High Intensity Laser Therapy (HILT) versus Extracorporeal Shockwave Therapy (ESWT) in the treatment of noncalcifying tendinopathies of the rotator cuff: a retrospective study.

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ABSTRACT

Instrumental physical therapies are extensively used in clinical practice to manage tendinopathies. However, there is still a lack of scientific evidence to support their efficacy.

This retrospective study evaluated the short- and long-term effectiveness of High Intensity Laser Therapy (HILT) and Extracorporeal Shockwave Therapy (ESWT) in treating non-calcific rotator cuff tendinopathy.

The study included twenty patients divided into two groups. Group A (n=10) treated daily with HILT for one week, whereas Group B (n=10) received ESWT once a week for four weeks. The principal outcome of the study was the degree of pain reduction using the numeric rating scale (NRS). Moreover, mobility, shoulder strength, and functional improvement were assessed via the Constant-Murley questionnaire and the Disability of the Arm, Shoulder and Hand (DASH) questionnaire.

The results of the study indicated noteworthy improvements in the Constant-Murley scale scores, DASH questionnaire and NRS scores after both HILT and ESWT treatment. However, the outcomes of HILT laser therapy were found significant at first follow-up and the effects remained almost consistent over the three-month follow-up period. On the other hand, ESWT resulted in more gradual clinical improvement over time, with significant outcomes visible at three months.

In conclusion, HILT and ESWT have been demonstrated to be effective therapies for patients with non-calcific rotator cuff tendinopathy. However, HILT laser therapy resulted in more rapid clinical improvement.

INTRODUCTION

Shoulder pain is the third most common cause of musculoskeletal disorder resulting in pain and functional limitation of the upper limb (1). Among the various causes, the rotator cuff tendinopathy is the most common (65%) and the incidence ranges from 5% to 40% (2). This wide range is due to the initial asymptomatic phase in which the structural alterations of the tendon matrix are clinically silent (3-5). Cuff tendinopathy predominantly affects people over 50 years of age, although it is also frequent in overhead athletes, such as volleyball, water polo, basketball, baseball, tennis (6-7), and workers who overload the shoulders with repetitive movements (8), maintaining incorrect postures for prolonged periods or subjected to vibrations (9-11). The most affected structure is the tendon of the supraspinatus muscle (80%), followed by infraspinatus (15%) and subscapularis (5%). The etiology of rotator cuff tendinopathy is multifactorial, and the responsible factors can be either intrinsic or extrinsic (12-13). Intrinsic factors include age, gender, biomechanical abnormalities, joint laxity, reduced muscle strength and elasticity, metabolic diseases (obesity, diabetes, hyperlipidemia), cardiovascular diseases, and rheumatic diseases; the extrinsic factors include the intake of tenotoxic drugs such as ciprofloxacin, steroids, statins, and oral contraceptives. Histologically, rotator cuff tendinopathy is characterized by the appearance of a degeneration of collagen fibers, reduction of the content of Type I collagen with increase of the content of Type III (reparative), considerable variability in cell density, increased extra-cellular matrix without clear signs of inflammation (14). Clinically it manifests with increasing pain in the anterior and lateral region of the shoulder and functional limitation (loss of strength and movement); in severe cases, the execution of normal activities of daily living is compromised (15). Treatment is essentially conservative and involves rest/ modification of activities (how to avoid performing overhead movements), non-steroidal anti-inflammatory drugs, personalized rehabilitation plan, injections, and the use of physical therapies. The surgical referral is indicated only after six months of conservative treatment or in cases in which shoulder function worsens during appropriate nonsurgical treatment.

Instrumental physical therapies are widely exploited in clinical practice for the management of tendinopathies; however, the scientific evidence in support of many of these treatments are often lacking. In this context, both Laser therapy and shock wave therapy have been shown to be a successful therapy in reducing the pain and improve joint function in patients with rotator cuff tendinopathy (16-21). In details, Laser therapy acts through various biological effects such as the photo-thermal effect, the photo-mechanical effect, and the photochemical effect. It is therefore able to reduce pain, inflammation, and edema, allowing for an earlier onset of tissue healing and earlier initiation of rehabilitation treatment. In particular, studies on the effect of low-level laser therapy – (LLLT) (16,17) or High intensity laser therapy - (HILT) (18-20) in patients with non-calcific tendinopathy of the rotator cuff, have demonstrated good efficacy and safety. Three randomized controlled trials of the effect of high-power laser therapy were conducted in noncalcifying tendinopathy of the rotator cuff. Elsodany et al. have shown that Nd:YAG laser therapy associated with therapeutic exercise is more long-term efficacy (3-month and 6-month follow-up) compared to therapeutic exercise alone in decreasing pain and in improving ROM and shoulder function in a sample of 60 patients affected by non-calcifying tendinopathy of the rotator cuff (18). Santamato et al. and Pekyavas et al. have instead demonstrated the greater effectiveness of HILT in the short term compared to other classic treatments of non-calcific tendinopathy of the rotator cuff (ultrasound therapy, kinesio-taping and exercise therapeutic) in reducing pain and in improving joint function and muscle strength (19, 20).

Moreover, extracorporeal shock wave therapy (ESWT) has been advanced as a possible alternative treatment in those patients with no results with traditional conservative management (22). It is believed that shockwave therapy alleviates pain due to insertional tendinopathy by the induction of neovascularization and improvement of blood supply to the tissue and initiating repairs of the chronically inflamed tissues by tissue regeneration. A shock wave is a non-linear type of 15-20 MHz frequency pressure wave with an around 10 μs rise time. These soundwaves define a positive and negative phase, producing at the tissue interface, the cavitation effect, namely the formation of bubbles and their subsequent implosion with the genesis of a second wave (23). The propagation wave, through direct mechanical perturbation polarizing membrane cells, increases the density of the tissue and, therefore radical production, cell proliferation and growth factors formation (24). It is an economic and noninvasive physical therapy with good clinical effects and had been proved to be beneficial in calcific tendinosis; however, the treatment efficacy in not calcific tendinosis of rotator cuff remains controversial (25). Thus, the aim of the study was to evaluate the short- and long-term efficacy of HILT and ESWT in the treatment of tendinopathy of the rotators cuff.

MATERIALS AND METHODS

The study has been conducted in 2019 at the U.O.C. "Orthopedic Rehabilitation" of the Padua Hospital.

Population

We included patients, aged between 18 and 80 years, with clinical and instrumental diagnosis (Ultrasounds or MRI) of non-calcific tendinopathy of the rotator cuff. Inclusion criteria: shoulder pain during overhead movements; symptoms for at least 3 months not responsive to NSAIDs and/or physiotherapy; pain on the insertion of the rotator cuff tendons and positivity to clinical tests for rotator cuff disease; reduced shoulder range of motion (ROM). Exclusion criteria: complete or partial rupture > 50% of the tendons of the rotator cuff diagnosed by ultrasound or MRI; presence of tendon calcifications on ultrasound evaluation; pregnancy or breastfeeding; cancer; acute rheumatic diseases; coagulation disorders; significant shoulder trauma in the last 6 months.

Study Design

A retrospective analysis evaluated patients treated with (HILT) Group A and (ESWT) Group B. Group A received a cycle of 4 laser sessions each day for a week; while the patients in the Group B received 4 ESWT sessions, once a week for 4 weeks. Each HILT session lasted approximately 15 minutes divided into an initial phase, an intermediate phase, and a final phase. The initial and final phases (fluence 810-1320 mJ/cm^2-frequency of 30-40 Hz-total energy of 3000 J) were performed with a slow scanning mode (speed of about 10 cm every 2 seconds) using a standard handpiece with spacer, along the course of the rotator cuff, upper trapezius, deltoid, and pectoral muscles. In the intermediate phase (fluences 360-610 mJ/cm², frequency 15-17 Hz) the painful points (trigger and tender points) were treated with a fixed handpiece equipped with a spacer, perpendicular to the painful point for a duration of about 5-7 seconds. Both the operator and the patient wore specific laser light protection goggles. HILT was delivered using the Hiro 3 device, a Nd:YAG laser with a wavelength of 1064 nm and a pulsed emission that is part of the Hilterpia® (ASA S.r.l.)

ESWT sessions had an average duration of 15 minutes during which 1600 strokes were delivered at a frequency of 4 Hz. The energy applied was adjusted based on the patient's tolerance, however reaching a maximum level not exceeding 0.15 mJ /mm². The shock wave generator was MODULITH® SLK, (StorzMedical, MODULITH® SLK). After applying a transparent and odorless gel to the skin surface of interest, which facilitates the propagation of the waves to the biological tissues, the therapeutic head was positioned using ultrasound guidance to focus the shock wave beam precisely on the target area.

Clinical Outcomes

The principal outcome was the pain reduction through the numeric rating scale (NRS); moreover, we analyzed the Constant-Murley questionnaire and the Disability of the Arm, Shoulder, and Hand (DASH) questionnaire to evaluate mobility, shoulder strength and functional improvement.

The Constant-Murley evaluate the assessment of pain, strength, and joint function of the upper limb. This scale is constituted by four parameters: two subjective (pain and daily activities) and two objectives (active mobility and strength). The degree of pain reported by the patient is evaluated on a scale from 0 to 15; the ability to perform normal activities of daily living on a scale from 0 to 20; the articular excursion evaluates intra- and extra- rotation, anterior elevation, and abduction with a score ranging from 0 to 10, for a total of up to 40 points; finally, the strength of the shoulder is measured on a scale from 0 to 25. The measurement of strength consists in asking the patient to keep the arm in 90° abduction for 5 seconds with a weight ranging from 0.5 kg to 12.5 Kg. Every 0.5 kg corresponds to a point on the scale. The total score ranges from 0 to 100 and is given by the sum of the scores of the individual parameters. A higher score indicates a better patient functionality.

DASH investigates the difficulties that the patient encounters in carrying out the activities of daily living (ADL). It is questionnaire made of 30 questions each of which is assigned a score from 1 to 5. A higher score indicates a higher is the disability/ difficulty during daily activity.

For both groups, were evaluated the data collected at baseline visit before treatment (T0), at the end of treatment cycle (T1), and at 3 months follow-up visit (T2).

Statistical Analysis

The data were entered in an EXCEL sheet and analyzed with the SAS 9.4 program (AS Institute Inc., Cary, NC, USA) for Windows. The quantitative variables were analyzed descriptively reporting as mean and standard deviation, while for the qualitative variables the number and percentage of subjects in each category were reported. The verification of the normality of the quantitative variables was carried out with the Shapiro-Wilk test. The comparison between groups was carried out with the Wilcoxon test of the sum of the ranks in the case of quantitative variables with non-normal distribution (age), with the analysis of variance for repeated measures in the case of the evaluation scales used, with the exact test Fisher's in the case of qualitative variables. The result of the analysis of variance was expressed with the value of the statistical significance p for the effects of treatment group, time and for the interaction group-time.

The withing group and between group comparison at each time was carried out with the Student's t test and the result is expressed with the value of the statistical significance p, the estimate of the difference between the means and the relative confidence interval at 95%. The level of statistical significance was set at 5%.

RESULTS

Twenty patients have been included in the study, aged between 47 and 69 years (average age 57.95 years). Group A (n=10, mean age 58.2 years old, F:M ratio =7:3); Group B (n=10, mean age 57.7 years old, F:M ratio = 8:2). No statistical difference was encountered between the two groups for the distribution of the gender variable (Fisher exact test $p = 1.000$) and for the distribution of the age variable (Wilcoxon rank sum test $p=0.9093$).

Both groups had a significant improvement in the Constant-Murley scale score. Patients in the HILT group showed an increase of 15.0 points at T1 ($p < 0.0001$) and 15.8 points at T2 ($p = 0.0002$). Patients in the ESWT group showed an increase of 9.2 points at T1 (p = 0.0045) and 18.1 points at T2 (p < 0.0001). (See Figure 1)

DASH questionnaire decreased significantly (p < 0.001) in both group at the end of the treatment cycle and at the three-month follow-up compared to T0. Patients in the HILT group presented a decrease of 14.7 points at T1 (p < 0.0001) and of 15.1 points at T2 (p < 0.0001). Patients in the ESWT group presented a decrease of 10.3 points at T1 (p < 0.0008) and of 16.9 points at T2 (p < 0.0001). (See Figure 2)

NRS score decreased in both groups at the end of the cycle and at the three-month follow-up compared to T0. Patients in the HILT group showed a decrease in pain of 2.0 points at T1 (p < 0.0001) and of 1.5 points at T2 (p < 0.0002). Patients in the ESWT group showed a decrease of 0.3 points at T1 (p = 0.2624) and of 1.6 points at T2 (p = 0.0001). (See Figure 3)The between group difference in Constant-Murley and the DASH scores was not significant both T1 and T2. At T1, group A showed a higher decrease in NRS compared to group B.

All the evaluations registered during the study have been reported in the following table.

DISCUSSION

Rotator cuff tendinopathy is among the most common causes of painful shoulder and its prevalence is 2.8%-3% in the general population (26). Age of over 50 years and female gender represent relevant risk factors. In line with those expectations, the study population analyzed presented a mean age of 57.95 years (57.7 years in the ESWT group and 58.2 years in the HILT group, p = NS) and a prevalence of women 3 times higher than men (15 women and 5 men). The treatment of rotator cuff tendinopathy is mainly conservative; however, to date, the most effective approach has not yet been defined. Physical therapies in combination with exercise have shown important synergistic effects. Among the most recent technologies, HILT (18) and ESWT (27) have shown interesting results in the treatment of rotator cuff tendinopathy. ESWT stimulate tissue healing through upregulation of inflammatory cytokine receptors and afferent pain receptors, promote cell proliferation, neo-angiogenesis, and extracellular matrix synthesis (28). Their efficacy in the treatment of musculoskeletal problems is proven (29-30).

The HILT laser utilized have a primarily photomechanical action, resulting in cytoskeleton remodeling and changes in the concentrations of cytoskeleton proteins such tubulin, vimentin, and actin (31-32). This laser also appears to increase

	ESWT (N°=10)	HILT (N°=10)		
	Mean (SE)		MD	p-value
Constant-Murley				
T0	51.3 (6,9037)	49.1 (6,9037)	2,2	NS
T1	60,5 (5,3393)	64,1 (5,3393)	-3,6	NS
T2	69,4 (4,7418)	64,9 (4,7418)	4,5	NS
	P≤ 0,001	**P≤ 0,001**		
DASH				
T0	87,2 (4,7011)	89,4 (4,7011)	-2,2	NS
T1	76,9 (4,6410)	74,7 (4,6410)	2,2	NS
T2	70,3 (4,4995)	74,3 (4,4995)	-4	NS
	P≤ 0,001	**P≤ 0,001**		
NRS				
T0	6,7 (0,3342)	7,0 (0,3342)	-0,3	NS
T1	6,4 (0,3367)	5,0 (0,3367)	1,4	**0,0087**
T2	5,1 (0,2728)	5,5 (0,2728)	-0,4	NS
	P≤ 0,001	**P≤ 0,001**		

SE = standard Eror; **MD** = mean different.

the formation of important extracellular matrix components such as collagen, fibronectin, and aggrecans (32), fibronectin fibril rearrangement (33), and cell differentiation (34). These effects lead to changes in cell-matrix interactions and this influences important cellular processes such as: spreading, adhesion, motility. Hilterapia® is used for the treatment of numerous musculoskeletal disorders (35-36-37); due to its important anti-inflammatory, anti-edema, antalgic, and biostimulating effects (38), it has proven to be a successful therapy in reducing pain and improving joint function in patients with rotator cuff tendinopathy, both in the short and long term (18, 19, 20).

The results of our study showed a functional improvement, assessed by clinical scales, of both groups. In particular, there was a statistically significant higher score in the Constant-Murley scale, and a reduction of the pain during the activity of daily living. Moreover, both groups reported a reduction of the DASH score, and an improvement of the upper limb function. Furthermore, we found a statistical improvement of the shoulder pain, assessed by NRS scale. In details, both groups, treated with HILT and ESWT showed a reduction of the pain at the end of the treatment and at the three months follow-up. Interestingly, we found a between group difference at the end of the therapy, with a higher improvement of the shoulder pain in patients treated with HILT.

However, this difference is no longer detected at three months, with ESWT also showing a significant improvement.

Regarding the HILT therapy, our findings are consistent with those of Elsodany and colleagues, who evaluated the short- and long-term therapeutic effects of HILT laser therapy treatment on 60 patients with rotator cuff tendinopathy.

Their results demonstrated an important effect of HILT laser treatment on pain reduction in conjunction with a physiotherapy compared with physiotherapy only (18). Regarding ESWT our results confirm the conclusions of Galasso et al. that showed, in a study of 20 patients with non-calcific tendinopathy of the supraspinatus, the higher effect of ESWT therapy compared to placebo, in reducing pain symptoms and improving joint function (39). We are aware that our study is not free of limitations. In particular, the number of patients could affect the generalizability of the results and further studies are requested to confirm our results.

CONCLUSION

In both the short and long term, HILT and ESWT have been demonstrated to be effective therapies for patients with non-calcific rotator cuff tendinopathy. However, HILT laser therapy resulted in more rapid clinical improvement at the end of the cycle, and that these effects were almost constant at the three-month follow-up, whereas ESWT resulted in more gradual clinical improvement over time, with significant results at three months.

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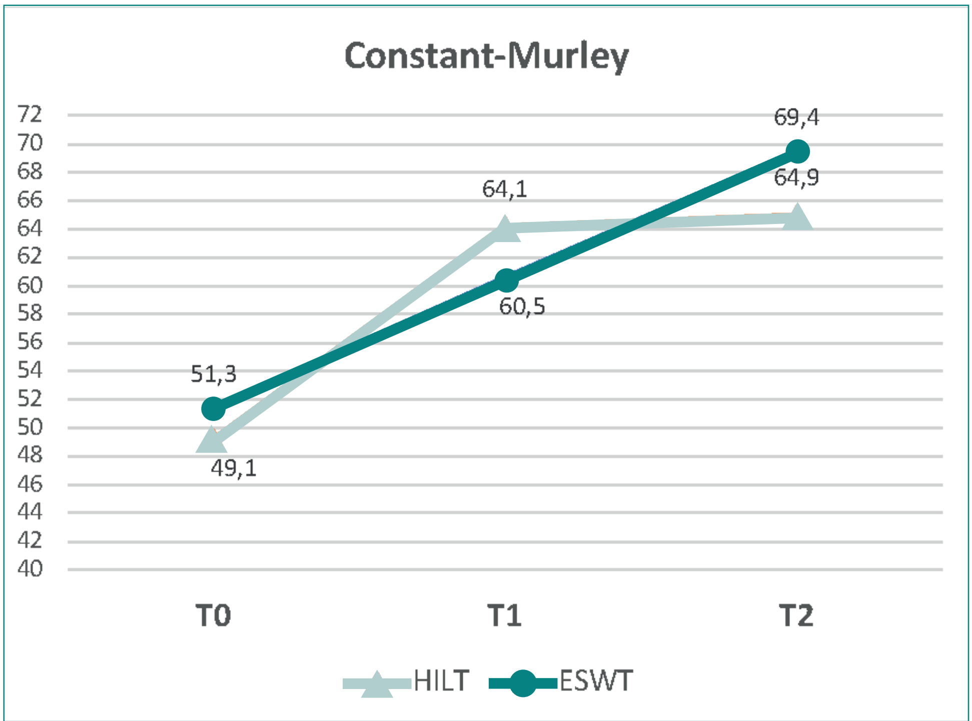

Figure 1
Representation of Constant-Murley scale scores over time for the two groups: HILT and ESWT.

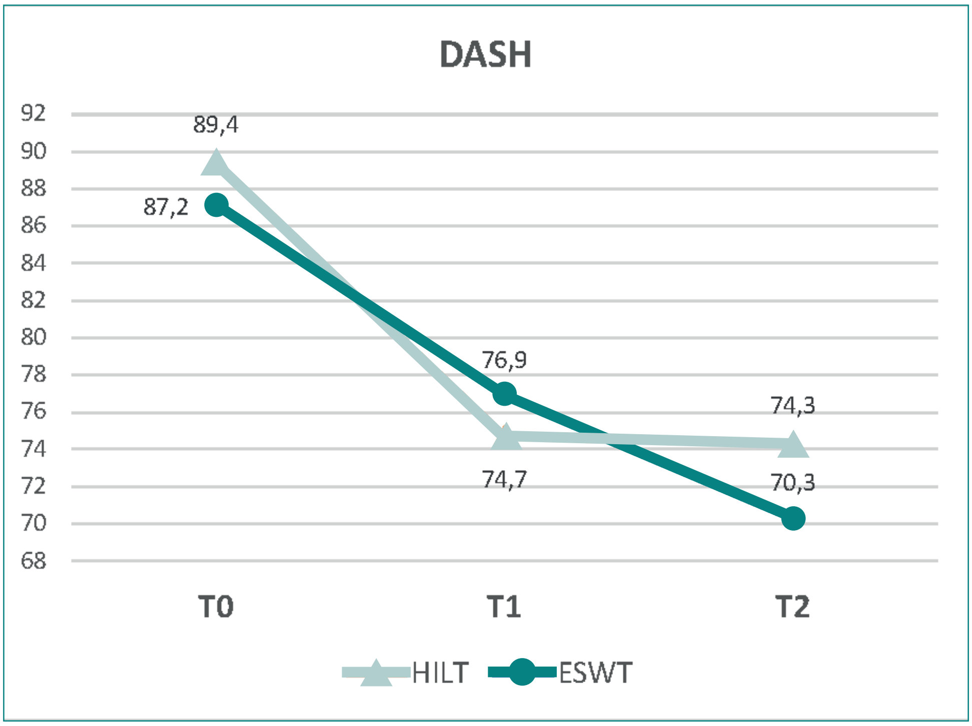

Figure 2
Representation of the DASH scores over time for the two groups: HILT and ESWT.

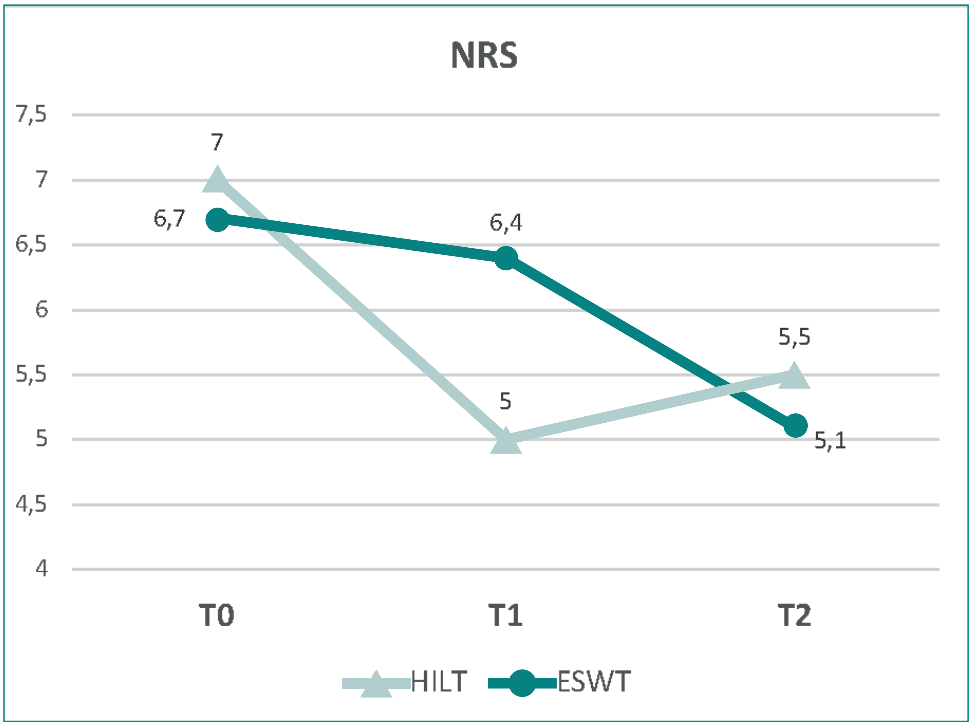

Figure 3
Representation of the NRS scores over time for the two groups: HILT and ESWT.