MEDWIN PUBLISHERS
Committed to Create Value for Researchers

Journal of Orthopedics & Bone Disorders
ISSN: 2577-297X

The Effectiveness of Thermal Mode of 448 KHz Capacitive Resistive Monopolar Radiofrequency in Continuous Wave in Patients with Chronic Rotator Cuff Tendinopathy: A Clinical Trial

Stasinopoulos D[1]*, Constantinou A[2] and Lamnisos D[3]

[1]Assistant Professor, Department of Physiotherapy, Faculty of Health and Caring Sciences, University of West Attica, Member of Laboratory of Neuromuscular & Cardiovascular Study of Motion (LANECASM), Greece

[2]Physical therapist/ clinical trainer, Cyprus Musculoskeletal and Sports Trauma Research Centre (CYMUSTREC)Department of Health Sciences, Physiotherapy Program, School of Sciences, European University of Cyprus, Greece

[3]Chairperson/Assistant Professor Biostatistics, Coordinator of MSc in Public health, Department of Health Sciences, Cyprus Musculoskeletal and Sports Trauma Research Centre (CYMUSTREC) Physiotherapy Program, School of Sciences, European University of Cyprus, Greece

***Corresponding author:** Assistant Professor, Physiotherapy, Department of Physiotherapy, Faculty of Health and Caring Sciences, University of West Attica, Member of Laboratory of Neuromuscular & Cardiovascular Study of Motion (LANECASM), Agiou Spyridonos 28, Egaleo 12243, Athens, Greece, Email: dstasinopoulos@uniwa.gr

Research Article

Volume 4 Issue 1

Received Date: July 29, 2020

Published Date: August 18, 2020

DOI: 10.23880/jobd-16000196

Abstract

The aim of the present clinical trial was to compare the clinical results of the use of an exercise program with those of an exercise program and thermal (thermia or hyperthermia) mode of 448 kHz Capacitive Resistive Monopolar Radiofrequency in continuous wave in patients with chronic rotator cuff tendinopathy. Patients were allocated to two groups by drawing lots. Pain, function and strength were measured. An exercise programme and thermal (thermia or hyperthermia) mode of 448 kHz Capacitive Resistive Monopolar Radiofrequency in continuous wave, had reduced the pain and improved function and strength in patients with chronic rotator cuff tendinopathy at the end of the treatment and at the follow-ups. Future well-designed randomised controlled clinical trials are needed to establish the effectiveness 448 kHz Capacitive Resistive Monopolar Radiofrequency in the management of chronic rotator cuff tendinopathy.

Keywords: Thermal Mode; Thermia or hyperthermia; Tendinopathy; Monopolar

Introduction

Tendinopathies are not only common among professional and recreational sports players but also among people in general, especially those in jobs that involve manual labour. Tendinopathies may affect a variety of tendons including Achilles, patellar, rotator cuff (mainly supraspinatus) and extensor carpi radialis brevis (ECRB, commonly referred to as tennis elbow and /or lateral epicondylitis (LE)).

Rotator cuff tendinopathy (RCT) is the most common tendinopathy in the shoulder area and one of the two most common tendinopathies of the upper limb. Pain and decreased function are the main symptoms of RCT. Diagnosis

are simple. The symptoms are reproduced by (1) overhead activities; (2) palpation on the site of pain; (3) clinical tests such as Hawkins and Neer [1].

Many clinicians advocate a conservative approach as the choice of treatment for chronic RCT. Chronic RCT is degenerative or failed healing tendon response rather than inflammatory. Physiotherapy is a conservative treatment that is usually recommended. A wide array of physiotherapy treatments has been recommended for the management of chronic RCT such as electrotherapeutic modalities, exercise programmes, soft tissue manipulation, and manual techniques. These treatments have different theoretical mechanisms of action, but all have the same aim, to reduce pain and improve function. Such a variety of treatment options suggests that the optimal treatment strategy is not known, and more research is needed to discover the most effective treatment in patients with tendinopathy. One of the most common physiotherapy treatments for tendinopathy is an exercise programme. One consisting of strengthening and static stretching exercises has shown good clinical results in tendinopathies such as chronic RCT.

Although an exercise program is an effective treatment approach, a supplement to the exercise program should be found to reduce the treatment period. One such modality is 448 kHz Capacitive Resistive Monopolar Radiofrequency (CRMRF) which is a relatively new treatment approach, but it is reported to be used by clinicians worldwide. A previous pilot trial showed that the thermal (thermia or hyperthermia) mode of 448 kHz CRMRF in continuous wave had reduced the pain and improved function and strength in patients with chronic RCT at the end of the treatment and at the follow-ups [1]. To our knowledge, there have been no studies to investigate the effectiveness of the thermal (thermia or hyperthermia) mode of 448 kHz CRMRF in continuous wave as a supplement to an exercise program in the management of chronic RCT. Therefore, the aim of the present study was to compare the clinical results of the use of an exercise program with those of an exercise program and thermal (thermia or hyperthermia) mode of 448 kHz CRMRF in continuous wave in patients with chronic RCT.

Methods

A monocenter trial was conducted in a research centre over 12months to assess the effectiveness of a protocol that was constituted from an exercise program in comparison to another protocol constituted by an exercise program and thermal (thermia or hyperthermia) mode of 448 kHz CRMRF in continuous wave in patients with chronic RCT.

Patients over 18 years old with shoulder pain were examined and evaluated in the Cyprus Musculoskeletal and Sports Trauma Research Centre located in Nicosia between July 2018 and July 2019. All patients lived in Nicosia, Cyprus, were native speakers of Greek, and were either self-referred or referred by their physician or physiotherapist.

Patients were included in the study if, at the time of presentation, they had been evaluated as having clinically diagnosed RCT for at least four weeks. Patients were included in the trial if they reported pain on palpation (upper aspect of the head of the humerus), positive Hawkins, neer and epty can position test [2]. Patients were excluded if they: (1) had a history of rotator cuff surgery; (2) reported a history of glenohumeral dislocation, or other traumatic injury to the shoulder; (3) reported only periscapular or cervical pain during arm elevation; or (4) had shoulder symptoms reproduced by a cervical assessment. In addition, an x-ray was performed to detect calcifications and whether there were signs of arthrosis in the acromio-clavicular joint. Patients with signs of arthrosis in the acromioclavicular joint and/or calcifications in the rotator cuff were also not included in this pilot study.

All patients received a written explanation of the trial before entry into the study and then gave signed consent to participate. They were allocated to two groups exercise program and placebo 448 kHz CRMRF and exercise programme and thermal (thermia or hyperthermia) of 448 kHz CRMRF in continuous wave by drawing lots.

All patients were instructed to use their arm during the course of the study but to avoid activities that irritated the shoulder such as full elevation of the shoulder, sleep on the affected shoulder and quick movements of the shoulder. They were also told to refrain from taking anti-inflammatory drugs throughout the course of study. Patient compliance with this request was monitored using a treatment diary.

All treatments were administered at the centre by a qualified physiotherapist (DS) with about 20 years' experience in the management of tendinopathies. Communication and interaction (verbal and non-verbal) between the therapist and patient were kept to a minimum and behaviours sometimes used by therapists to facilitate positive treatment outcomes were purposefully avoided. For example, patients were given no indication of the potentially beneficial effects of the treatments or any feedback on their performance in the pre - and post - application measurements.

Patients received 448 kHz CRMRF intervention. The CRMRF at 448 kHz was delivered using 'INDIBA Activ 902', a new factory calibrated device with a peak power of 200 W and 450VA, which delivered continuous-wave RF energy in two modes: Capacitive (CAP) and Resistive (RES), using metallic electrodes via a coupling medium. The CAP mode

was delivered in thermal dose (according to patient feedback on his perception of moderate heating) in muscles around the shoulder. CAP mode was delivered 5 minutes for each muscle. The RES mode was delivered in thermal (thermia or hyperthermia) in continuous wave. The RES mode was delivered for 10 minutes. Finally, CAP mode in non-thermal dose was delivered in the symptomatic area for 5 minutes. The return electrode was placed in the scapular area. Treatment was delivered once per day for five consecutive days providing twenty sessions in total. The placebo 448 kHz CRMRF was performed in the same way as the active 448 kHz CRMRF but without activating the radiofrequency device (with the machine virtually inactive) to ascertain the effect of manual friction as well as the actual effect of radio frequencies at 448 kHz on the area of RCT.

Patients in two groups followed an exercise programme that was given daily (apart from weekends) for 4 weeks [3]. The exercise programme consisted of slow progressive isotonic, including eccentric, strengthening exercises and static stretching exercises. the strengthening exercises including (i) shoulder medial and lateral rotation with the elbow in 0 and 90 degrees of abduction; (ii) shoulder abduction to 90 degrees with elbow in flexion: (iii) scaption-the arm was kept at 30 degrees of horizontal abduction with the thumb pointing downwards; and (iv) diagonal pattern from full flexion to extension. Each exercise was performed twice at each treatment session with 12 repetitions in each set and 1 min rest interval between each set. Patients were told to continue with the exercise even if they experienced mild pain. However, they were told to stop the exercise if the pain became disabling. When patients were able to perform the strengthening exercises without experiencing any minor pain or discomfort, the load was increased using free weights or therabands. Static stretching exercises including

1. Posterior and inferior capsule stretch according to prentice (1999) [4]
2. External rotators.

Static stretching exercises were repeated three times at each treatment session, after the strengthening exercises with a 30-s rest interval between each repetition. Each stretching was held for 30-45 s each time and then released. The exercise programme treatment was individualized one the basis of the patient's description of pain experienced during the procedure.

Pain, Function, strength and dropout rate were measured in this study. Each patient was evaluated at the baseline (week 0), at the end of treatment (week 4) three months (week 12) and six months (week 24) after the end of treatment in order to see the short, intermediate and long-term effects of the treatments. Pain and function were measured using the Greek version of Shoulder Pain and Disability Index (SPADI) which is a reliable and valid measure when administered to patients aged over 18 years old with shoulder pain for at least 4 weeks [5]. Strength was measured using the hand held dynamometer according to Savva et al., (2018) [6] which are a valid and reliable outcome measures for patients with RCT. The dropout rate was also used as an indicator of treatment outcome. Dropouts were categorized as follows: (a) withdrawal without reason; (b) did not return for follow up; (c) request for an alternative treatment.

The change from baseline was calculated for each follow-up. Differences between groups were determined using the independent t-test. The difference within groups between baseline and end of treatment was analyzed with a paired t-test. A 5% level of probability was adopted as the level of statistical significance. SPSS version 21 statistical software was used for the statistical analysis.

Results

Thirty-five patients eligible for inclusion visited the CYPUSTREC within the trial period. Six were unwilling to participate in the study, and 4 did not meet the inclusion criteria described above. The other 25 patients were allocated to one of the two possible groups: (1) exercise programme and placebo 448 kHz CRMRF [n=12; 8 men, 4 women; mean (SD) age 47.34 (6.75)y]; (2) exercise program and thermal (thermia or hyperthermia) mode of 448 kHz CRMRF in continuous wave [n=13;6 men, 7 women; mean (SD) age 47.75 (6.71) y].

At baseline there were more men than women in the study groups (three more in total). The mean age of the patients was about 47y, and the duration of RCT was about 6months. RCT was in the dominant arm in 80% of patients. There were no significant differences in mean age ($p>0.0005$ by independent t-test) or the mean duration of symptoms ($p>0.0005$ on independent t-test) between the groups. The patients had received drug therapy as previous treatment. All patients were manual workers.

Baseline SPADI was 88 (95% CI 84.5, 89.9) for the entire sample. There were no significant differences between the groups for baseline SPADI ($p>0.05$ on independent t-test) At week 4, there was a decline in SPADI of about 80 units in the exercise programme and thermal (thermia or hyperthermia) of 448 kHz CRMRF in continuous wave group and 60 units in the exercise programme and placebo 448 kHz CRMRF group compared with the baseline ($p<0.0005$, paired t test). There were significant differences in the magnitude of reduction between the groups at weeks 12 and 24 ($p>0.0005$ independent t test).

Baseline grip strength was 29.2 lb (95% CI 25.53 to

32.08) for the whole sample. There were no significant differences between the groups for baseline grip strength ($p>0.05$ independent t test). At week 4, there was a rise in pain-free grip strength of approximately 40 units in the exercise programme and thermal (thermia or hyperthermia) of 448 kHz CRMRF in continuous wave group and 21 units in the exercise programme and placebo 448 kHz CRMRF group compared with the baseline ($p<0.0005$, paired t test). There were significant differences in the magnitude of improvement between the groups at weeks 12 and 24 ($p>0.0005$ independent t test).

There were no drop outs, no adverse effects were referred and all patients successfully completed the study.

Discussion

The results obtained from this controlled clinical trial are novel; as to date, there have been no data comparing the effectiveness of an exercise programme and thermal (thermia or hyperthermia) of 448 kHz CRMRF in continuous wave and an exercise programme and placebo 448 kHz CRMRF for the reduction of pain and improvement of function and strength in chronic RCT. The exercise programme and thermal (thermia or hyperthermia) of 448 kHz CRMRF in continuous wave produced the largest effect at the end of the treatment and at the follow ups.

Exercise programs appear to reduce the pain and improve function, reversing the pathology of tendinopathy such as RCT as supported by experimental studies on animals. The way that an exercise program achieves its goals remain uncertain, as there is a lack of good quality evidence to confirm that physiological effects translate into clinically meaningful outcomes and vice versa.

There are two types of exercise programs: home exercise programs and exercise programs carried out in a clinical setting. A home exercise program is commonly advocated for patients with tendinopathies such as RCT because it can be performed any time during the day without requiring supervision by a physiotherapist. Our clinical experience, however, has shown that patients fail to comply with the regimen of home exercise programs [7]. This problem can be solved by exercise programs performed in a clinical setting under the supervision of a physiotherapist. For the purposes of this report, ‘‘supervised exercise program’’ will refer to such programs. Therefore, such a supervised exercise program was used in the present trial.

Although a supervised exercise program is an effective treatment approach, a supplement to the exercise program should be found to reduce the treatment period. One such modality is 448 kHz CRMRF which is a relatively new treatment approach, but it is reported to be used by clinicians worldwide. Many clinicians think that Shortwave Diathermy (SWT) and 448 kHz CRMRF is the same. However, the 448 kHz CRMRF differs from SWT mainly in two ways - firstly the operating frequency (SWT commonly operates at 27.12 MHz) and secondly, unlike SWT it is applied using a coupling medium since CRMRF cannot be delivered through air [8]. Hence, one hypothesized advantage of 448 kHz CRMRF over SWT is that scattering of the RF waves is potentially considerably lower [8].

Since pain relief and improvements in function and strength were noted in the present study on a long term, it is proposed that the 448 kHz CRMRF energy may potentially have promoted an important effect in the management of soft tissues [8]. However, to understand the potential changes to the tissues in response to 448 kHz CRMRF treatment, future studies should consider employing outcome assessments that are capable of monitoring the changes in deeper tissues.

The present pilot trial was the first trial to examine the effectiveness of 448 kHz CRMRF on chronic RCT. One previous study assessed the effectiveness of this treatment on chronic knee osteoarthritis [8]. However, RCT and knee osteoarthritis are two different conditions and the results are not comparable. The two previously reported trials found that a course of 448 kHz CRMRF may improve patients’ symptoms. The findings of these two trials encourage the design of future well-designed RCTs that might produce strong evidence for the effectiveness of 448 kHz CRMRF on sports/musculoskeletal injuries.

A course of 448 kHz CRMRF treatment was applied in the present pilot study based on manufacturers’ claims. It is a dose-response modality and the optimal treatment dose has obviously not yet been discovered. Future studies are needed to standardize 448 kHz CRMRF parameters in the management of RCT (acute, chronic and calcific).

However, this study does have some shortcomings. First, the sample was small. Second, other activities treatments patients might be getting when not in the clinic were not monitored. Patients’ diaries suggested that patients were compliant to the study instructions, although patients may have given incorrect details to please the investigators. For example, it was possible that patients followed the treatment but took analgesic medications at the same time, and the improvement of symptoms may be due to those medications. Therefore, ways should be found to measure how other treatments such as analgesic medications contribute to the improvement of symptoms. Finally, the blinding of patients and therapists would be problematic in that case, if not impossible, because patients know if they are receiving the exercise programme treatment and therapists need to be

aware of the treatment to administer it appropriately. Further research is needed to establish the possible mechanism of action of this treatment approach, and the cost-effectiveness of such treatment, because reduced cost is an important issue for the recommendation of any given treatment.

Conclusion

This trial showed that an exercise programme and thermal (thermia or hyperthermia) mode of 448 kHz CRMRF in continuous wave had reduced the pain and improved function and strength in patients with chronic RCT at the end of the treatment and at the follow-ups. However, future well-designed randomized controlled clinical trials are needed to establish the effects and the mechanism of action of 448 kHz CRMRF in chronic RCT. Furthermore, a cost effectiveness analysis should be incorporated into the analysis of the effectiveness of 448 kHz CRMRF in a future trial, because reduced costs are important issues for the recommendation of a treatment.

References

1. Stasinopoulos D, Constantinou A, Lamnisos D (2020) 448 kHz Capacitive Resistive Monopolar Radiofrequency in patients with rotator cuff tendinopathy. A pilot study. Submitted article in Acta Scientific Orthopaedics

2. Factor D, Dale B (2014) Current concepts of rotator Cuff tendinopathy. The International Journal of Sports physical therapy 9(2): 274-288.

3. Stasinopoulos D, stasinopoulos I, stasinopoulou K (2014) A pilot trial to study the effectiveness of an exercise programme in the treatment of rotator cuff tendinopathy. JBE 10(2): 69-77.

4. Prentice W (1999) Rehabilitation techniques in sports medicine, 3rd (Edn.), WCB/mcgraw-hill, Boston.

5. Spanou A, Mamais I, Lamnisos D, Stasinopoulos D (2019) Reliability and validity of the Greek shoulder pain and disability index in patients with shoulder pain. Disabil Rehabil 42(9): 1299-1304.

6. Savva C, Mougiaris P, Xadjimichael C, Karagiannis C, Efstathiou M (2018) Test-Retest Reliability of Handgrip Strength as an Outcome Measure in Patients With Symptoms of Shoulder Impingement Syndrome. J Manipulative Physiol Ther 41(3): 252-257.

7. Stasinopoulos D, Stasinopoulos I (2006) Comparison of effects of Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) for the treatment of lateral epicondylitis. Clinical rehab 20(1): 12-23.

8. Kumaran B, Watson T (2019) Treatment using 448kHz capacitive resistive monopolar radiofrequency improves pain and function in patients with osteoarthritis of the knee joint: a randomised controlled trial. Physiotherapy 105(1): 98-107.