Akyol Y, Ulus Y, Durmus D, and et al. Effectiveness of microwave diathermy on pain, functional capacity, muscle strength, quality of life, and depression in patients with subacromial impingement syndrome: a randomized placebo-controlled clinical study. Rheumatology International 2012; 32:3007–3016.

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Design: Randomized clinical trial

Objective: To evaluate the effectiveness of microwave diathermy (MD) in addition to superficial heat and an exercise program on pain, functional capacity, muscle strength, quality of life, and depression compared to placebo MD with superficial heat and an exercise program in the treatment of patients with subacromial impingement syndrome (SIS).

Population /sample size/setting:

- 40 patients (10 males, 30 females) who were experiencing unilateral shoulder pain consistent with subacromial impingement syndrome (SIS) for at least 3 months and examined by the same physician were enrolled in the study.
- Eligibility criteria included shoulder pain aggravated with overhead activity, positive impingement tests (Neer, Hawkins-Kennedy), marked loss of active and passive shoulder motion or painful range of motion, and diagnosis of SIS by magnetic resonance imaging.
- Exclusion criteria included a history of frozen shoulder, disorders of the acromioclavicular joint, degenerative arthritis of the glenohumeral joint, calcific tendinopathy, history of physical therapy treatment within the past 6 months, shoulder instability, post-traumatic disorders, or shoulder surgery and/or elbow, hand, wrist and cervical spine disorders, specific contraindication to MD (such as conditions known to be sensitive to increase cell proliferation rates or skin treated in the past 6 months with radiotherapy, ischemia, local thrombosis or defective arterial circulation).
- All participants were initially examined by the same physician with regards to the selection criteria.

Interventions:

- Forty patients were randomized into one of two groups using concealed envelopes. All 40 patients completed the 3-week program. The treatment group received therapeutic MD (n=20, mean age = 55.4), and the control group received sham MD (n=20, mean age = 51.2).
- Sociodemographic data was collected on all participants at the onset of the study.
- Superficial heat using moist hot packs was applied for 20 minutes before MD or sham MD and exercise. A 30 minute exercise program was given to both groups. The active MD treatment or sham MD, heat, and exercise were performed 5 days a week for a duration of 3 weeks, and a total of 15 sessions as an inpatient for all participants.
- The participants in both groups were treated with the same standardized exercise program composed of 15 minute shoulder active range of motion exercises (Codman’s pendulum, wall-climbing, and shoulder wheel), 5 minutes of stretching, and 10 minutes of strengthening exercise including rotator cuff muscles, rhomboids, levator scapula, and serratus anterior with an elastic band under the supervision of the same physiatrist.

- The Curadar 409 (Enraf–Nonius, The Nederland) was used for active and sham MD treatment. It was equipped with a 2,450 MHz microwaves generator with a maximum output power of 100 Watts. MD was applied for 20 minutes while the subjects were sitting on a chair. For the control group, the MD device was set to the "on" mode, dials were lit, but no energy was delivered to the tissue.
- One physiatrist administered all exercise therapy and MD treatments for all patients and was not blinded to the patient's treatment group.
- Patients were assessed 3 times by the same physician, who was blinded to the patient's treatment group: (1) before treatment, BT; (2) after 3 weeks of treatment, AT; and (3) one month following the last treatment (follow-up, F). Patients were also blinded to their treatment group.

Main outcome measures:

- No dropouts occurred during the trial, and all participants in both groups completed the entire treatment program.
- Outcome variables included 1) pain measured using the visual analog scale (VAS) for pain on activity, at rest and during sleep; 2) function using the Shoulder Pain and Disability Index (SPADI); 3) function using the Shoulder Disability Questionnaire (SDQ); 4) muscle strength using a dynamometer measuring 5 forces; 5) range of motion (ROM) for flexion, extension, abduction, adduction, external and internal rotation; 6) quality of life using the Short Form 36 (SF-36); and depression assessed with Beck depression inventory (BDI).
- There were no statistically significant differences at baseline between the 2 groups with respect to age and gender or other demographic variables, VAS scores, symptom duration, ROM, disability, shoulder function, muscle strength, quality of life, and depression scores.
- After treatment, there were statistically significant improvements from baseline in VAS pain, SPADI, SDQ scores, most BDI and SF-36 scores, shoulder ROM and some muscle strength within both groups. Improvements were seen after treatment and at one month follow-up.
- In comparison between the two groups, there were no statistically significant differences between the groups for VAS pain, SPADI, SDQ, BDI, SF-36 scores, shoulder ROM, and muscle strength in the change scores between before treatment/after treatment and before treatment/follow-up.

Authors' conclusions:

- The results of this study demonstrated no differences between the treatment group (therapeutic MD + superficial heat + exercise) and the control group (sham MD + superficial heat + exercise) on pain, ROM, disability, shoulder muscle strength, quality of life, and depression after 3 weeks of treatment in patients with subacromial impingement syndrome.
- After 3 weeks of exercise, heat, and therapeutic or sham MD treatments, both groups showed similar improvements in outcome measurements of pain, ROM, shoulder function and disability, shoulder muscle strength, quality of life, and depression.

Superficial heat and exercise were effective on outcomes alone and for efficiency may be preferable for the treatment of SIS alone.

- The addition of MD to superficial heat and an exercise program for SIS was not superior to heat and exercise alone.
- Superficial heat and exercise with and without MD improved the patients' muscle strength, quality of life, and depression scores.
- MD treatment was not effective in patients with SIS in this study. The lack of a difference between the 2 groups might be due to a short treatment period, an individual treatment session of too short duration, and a high frequency setting for the device.
- There is no fundamental difference between therapeutic MD and sham MD when they are supplementing an exercise program for rehabilitation of patients with shoulder impingement syndrome.

Comments:

- One limitation of this study was the small sample size.
- It is unclear which of the many outcomes, is the primary outcome measure.
    - Even with multiple outcomes, none resulted in statistically significant differences, which adds further support to the validity of the conclusions of the study.
- One limitation of the study was the lack of any longer-term follow-up after treatment that included outcome assessments beyond the one month follow-up.
- Although the treating physical therapist was blind to the assessments, the treating physical therapist was not blind to group allocation and the nature of this intervention. Therefore, treatment bias, defined as a systematic difference in the application of the intervention, may be possible and may have affected the internal validity of the study. Even if the lack of blinding resulted in treatment bias in this study, no statistically significant differences were found, which further strengthens the conclusions of the study.
- It is unclear how the participants were initially recruited into the study.
- This study was methodologically satisfactory as there were no major threats to the internal validity of the study.
- One of the strengths of this study was that no participants were lost to follow-up and all participants completed the study.
- Both groups showed significant improvements compared to baseline in pain severity, ROM measurements, shoulder function, and disability after treatment. Improvements in both groups may be due to the additional superficial heat application and exercise program.
- The authors did not include any information on sample size calculations. It is unknown if the sample size of this study was adequate to show any statistical differences between the 2 groups. However, with the current sample size, a one standard deviation difference would be detected.
- Most of the ROM improvements seen at post-treatment and the one month follow-up in both groups were statistically significant, but the increases were small and would be considered clinically unimportant. It appears the authors overestimated the statistical importance of the small differences detected and that these differences do not demonstrate a significant clinical improvement. However, exercise intensity and therapy duration may not have been sufficient to increase ROM any further in this study.

- The biological plausibility of MD therapy in the treatment of subacromial impingement syndrome is very weak at best and should be questioned. Is there any real biological mechanism of action for this type of treatment to work?

Assessment*:*

This study is adequate for some evidence that microwave diathermy plus superficial heat and exercise is not more clinically effective than placebo microwave diathermy plus superficial heat and exercise in the reduction of pain and disability, and the improvement of ROM, muscle strength, functional status, quality of life, and depression after 3 weeks of treatment in patients with subacromial impingement syndrome.