

# Short-Term Outcome of Ultrasound Therapy in Sudanese Patients with Knee Osteoarthritis

Salih A Mohamed<sup>1</sup>, Zeinab A Mohammed<sup>2</sup>, Mohamed A El Hussein<sup>3</sup>,  
Azza Babiker<sup>4</sup>, Abdel R M El Hussein<sup>4</sup>, Mohamed A Ismaiel<sup>2</sup>, Sami A Nogod<sup>2</sup>

<sup>1</sup>Faculty of Physiotherapy, IBN Sina University, Khartoum, Sudan.

<sup>2</sup>Faculty of Physiotherapy and Rehabilitation, Alneelain University, Khartoum, Sudan.

<sup>3</sup>Colorado Kidney Care Research Office, Denver, CO.USA.

<sup>4</sup>Central Laboratory, Ministry of Higher Education, Khartoum, Sudan.

Corresponding Author: Salih A Mohamed

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## ABSTRACT

**Objectives:** the aim of this study is to evaluate the short-term effectiveness of therapeutic ultrasound therapy modalities in patient with knee OA.

**Methodology:** This is a prospective, double blinded clinical trial, conducted among 45 participants. Participants were divided into three groups each of 15 patients. In Group A – continuous ultrasound was used, in Group B – pulsed ultrasound was used and in Group C – traditional physiotherapy without ultrasound therapy was used. Groups A and B also received traditional physiotherapy in addition to ultrasound. Visual analog scale, WOMAC questionnaire, range of motion assessment, manual muscle test, and circumference were used for evaluation before and after rehabilitation program. Data were analyzed using Statistical Package for the Social Sciences (SPSS) and multiple regression analysis of variables was done. The ethical approval was obtained from the institutional review board at Alneelain University and a verbal and written consent was obtained from the participants before the interview.

**Result:** When comparing the three groups, we Found that no difference in WOMAC score,

and there were no differences in the edema and stiffness between the three groups. The only difference was in reduced pain (VAS) in the pulsed group (P-value 0.004\*), when compared to the other two groups.

**Conclusion:** Among 45 patients in this study, we found that pulsed ultrasound therapy was very effective in reduction of pain, and there was no difference in the WOMAC index score, edema between the three groups at the end of treatment. When comparing the range of motion, Group B showed the greatest improvement in the motion. The traditional physiotherapy group(c) and the two ultrasound therapy groups (A & B) had the same outcomes at the end of treatment programs.

**Keywords:** Knee osteoarthritis, Ultrasound therapy, Pulsed ultrasound, Continuous ultrasound, Traditional physiotherapy, Effect of ultrasound therapy, Outcome of ultrasound therapy.

## INTRODUCTION

Osteoarthritis (OA) is a serious and debilitating health problem that affects large numbers of people and is a prevalent work-related condition instigated by repetitive

stresses (Lawrance et al,2008). Arthritis impacts nearly one third of adults between the ages of 45 and 65 and half of all adults over 65 irrespective of races and ethnicities [Bolen et al, 2006]. The number of OA patients is visioned to increase as larger percentage of the population grows older and obesity rates rise.

Osteoarthritis is degenerative inflammation of cartilage and joint of accompanied with chronic pain, stiffness, swelling, and limitation in the range of motion (Lawrence et al, 2008). Chronic pain from OA significantly impacts patients' quality of life, work productivity, and is associated with comorbidities such as depression, anxiety, and sleep disturbance [Lawrence et al, 2008]. The disease can develop from trauma, overuse, and genetic factors, and may affect any joint of the body, but most commonly found in the knee, shoulders, hip, spine, and hands (Lawrence et al, 2008). Furthermore, OA also have a considerable economic burden on the healthcare system(Brooks,2006) and is considered as the second leading expensive condition for US hospitals, with a total costs of \$14.8 billion in 2011 alone (Lawrence et al, 2008).

Knee OA, is considered the most common and important joint disease particularly in the elderly people that is associated with substantial physical disability (Felson et al, 1993;1995). Radiographic abnormalities are present in more than 30% of people aged 65 years or older; of whom approximately 40% are symptomatic. As more people live longer, there is a dire need for effective, safe, and efficient interventions that decrease pain and improve functioning in patients with knee OA (Bitton, 2009).

The treatment of knee OA is mainly geared toward the alleviation of pain. In this respect, Non-steroidal anti-inflammatory drugs (NSAIDs) can help in decreasing pain and improving function (Draper et al,2018). NSAIDs are thus, commonly and widely used

to treat the pain and stiffness associated with knee OA. However, the high incidence of serious upper gastrointestinal side-effects associated with the use of these drugs and the increased risk for hospitalization can limit their use (Scheiman,1996). Intra-articular hyaluronic acid injections provide an alternative but are not a consistent approach to pain relief and can be painful to administer to patients (Cleveland et al,2013). To avoid or to reduce the side-effects associated with NSAIDs and invasive methods, modes of treatment such as physical therapy methods are being frequently used.

Physiotherapy is a non-pharmacological intervention for knee OA recommended by the American College of Rheumatology and the European League Against Rheumatism (Jordan, 2003; Anon,2000). Physiotherapy methods comprise numerous treatment modalities such as short-wave diathermy, transcutaneous electrical nerve stimulation (TENS), hot packs and exercise (Cetin et al, 2008; Cheing et al, 2008; Doi et al, 2008).

Therapeutic ultrasound is a form of mechanical energy consisting of high-frequency vibrations that can be continuous or pulsed. Pulsed ultrasound produces non-thermal effects and is used to aid in the reduction of inflammation, however, continuous ultrasound generates thermal effects (Rutjes et al, 2010; John, 2002). Therapeutic ultrasound is also known to reduce edema, relieve pain and stimulate tissue repair (Rutjes et al,2010; Fu et al,2008; Korstjens et al,2004). In spite of its widespread use in the treatment of various musculoskeletal diseases, very few controlled clinical studies using therapeutic ultrasound application to the treatment of knee OA have been reported and the results of such clinical studies have been somewhat conflicting. However, the results of a number of placebo-controlled/controlled studies indicated that therapeutic ultrasound may be useful for reducing the pain and disability associated

with knee OA (Cetin et al,2008; Kozanog et al,2003; Huang et al,2005; Huang et al,2005; Ozgonenel et al,2009 ). In contrast, a placebo-controlled, randomized, double-blinded study by Falconer *et al*(1992), did not show significant or convincing clinically-relevant effects over placebo in the treatment of knee OA. Although physical treatment modalities are commonly used in physical medicine and rehabilitation clinics, scientific evidence supporting their use is insufficient because randomized controlled trials are limited. In addition, physical treatment modalities, such as hot packs, TENS and exercise, are usually prescribed together in rehabilitation practice (Kozanog -lu et al, 2003).

Pulsed ultrasound, especially low-intensity, has been shown to accelerate osteogenesis and fracture healing, and to exert anabolic effects on cartilage formation (Nolte PA, et al, 2001; Korstjens CM, et al, 2004).

A recent in vitro study by Korstjens et al. (2004), Showed that low-intensity pulsed ultrasound stimulates chondrocyte proliferation and matrix production in human articular cartilage obtained from the degenerative compartment and the collateral compartment from donors with uni-compartmental Knee OA. These findings, suggested that low intensity pulsed ultrasound might provide a feasible tool for cartilage tissue repair in osteoarthritis patients. (Korstjens CM et al, 2004).

This present trial specifically aimed to evaluate the short-term effectiveness of two modalities of ultrasound therapy, namely; continuous and pulsed ultrasound on pain, physical function, ambulation activity, and disability status in Sudanese patients with knee OA.

## **MATERIALS AND METHODS**

### **Study Design:**

This was a prospective, Clinical Trial.

### **Study Areas:**

This study was conducted at Shargalneel Hospital Physiotherapy Department, Khartoum State, Sudan.

### **Study Population:**

The targeted population of this study was patients diagnosed with knee OA who were referred to the Physiotherapy Department during the period from October 2018 to July 2019. The ages of the patients ranged between 54 and 70 years old.

### **Inclusion Criteria:**

All adult patients diagnosed with mild to moderate knee OA referred for Physiotherapy Department in the hospital were enrolled in the study.

### **Exclusion Criteria:**

- Patients with late stage knee OA.
- Patients with deformities.
- Undiagnosed patient with knee OA.

### **Sampling Size and Sampling Technique:**

This study included 45 patients randomly divided in three groups of 15 patients each as follow:

Group A – used continuous ultrasound plus traditional physiotherapy.

Group B – used pulsed ultrasound plus traditional physiotherapy.

Group C (control) – used traditional physiotherapy treatment including exercise, and infra-red.

### **Treatments:**

Each group of patients received five sessions per week for two weeks (total number of sessions was ten physiotherapy sessions) of five minutes per session. Each patient in the three groups was required to fill the WOMAC format before start of the sessions and re-fill at the end of ten sessions to assess and evaluate the prognosis of disease before and after physiotherapy treatment.

Application method for the treatment was applied on both side of the knee. In group 1 (continuous ultrasound group), continuous ultrasonic waves of 1 MHz frequency and 2 W/cm<sup>2</sup> power were applied with a 5-cm diameter applicator (Sonopuls490-491; Enraf Nonius, Delft, The Netherlands) for 5 min per session. The patients were in the supine position and an acoustic gel that did not contain any pharmacologically active substance was applied. In both continuous and pulsed groups ultrasound equipment was set at a frequency of 1 MHz and a power of 2 W/cm<sup>2</sup> however, for group B a pulsed mode duty cycle of 1:4. Ultrasound therapy was applied to the superior-medial pulse lateral aspect of the knee in circular maneuvers with the head at the right angles to make sure maximum absorption to the energy. In group 2 (pulsed ultrasound group),. The timing of ultrasound therapy applied and the positioning of the patient treated were similar for the continuous ultrasound therapy group. Group 3 (traditional physiotherapy), on the other hand, didn't receive any ultrasound therapy but groups 1 and 2 had traditional physiotherapy modalities intervention in addition to ultrasound.

#### **Study instrument and tools:**

- **Visual Analog Scale (VAS):**

The VAS line measures the patients were instructed to place a single mark on the line or face to indicate the current level of pain, this is suitable for persons with visual or cognitive impairment or for a telephone administration to avoid error in interpretation. The VAS line measures were 100mm after printing or photocopying.

- **Range of motion assessment:**

A goniometer was used for this purpose.

- **Manual muscle test (MMT):**

To testing the muscle strength of each group. The muscle power was given 6 grades

(0,1,2,3,4, and 5) to characterize the degree of muscle strength upon performing the required movement as follows:

Grade [0] paralyzed muscle.

Grade [1] flicker muscle contraction.

Grade [2] contraction of the muscle with gravity elimination.

Grade [3] contraction of the muscle against gravity.

Grade [4] contraction of muscle with minimal resistance.

Grade [5] normal muscle

#### **Circumference:**

To measure the size of edema and swelling , a retractable, flexible and durable, 60-Inch/ 1.5 meters in Length that have large and clear markings in both Inches and centimeters(for easier reading) was used.

#### **WOMAC:**

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) was used to evaluate degree of pain, stiffness, and physical functions in the recruited subjects before and after treatment.

#### **Evaluation:**

Patients were evaluated at the beginning and at the end of the physiotherapy treatment course.

#### **Data management and analysis:**

Database management and analysis was performed using statistical package for the social science (SSPS) for Microsoft windows. Version 20, one-way ANOVA to compare between Three Groups. All demographics and quantitative data are expressed as mean  $\pm$  SD, differences with P-values  $\leq$  0.05 were statistically significant and all result were expressed with a 95% confidence interval.

#### **Ethical approval:**

This study was approved by the Ethics Committee of Faculty of Medicine, Elneelain University.

The patients were briefed about the study and written consent was obtained from all patients

years, were included in the trial, all 45 patients completed the study as described above.

**RESULTS**

**Patients:**

Forty-five patients diagnosed with knee OA (31 females, 14 male) aged between 40 – 70

**Baseline and post treatment:**

The results are shown in tables 1, 2 and 3 for groups A, B, and C respectively.

**Table 1: Baseline and post-treatment in continuous ultrasound group, Group A.**

Group A	Baseline	Post- treatment	P- value
WOMAC	34.87±11.606	11.27±8.004	0.0001*
VAS	7.20±1.014	1.53±1.246	0.0001*
Circumference (edema)	54.47±8.814	53.20± 8.571	0.0001*
Flexion of the knee	106.666±25.54	120.666±11.317	0.007*

- Data are presented as mean ± SD.
- Comparison within the group A was not statistically significant (p->0.05).
- The entire mean was inside the confidences 95% interval.

In Group A (continuous ultrasound) comparison between pre and post-treatment revealed that there were significant differences in the WOMAC questionnaire (P-

value =0.0001\*), in VAS (visual analog scale) (P-value =0.0001\*), in circumference (P-value = 0.0001\*), and in range of motion (flexion of the knee) (P-value = 0.007\*).

**Table 2: Baseline and post-treatment in pulsed ultrasound group. Group B.**

Group B	Baseline	Post- treatment	P- value
WOMAC	43.80±14.654	10.60±9.716	0.0001*
VAS	5.73±1.387	0.60±0.828	0.0001*
Circumference (edema)	57.00±8.856	54.67±8.882	0.0001*
Flexion of the knee	122±14.11686	129.33±9.03	0.0001*

- Data are presented as mean ± SD.
- Comparison within the group A was not statistically significant (p->0.05).
- The entire mean was inside the confidences 95% interval.

In Group B (Pulsed ultrasound) comparison between pre and post-treatment revealed that there were significant differences in the WOMAC questionnaire (P-value =0.0001\*),

in VAS (visual analog scale) (P-value =0.0001\*), in circumference (P-value = 0.0001\*), and in range of motion (flexion of the knee) (P-value = 0.001\*).

**Table 3: Baseline and post-treatment in traditional physiotherapy group (Group C).**

Group C	Baseline	Post- treatment	P- value
WOMAC	40.93±9.617	14.80±6.383	0.0001*
VAS	6.67±0.900	1.73±0.884	0.0001*
Circumference (edema)	50.87±8.323	49.40±8.270	0.0001*
Flexion of the knee	105.333±25.2460	120.333±12.74288	0.004*

- Data are presented as mean ± SD.
- Comparison within the group A was not statistically significant (p->0.05).
- The entire mean was inside the confidences 95% interval.

In Group C (traditional physiotherapy) comparison between pre and post-treatment indicated significant differences in the

WOMAC questionnaire (P-value =0.0001\*). In VAS (visual analog scale) (P-value =0.0001\*). In circumference (P-value =

0.0001\*). And in range of motion (flexion of the knee) (P-value = 0.004\*).

### **Comparisons between Groups A, B, and C:**

Further comparisons between the results showed that there were no significant differences in in the WOMAC scores or in the circumference (edema) between the three groups at the end of treatment. As regards VAS, there was no significant difference in VAS between groups A and C, but group B showed significant difference (P-value is 0.004) and the mean reduction in pain was also better in this group than in groups A and B Group B (pulsed ultrasound) also showed the greatest improvement in ROM ( P-value is 0.0001), whereas in Group A ( continuous ultrasound ) the P-value was 0.007 , and in the control group the P-value was 0.004.

## **DISCUSSION**

Ultrasound therapy treatment has minimal safety risks for the symptomatic treating OA pain for long years. In 2010, a Cochrane review determined that ultrasound may provide clinical value for knee OA patients by reducing pain and improving function and quality of life and that larger-scale clinical trials were justified (Rutjes et al,2019). More recently, clinical trials on OA and rheumatoid arthritis, along with multiple meta-analyses of the literature, have found statistical support indicating that consistent ultrasound therapy of OA symptoms is more efficient than placebo groups (Zhang et al,2014).Specially for knee pain, ten randomized controlled trials consist of 645 clients treated with ultrasound therapy had a positive result in the outcomes for the placebo group in knee pain and the WOMAC Index score (Zhangetal,2016).Current existing evidence suggests ultrasound administered daily is effective for OA symptomatic management(Zhang et al 2016). Unfortunately, daily ultrasound treatment in

the clinical setting is unrealistic for many patients and medical professional.

The present prospective randomized study was conducted to evaluate the effectiveness of ultrasound therapy in Sudanese patients with knee osteoarthritis by using three modalities of ultrasound therapy.

In contrast to Falconer *et al* (1992) who claimed no benefit for ultrasound in treatment of Knee OA, our results reported herein indicated much improvement in all the tested parameters in all three groups of patients using 3 treatment modalities. This should not be surprising in view of the reviews and meta-analysis results regarding the efficacy of ultrasound therapy carried out by eg. Zhang et al,(2014,2016), Loyola-Sanchez et al(2010), :Aiyer et al(2019) and Wu et al (2020) clearly indicated the effectiveness of ultrasound as a viable treatment of OA . It is of note that the greatest improvement in all parameters tested in our trial occurred in in group B (pulsed ultrasound group) patients, similar results were obtained by Tascioglu et al (2010) who reported that reductions in pain and WOMAC scores were significantly higher in patients treated with pulsed ultrasound as compared to other modalities of treatments. It is also in line with the results reported by Rodríguez-grande et al,(2017) which recorded a significant reduction in pain intensity at the end of functional activities as well as a significant increase in function and in quadriceps muscle strength, but in contrast to Alfredo et al,(2020) who stated that prolonged applications of continuous ultrasound combined with exercises are more effective in improving pain, mobility, functionality and activity in subjects with knee osteoarthritis better than pulsed ultrasound. It is worth mentioning here that Draper et al (2018) who used a wearable long-duration low-intensity device for the daily treatment of musculoskeletal pain in patients with knee osteoarthritis found that this treatment significantly reduced pain and

improved joint function in patients with moderate to severe osteoarthritis knee pain. Technological innovations might facilitate the application of this modality of treatment.

In conclusions ultrasound treatment especially pulsed ultrasound in our study significantly reduced pain and improved joint function in Knee OA in Sudanese patients with moderate to severe knee pain. Our results showed that pulsed ultrasound was more superior in decreasing pain and in improving WOMAC, ROM and VAS scores in knee OA. This strongly implies that this method can be useful as an adjunct to traditional physiotherapy methods and in helping the patients to resume reasonable daily life activity. In general, the clinical findings in our study and in all of the studies mentioned above suggest that ultrasound modalities including pulsed ultrasound may be used as a safe, conservative non-pharmaceutical and non-invasive treatment option for patients with knee osteoarthritis. However additional research is warranted on Knee OA as well as on non-weight bearing joints of the musculoskeletal system. Such research should also consider extended treatment time frames and follow-up of patients.

Finally, and to the best of our knowledge, the present study is the first study to quantitatively evaluate the short-term effectiveness of traditional, continuous, and pulsed ultrasound in the treatment of OA in Sudanese patients.

## CONCLUSIONS

- In this study we concluded that pulsed ultrasound therapy is very effective in reduction of pain.
- There is no difference in WOMAC index score and Circumference (edema), between the ultrasound and traditional therapy at the end of the treatment,
- Range of Motion pulsed ultrasound therapy showed the greatest improvement in motion.

- The traditional physiotherapy and ultrasound therapy had the same outcome at the end of treatment programs.
- Pulsed ultrasound therapy showed significant outcome in improving in pain, edema and range of motion.

## Declaration by Authors

**Ethical Approval:** Approved

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**Conflict of Interest:** The authors declare no conflict of interest.

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