Pharmacophore

ISSN-2229-5402

Journal home page: http://www.pharmacophorejournal.com

HIGH-INTENSITY LASER THERAPY VERSUS SHOCK WAVE THERAPY IN THE MANAGEMENT OF DIABETIC FROZEN SHOULDER

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ARTICLE INFO

Received:
09 January 2024
Received in revised form:
19 April 2024
Accepted:
21 April 2024
Available online:
28 April 2024

Keywords: Diabetic frozen shoulder, Pain, Extracorporeal shockwave therapy, Laser therapy

ABSTRACT

This study aimed to compare the effects of high-intensity laser therapy (HILT) versus shock wave therapy (SWT) on the respective pain levels, shoulder range of motion (ROM), and function in patients with diabetic frozen shoulder (DFS). 84 patients (age range 40-60) were randomly assigned into two groups; shock wave group (G1; n=41) and HILT group (G2; n=43). Shoulder function was assessed by American Shoulder and Elbow Surgeons (ASES) score, shoulder pain was evaluated by visual Analog scale (VAS), and shoulder flexion ROM by a goniometer. The G1 participants received 1 session/week (8 weeks) of shock wave (at 5 Hz, and 1.5 bar). Participants in G2 received 2 sessions/week (8 weeks) of HILT total energy 1,080 J in three phases. Additionally; both groups received an exercise program. There were non-significant pre-study differences between groups in all measured variables. Post-study; within group's comparisons revealed significant decreases in pain within group-1 by 49.38% (P=0.00) and within group-2 by 60.09% (P=0.00), significant increases in shoulder flexion ROM within group-1 by 25.74% (P=0.00), and within group-2 by 19.29% (P=0.00), and significant increases in shoulder function within group-1 by 96.66% (P=0.00), and within group-2 by 104.58% (P=0.00). The post-study results revealed significant differences in pain (VAS) (P= 0.0001) in favor of group 2, shoulder flexion range of motion (P= 0.04) in favor of group 1, but non-significant difference in shoulder function (P= 0.19). Shock wave therapy showed a better effect in increasing the ROM, while HILT was more effective in reducing pain and improving shoulder function.

To Cite This Article: Salem MMI, Abdelaal AAM, El-Fiky AAR, Ebid AA, Battecha KH, Thabet AAEM, et al. High-Intensity Laser Therapy Versus Shock Wave Therapy in the Management of Diabetic Frozen Shoulder. Pharmacophore. 2024;15(2):113-8. https://doi.org/10.51847/twO5acnaXy

Introduction

Frozen shoulder (FS) or alternatively; Adhesive capsulitis (AC) is an inflammatory orthopedic disorder, manifested by pain, stiffness, and reduced active and passive joint ranges, the overall mean prevalence of AC in diabetes mellitus (DM) reached 13.4%. In addition, the affection risk to develop the AC is 5 times higher in diabetic subjects compared to the non-diabetic controls [1], with the patients, aged 40-65 being the most commonly affected [2]. The AC negatively impacts function, and quality of life (QOL), and results in progressive painful restriction in range of movement (ROM) [1].

The AC is a well-known, frequently encountered orthopedic disorder, yet the etiology remains uncertain. Patients with AC present a characteristic natural course of recovery, physical examination, and history. Several interventions have been investigated examining long and short-term outcomes [3]. Without intervention, the AC hinders patients' activities of daily living (ADL), reduces QOL, and the shoulder movement restrictions range from partial degrees to complete limitations [1]. Management of the AC includes non-operative or operative procedures, though the best intervention option remains controversial [4].

Varieties of conservative treatment options are available for the diabetic FS including therapeutic ultrasound, manual therapy, taping techniques, and heat application. Extracorporeal shockwave therapy (ESWT) appears to be an alternative promising

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modality, with its great beneficial effects on several musculoskeletal disorders including Achilles tendinitis [5], plantar fasciitis [6], patella tendinitis [7], and elbow epicondylitis [8].
Quiet recently, HILT was introduced in the field of Physical Therapy. With a specific wavelength (1064 nm) and a high-power laser (3 kW), HILT can effectively treat and stimulate larger areas to reach deeper into the tissues than other types of lasers [9]. Research using, HILT reported its beneficial effects in the management of several musculoskeletal disorders, with proven efficacy in decreasing pain [9, 10]. The HILT proved efficacy in alleviating frozen shoulder-associated pain on a short-term basis [11], also studies found that the combination of HILT with exercises effectively increased functional activity, ROM, and reduced pain after 6 weeks of treatment [12, 13] and 4 weeks after treatment as a follow up [13], HILT showed a better therapeutic effect in long-term follow-up [14]. Despite a limited number of publications about using HILT in the treatment of shoulder disorders, HILT is a preferable Physical Therapy modality because of its high efficacy [11, 15, 16].
Although ESWT is widely used in the treatment of many musculoskeletal disorders, its application in FS is still limited [17] and comparisons of its effect with other therapeutic modalities are not yet established. Therefore, this study aimed to compare and examine the effects of SWT and HLLT on diabetic FS.

Materials and Methods

Study Design
Randomized, single-blinded, clinical trial study.

Sample Size Calculation
Using the G-Power program for Windows, G Power Win_ 3.1.9.4, a suitable sample size was determined, considering the two-group allocation, 2 measurements (pre-and post-study), precision value of 0.05, power of 0.95, and effect size value (Cohen's f) of 0.41, determined a sample size of 80 participants in this study.

Subjects
Patients established with type 2 diabetes mellitus (T2DM) for ≥ 5 years duration, and diabetic FS were invited to participate in this study to recruit a suitable sample for this study. Initially; 92 patients from Makkah hospitals were screened; 8 patients were excluded and 84 volunteer patients with T2DM and diabetic FS were enrolled in this study **(Figure 1)**.
Patients younger than 40 or older than 60 years, smokers, with a history of serious severe musculoskeletal problems, cerebrovascular or cardiovascular diseases, previous treatment by Physical Therapy modalities, carcinoma patients, severe cardiac or psychiatric conditions, patients with pacemaker or other serious conditions that may affect treatment application or accuracy of the study results were all excluded from the study
All patients fulfilled the inclusion criteria and had no exclusion criteria, and signed an informed consent form giving agreement for participation and publication of the results of the study. This study protocol was approved and reviewed by the Umm Al-Qura ethical committee, Umm Al-Qura University (TZHT07123).
Before the start of the study, participants were completely informed about the aims of the study. They were asked to continue their regular diet, pharmacological regimen, and lifestyle throughout the study. After medical counseling, the 84 participants were randomly allocated through computer-generated random numbers into either the shock wave therapy group (G1; SWT; n=41) or High-Intensity Laser Therapy (G2; HILT; n=43).

Outcome Measures
All subjects underwent an identical battery of tests. The principal evaluated parameters were:

- *Shoulder Function (Using the American Shoulder and Elbow Surgeons (ASES) Score)*

The ASES has adopted a standardized form for examination of the shoulder functions [18]. The evidence supported the use of the ASES to discriminate among groups' or patients' evaluations at one point in time [19]. The ASES score measures functional limitations and pain in the shoulder. It consists of 100 points. The patient can complete the self-evaluation part of the questionnaire and the physician assessment section includes an area to collect demographic data.

- *Pain Intensity Through the Visual Analog Scale (VAS)*

The visual analog scale (VAS) was used to evaluate the intensity of pain and was introduced by asking the patient to record the intensity of encountered pain using numbers between "0: no pain" to "10: highest pain".

- *Shoulder ROM (Using the Goniometer)*

The Goniometer was used to measure ROM (Shoulder flexion) from a sitting position according to the previously described procedure [20].
All evaluations were performed pre-study (evaluation-1) and at the end of the study (evaluation-2). All participants' data were collected using standard laboratory procedures.

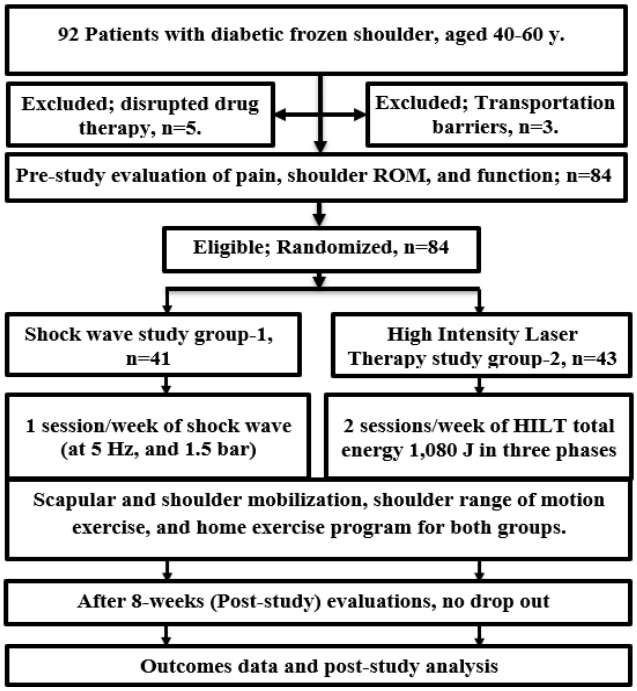

Figure 1. Patients flow chart

Demographic characteristics including height; were measured to the nearest 0.1 cm with the subject standing in an erect position against a vertical stadiometer scale (Detectors ProMed® 6129, USA). Weight in kg; measured to the nearest 0.1 kg was evaluated from standing, weighting scale was calibrated every day with a weight of 50 g**.** Body mass index (BMI) was calculated by the formula= weight kg / height^2.

Interventions

Each group adhered to the prescribed regimen throughout the study.

Shock Wave Therapy (G1; SWT; n=41)

Following the previously described procedure by Kvalvaag *et al*. [21] Participants in the SWT group-1 seated comfortably, for about 10 minutes before the commencement of treatment with SHOCKMASTER in a slowly scanning manner over the soft tissue, using a gel as a transfer media. Treatment was applied on a frequency of one session per week, with the intensity of 2000 impulses of shock waves per session at 5 Hz, and 1.5 bar.

High Intensity Laser Therapy (G2; HILT; n=43)

Following previous guidelines by Dundar *et al*. [22] after seated resting for 10 minutes; the HILT was delivered to the patients using the HIRO 3 (ASA laser, Arcugnano, Italy) device which provided pulsed emission (1,064 nm), a high-level of fluency/energy density (360–1,780 mJ/cm), very high peak power (3 kW), and a brief duration (120–150 μs), while both patient and therapist were wearing the safety glasses.

The HILT treatment was applied on a frequency of two sessions per week and patients received 500 J in the initial phase, 80 J in the intermediate phase (8 trigger points), and 500 J in the final phase. The total energy delivered to the participant during one session was 1,080 J in three phases of treatment [22]. During the initial phase, a slow-scanning mode was applied over the joint line (focusing on the anterior and inferior shoulder capsule margins) and muscles surrounding the joint. During the trigger points phase; the trigger points located around the shoulder joint were irradiated in a stationary manner for each point (8 points). During the final phase, a speed-scanning mode was applied over the joint line (focusing on the anterior and inferior capsule margins) and muscles surrounding the joint.

Therapeutic Exercises and Mobilization for Both Groups

Both groups received an identical battery of exercise training by the same therapist in the form of shoulder range of motion, strengthening exercises, and scapular and shoulder mobilization in addition to a home exercise program.

Statistical Analysis

Statistical analyses were performed using SPSS software (version 16.0). Descriptive analysis was performed to express data as mean ± SD. Changes in mean values of ASES score, range of motion, and pain score within and between groups were analyzed to test the hypothesis within (Paired t-tests) and between (Unpaired t-test) groups. The level of significance was set at $p < 0.05$.

Results and Discussion

The purpose of the study was to compare the effect of SWT and the HILT on pain, shoulder ROM, and function in patients with diabetic Frozen shoulders.

Eighty-four patients with diabetes and diabetic frozen shoulder were enrolled and randomly allocated to either the shock wave group (G1; n=41) or the HILT group (G2; n=43) **(Figure 1)**. Pain, shoulder flexion ROM, and function were evaluated by using the VAS scale, Goniometer, and ASES score respectively. All evaluated parameters were assessed pre- and post-study in both groups.

Patients' Characteristics

The general participants' characteristics are listed in **(Table 1)**. There were non-significant differences in the participants' age (P= 0.32), weight (P= 0.46), height (P= 0.79), BMI (P= 0.35), Random Blood Glucose (P=0.09), glycated hemoglobin (HbA1c) (P= 0.38), and diabetes duration (P= 0.43) **(Table 1)**. Results revealed the homogenous distribution of variances between groups (P< 0.05).

Table 1. The demographic characteristics of patients in both groups.

Variables	Group-1 (n=41)	Group- 2 (n=43)	F value	P value☼
Age (year)	51.46±5.11	52.65±5.65	1.02	0.32 **
Weight (kg)	74.52±4.07	73.88±59	0.55	0.46**
Height (cm)	1.68±0.04	1.68±0.01	0.8	0.79**
Body mass index (Kg/m^2)	26.57±1.77	26.25±1.28	0.88	0.35**
Diabetes Duration (years)	6.27 ± 1.66	6.53±1.4	0.64	0.43**
Random Blood Glucose Level (mg/dl)	204.62±20.73	205.03±17.74	0.009	0.09**
HbA1C%	8.1±0.11	8.22±0.57	0.78	0.38**

Level of significance at P<0.05. * = significant ** = non-significant, HbA1C: Glycosylated hemoglobin

Within Group Comparisons revealed significant decreases in pain within group-1 by 49.38% (P=0.00) and within group-2 by 60.09% (P=0.00), significant increases in shoulder flexion range of motion within group-1 by 25.74% (P=0.00), and within group-2 by 19.29% (P=0.00), and significant increases in shoulder function in the American Shoulder and Elbow Surgeons (ASES) within group-1 by 96.66% (P=0.00), and within group-2 by 104.58% (P=0.00) **(Table 2)**.

Between Groups' Comparison

The pre-study results revealed non-significant differences between groups in the pain (visual analog scale) (P= 0.69), shoulder flexion range of motion (P= 0.97), and shoulder function (P= 0.59). The post-study results revealed significant differences in pain (visual analog scale) (P= 0.0001), and shoulder flexion range of motion (P= 0.04), but non-significant differences in shoulder function (P= 0.19).

Table 2. Within and between-group comparison of pain, shoulder flexion range of motion, and shoulder function mean values in both groups.

Variable		Shock wave group (n=41)	HILT group (group-2; n=43)	F value	P value
Pain	Pre-study	6.54±1.002	6.63±1.07	0.16	0.69**
	Post-study	3.29±0.84	2.63±0.58	17.88	0.0001*
	T, P values	22.03, 0.00*	29.15, 0.00*		
Flexion ROM	Pre-study	103.02±11.4	103.14±12.77	0.002	0.97 **
	Post-study	128.95±10.81	122.77±15.13	4.61	0.04*
	T, P values	-27.09, 0.00*	-17.89, 0.00*		
Shoulder Function	Pre-study	42.89±12.96	41.5±10.57	0.29	0.59 **
	Post-study	77.48±9.5	80.62±7.58	2.82	0.19 **
	T, P values	-30.07, 0.00*	-49.45, 0.00*		

Level of significance at P<0.05.* = significant ** = non-significant, HILT: High Intensity Laser Therapy, ROM: Range of motion.

Patients with frozen shoulders have difficulties performing everyday activities due to disturbed physical function, pain, and experienced restrictions [17]. This study was conducted to compare the effects of the SWT and the HILT on shoulder pain, ROM, and function in patients with diabetic frozen shoulder. Both SWT and the HILT showed positive results regarding their

effectiveness in modulating shoulder pain, ROM, and function. Shock wave therapy showed a better effect in increasing the ROM, while HILT was more effective in reducing pain and improving shoulder function.

The results of the current study revealed that participants treated with shock wave therapy showed a significant reduction in pain and more improvement in ROM and shoulder function which was explained and supported by the results of previous research. Park *et al*. [17] reported that the ESWT was suggested as a new modality to treat patients with frozen shoulders and was considered an effective intervention for improving shoulder functions and reducing pain. Kim *et al*. [20] demonstrated that 8 sessions of radial ESWT on the supraspinatus and subscapularis insertion sites of a hemiplegic shoulder significantly reduced the pain and its effects lasted for at least four weeks. It is also postulated that the ESWT can induce the repair of the inflamed tissues by tissue regeneration (anti-inflammatory and anti-fibrotic effects) [23], other researchers speculated that the ESWT can relieve pain by hyper-stimulation analgesia in insertional tendinopathy [24]. Li *et al*. [25] concluded that both focused-SWT (F-SWT) and radial–SWT (R-SWT) were effective in the treatment of non-calcific rotator cuff tendinopathy, with the focused shockwave therapy proved to be significantly superior to radial shockwave therapy at long-term follow-up (more than 24 weeks). Notarnicola and Moretti [26] also reported the beneficial effects of the ESWT including neovascularization, local release of angiogenetic factors, and differentiation of mesenchymal stem cells. Xiangzheng *et al*. [27] supported the usage of high-energy R-SWT as a supplementary therapy over physical therapy alone for rotator cuff disease. Carlisi *et al*. [28] also concluded that SWT is effective modiality in reducing pain and improving shoulder function in calcific supraspinatus tendinopathy. Wu *et al*. [29] concluded that the high-dose ESWT had superior clinical efficacy in type II/III calcification tendinopathy rather than type I and noncalcific shoulder tendinopathy. Louwerens *et al*. [30] supported the usage of high-energy ESWT in the treatment of rotator cuff calcific tendinitis that are successful improving function and pain with high satisfaction rates after 1-year follow-up.

Patients treated with HILT showed a significant reduction in pain and improvement in ROM and shoulder function, these results were in accordance with the results of previous research. Santamato *et al*. [15] concluded that patients treated with HILT showed a greater reduction in pain and more improvement in the functionality, articular movement, and muscle strength of the affected shoulder than the patients treated with ultrasound. Studies using the HILT reported its beneficial effects in the treatment of several orthopedic disorders, with proven efficacy in reducing pain [9, 10]. HILT proved efficacy in decreasing frozen shoulder pain on a short-term basis [11], it also researchers found that the combination of HILT with exercises could effectively increase functional activity, and ROM and reduce pain after 6 weeks of treatment [12, 13] and 4 weeks after treatment cessation as a follow-up [13]. The HILT showed significant therapeutic effects in long-term follow-up [14].

Conclusion

Both Shock wave therapy and HILT are effective in reducing pain, and increasing shoulder flexion ROM and shoulder function in patients with DFS. Shock wave therapy showed a better effect in increasing the ROM, while HILT was more effective in reducing pain and improving shoulder function.

Acknowledgments: None

Conflict of interest: None

Financial support: None

Ethics statement: This study protocol was evaluated and received approval from the “Biomedical Ethics Committee at Umm Al Qura University, Saudi Arabia (TZHT07123).

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