Calis HT, Berberoglu N, and Calis M. Are ultrasound, laser and exercise superior to each other in the treatment of subacromial impingement syndrome? A randomized clinical trial. European Journal of Physical Rehabilitation Medicine 2011; 47:375-80.

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Design: Randomized clinical trial

Objective: To compare the effectiveness of therapeutic ultrasound, laser, and exercise in the treatment of patients with subacromial impingement syndrome.

Population /sample size/setting:

- 52 volunteer patients (17 males, 35 females) who were admitted to a research hospital in Turkey with the complaint of shoulder pain and were diagnosed with subacromial impingement syndrome (SIS) were included.
- Eligibility criteria included diagnosis of SIS stage 2 according to Zlatkin's MRI staging, and aged 18-65.
- Exclusion criteria included infections, malignancy, inflammatory rheumatic disease, heart failure, shoulder or neck surgery, calcified tendonitis, bursitis, or cervical radiculopathy.
- All participants answered questions about their demographics and medical history, and underwent a routine physical exam. Shoulder MRI's were taken.

Interventions:

- Fifty-two patients were randomized into one of three groups by opening sealed envelopes containing their written treatment group. The 3 groups were ultrasound (US) (n=21, mean age =50), laser (n=15, mean = 46), and exercise alone (n=16, mean = 50). Fourteen patients were excluded from the study due to incompliance.
- Participants in all 3 groups received their interventions every weekday for 3 weeks (15 sessions). Each session for all patients consisted of moist heat application using hot packs for 20 minutes on the shoulder. All 3 groups received the same exercise program which included passive range of motion exercises and Codman's exercises progressing to stretching and strengthening exercises with the same physiotherapist in the physical therapy unit. Each exercise session consisted of 5 repetitions for 5 seconds for the rotator cuff, biceps brachia, deltoid, and other shoulder muscles.
- In addition to the hot packs and the exercise program, the ultrasound group received ultrasound for 5 minutes daily for each of the 15 sessions.
- In addition to the hot packs and the exercise program, the laser group received laser treatments for 2 minutes daily for each of the 15 sessions using a direct contact technique with a 90 degree straight angle to the shoulder. A Ga As laser device (Model Laserpet 100, Petas Co.) was used at 904 nanometers wavelength, 6 mW average power, 1 J/cm^2 dosage, and 16 Hz frequency for 2 minutes duration.
- The exercise group received the hot packs and the same exercise program.
- A home exercise program was not prescribed for any of the groups.

Main outcome measures:

- Outcome variables included pain at rest, night pain, and pain with movement measured using the visual analog scale (VAS). Functional assessment of the shoulder was measured using the Constant score. Range of motion (ROM) outcome variables included flexion, abduction, and internal and external rotation. All measurements were taken before treatments at baseline, and post-treatment at the end of 3 weeks.
- There was no statistically significant difference between groups with respect to age and gender or other demographic variables.
- There were no statistically significant differences between the 3 groups in any of the mean VAS scores for pain at rest, night pain, or pain with movement either before or after treatment. All 3 pain scores decreased significantly after treatment in all 3 groups.
- Similarly, there were no statistically significant differences between the 3 groups in any of the mean ROM scores for flexion, abduction, and internal and external rotation either before or after treatment. Statistically significant improvements were observed for all 4 measures of ROM after treatment within all 3 groups.
- For shoulder function assessments, there were no statistically significant differences between the 3 groups in the mean Constant scores before and after treatment. All Constant scores showed significant functional improvements after treatment in all 3 groups compared with the baseline scores.

Authors' conclusions:

- A significant improvement compared to pretreatment was achieved in all 3 groups regarding pain, range of motion and shoulder function, but no significant difference between the groups was observed after the treatment.
- Laser and ultrasound as physical therapy treatments could not be found superior to each other in the treatment of subacromial impingement syndrome.
- The presence of an exercise group was the superior part of our study. Exercise is an efficient treatment method for both restoring the shoulder function and pain relief. Exercise may be sufficient for short term treatment of SIS and should form the primary foundation for conservative treatment.
- The major limitation of the study is the lack of a control group that receives no treatment.
- Randomized placebo-controlled trials of larger populations are needed to clarify the long term effectiveness of ultrasound and laser treatments in SIS.

Comments:

- The participants did know which treatment group they were in and were informed of the study protocol.
- It is unclear which outcome is the primary outcome measure.
- A total of 14 eligible participants were excluded from the study due to non-compliance with the study protocol. The authors did not elaborate and reveal what exactly they were non-compliant with. Did they miss too many physical therapy sessions? The authors failed to report if there were any differences in attendance at physical therapy sessions between the 3 groups.

- All patients were instructed on the exercises and therapy by the same physiotherapist. It is not clear if the physiotherapist was blinded to the treatment groups, or performed the ultrasound, laser and hot pack treatments, or if the physiotherapist conducted the outcome assessments on ROM. The authors did not report who conducted the outcome assessments and if they were blinded to the participant's treatment group. Unblinded physiotherapists may have conducted their therapy sessions, instructions for exercise, and assessments differently between the 3 groups.
- The study originally planned for a minimum of 22 subjects in each intervention group. This study included only 21, 15, and 16 in each of the 3 groups. The relatively small number of patients in each group resulted in an underpowered study which was not sensitive enough to detect a difference in Constant scores between intervention groups. For the means of the Constant scores, the group differences between treatment groups was small compared to the large standard deviations of the means of the 3 groups. A real difference in the means between the 3 groups for the Constant scores cannot be excluded. The small sample size would result in great uncertainty in the estimate of the effect.
- Limiting the study protocol to 3 weeks of treatment may have impacted the ability of the study to achieve the maximal therapeutic benefit of ultrasound or laser for many patients and thereby reduced the ability of the study to show an effect for these 2 interventions. This would underestimate the effect of the intervention.

Assessment*:*

- This study is inadequate for evidence to support a conclusion about the effectiveness or ineffectiveness of the interventions, because the study was underpowered (due to a small sample size) to detect any real effects.