	0 (0%)	0 (0%)
	Medial	5 (25%)	0 (0%)
	Patellofemoral	2 (10%)	2 (10%)
	Mixed	13 (65%)	18 (90%)
Radiologic Grade	Right Knee		
	Grade 2	12 (60%)	10 (50%)
	Grade 3	7 (35%)	6 (30%)
	Grade 4	1(5%)	4 (20%)
Radiologic Grade	Left Knee		
	Grade 2	12 (60%)	10 (50%)
	Grade 3	6 (30%)	7 (35%)
	Grade 4	2 (10%)	3 (15%)

*BMI: Body mass index

Table 2. Baseline clinical parameters before administration of US and PH therapies

Clinical parameters	Phonophoresis n=20	Ultrasound n=20
Maximum flexion of knee right	123.1±7.18	122.55±6.29
Maximum flexion of knee left	123.1±6.8	122.35±3.89
Painless walking duration (min)	9.9±7.98	6.75±5.19
Painless walking distance (m)	195±174.64	155±187.71
Walking VAS	64.5±14.68	61±13.72
Resting VAS	49.25±26.66	48±22.14
Flexion movement VAS	53.25±30.18	61±22.45
WOMAC pain	6.37±1.70	7.05±1.83
WOMAC stiffness	1.8±2.19	1.17±1.60
WOMAC physical function	6.55±2.45	7.73±1.39
WOMAC total	14.73±5.14	15.95±3.95
Lequesne Index	11.8±4.33	12.5±2.25
HAQ	0.83±0.66	0.66±0.30
STAI TX-1	44.45±9.20	43.35±8.05
STAI TX-2	50.3±5.71	49.4±5.59
Beck Depression Inventory	6.7±6.56	10.15±8.43

min: minute, m: meter, VAS: Visual analog scale, WOMAC: Western Ontario and McMasters Universities Osteoarthritis Index, HAQ: Health Assessment Questionnaire, STAI TX: State/Trait Anxiety Inventory

There was no improvement in either State-Trait Anxiety Inventory or Beck Depression Inventory scores. Changes in the goniometric measurements were not statistically significant when compared to the baseline values.

Clinical changes in the US group

All the patients in the US group were evaluated at the same intervals as the PH group. Fifteen days after the initiation of the therapy statistically significant changes occurred in almost the same parameters where the PH group showed improvements. Painless walking distance (p=0.011), walking VAS scores (p=0.001), resting VAS scores (p=0.008), flexing of the knee VAS scores (p=0.005), WOMAC pain scores (p=0.001), WOMAC physical function scores (p=0.001) and total WOMAC scores (p=0.001) significantly improved in relation to the baseline values.

Improvements in the above mentioned parameters continued in the first month.

In the second month, statistically significant improvements continued in walking VAS scores (p=0.007), flexion of the knee VAS scores (p=0.001), WOMAC pain scores (p=0.001), WOMAC physical function scores (p=0.003) and total WOMAC scores (p=0.003); however, there was no improvement at this time in painless walking distance and resting VAS scores.

Improvements in walking VAS scores (p=0.024), flexion of the knee VAS scores (p=0.003) and total WOMAC scores (p=0.004) were sustained for 3 months after initiation of the therapy. On the other hand, unlike the 15th day and the first month, painless walking distance (p=0.644) and resting VAS scores (p=0.096) showed no significant improvement in the second month (Table 4).

Clinical differences between the treatment groups

In the comparison of parameters between the two groups, it was observed that painless walking duration improved more significantly in the PH group in all follow-ups except for the 15th day (p<0.05).

On the 15th day, 5% of the patients rated the therapy ineffective in the PH group versus 15% in the US group. In the first month, only 10% of the patients in the PH group rated the therapy ineffective versus 25% in the US group. Those who rated the therapy ineffective in the second month constituted 25% and 35 % of the patients in the PH and US groups, respectively. In the third month of the therapy, only 30% of the patients rated the therapy ineffective in both the groups.

We suggest that the US and PH groups are similar to each other in most of the parameters; however, PH therapy is superior to the US in improving painless walking duration (p<0.05).

DISCUSSION

In this randomized controlled study, there were significant improvements in most of the clinical parameters in both of the groups. Neither modality was found to be superior to the other in most of the clinical parameters except for painless walking duration where PH therapy was more successful in improving the patient's condition than US therapy.

Ultrasound is one of the deep heating modalities used in the clinics of physical therapy. Therapeutic ultrasound is generated by a transducer that converts electrical energy to ultrasound by utilizing the piezoelectric principle (30).

Although the exact mechanism of action is unknown, one of the important effects is heating. It increases regional blood flow and connective tissue extensibility. Non-thermal effects may be related with molecular vibration that increases cell membrane permeability and enhances metabolic product transport (31).

In our trial, we used diclofenac diethylamonium gel. Diclofenac is a NSAID that is derived from phenyl acetic acid. It inhibits both COX 1 and COX 2. It has been in use for more than 30 years (32, 33). It has a poor acidic structure which allows it to pass through most of the tissues more easily than many other NSAIDs (24, 32, 33).

Therapeutic ultrasound administration enhances percutaneous penetration of topical diclofenac gel (25). Therefore, diclofenac seems to be a good candidate for phonophoresis administration.

We suggest that deeper penetration of diclofenac results in clinical benefits due to sonographic administration, but still both treatment modalities were found effective.

We made a search in the literature regarding ultrasound and phonophoresis in knee OA and found only a limited number of articles about these modalities.

Table 3. Changes in the clinical outcomes after administration of therapy in the PH group

Clinical parameters	Baseline	15th Day	1st month	2nd month	3rd month
Maximum flexion of knee (right)	123.1±7.18	123.75±6.85 p=0.263	123.15±6.32 p=0.934	122.50±7.34 p=0.586	123.50±6.90 p=0.701
Maximum flexion of knee (left)	123.1±6.8	123.65±6.79 p=0.547	123.30±5.93 p=0.799	123.90±6.40 p=0.500	124±5.75 p=0.299
Painless walking duration (min)	9.9±7.98	11.2±8.88 p=0.086	13.9±9.77§ p=0.006	15.25±14.34¶ p=0.035	15.5±14.38β p=0.034
Painless walking distance (m)	195±174.64	245±205.77 p=0.033	285±218.90 p=0.027	293.5±275.01 p=0.023	298.5±271.72 p=0.017
Walking VAS	64.5±14.68	52±12.81 p=0.002	41.5±19.80 p=0.001	47±22.73 p=0.002	47.75±19.89 p=0.003
Resting VAS	49.25±26.66	33.5±22.77 p=0.001	31±23.37 p=0.001	32±21.17 p=0.002	32.5±23.59 p=0.007
Flexion movement VAS	53.25±30.18	39±25.73 p=0.004	33.5±25.39 p=0.001	37±29.39 p=0.005	35.5±31.03 p=0.007
WOMAC pain	6.37±1.70	5.85±1.77 p=0.153	5.7±2.51 p=0.199	5.57±2.78 p=0.115	5.85±2.76 p=0.309
WOMAC stiffness	1.8±2.19	1.56±2.10 p=0.467	1.18±1.43 p=0.107	1.35±2.09 p=0.261	1.70±2.35 p=0.852
WOMAC physical function	6.55±2.45	5.65±2.14 p=0.020	5.08±2.65 p=0.005	6.06±2.57 p=0.316	6.32±2.69 p=0.670
WOMAC total	14.73±5.14	13.14±4.85 p=0.019	11.96±5.25 p=0.008	12.97±6.03 p=0.071	13.88±6.84 p=0.480
Lequesne Index	11.8±4.33	10.8±4.25 p=0.027	10.65±4.59 p=0.010	11.35±4.72 p=0.342	11.05±5.38 p=0.276
HAQ	0.83±0.66	0.75±0.53 p=0.299	0.66±0.50 p=0.017	0.76±0.55 p=0.361	0.77±0.61 p=0.321
STAI TX-1	44.45±9.20	43.85±6.63 p=0.666	42.8±7.25 p=0.256	43.8±5.88 p=0.689	45.75±5.30 p=0.526
STAI TX-2	50.3±5.71	49.65±4.38 p=0.352	49.95±5.15 p=0.702	50.1±4.59 p=0.763	49.75±5.67 p=0.516
Beck Depression Inventory	6.7±6.56	5.45±7.79 p=0.154	5.95±6.70 p=0.231	7±7.19 p=0.781	7.5±7.94 p=0.269

§First month values significantly different from US group $p<0.05$
¶Second month values significantly different from US group $p<0.05$
βThird month values significantly different from US group $p<0.05$
min: minute, m: meter, VAS: Visual analog scale, WOMAC: Western Ontario and McMasters Universities Osteoarthritis Index, HAQ: Health Assessment Questionnaire, STAI TX: State/Trait Anxiety Inventory

Welch et al. (34) researched the literature about knee OA and found only 3 randomized controlled trials which suggested that ultrasound was not superior to placebo, short wave diathermy or galvanic current (21). Bansil et al. (35) compared short wave diathermy to ultrasound therapy in patients with primary knee OA and suggested that US therapy was superior to short wave diathermy.

In an interesting study, it was shown that low intensity ultrasound therapy could affect human cartilage explants by stimulating expression of proteoglycans and type II collagen in 200 mV/cm^2 dosage (36).

Kozanoglu et al. (21) compared the effectiveness of ibuprofen phonophoresis versus conventional ultrasound therapy in knee OA. They noted 30% improvement in WOMAC scores in both of the groups. They also found improvements in pain scores, range of knee motion and walking distance in the two groups. They suggested that both the US and PH were effective and ibuprofen phonophoresis was not superior to conventional US therapy in patients with knee OA.

In a study, diclofenac diethylamonium was used in the painful shoulder syndrome. A total of 64 patients were divided into two groups to receive either US or diclofenac PH therapy. It was sug-

Table 4. Changes in the clinical outcomes after administration of therapy in the US group

Clinical Parameters	Baseline	15th day	1st month	2nd month	3rd month
Maximum flexion of knee (right)	122.55±6.29	123.4±5.34 p=0.047	124.3±4.97 p=0.017	124.35±4.79 p=0.011	124±4.53 p=0.096
Maximum flexion of knee (left)	122.35±3.89	122.8±3.94 p=0.407	123.35±4.05 p=0.135	123.35±3.84 p=0.084	123.8±4.02 p=0.025
Painless walking duration (min)	6.75±5.19	7.75±6.58 p=0.163	8±6.76 p=0.135	6.5±5.64 p=0.666	7.5±6.97 p=0.419
Painless walking distance (m)	155±187.71	178.75±194.88 p=0.011	181.25±185.11 p=0.029	160.75±191.06 p=0.074	163.50±192.66 p=0.644
Walking VAS	61±13.72	50±11.23 p=0.001	51±11.19 p=0.003	52.5±7.86 p=0.007	53.5±9.33 p=0.024
Resting VAS	48±22.14	40±17.16 p=0.008	41.5±13.08 p=0.033	43.5±13.08 p=0.234	40±13.76 p=0.096
Flexion movement VAS	61±22.45	49.5±15.71 p=0.005	45.5±18.77 p=0.001	47±18.66 p=0.001	46±19.02 p=0.001
WOMAC pain	7.05±1.83	5.3±1.16 p=0.001	5.45±1.59 p=0.001	5.32±1.19 p=0.001	5.6±1.20 p=0.005
WOMAC stiffness	1.17±1.60	0.93±1.20 p=0.301	0.93±1.27 p=0.268	0.93±1.06 p=0.441	0.93±1.13 p=0.419
WOMAC physical function	7.73±1.39	6.39±0.86 p=0.001	6.20±1.11 p=0.001	6.45±0.94 p=0.003	6.35±0.87 p=0.003
WOMAC total	15.95±3.95	12.63±2.02 p=0.001	12.56±2.61 p=0.001	12.71±2.03 p=0.003	12.85±2.03 p=0.004
Lequesne Index	12.5±2.25	12.05±2.35 p=0.058	12.1±2.38 p=0.189	13.15±2.03 p=0.073	12.85±1.72 p=0.367
HAQ	0.66±0.30	0.67±0.35 p=0.899	0.58±0.27 p=0.095	0.68±0.30 p=0.766	0.71±0.26 p=0.399
STAI TX-1	43.35±8.05	42.3±6.79 p=0.378	40.8±6.32 p=0.07	40.9±7.49 p=0.257	40.80±5.15 p=0.156
STAI TX-2	49.4±5.59	49.55±5.23 p=0.769	47.4±3.80 p=0.039	48.45±4.80 p=0.138	49.55±5.06 p=0.842
Beck Depression Inventory	10.15±8.43	8.25±5.55 p=0.034	8.8±6.5 p=0.139	8.75±5.73 p=0.116	8.85±6.13 p=0.174

min: minute, m: meter, VAS: Visual analog scale, WOMAC: Western Ontario and McMasters Universities Osteoarthritis Index, HAQ: Health Assessment Questionnaire, STAI TX: State/Trait Anxiety Inventory

gested that both the modalities were successful in improving pain and increasing the range of joint motion in relation to the baseline values. It was also stated that PH was superior to conventional US in increasing the range of joint motion (13).

Shin and Choi (12) evaluated the effects of indomethacin phonophoresis on the relief of temporomandibular joint pain. They suggested that indomethacin phonophoresis decreased the pain and increased the pressure pain threshold in the phonophoresis group versus the placebo group which was given placebo cream.

Recently, Luksurapan (37) suggested that piroxicam phonophoresis was more effective than US therapy in reducingpain and improving knee functioning in patients with knee OA.

When searched the literature reviews, we found contradictions between clinical trials. Such contradictions may have originated from non-standardized administration of US regarding frequency and power (21, 34, 35, 38-40).

Our trial is one of the few studies which compares US and PH in patients with knee OA, and diclofenac diethylamonium is one of the rare agents used in PH trials.

Our trial indicated improvements in the VAS scores during walking, resting and flexion of the knee in both of the groups. In this respect, there are similarities between our trial and ibuprofen phonophoresis trial by Kozanoglu et al.

In our trial, these improvements continued in the first, second and third months in both of the groups. However, improvements in resting VAS scores lasted only until the second month in the US group. When we compared the PH and US groups, we found therapeutic modalities effective and generally well tolerated, but diclofenac phonophoresis was superior to conventional US therapy in improving painless walking duration.

Our study differs from many other studies because it compares PH and US in a 3-month-follow-up period. Such a follow-up period may give us some clues about whether the effects of PH and US are permanent.

In this trial, we did not administer any physical therapy modality besides US and PH therapies. This approach helps to evaluate the solitary effects of the two modalities in each group and compare the effects between the groups.

Study limitations

One of the most important limitations of this study is the absence of SHAM US therapy. Addition of a SHAM US group might allow us to comment on the additional effects of US and PH alone.

CONCLUSION

We suggest that both of the therapeutic modalities are effective and safe for patients with primary knee OA. However, PH may be particularly helpful in patients with gastric problems and hypertension who are sensitive to any systemic form of NSAIDs as well as the elderly population in whom the use of NSAIDs is considered to increase the risk of gastric, renal and cardiac events (6-9).

Large and long term studies are needed for more data on the use of PH and conventional US therapies.

Informed Consent: Written informed consent was obtained from patients who participated in this study.

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