

Efficiency of Action Potential Simulation (APS) therapy in compare to Transcutaneous Electrical Nerve Stimulation (TENS) in knee osteoarthritis

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Abstract: Introduction: The knee joint osteoarthritis is one of the most important causes of musculoskeletal pains and disability. Beside the medical treatments, rehabilitation and physiotherapy has a major role in reducing the pain and improving the function of patients with knee osteoarthritis. The aim of this study was the evaluation of the Action Potential Simulation (APS) and Transcutaneous Electrical Nerve Stimulation (TENS) modalities in patients with knee osteoarthritis. Methods and Materials: In a clinical trial in the Physical medicine and rehabilitation department of Tabriz University of Medical Sciences on 70 patients with knee joint osteoarthritis, we compared the two APS and TENS in patients with knee osteoarthritis and their effect on the Visual Analogue Scale (VAS) and Western Ontario and McMaster Universities Osteoarthritis (WOMAC) index. Results: Over all, 5(7.1%) of patients was male and 65(92.9%) was female, the mean age of the patients was 57.1 ± 7.7 years in the range of 50 to 85 years. The mean VAS score before the intervention was 7 ± 1.9 in the APS group which was reduced to 4.5 ± 1.9 . The mean VAS score in the TENS groups was decreased from 6.8 ± 1.2 to 4.6 ± 1.9 which there was significant difference for two groups ($p < 0.001$). The overall changes in the total score of the WOMAC and Timed up and go test before and after the treatment was significant in both groups ($P < 0.001$). Conclusion: With regard to the findings of our study we can conclude that both APS and TENS modalities are effective in the pain relief and improving the functions of knee joints in the patients with knee osteoarthritis and they have no benefits to each other.

[Toopchizadeh V, Babaei-Ghazani A, Eftekhari Sadat B. **Efficiency of Action Potential Simulation (APS) therapy in compare to Transcutaneous Electrical Nerve Stimulation (TENS) in knee osteoarthritis.** *Life Sci J* 2012;9(4):3790-3794] (ISSN:1097-8135). <http://www.lifesciencesite.com>. 563

Keywords: Knee Osteoarthritis; Action Potential Simulation; Transcutaneous Electrical Nerve Stimulation

1. Introduction

The knee joint osteoarthritis is one of the important causes of musculoskeletal pains and disability of affected patients and because of performance loss and early retirement cause a heavy burden and cost on society (Salaffi, 2003).

The Symptomatic knee osteoarthritis is more common in women and its prevalence increases with age (Faik, 2008). The knee osteoarthritis is more common upon radiographic evidences (Faik, 2008).

Beside the medical treatments, rehabilitation and physiotherapy has an important effect on pain relief and improving the performance of patients with knee osteoarthritis. For assessing the effect of treatment in each treatment modality the acceptable measures are needed (Carr, 1999).

Electrotherapy is one of the effective rehabilitations in patients with osteoarthritis. Electrotherapy is based on using electricity for creating a known physiologic response with the aim of pain relieving (Papendrop, 2000)

Transcutaneous Electrical Nerve Stimulation (TENS) activates the A – beta neurons and by this way decreases the afferent pain neurons irritability (A-delta and c) in spinal cord (Papendrop, 2000).

Action potential stimulation is one of the newest pain relief methods which is introduced in

1992 and widely used for the chronic pain reliefs by physiotherapists (Fengler, 2007).

The APS has a different pulse waves from TENS and several physiologic effects like increasing in leucine, enkephalin, plasma melatonin, tissue ATP, decrease in plasma beta endorphin and topical vascular vasodilation which all of these factors has a positive effect on pain relief (Oosthuizen, 2011).

With regarding several studies about different modalities of knee joint osteoarthritis treatment in different research centers worldwide, considering the high prevalence of the osteoarthritis of knee joint in our country and debilitating pains of this condition, there seems a need for new treatment for this disease.

So we decided to plan a study for evaluating the effect of APS therapy in patients with knee joint osteoarthritis and its comparison with TENS method for improving the treatments and reducing the commercial burdens on the healthcare system.

The aim of this study is the comparison of Action potential simulation method with Transcutaneous Electrical Nerve Stimulation method in patients with knee joint osteoarthritis.

2. Material and Methods

In a clinical trial study in the rehabilitation department of Tabriz University of medical sciences on patients with knee osteoarthritis, we compared Action potential simulation method with Transcutaneous Electrical Nerve Stimulation method in treatment of knee osteoarthritis.

We selected 70 patients with mild or moderate knee osteoarthritis after achieving inclusion criteria and randomized them into two equal groups.

The group A of patients received APS therapy and the group B received TENS. One of patients in group A could not complete the treatment course because of personal problems and 2 of TENS group could not complete the treatment course one for personal problems and the other for the trauma.

This study was done in the physical medicine and rehabilitation clinic of Shohada Hospital, in Tabriz University of medical sciences.

There was no non-normative interventional treatment for patient. All data from patients were confidential. Each of treatment used in this study is based on valid references and academic methods which are used regularly by physicians and there is no ethical limitation for the study. With regard to these issues the written consent was obtained for all patients.

In addition we did not impose any additional cost to the patient. For illiterate patients questionnaires read and completed by medical staff.

It should be stated that the research has been approved by the ethics committee of Tabriz University of Medical Sciences. This study is registered under number 201112171292 N2, as a clinical trial in IRCT site.

All participants met the inclusion criteria and provided consent to participate in the study period of one year within the two groups was examined. Patients were randomly assigned to one of the groups simply by sealed envelopes A and B.

To determine the sample size we used the results of the Van Papendrop and colleagues' study (4). In this study, the scores of pain intensity were reduced to 2.7 from 6.6 before the intervention. With $\alpha=0.05$ and the 20 percent decrease in the pain, the cases assigned 70 patients.

The American college of rheumatology criteria for knee joint osteoarthritis was used in our study.

The radiologic criteria for defining the severity in knee joints include;

Radiological scoring (X-ray finding):

- 0 Normal
- 1 Doubtful narrowing of joint space/possible osteophytes lipping

2 Definite osteophytes/absent or questionable narrowing of joint space

3 Moderate multiple osteophytes, definite narrowing of joint space, some sclerosis, possible joint deformity of bone ends

4 Large osteophytes marked narrowing of joint space, severe sclerosis, definitive joint deformity of bone ends and subchondral cysts may be present.

Group A of patients underwent APS therapy intervention and the second group received TENS intervention. During the study all patients in both groups received common treatment for the osteoarthritis including Glucosamine and Acetaminophen.

The VAS and WOMAC questionnaires was completed for all patients and the Timed up and go test was done for patients after obtaining written consent.

WOMAC questionnaire is designed to measure patients' pain and dysfunction, associated with osteoarthritis of the lower extremities, and assesses the functional activity in 17 subscales, 5 subscales of pain and two categories of activities related to the stiffness (Mc Conelli, 2001).

The Timed Up and Go Test was administered to patients in this way: the patient was still sitting on the chair and began walking in three meters long path then coming back and sitting on the same chair. We measured the time for this test in seconds.

The steps of the treatment intervention concluded 10 sessions of physiotherapy (5 sessions a week). In physiotherapy sessions normal physical modalities like deep and superficial heat, the strengthening exercises of the muscles near the knee, stretch of hamstring tendons and heel cords was done equally for all patients.

The only different modality for two groups is the type of the electrotherapy. That the APS was for group A and TENS method for group B. The time needed for APS modality was 15 minutes and for the TENS method it was 30 minutes.

The specifications of two modalities are as below:

APS: Frequency 151 Hz, pulse width 800 microseconds, Constant current, maximum amplitude 1.5 m amp

TENS: Pulse duration 20-600 microseconds, 50% duty cycle, Current amplitude, maximum tolerated painful tangling, Frequency < 200 pps

In different groups patients was not informed for intervention. Due to the different types and manuals of electrotherapy devices on patients, unawareness of therapist was not possible. The

person responsible for statistical analysis was not informed the type of the electrotherapy modality.

After receiving the treatment (upon the group of patients) in the last treatment session, the VAS and WOMAC questionnaires' was completed for patients and timed up and go test was done for second time.

In this study the primary outcome was done upon the VAS and WOMAC scoring system and the 20% decrease in the VAS and 30% decrease in WOMAC after the treatment defined as improvement in patients. All data after reviewing all the necessary information's from the patients, we analyzed them with proper analytical tests.

Inclusion criteria were:

1 - Mild or moderate knee osteoarthritis (Mild or Moderate) upon America College of Rheumatology criteria (ACR)

2- Age more than 50 years of old.

Exclusion criteria were:

1- Patients with rheumatologic problems such as rheumatoid arthritis

2 - The history of surgery on knee

3 - A history of lower extremity fractures in the bones with knee joint surface involvement

4 - severe osteoarthritis of the knee (severe): radiological score 4

5 - People with electrical implants such as pacemakers and...

6 - A history of heart disease, conduction block

7 - People with Epilepsy

8 - Patients with Cancer

9 - Pregnant women

10 - People with lower extremity thrombosis (DVT)

11-People who for every reason are not able to cooperate in order to complete the questionnaire and complete the survey

12-history of knee injections in 6 months

13-People with balance disorders

14-People with neuropathy and Sensory Disorders

15- Presence of skin injuries around the knee

Statistical analysis:

The obtained data was coded and then entered into a computer and statistically analyzed by SPSS software. T-Test and chi-square test were used for data analysis. Significance level for tests was determined as 95% ($P < 0.05$).

3. Results

In a clinical trial study, we evaluated 70 patients with mild or moderate knee osteoarthritis in the form of two groups.

The group A of patients received APS therapy and the group B received TENS. One of patients in group A could not complete the treatment course because of personal problems and 2 of TENS group could not

complete the treatment course one for personal problems and the other for the trauma.

5 of patients (7.1%) were male and 65 of patients (92.9%) were female. In group A, 2(5.7%) were male and 33 (94.3%) were female and in group B, 3(8.6%) were male and 32 (91.6%) were female. Two groups were similar in both sexes ($p=0.29$).

The mean age of patients was 57.1 ± 7.7 years in the range of 50 to 58 years.

The demographic findings of patients like weight, height and Body Mass Index (BMI) in two groups are shown in table 1.

The description and comparison of variables between two groups before and after the intervention is shown in table 2.

The description and comparison of variables before and after the intervention in each group is shown in table 3.

As mentioned earlier, as a 20% decrease in the VAS score and 30% decrease in the WOMAC score defined as the primary outcome for study. With regard to this issue, 91.4 % of patients in group APS and 93.8% of patients in group TENS has achieved the defined outcome.

Table 1. Demographics finding of two groups

	Group A	Group B	P
Weight(Kg)	75.2 ± 11	73.3 ± 10.5	0.48
Height(cm)	156.3 ± 0.06	155.8 ± 0.06	0.71
BMI(Kg/m^2)	29 ± 5	28.1 ± 3.5	0.44

4. Discussions

Knee joint osteoarthritis is one of the most prevalent disorders of adulthood which cause a lot of functional impairments. These patients have more needs for health care systems services (Faik, 2008). These debilitating diseases are associated with decrease in the quality of life. Nowadays despite the increasing life expectancy, the prevalence of these diseases rises so the world health organization have designed a comprehensive program in association with international society of rheumatology as the name Community Oriented Programmed for Control of the Rheumatic Disease (COPCORD) for controlling the rheumatic diseases (Mc Conelli, 2001).

The WOMAC questionnaire is designed specially for evaluating the patients with knee and hip osteoarthritis. Original English version of the questionnaire has been translated into 50 languages and has been used by physicians so far (Faik, 2008).

Electrotherapy is one of the effective treatments of rehabilitations in patients with knee osteoarthritis which cause a known physiologic response for pain relieving (Papendrop, 2000).

Table 2. Evaluation of VAS and WOMAC subscales of patients in pre and post treatment between two groups

	Pre treatment			Post treatment		
	Group A	Group B	P	Group A	Group B	P
VAS(0-10)	7±1.9	6.8±1.2	0.73	4.5±1.9	4.6±1.9	0.87
WOMAC subscales						
Pain, 0-20	12.2±4	11.1±3.3	0.22	7.5±3.2	6.6±3.3	0.27
Stiffness, 0-8	3.9±2.2	2.8±1.9	0.03	2.5±1.7	1.8±1.4	0.09
Physical function, 0-68	38.4±12.3	34.6±10.6	0.18	25.2±11.3	25.1±11.4	0.96
Total, 0-96	54.6±17.3	48.6±13.1	0.11	35.2±15.5	33.6±15.1	0.66
Timed up and go test, second	11.2±2.7	12.1±3.9	0.30	9.5±2.1	10.4±2.8	0.11

Table 3. Evaluation of VAS and WOMAC subscales of patients in each group at pre and post treatment

	APS Group			TENS Group		
	Pre Trial	Post Trial	P value	Pre Trial	Post Trial	P value
VAS, 0-10	7±1.9	4.5±1.9	<0.001	6.8±1.2	4.6±1.9	<0.001
WOMAC subscales						
Pain, 0-20	12.2±4	7.5±3.2	<0.001	11.1±3.3	6.6±3.3	<0.001
Stiffness, 0-8	3.9±2.2	2.5±1.7	<0.001	2.8±1.9	1.8±1.4	0.004
Physical function, 0-68	38.4±12.3	25.2±11.3	<0.001	34.6±10.6	25.1±11.4	<0.001
Total, 0-96	54.6±17.3	35.2±15.5	<0.001	48.6±13.1	33.6±15.1	<0.001
Timed up and go test, second	11.2±2.7	9.5±2.1	<0.001	12.1±3.9	10.4±2.8	<0.001

The electrical modalities like Transcutaneous Electrical Nerve Stimulation (TENS) with original mechanism of activating A – Beta neurons which are cutaneous mechanoreceptors with Low skin irritation threshold cause decrease in irritability of pain afferent neurons in spinal cord (Papendrop, 2000).

Panahi and his colleague in 2008 showed that APS therapy can reduce the pain in patients with musculoskeletal pains (P<0.005). There was not a significant relation between pain relief and level of education, duration of illness and past history of the physiotherapy, they also introduced the APS method as a pain relief method in patients with musculoskeletal pains (Shariatpanahi and Mehdiabarzi, 2007).

In our study the both APS and TENS modalities was effective and there was not significant difference in the results of treatments between tow groups (p=0.62).

Atamaz and colleagues in 2012 assessed the effects of TENS and Shortwave diathermy in the treatment of the knee osteoarthritis and stated that there is no difference between physical modalities in the treatment of the knee joint osteoarthritis and they have no benefits to each other but they are effective in pain relief and improving the function of the patients in comparison to medical and educational treatments alone (Atamaz, 2012)

In 2011, Rahimi and colleagues compared the results of the conventional physiotherapy results versus APS in knee osteoarthritis and stated that APS has a greater effect on reducing the Knee pain and the swelling of the knee in patients with knee joint osteoarthritis. So using of this device is recommended in patients above (Rahimi, 2011).

Papendrop and colleagues in 2002 compared the results of the TENS , APS method and placebo in the treatment of the knee joint osteoarthritis and showed that using APS as long as 8 minutes has a significant effect on knee joint range of motion in comparison with TENS and placebo group(Papendrop, 2002).

The results of these studies had a similarity to present study whereas we did not assess the range of motion as an independent factor.

Myerz and colleague conducted a study in the Cape Town University and stated that the pain relief after using the APS modality has more persistence than normal physiotherapy methods (Myerz, 2001).

Despite the results of the study by Myerz et al in our study we did not assessed the pain relief persistence as a secondary outcome in each of study groups.

In the study by Fengler and his colleagues in 2007 it's stated that the effect of placebo on treatment of patients with fibromyalgia was more than effect of the APS therapy (Fengler, 2007).

This discrepancy may be due to different diseases, and subjects of the two studies. Because patients with fibromyalgia have a lower threshold of stimulation that are offended by the very low threshold of stimulation and is expected to be more satisfied with the placebo.

While those with mild to moderate osteoarthritis of the knee have normal threshold, as a result the difference between fibromyalgia and osteoarthritis patients compared to stimulation, seems logical.

Conclusion:

With regard to the results of the study both APS (Action Potential Simulation) and TENS modalities are effective in the pain relief and improvement of function in patients with knee osteoarthritis and have no benefits to each other.

Suggestions:

There were some limitation in our study and we can propose some suggestion with eliminating them.

- 1-Conducting a similar study and evaluating the patients in long term for assessing the persistency of two modalities and their comparison.
- 2- Conducting a similar study and evaluating the different frequencies of APS on knee osteoarthritis
- 3- Conducting a similar study and comparing the effects of the APS with placebo in knee osteoarthritis.
- 4- Conducting a similar study and evaluating the effects of APS with other analgesic modalities like interferential currents.

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2/11/2012