RESEARCH PROTOCOL

EFFİCACY OF HİGH-İNTENSİTY LASER THERAPY İN PATİENTS WİTH PARTİAL SUPRASPİNATUS TEARS

PRIVACY NOTICE

1. ABSTRACT

90 patients aged 20-60 years who were diagnosed with partial supraspinatus tear and met the inclusion criteria of the study will be included in the study. Patients will be randomized into three groups: 30 patients in the first group who have 5 sessions of high-intensity laser, 30 patients in the second group who have 10 sessions of high-intensity laser, and 30 patients in the third group control group who have only exercises. It was planned to give 5 sessions of laser+exercise every other day to the the first group, 10 sessions of laser+exercise every other day to the second group, and only exercise program three days in a week to the control group. All groups will be evaluated with joint range of motion (ROM) (measurements including abduction, adduction, flexion, extension, internal and external rotation by goniometer according to neutral 0 position), visual analog scale (VAS), shoulder pain dissability index, quickdash, constant score at 0th month, 1st month, 3rd and 6th months.

2. AIM and PURPOSE

Rotatorcuff lesions constitute 10% of the causes of shoulder pain. Supraspinatus tear is one of the common rotatorcuff lesions (1). It affects the quality of life negatively and causes loss of range of motion and muscle strength (2,3). It can be seen due to traumatic or degenerative causes. Its incidence increases with advanced age. While the incidence was reported as 4% in the population aged 40-60 years, this rate was reported to be 17-50% in the group over the age of 60 and 80% in the group over the age of 80 (3,4). Radiologically, classification is made as partial or full-thickness tears. Rotatorcuff tears can be treated conservatively or surgically (5). Although the risk of post-surgical rupture is reduced with new methods, the lack of desired tendon healing has led to the search for alternative applications such as biological augmentation (6) and high-intensity laser (7). The aim of this study is to reveal the effectiveness of high-intensity laser therapy in patients with partial supraspinatus tear.

PRİMARY PURPOSE

Demonstrating the efficacy of high-intensity laser therapy in patients with partial supraspinatus tears

SECONDARY PURPOSE

Comparison of two different applications of high-intensity laser with 5 sessions and 10 sessions in terms of

effectiveness in patients with partial supraspinatus tear

3. HYPOTHESIS OF THE STUDY

H0: High-intensity laser therapy is ineffective in patients with partial supraspinatus tears.

H1: High-intensity laser therapy is effective in patients with partial supraspinatus tears.

4. SELECTION OF POPULATION & PATIENTS TO BE RESEARCHED

Disease	Partial supraspinatus tear
Number of Patients & Characteristics	**women Man Age 20-65** **Healthy :** **Patient :90** **Total : 90**

Volunteers will be included in the study among the patients who applied to the FTR outpatient clinic and were diagnosed with a partial supraspinatus tear of the shoulder.

Inclusion Criteria:

*age between 20-65 years
*Patients with VAS>4 pain in the shoulder for at least 3 months
*Patients with at least 25% loss in the range of motion of the joint compared to the contralateral side, especially in abduction and external rotation, or on physical examination or positivity of at least one of the impingement tests including jobb, lift off, ERLS , speed, yergeson, O Brien's test, dropparm tests or popeye signs.
*Diagnose of partial supraspinatus with ultrasound or MR -

Exclusion Criteria:

* Patients with incomplete skin integrity, hyperemia, signs of infection or tattoos

*Patients with suspected full-thickness tear

*History of rheumatic disease (rheumatoidarthritis, osteoarthritis, PMR)

*Patients with accompanying shoulder pathology such as calcifictendinitis

*History of malignancy

*Surgery, manipulation, mobilization, arthroscopy performed on the affected shoulder

*Steroid, local anesthetic, hyaluronic acid injection, cnesiotaping or neural therapy in the affected shoulder in the last 3 months

*Reflex sympathetic dystrophy, neurodeficit in the affected extremity

*Diabetes patients or any Patients who cannot feel the burning pain due to a peripheral neuropathy or sensory defect

*Patients with epilepsy

Exclusion Criteria and Practices in this Case

Patients will be excluded from the study if they do not attend follow-up and laser sessions regularly.

5. STUDY DESIGN & METHOD

STUDY DESIGN

90 patients aged 20-60 years who were diagnosed with partial supraspinatus tear and met the inclusion criteria of the study will be included in the study. Patients will be randomized into three groups: 30 patients in the first group who have 5 sessions of high-intensity laser, 30 patients in the second group who have 10 sessions of high-intensity laser, and 30 patients in the third group control group who have only exercises. It was planned to give 5 sessions of laser+exercise every other day to the the first group, 10 sessions of laser+exercise every other day to the second group, and only exercise program three days in a week to the control group. All groups will be evaluated with joint range of motion (ROM) (measurements including abduction, adduction, flexion, extension, internal and external rotation by goniometer according to neutral 0 position), visual analog scale (VAS), shoulder pain dissability index, quickdash, constant score at 0th month, 1st month, 3rd and 6th months.

DETAİLS of METHOD

Patients in the laser group will be given hiltherapy (high-intensity laser) with the HIRO 3 device every other day. One session of laser therapy application consists of 3 phases: the beginning, the middle and the ending phase. The initial phases are fast scanning and the ending phase is slow scanning. A total of 2000 J will be applied to the rotatorcuff muscles, the upper part of the trapezius muscle, the deltoid muscle and the pectoralis major muscle, 1000 J in the rapid scan phase and 1000 J in the finishing phase. In the middle phase, 50 J will be applied for the trigger point (hard intramuscular points that cause referred pain) in each muscle and a maximum of 500 J in total. The total dose prescribed for patients in one session will be 2500 J. Each phase will be 15 minutes on average and the session will last for 45 minutes in total. The laser probe will be applied with 90 degrees. During the application, the practitioner and the patient will have protective glasses.

Patients in the laser group will be given hiltherapy (high-intensity laser) with the HIRO 3 device every other day. One session of laser therapy application consists of 3 phases: the beginning, the middle and the ending phase. The initial phases are fast scanning and the ending phase is slow scanning. A total of 2000 J will be applied to the rotatorcuff muscles, the upper part of the trapezius muscle, the deltoid muscle and the pectoralis major muscle, 1000 J in the rapid scan phase and 1000 J in the finishing phase. In the middle phase, 50 J will be applied for the trigger point (hard intramuscular points that cause referred pain) in each muscle and a maximum of 500 J in total. The total dose prescribed for patients in one session will be 2500 J. Each phase will be 15 minutes on average and the session will last for 45 minutes in total. The laser probe will be applied with 90 degrees. During the application, the practitioner and the patient will have protective glasses.

30 patients will be included to control group. They will take only exercise program three times in a week.

Description of Transactions on Working Days & Visits

Patients diagnosed with partial supraspinatus tear on working days will be evaluated in the ftr outpatient clinic and suitable patients will be included in the study. Demographic information of the patients will be recorded. Consent will be obtained from the patients on the same day. Patients randomized to 3 groups will be included in the treatment protocol prescribed for each group at 0, 1, 3 and 6 month will be evaluated with VAS, shoulder

pain dissability index, quickdash, constant score and range of motion including abduction, adduction, flexion, extension, internal and external rotation by goniometer according to the neutral position.

Randomization

After the subjects included in the study are informed about the study, they will be randomized into 3 groups according to their order of application.

Blindness

None

Ensuring Patient Compliance

Detailed information about the purpose of the study and its scientific contribution will be given to the patients and their relatives. Patients and their relatives will be informed that their names will be kept confidential. Parts that cannot be understood in the informed consent form will be explained in more detail. They will be informed that the study has the right to withdraw from the study at any time.

Materials to be Used & Storage Conditions & Responsibilities

Thera band will be used for the exercises.

6. COLLECTION OF STUDY DATA

Data Recording/ Case Report Forms

A Case Report Form will be completed for each registered patient and signed by the responsible investigator or an authorized representative of the study staff. This also applies to enrollments for patients who did not complete the study (even during pre-randomisation screening, if a case report form was prepared). If a patient withdraws from the study, the reason for this will be recorded on the Case report form. If a patient is withdrawn from the study due to a treatment-limiting adverse event, every effort will be made to clearly document the outcome. All forms must be typewritten or filled with indelible ink and be legible. Errors can be crossed out, but errors cannot be erased; correction is entered and the change is initialed and dated by the researcher or his authorized representative. The investigator will ensure that the data reported to the sponsor in case report forms and all required reports are correct, complete, legible and processed in a timely manner. The researcher is responsible for the accuracy of the data transferred on the forms and will sign these forms to show their compatibility with the recorded data.

7. SURGICAL PROCEDURES

None

8. PRECAUTIONS & WARNINGS FOR ENSURING PATIENT SAFETY

In the physical therapy unit, there will be an emergency kit and healthcare personnel ready for intervention in terms of possible complications (hypotension, emergency cardiological conditions, skin reactions, burns, etc.) that may develop during treatment. During the application, the practitioner and the patient will have protective

glasses.

9. CONDITIONS TO STOP THE STUDY

There is an unresolved malfunction in the device in the protocol

10. STATISTICAL PROCEDURES

Sample Size

Sample size calculation was made using G*POWER 3.1.9 program. Using the findings of a similar study conducted before (6), it was predicted that a high level of effect size would be obtained between the groups (f=0.40) for the SPADI score of 22±1.2 for the 6th month before and after the treatment and 41.4±2.6 for the control group (f=0.40), 90% power, and type 1 error level: 5%, it is aimed to reach at least 84 people in total, and at least 90 people considering that there may be losses in the follow-up.

Statistical & Analytical Methods

The data will be analyzed with the SPSS 18.0 package program. GraphPad for Windows will be used in the randomization process. Continuous variables will be presented as mean and standard deviation or median (25p-75p). Categorical variables will be presented as percentages. The conformity of the data to the normal distribution will be evaluated with the Shapiro Wilk test. Analysis of variance (ANOVA) and split-mixed ANOVA will be used in the analysis of within-group changes and in repeated measures of significance between the differences between groups. Tukey and Games Howell tests will be used in post-hoc tests.

11. ETHICAL & LEGAL REQUIREMENTS & QUALITY ASSURANCE

Informing Patients and Informed Consent

Consent will be obtained from patients acording to Helsınkı declaratıon.

Ensuring Confidentiality

The investigator will ensure that the names of the patients are kept confidential and that the identities of the individuals are protected from unauthorized parties, that the patients will be identified only by the initials of the name-surname and randomization number on the Case Report Form; It will be explained that any document that identifies the patient will be kept in complete confidentiality by the principal investigator, and that the investigator may authorize appropriate legal authority(s) to review patients' files in line with Good Clinical Practices and legal requirements.

Protocol Changes and Approval of Changes

All protocol adjustments will not be made without the approval of the local ethics committee for any regulation that may affect the safety of patients or the conduct of the study, prior to the implementation of any changes to the protocol.

Records Retention and Quality Assurance Measures

The records will be saved on our encrypted computer and the patient's privacy will be protected by deleting the data after it is used for scientific purposes.

Financial and Criminal Liability

It will be stated that the expenses of non-routine procedures and in cases where the patient is harmed within the scope of the trial, the costs will be covered by the sponsor, and in case of going out of the protocol of the study,

the financial and penal responsibility belongs to the responsible investigator.

-

13. REFERENCES

1. Meislin RJ, Sperling JW, Stitik TP. PersistentShoulderPain: epidemiology,pathophysiologyanddiagnosis. Am J Orthop, 2005;34(12):5-9.
2. Bayram K.B, Bal S, Satoglu I.S, Kocyigit H, Gurgan A, Akcay S, Kazimoglu C. DoesSuprascapularNerveBlockImproveShoulderDisability in ImpingementSyndrome? A RandomizedPlacebo-ContolledStudy.Journal of Musculoskeletal Pain,2014;22(2): 170–174.
3. Boilaeu P, Brassart N, Watkinson DJ et al. Arthroscopicrepair of full-ticknesstears of thesupraspinatus: doesthetendonrealyheal? J Bone JointSurg Am. 2005;87:1229-1240.
4. Alexander WA, Robert HB. Outcomes of rotatorcuffsurgery.Clinical Sports Medicine. 2012;31: 665-674.
5. Taiceer A. Abdul-Wahab, Jean P. Betancourt, Fadi Hassan, Saeed Al. Thani, HenedChoueiri, Nitin B. Jain, Gerard A. Malanga, Wiliam D. Murrell, AnilPrasad, OliverVerborgt.Initialtreatment of completerotatorcufftearandtransitiontosurgicaltreatment: systematicreview of theevidence. Muscles, LigamentsandTendonsJournal, 2016;6(1):35-47.
6. Elsodany AM, Alayat MSM, Ali MME, Khaprani HM. Long-Term Effect of Pulsed Nd: YAG Laser in theTreatment of Patients with Rotator Cuff Tendinopathy: A RandomizedControlled Trial. PhotomedLaserSurg. 2018 Sep;36(9):506-513.
7. Sturla H, Liv Heide M, Jon J et al. The Efficacy of Low‐Level Laser Therapy for Shoulder Tendinopathy: A Systematic Review and Meta‐Analysis of Randomized Controlled Trials.Physiother Res Int. 2015 June; 20 (2): 108-25.

Date/ Sıgnature
02.12.2020
RESPONSIBLE RESEARCHER