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DICLOFENAC SODIUM PHONOPHORESIS VERSUS CONVENTIONAL THERAPEUTIC ULTRASOUND IN KNEE OSTEOARTHRITIS

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Abstract

Purpose: to compare the effect of diclofenac sodium phonophoresis (**DSPH**) with conventional therapeutic ultrasound (**TUS**) on knee OA. **Subjects and methods**: Fifty patients (two groups) participated in this study. **Group (A);** consists of 25 patients (5 males, 20 females), with mean age 57 years, treated with **TUS** plus exercises. **Group (B);** consists of 25 patients (8 males, 17 females), with mean age 54 years, treated with **DSPH** plus exercises. Each patient was assessed for knee pain intensity level and physical function using the **WOMAC** score and knee flexion **ROM** using the digital inclinometer pretreatment, posttreatment and follow up one month after treatment. **Results**: There were non-significant differences among **group (A)** for **WOMAC** score, and significant only at posttreatment and follow up compared to pretreatment for **group (B)** (P- value <0.003*). Significant differences between posttreatment compared to pretreatment and follow up among **group (A)** for knee flexion **ROM** (P- value <0.03*), and significant only between post and pretreatment for **group (B)** (P- value = 0.000*). However, there was no significant difference between groups neither at posttreatment nor at follow up. **Conclusion**: **DSPH** had improvement but not significant in pain intensity level, physical function, and knee flexion **ROM** posttreatment but it had no superior effect on **TUS**. Knee flexion **ROM** improved significantly posttreatment in both groups, but only in **PH** the improvement sustained for one month after treatment. **PH** had long term effect than T**US**.

Key words: Knee osteoarthritis, Diclofenac sodium phonophoresis, Therapeutic ultrasound

INTRODUCTION

OA is a highly prevalent degenerative joint disease that impacts people's quality of life and puts a burden on health care costs [1, 2]. OA of the knee is most common among persons have 50 years and older and may cause physical disability [3]. Symptoms of knee **OA** include stiffness and knee pain limit weight-bearing activities such as walking, going up and down stairs, and standing up from a chair[4]. Treatment of knee **OA** is mainly directed toward reducing joint pain, as well as improving joint mobility [5].

TUS is a deep heating agent that has been widely used to reduce pain in patients with knee **OA**[6,7]. **TUS** transforms electrical energy into an acoustic waveform, which is then converted into heat as it passes through tissues of varying resistances. Biological responses to **US** therapy, through thermal mechanism, include elevation of the pain threshold, alteration of neuromuscular activity leading to muscle relaxation, induction of tissue regeneration, and reduction of inflammation [8, 9].

PH is a therapeutic method that uses **US** to enhance percutaneous transportation of drugs. **PH** with nonsteroidal anti-inflammatory drugs (**NSAIDs**) has been reported to treat pain and inflammation in many musculoskeletal conditions such as carpal tunnel syndrome, heel pain, myofascial pain, epicondylitis, muscle injury, shoulder pain, and **OA** [10-16]. Advantages of this method include noninvasiveness, minimal risk of adverse effects associated with systemic administration of **NSAIDs**, and the combined therapeutic effects of both **US** and **NSAIDs**[11].

Diclofenac sodium gel is **NSAIDs**. It is used for treating pain in certain joints (eg. in the knees or hands) caused by **OA** [17].

Randomized controlled trial was conducted to compare the effects of **DSPH** with **TUS** on pain intensity level, function ability and knee flexion **ROM** in patients with symptomatic knee pain caused by mild to moderate **OA**.

SUBJECTS AND METHODS

This study was conducted at the outpatient clinic of orthopedic physiotherapy unit, Cairo University Hospitals, upon approval of Faculty of Physical Therapy, Cairo University, Egypt. The study extended from March 2018 to December 2018.

Each patient was examined by the researcher for the inclusive and exclusive criteria. WOMAC score and ROM of knee flexion were measured pretreatment, posttreatment and, one month after treatment as follow-up. Prior starting of the study each patient signed informed consent. Patients were assigned to two groups randomly.

Subjects

Fifty patients referred by orthopedic surgeons as knee **OA** participated in this study, with age range from 50 to 65 years [18], from both genders; diagnosed with mild to moderate knee **OA** according to Kellgren-Lawrence grades [19] and have

body mass index ≤ 32 kg/m^2. Patients randomly divided into two groups, 25 patients in each group. **Group (A)** received **TUS** waves of 1MHz frequency and 1watt/cm^2 was applied to the target knee with aquasonic gel only. In addition, conventional therapeutic exercises including strengthening exercises for hip abductors and adductors, quadriceps, hamstring muscles, and stretching exercise of hamstring [20-22]. **Group (B)** will receive Ultrasound waves of 1MHz frequency and 1watt/cm^2 was applied to the target knee with a topical pain relieving gel (1% diclofenac sodium), and the same conventional therapeutic exercises as **Group (A)**.

Inclusion Criteria

Patient's age range from 50 to 65 years old[18]; knee pain off at least 6 months duration; moderate to severe knee pain; self reported restricted range of motion and / or joint deformity of the knee; have grade 2 (minimal) or 3 (moderate) knee OA according to the Kellgren and Lawrence criteria, based on the radiographs[19]; able to walk on their own for 10 minutes.

Exclusion Criteria

Concomitant disease affecting the knee, such as rheumatoid arthritis, systemic lupus erythema, psoriatic arthritis; Intra-articular corticosteroid or hyaluronic acid injection into the knee within the last 3 months; arthroscopy of the knee within the past year; significant injury to the knee within the past 6 months; using of assistive device other than a knee support; diseases of spine or other lower extremity joints of sufficient degree to affect assessment and treatment procedures; joint replacement of the involved knee.

PROCEDURES INSTRUMENTATIONS: -

Measurements Instrumentations:

Digital Inclinometer: The range of motion (ROM) of the flexion and extention of the target knee measured by digital inclinometer in degrees from prone lying position. Normal knee flexion is 135^0 and normal knee extention is 0^0.

Therapeutic Instrumentations:

Therapeutic ultrasound machine;

(Uniphy – phyaction U). Ultrasound unit for all ultrasound therapy applications. Multi-frequency ultrasound head 1 MHz and 3 MHz, 4 cm². Acoustic and visual contact control (**www.gymna-uniphy.com**). 1MHz frequency and 1watt/cm^2 was used in application of continuous US with and without diclofenac sodium.

MATERIALS

1. **WOMAC Questionnaire**[23-25].
2. **Aquasonic gel** in **Group (A)**, the skin coated with an aquasonic gel not containing a pharmacologically active substance.
   Features: Acoustically correct for the broad range of frequencies used. Completely aqueous, not stain clothing or damage transducers. Unique "can't be copied" formula is bacteriostatic, non-sensitizing and non-irritating. No formaldehyde. Not a spermicide. It was used and

recommended by leading manufacturers of medical ultrasound equipment worldwide (**www.parkerlabs.com/aquasonic-100.asp**).

3. **(1%) Diclofenac sodium gel** preparation In **Group (B)**, 3g of topical gel containing 1% diclofenac sodium applied over the target knee [(17)]. **TUS** then applied to the superomedial and lateral parts of the knee through the applicator head in circular movements [(26)].

ASSESSMENT PROCEDURES

All subjects were evaluated for their pain intensity level, stiffness and physical function assessment of the target knee by **WOMAC** questionnaire [(23-25)] and knee flexion **ROM** by a digital inclinometer in degrees from prone lying position. All patients were tested before and after the treatment program with follow-up one month after the treatment.

TREATMENT PROCEDURES

Treatment program: 12 treatment sessions (3 sessions per week for 4 weeks).

1-Therapeutic ultrasound

Group (A) received ultrasound waves of 1MHz frequency and 1watt/cm^2. Patients were put in a sitting position with the knees 90^o flexed. Therapeutic ultrasound was applied to the superomedial and lateral parts of the target knee through the applicator head in circular movements with aquasonic gel only for 5 min[(26)].

2-Diclofenac Sodium Phonophoresis

Group (B) received ultrasound waves of 1MHz frequency and 1watt/cm^2. Patients were put in a sitting position with the knees 90^o flexed. Therapeutic ultrasound was applied to the superomedial and lateral parts of the target knee through the applicator head in circular movements with a topical pain relieving gel (3g (1%) Diclofenac Sodium) for 5 min [(26)].

3-Exercises

Active strengthening exercises for quadriceps (sitting knee extension) [(27)], hamstrings (prone lying), hip abductors (standing & supine lying) and hip adductors muscles (supine lying) (10 repetitions with 3 sets, 6 seconds rest between each repetition, and 1 minute rest between the sets) [(20-22)].

Stretching exercises for hamstrings and the calf muscles were done (3 repetitions, 30 seconds in position of stretching, 30 seconds in position of relaxation, and 3 repetitions with 3 sets).

DATA ANALYSIS

All statistical analyses were done using SPSS version 18 (IBM Inc., Chicago, IL) with the p-value set at ≤ 0.05. Descriptive statistics are presented as means and SD for all patients. Normality test of data using Shapiro-Wilk test was conducted. Accordingly, repeated measures ANOVA and multiple pairwise comparisons (post hoc test with bonferroni adjustments) were used to compare within groups differences in both dependent variables. Independent t-test was conducted to detect among groups differences in dependent variables and in demographic

data (as assumptions were not all and not very significantly violated). Z test was used to compare proportions of male and female in both groups.

RESULTS

Shapiro-Wilk test reflected that all the data was normally distributed for all data (P<0.05) except age (P=0.04) and BMI. Levene's test for equality of variances showed non-significance except for posttreatment of **WOMAC** score, but it did not matter due to equal sample sizes.

General Characteristics of the Subjects:

Group (A): Twenty five (5 males, 20 females) patients were included in this group. Their mean ± SD of age, weight, height, and BMI were 56.8 ± 4.3 years, 73.12 ± 9.85 kg, 1.62 ± 0.013m, and 28.25 ± 2.8kg/m² respectively as shown in **table (1).**

Group (B): Twenty five patients (8 males, 17 females) were included in this group. Their mean ± SD, age, weight, height, and BMI were 54.12 ± 5 years, 77.2 ± 8.7kg, 1.63 ± 0.086 m, and 28.99 ± 3kg/m² respectively as shown in **table (1).**

Comparing demographic data between both groups, with independent t-test, revealed non-significant differences.

Table (1) Comparison of the mean age, weight, height, and BMI of both groups (A, B) and sex distribution

	Group (A)	Group (B)	p-value	Sig
Age (years) $\bar{X}$ ±SD	56.84± 4.308	54.12± 5.093	0.087	NS
Weight (kg) $\bar{X}$ ±SD	73.12± 9.850	77.20± 8.727	0.13	NS
Height (cm) $\bar{X}$ ±SD	1.62 ± .013	1.63± .086	0.57	NS
BMI (kg/m²) $\bar{X}$ ±SD	28.25± 2.839	28.99± 3.043	0.15	NS
Male/female (count)	5/25	8/25	0.33	NS

$\bar{X}$: Mean SD: Standard deviation p value: Probability value Sig: significant NS: Non significant

INFERENTIAL STATISTICS FOR DEPENDENT VARIABLES

A-WOMAC score

1- Among groups differences Group (A) (TUS)

The mean ± SD values of WOMAC score at pretreatment, posttreatment and follow-up were 64.44±19, 54.28 ±23.6, and 53.62 ±15.66 respectively.

Repeated measures ANOVA (with Bonferroni adjustment) revealed non-significant differences among pretreatment, posttreatment, and follow up (F=1.9, P- value= 0.2), so no need for multiple pairwise comparisons (post hoc test). See **table (2) and figure (1).**

Group (B) (PH)

The mean ± SD values of WOMAC score at pretreatment, posttreatment and follow-up were 69.7±14.3, 50.36± 13.48, and 52.94± 19.87, respectively.

Repeated measures ANOVA (with Bonferroni adjustment) revealed significant differences between pretreatment, posttreatment, and follow up (F=23.8, P- value= 0.000*).

Multiple pairwise comparisons (post hoc test with bonferroni correction) revealed that there were significant differences of WOMAC score between pre and post treatment (P=0.000*) and between pretreatment and follow up (P-value=0.003*), but not between posttreatment and follow up (P=0.98), see table (1) and **figure** (1).

Table (2) Multiple pairwise comparison tests (Post hoc tests) for the WOMAC within groups at different measuring periods

	Pre VS. Post	Pre VS. FU	FU VS. Post
Group (A)	0.26	0.26	1
Group (B)	0.000*	0.003*	0.98

*Significant at alpha level <0.05

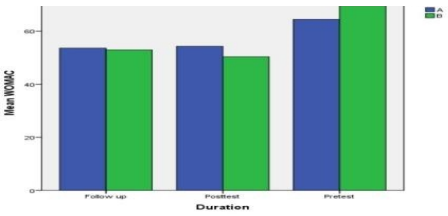

Figure (1)Mean values of WOMAC score pre, post-treatment and follow up between each group.

2- Between groups differences

Independent t-test revealed that the mean values of the pretreatment, posttreatment and follow up between groups showed non-significant differences with (P>0.27), **see table (2).**

Table (2) Independent t-test between pre and post treatment, and follow up (FU) values for WOMAC score between groups

Group (A) VS. Group (B)	Pre	Post	FU
p-value	0.27	0.48	0.92

B-ROM of knee flexion

1- Among groups differences Group (A) (TUS)

The mean ± SD values of knee flexion ROM at pretreatment, posttreatment and follow up were 106.68±14.07, 117.92 ±9.46, and 108.23 ±8.02, respectively. Repeated measures **ANOVA** (post hoc test with Bonferroni adjustment) revealed significant differences between pre, posttreatment, and follow up (F=10.34, P- value=0.003*).

Multiple pairwise comparisons revealed that there were significant difference in knee flexion **ROM** between pre and posttreatment (P-value =0.03*), and between posttreatment and follow up (P-value =0.002*), but not between pretreatment and follow up (P=1), see **table (3) and figure (2).**

Group (B) (PH)

The mean ± SD values of knee flexion ROM at pretreatment, post treatment and follow up were 106.08±17.685, 118.44±13.2, and 110.67±24.67, respectively. Repeated measures ANOVA (post hoc test with Bonferroni adjustment) revealed significant differences between pre, post treatment, and follow up (F=15.85, P-value= 0.000*).

Multiple pair wise comparisons revealed that there were significant differences in knee flexion ROM between pre and post treatment (P=0.000*), but neither between pretreatment and follow up nor between post treatment and follow up (P>0.66), **see table (6) and figure (4).**

Table (3) Multiple pairwise comparison tests (Post hoc tests) for the knee flexion ROM within groups at different measuring periods

	Pre VS. Post	Pre VS. FU	FU VS. Post
Group (A)	0.03*	1	0.002*
Group (B)	0.000*	1	0.66

*Significant at alpha level <0.05

2- Between groups differences

Independent t-test revealed that the mean values of the pretreatment, posttreatment and follow up between groups showed non-significant differences with (P-value>0.74), **see table (4) and figure (2).**

Table (4) Independent t-test for pre and post treatment, and follow up (FU) differences in knee flexion ROM between groups

Group (A) VS. Group (B)	Pre	Post	FU
p-value	0.9	0.87	0.74

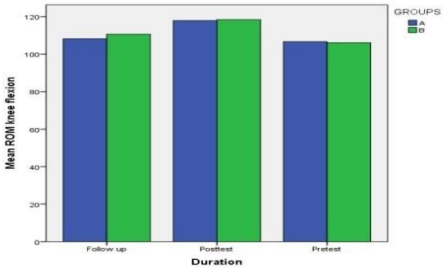

Figure (2) Mean values of ROM of knee flexion pre, post-treatment and follow up between each group.

DISCUSSION

The main purpose of this study was to compare the effect of **DSPH** with **TUS** on knee **OA**.

The study general hypothesis stated that there would be no significant difference between **PH** and **TUS** in treating knee **OA** patients. The results of this study failed to reject this general hypothesis, as there were non-significant difference between groups at all measuring periods in all dependent variables (**WOMAC** score and **ROM** of knee flexion).

WOMAC score (pain intensity level, stiffness, physical function)

It was hypothesized that there would be non-significant difference between **PH** and **TUS** in **WOMAC** score in knee osteoarthritis patients. Findings of the present study revealed that there were non-significant differences among **group (A)** for **WOMAC** score, and significant at post treatment and follow up compared to pretreatment for **group (B)** (P-value < 0.003*), but non-significant between post treatment and follow up.

The current study showed that **PH** had improvement but not significant effect on pain intensity level and physical function (WOMAC score) of knee osteoarthritis patients. This suggests that **PH** are important in decreasing pain intensity level and disability in patients with knee **OA**, fortunately this effect was maintained one month posttreatment (follow up). However, there was non-significant difference between groups, clinical improvements in **WOMAC** score was found posttreatment in **PH** group.

The finding of the current study regarding effect of **DSPH** on **WOMAC** score agree with Deniz et al. (2009) who found that **DSPH** had significant effect on pain intensity level and physical function (WOMAC score) in knee **OA** patients.

The finding of the current study regarding non-significant difference between **PH** and **TUS** agree with Kozanoglu, et al. (2003) who found that ibuprofen **PH** and **TUS** were effective in reducing pain intensity level and Ibuprofen **PH** was not superior to conventional **TUS** in patients with knee **OA**.

The finding of the current study regarding non-significant difference between **PH** and **TUS** agree with Moubark et al[28] (2007) who found non- significant difference between **PH** and **TUS** in pain intensity level score and physical function score, but in lateral epicondylitis patients.

Findings of the current study disagree with Akinbo et al. (2011) found a significant improvements in **WOMAC** score (pain intensity level, stiffness, physical function) and knee flexion **ROM** using **DSPH** than **TUS**. The contrast findings between the present study and that of Akinbo et al. (2011) may be to the sessions in the latter study were daily and used heat and bike without exercises.

The finding of the current study regarding non-significant difference between **PH** and **TUS** disagree with Luksurapan and Boonhong (2013) who found that **PH** was significantly more effective than **TUS** in reducing pain intensity level and tended to improve knee functioning in knee OA patients. Differences between the present study

and that of Luksurapan and Boonhong (2013) may be due to using longer duration of **PH** (10 min) without exercises in the latter study.

Knee flexion range of motion

It was hypothesized that there would be non-significant difference between **PH** and **TUS** in **ROM** of knee flexion in knee **OA** patients.

There were significant differences between pre and posttreatment and between post treatment and follow up among **group (A)** for knee flexion **ROM** (P- value <0.03*), and significant at posttreatment compared to pretreatment for **group (B)** (P- value = 0.000*). However, there was no significant difference between groups neither at posttreatment nor at follow up.

Findings of the present study showed that knee flexion **ROM** improved but not significant posttreatment, unfortunately this improvement not sustained at one month posttreatment (follow up) for **group (A)**, but in **group (B)** the improvement sustained for one month posttreatment. This means that **PH** had long term effect than **TUS**.

The finding of the current study regarding non-significant difference between **PH** and **TUS** in **ROM** agrees with Moubark et al. (2007) who found that non- significant difference between **PH** and **TUS** in **ROM**, but in lateral epicondylitis patients.

Findings of the current study disagree with Akinbo et al. (2011) found a significant improvements in knee **ROM** using **DSPH** than **TUS**. The contrast findings between the present study and that of Akinbo et al. (2011) may be to the sessions in the latter study were daily and used heat and bike without exercises.

LIMITATIONS

This study has a few limitations that should be considered in future research studies:

- Small sample size, due to poor patients' compliance.
- Several patients were illiterate, which might cause difficulties in comprehending the index well.

CONCLUSION

DSPH had improvement but not significant in pain intensity level, physical function, and knee flexion **ROM** posttreatment but it had no superior effect on **US**. Knee flexion **ROM** improved significantly posttreatment in both groups, but only in **PH** the improvement sustained for one month after treatment. **PH** had long term effect than **US**.

RECOMMENDATIONS

- Further studies are required to investigate.
- How the results of the study might be influenced by using only biophysical modalities without exercises.
- Effect of using objective measures for pain intensity level and physical function.

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Web Resources

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