Effects of Transcutaneous Electrical Nerve Stimulation (Tens) and Therapeutic Ultrasound (US) Given Concurrently (Combination Therapy) Versus Consecutively on Pain and Disability in Patients with Osteoarthritis Knee- A Randomized Clinical Trial

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Abstract

Background : The severity of pain and disability due to osteoarthritis of the knee can lead to an increase in replacement surgeries making conservative management important in improving quality of life. By combining US and TENS, effects of both treatments can be achieved simultaneously also making it time efficient.

Objective : To investigate the effects of combination therapy in reducing pain and disability in patients with OA knee.

Method: 26 participants were recruited for the study and were randomly assigned into two groups. Group A received TENS and US as combination therapy. Group B received TENS and US separately. Both groups received the exercise program for 30 minutes per day for 10 days. The pain was measured by using VAS and WOMAC. Physical function and stiffness was also assessed by using WOMAC scale on the first and tenth day.

Results : Both the groups showed a significant difference in pain outcomes for VAS, physical function, and stiffness in WOMAC ($p<0.001$) but there was no significant difference seen between the groups ($p= 0.5$).

Conclusion : Both treatment modalities are safe and effective in reducing pain and disability in patients with OA knee. Combination therapy had an added benefit of achieving the similar result in a shorter period as compared to when given consecutively

Keywords: *Osteoarthritis, Combination therapy, TENS, Therapeutic ultrasound.*

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Introduction

Osteoarthritis (OA) is the most common musculoskeletal disorder affecting a large population of all genders, races, and countries.[1] It is found to be more common in women than in men and its prevalence

increases with age. This may be due to genetic and hormonal factors, the anatomical difference in the alignments of structures, differences in knee cartilage volume and previous trauma.[2,3]

OA is a heterogeneous chronic disease involving the entire joint, including the articular cartilage, subchondral bone, menisci, and periarticular soft tissues such as the synovial membrane. Articular cartilage has low metabolic activity due to lack of blood vessels lymphatic vessels and nerves; it consists of chondrocytes and a dense extracellular matrix composed primarily of water, collagen, and proteoglycan. The mixture of fluid and matrix provides hyaline cartilage with viscoelastic and mechanical properties for efficient load distribution. If any compositional changes occur, then it will affect the mechanical stability of the extra cellular matrix (ECM) network. It will lead to excessive mechanical surface contact stress in the cartilage, and can directly damage the articular cartilage while weight- bearing. The loss of cartilage and modifications to the bone and synovial membrane contributes to an unfavourable biomechanical environment which increases stress on the joint and causes further progression of cartilage degradation.[4,5,6]

As the prevalence of OA knee increases, the rate of knee arthroplasty also increases. Therefore the main aim of physical therapy management is to decrease pain, improve functional activities and minimize the disability for enhancing the quality of life.[7]

Current clinical practice guidelines (CPGs) for the management of nonsurgical knee OA recommend using a combination of pharmacologic and non-pharmacologic interventions many of which are offered by physical therapists

In the UK and USA, US and IFT are being used together as combination therapy. In general terms, combination therapy involves the simultaneous application of ultrasound (US) with electrical stimulation therapy.[8] But there is a lack of evidence in the literature to support its effectiveness. Mukkannavar P B[9] conducted a study on the effect of combination therapy [TENS & Ultrasound] and ischemic compression in the treatment of active myofascial trigger points. This study found that combination therapy resolved acute active trigger point pain and increases range of motion more rapidly when compared to the ischaemic compression treatment.

By combining US with TENS, the effects of each treatment modality can be achieved, but lower intensities are used to gain the effect. In addition to this, application of combination therapy renders a time-efficient treatment with the similar effects. Hence the study aimed at evaluating if combination therapy would be beneficial when compared to the application of TENS and US separately.

Methods

The study was conducted in the Department of Physiotherapy. Individuals clinically diagnosed with osteoarthritis of the knee were recruited for the study. A sample size of 26 (13 subjects per group) was included in the study using a purposive sampling technique.

Participants

The study was performed with the approval of the Father Muller Medical College Institutional Review Board for studies involving human subjects and written informed consent was obtained from each participant

The inclusion criteria were 1) Individuals with clinically diagnosed with tibiofemoral osteoarthritis of the knee in any age group, 2) all genders, 3) Altman's clinical classification criteria for osteoarthritis knee pain[10] which included knee pain, joint stiffness < 30

min, crepitus, bony enlargement, bony tenderness, no palpable warmth. The subject was included if they fulfilled any two of these criteria. Patients were excluded if they had any 1) sensory deficits, 2) recent surgery over the knee joint, 3)trauma around the knee joint, 4)an open wound in the knee joint, 5) pacemaker, 6)any implants in and around the knee joint, 7)dermatological lesions in the knee, 8)intra-articular corticosteroid injection in the past 6 months.

Interventions

Subjects clinically diagnosed with tibiofemoral OA of the knee were included for this study and were recruited from Physiotherapy OPD. The subjects were screened and enrolled for the study based on inclusion and exclusion criteria. A brief introduction to the treatment procedure was explained to all the subjects. Demographic data were obtained from all the participants. Subjects were randomly assigned into two groups. Pre and Post-intervention outcome measures for the VAS and WOMAC were obtained and compared. The experimental group received TENS and US as combination therapy. Combination therapy of 10 minutes per day was administered to the patient. The control group received TENS and US separately. In this group, TENS was given for 10 minutes followed by the US for 10 minutes. Both groups received an exercise program for 30 minutes every day. Patients receiving TENS were explained that tingling sensation will be felt which should not be unpleasant. BTL -5000 machine (BTL Industries Limited) was used to deliver TENS and US for both the groups. Electrotherapy intervention parameters for both groups were as follows: TENS-2electrode (1channel), high-frequency 100Hz, pulse width: 100 μsec, duration; 10 minutes, intensity as tolerated by the patient. The dosage for US was: 1 MHz, power at 3.5w/cm^2, pulse ratio at 1:1 for 10 minutes at an intensity of 0.8 W/cm^2. The size of the transducer head was 5cm^2. The exercises included for both groups were static quadriceps, dynamic quadriceps, end range knee extension exercises, hamstring curls in prone lying and hip abductor strengthening exercises. Three sets of the exercises were performed with ten repetitions each.

Outcome Measures

Outcome measures were collected at the following time points: 1) on the first day before treatment and 2) the tenth day post-treatment. VAS consists of a straight line with the endpoints defining extreme limits such as "no pain at all" at one end to" most excruciating pain ever imaginable". The patients were asked to mark on the line between the two endpoints which indicated their pain levels. The distance between "no pain at all" and the mark, then defines the subject's pain[11] WOMAC consists of 24 items: 5 pain, 2 stiffness, and 17 physical function items. It produces three subscale scores (pain, stiffness, and physical function) and a total score. Patients were asked to answer each question concerning pain, stiffness, or difficulty experienced in the previous 48 hours.[12]

Sample size

A sample size of 26 (13 subjects per group) was included in the study using purposive sampling technique based on inclusion and exclusion criteria. The sample size was calculated using the following formula based on the parameters of Tascioglu F and Mascarin N C.[13,14]

Statistical Analysis

Statistical analysis was done using the software SPSS, version 23. The demographic data were analysed by t-test and Fishers Exact test. The comparison of pre and post-intervention values within the group was analysed using paired't' test. The comparison of pre and post-intervention values between the groups was analysed using unpaired't' test. The confidence interval was set at 95%.

Results

Twenty-six subjects were recruited for this study based on the inclusion and exclusion criteria. There were no dropouts seen during the study. Figure 1 shows a flow diagram of patient recruitment. All subjects were similar at the baseline with the mean age of 59.54 in Group A (SD±13.09) and 58.62 in Group B (SD±10.37). The within-group analysis by 't' test showed that there was a highly significant difference ($p < 0.001$) in the pre and post-test values for all the components of WOMAC i.e. physical function, pain, stiffness and the total score (Table 1 & table 2). Between-group analysis of Womac found no significant differences between the scores (Table 3). The mean value of VAS for group A and group B showed a difference in the reduction of pain from 70.23 to 30.08 and 66.69 to 21.31 respectively (Figure 2). The p values in both groups were highly significant ($p<0.001$). The intragroup calculation was done by using unpaired t test and there was no significant difference between the groups ($p=0.5$).

TABLE 1: Within group comparison of WOMAC- GROUP A

CATEGORY	GROUP A	MEAN	SD	MEAN DIFFERENCE	STANDARD DIFFERENCE	t value	p value
Physical function	Pre	35.62	13.137	18.69	9.85	6.84	.000<0.001,HS
	Post	16.92	5.852				
Stiffness	Pre	5.08	1.441	3.00	1.73	6.24	.000<0.001,HS
	Post	2.08	1.320				
Pain	Pre	10.92	3.796	7.00	2.89	8.74	.000<0.001,HS
	Post	3.92	1.801				
Total score	Pre	51.62	17.609	28.69	13.52	7.65	.000<0.001,HS
	Post	22.92	7.889				

TABLE 2: Within group comparison of WOMAC- GROUP B

CATEGORY	GROUP B	MEAN	SD	MEAN DIFFERENCE	STANDARD DIFFERENCE	t value	p value
Physical function	Pre	35.62	13.137	21.62	6.40	12.18	.000<0.001,HS
	Post	16.92	5.852				
Stiffness	Pre	5.15	1.573	3.31	1.80	6.64	.000<0.001,HS
	Post	1.85	1.405				
Pain	Pre	9.38	2.468	6.77	1.96	12.42	.000<0.001,HS
	Post	2.62	1.261				
Total score	Pre	48.38	10.300	31.69	65.50	13.80	.000<0.001,HS
	Post	16.69	6.550				

TABLE 3: BETWEEN GROUP ANALYSIS OF WOMAC

CATEGORY	GROUP	MEAN DIFFERENCE	STANDARD DIFFERENCE	t value	p value
Physical function	A	18.69	9.85	0.897	0.379, NS
	B	21.62	6.40		
Stiffness	A	3.00	1.73	0.444	0.661, NS
	B	3.31	1.80		
Pain	A	7.00	2.89	0.238	0.814,NS
	B	6.77	1.96		
Total score	A	28.69	13.52	0.682	0.502,NS
	B	31.69	8.28		

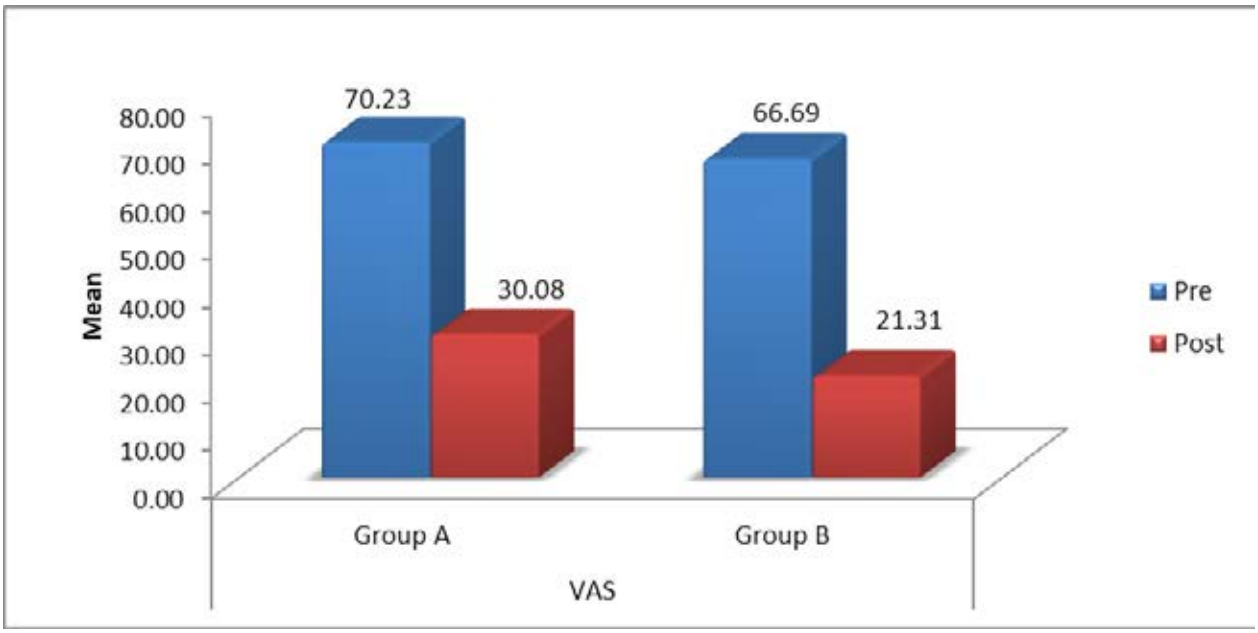

FIGURE 2: Differences in VAS

Discussion

The present study aimed to explore the effect of combination therapy in reducing pain and disability in patients with OA knee. The patients with OA knee included in this study showed significant improvement in the reduction of pain and disability post 10 days of intervention. To our knowledge, this is the first randomized control trial study to find out the effects of combination therapy in OA knee by combining TENS and US.

Previous study conducted by Mukkannavar PB[9] exploring the effect of combination therapy [TENS and ultrasound] and ischemic compression in the treatment of active myofascial trigger points found that combination therapy resolves acute active trigger point pain and increases range of motion rapidly compared to ischaemic compression treatment. Due to limited research in this area, the mechanism of action of combination therapy is unknown. According to Tim Watson[8], combination therapy is a simultaneous application of ultrasound and electrical stimulation namely IFT, TENS or any other form of electrical stimulation. He also describes the advantage of combination therapy; is such that the effects of each treatment modality which can be achieved by low intensities. Combination therapy provides the effects of TENS and US simultaneously. When a peripheral nerve comes in contact with US, its resting membrane potential decreases due to increase in the permeability of nerve membrane for various ions such as sodium and calcium. This will lead to a decrease in the threshold for nerve stimulation, thus the nerve can be depolarized with the use of smaller current. However, the exact mechanism of pain relief cannot be explained. In our study, there was a mean improvement of 70.23 to 30.08 in VAS score and 51.62 to 22.92 in WOMAC score in group A and mean improvement in 66.69 to 21.31 in VAS score and 48.38 to 16.69 in WOMAC score was found in group B, showing an improvement in VAS and WOMAC scores in both the groups. Therefore both treatments showed a positive effect of OA knee. But there was no significant differences in terms of VAS ($p=0.500$) and WOMAC ($p= 0.502$) scores between the groups.

In conclusion, our study found that there was a significant difference in pain outcomes VAS and

WOMAC scale. There was no significant difference seen in between the group. This study showed that both combination therapy and TENS and US given separately was effective in reducing pain and disability in patients with osteoarthritis knee. But with combination therapy the desired effect with respect to reduction of pain, stiffness and improvement in function was obtained in a shorter duration time, making the therapy time- effective for both the therapist and the patient.

Limitations

Simple randomization was done. Therefore, there was an unequal distribution of males and female in this study. Future studies can concentrate on collecting equal male and female samples in each group.

Conclusion

In conclusion, both treatment modalities are safe and effective in reducing pain and disability in patients with OA knee. The overall treatment time used for combination therapy is less than that of TENS and US given separately.

Ethical Clearance: The study was approved by the Father Muller Medical College institutional ethics committee. All the authors were affiliated to Father Muller Medical at the time of the study.

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Conflict of Interest: The authors have no conflict of interest relevant to this article.

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