Original Article

The Effect of Extracorporeal Shock Wave Therapy for Patients with Diabetic Frozen Shoulder

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ABSTRACT

Title: The Effect of Extracorporeal Shock Wave Therapy for Patients with Diabetic Frozen Shoulder

Background: Diabetes Mellitus (DM) is a combination of chronic disorders that affect many systems in individuals which requires self-management education and support to prevent acute and long-term complications. Frozen Shoulder (FS) is a common complication among patients with Diabetes Mellitus and tendency to become chronic is high because of inflammation and fibrosis of shoulder capsule.

Aim: To evaluate the effect of extracorporeal shock wave therapy for patients with diabetic frozen shoulder.

Materials and Methods: Thirty patients with diabetic frozen shoulder were included in the study and they were divided into two groups. Group A consists of 15 patients (9 male and 6 female) and they were treated with extracorporeal shock wave therapy and therapeutic exercises for five weeks. Group B consists of 15 patients (10 male and 5 female) and they were treated with traditional physical therapy which consists of 3MH ultrasonic therapy, infrared and therapeutic exercise for five weeks. Shoulder Pain and Disability Index (SPADI) and Digital Goniometer were used as outcome measures to evaluate the pain and functional activities and degree of movements respectively.

Results: Both group A and B showed significant improve-

المستخلص

العنوان: تأثير العلاج بالموجات التصادمية على مرضى السكري الذين يعانون من الكتف المتجمد

التمهيد: داء السكري هو مزيج من الاضطرابات المزمنة التي تؤثر على العديد من أجهزة الجسم والتي تتطلب تدعيم وتعليم الإدارة الذاتية للأشخاص لمنع حدوث مضاعفات حادة وطويلة المدى. يعتبر الكتف المتجمد من المضاعفات الشائعة بين مرضى داء السكري، ويميل إلى أن يصبح مزمنًا بسبب التهاب وتليف كبسولة الكتف.

هدف البحث: تقييم تأثير العلاج بالموجات التصادمية على مرضى السكري الذين يعانون من الكتف المتجمد.

طريقة البحث: شارك في الدراسة ثلاثون مريض بالسكري يعانون من الكتف المتجمد وتم تقسيمهم إلى مجموعتين. تكونت المجموعة (أ) من 15 مريضًا (9 ذكور و6 إناث) وتم علاجهم باستخدام بالموجات التصادمية والتمارين العلاجية لمدة خمسة أسابيع. وتكونت المجموعة(ب) من 15 مريض (10 ذكور و5 إناث) وتم علاجهم بالعلاج الطبيعي التقليدي الذي يتكون من العلاج بالموجات فوق الصوتية والأشعة تحت الحمراء والتمارين العلاجية لمدة خمسة أسابيع. تم استخدام مؤشر آلام الكتف والعجز (SPADI) ومقياس الزوايا الرقمي كوسائل قياس لتقييم الألم والأنشطة الوظيفية ومدى حركات مفصل الكتف على التوالي.

النتائج: أظهر كلا المجموعتين (أ) و (ب) تحسنًا كبيرًا مع وجود فروق ذات

ment (P=0.0001) in reducing the shoulder pain, increasing the functional activities and range of movements of shoulder joint. However group A showed good Improvement Ratio (IR = 91.26%) in reducing the shoulder pain, increasing the functional activities and range of movements of shoulder joint compare to the group B (IR = 81.81%).

Conclusion: Extracorporeal shock wave therapy and therapeutic exercises were effective in reducing the shoulder pain, increasing the functional activities and range of movements of shoulder joint for patients with diabetic frozen shoulder.

Key words: frozen shoulder, extracorporeal shock wave therapy, therapeutic exercise, diabetes mellitus.

دلائل إحصائية (P = 0.0001) في الحد من آلام الكتف، وزيادة الأنشطة الوظيفية وزيادة مجال حركة مفصل الكتف. وبالإضافة الي ذلك، أظهرت المجموعة (أ) نسبة تحسن مرتفعة (نسبة التحسن= 91.26٪) مقارنة بالمجموعة (ب) (نسبة التحسن= 81.81٪)

الخلاصة: العلاج بالموجات التصادمية والتمارين العلاجية كانت فعالة في الحد من آلام الكتف، وزيادة الأنشطة الوظيفية وزيادة حركات مفصل الكتف لمرضى السكري الذين يعانون من الكتف المتجمد.

الكلمات الدالة: الكتف المتجمد، العلاج بالموجات التصادمية، التمارين العلاجية، داء السكري.

Introduction

Diabetes Mellitus (DM) is a metabolic disease that increases the glucose in blood due to the defects in production of insulin, effect of insulin or both. The chronic hyperglycemia of diabetes is associated with progressive gradual damage, impairment, and insufficiency of many organs, exceptionally the nerves, muscles, joints, and blood vessels.[1]

DM is a combination of chronic disorders that need persistent health care with multi-dimensions risk-reduction strategies beside control of hyperglycemia. Although there are many patients acquire self-management education and support in preventing acute and long term complications and considerable interventions in improving DM outcomes, still the complications appear in many patients.[2] A systematic literature review identified 540 studies on the prevalence of diabetes conducted between the period of 1990 and 2015. Using an analytic hierarchy process, 196 sources from 111 countries were selected and it was estimated that in 2015 there were 415 million people with diabetes aged 20–79 years.[3]

Frozen Shoulder (FS) is a musculoskeletal disorder characterized by thickening of joint synovial membranes and attachment of glenohumeral joint surfaces which leads to gradual progression of decreasing in range of movements of flexion, abduction and external rotation of shoulder joint along with increasing shoulder pain. Due to inflammation and fibrosis of the shoulder joint, there is decreased shoulder girdle flexibility and elasticity that makes difficult in performing everyday activities. The severity of FS depends on the age of patients and the duration of DM.[4] The actual cause of frozen shoulder has not been well defined. Certain studies have explaind about the role of aging in decreasing blood supply to tendons, ligaments and joint capsule which causes degeneration of articular tissue leading to local necrosis.[5] A meta-analysis study showed that there is a strong relationship between DM and FS and the prevalence of DM in FS was found 30% (95% CI 24-37%). [6,7]

There are different techniques and mechanisms in physical therapy for treating diabetic frozen shoulder which include mobilization techniques, manual therapy, thermotherapy, psychotherapy, electric percutaneous nerve treatment, ultrasound therapy and taping ther-

apy. However Extracorporeal Shock Wave Therapy (ESWT) is a new treating method and not been used effectively for treating diabetic frozen shoulder. ESWT is a non-surgical treatment method. The therapeutic effect of ESWT is to aid revascularization, stimulation and reactivation of the bones and connective tissues healing, which lead to controlling pain and regain the functions.[8,9] ESWT was used to treat many musculoskeletal diseases such as calcific tenosynovitis and plantar aponeurositis.[5] However there are few studies have been found for treating diabetic frozen shoulder with ESWT. Therefore, our study is aimed to find the effect of extracorporeal shock wave therapy on diabetic frozen shoulder patients, and also to compare the efficacy of ESWT with traditional physical therapy techniques.

Materials and Methods

Thirty patients with diabetic frozen shoulder were recruited from the out- patient's clinic of orthopedic and rehabilitation at Zagazig University Hospital by using convenience sampling method for the study from May 2016 to February 2017. The subjects included for the study were: subjects ambulated without assistance and history of DM not less than 10 years, the age of subjects was from 40 to 59 years, having frozen shoulder not less than six months. The subjects excluded for the study were: traumatic frozen shoulder, rheumatoid arthritis, recurrent subluxation of shoulder, cervical radiculopathy, history of previous surgery of the shoulder, history of cancer, and bleeding disorders. Random assignment of patients was conducted in two stages: firstly; researcher screened potentially eligible patients and report all patients who fulfilled the inclusion criteria of the study. Secondly, the patients were randomly divided into two groups: Group A and Group B. Random process involved opening an opaque envelope prepared with random number generation using Excel to generate the allocation sequence by an independent person (registration clerk) who was not involved in any part of the study.

Group A consists of fifteen patients and they were treated with ESWT and therapeutic exercises for two sessions in a week for five weeks. ESWT probe was applied at anterior and posterior sides of the shoulder joint every session approximately 1200 shocks at intensity 0.2 mJ/mm2 till reach to the maximum threshold of pain tolerance in addition to mobilization and therapeutic exercises. Group B consists of fifteen patients and they were treated with 3MH ultrasonic therapy, infrared and therapeutic exercise for two sessions in a week for five weeks.

In order to find the effect of ESWT on diabetic frozen shoulder patients, and to compare the efficacy of ESWT with traditional physical therapy techniques on patients with diabetic frozen shoulder, a self-administered questionnaire – Shoulder Pain and Disability Index (SPADI) was used. It consists of 13 items in 2 domains; pain (5 items) and disability (8 items), scored on a visual analog scale, ranging from 0 to 100 (0 = no pain/no difficulty and 10 = worst pain imaginable/so difficult) required help. Each item score is

equally weighted, then added for a total percentage score from 0 to 100
(0 = best and 100 = worst). [10] Calibrated electro goniometer was used to measure the range of movements of shoulder joint.

Ethical clearance to conduct the study was obtained from Ethical Committee of Scientific Research, Zagazig University. After explaining the purpose of the study, an informed written consent was obtained from the patients on voluntary basis.

Data were analyzed by using Statistical Package for Social Sciences; SPSS Inc., Chicago, IL, USA, version 22 software. Differences were assumed significant at p-value <0.05. Variables were described in terms of mean and standard deviation. Paired sample t-tests were used for intra-group comparisons (within groups) while Independent t-test was used to find the differences between group A and B.

Results

The demographic data of all the participants in each group were shown in Table (1). There were no differences between the demographics of the patients between group A and group B. The results showed that both groups had similar characteristics regarding age, weight, height, BMI, duration of diabetes, p-value > 0.05.

Table 1. Demographic data of the both groups (group A and group B)

Item	Group (A) (9 male and (female 6	Group (B) (10 male and 5 female)	*t*-value	*P*-Value	Significance
	X ± SD	X ± SD			
Age (Years)	45.34±8.7	46.26±8.1	- 0.301	0.761	NS
Weight (kg)	78±5.3	79.06±8.4	- 0.411	0.68	NS
Height (cm)	168.5±0.04	169.4±0.06	-0.411	0.68	NS
BMI (Kg/m^2)	27.54±2.65	27.61±3.09	-0.061	0.951	NS
Duration of Diabetes (years)	14.87±2.77	13.73±2.31	1.224	0.231	NS

Table (2) showed the statistical analysis for the mean values of SPADI for intra groups (with in groups) and inter groups. In both groups (A and B) pre and post treatment results were appeared statistically significant ($p < 0.05$). However, the Improvement Ratio (IR) for group A was (91.26%) whereas the IR for group B was (81.81%). The pre-treatment values showed no significant difference between both groups ($p > 0.05$) whereas there was statistically significant in post treatment between both groups ($p < 0.05$) as shown in figure (1).

Table 2. Comparison between intra and inter group (pre and post) treatment regarding (SPADI):

Groups	SPADI X± SD	IR	MD	*t*-value	*p*-value	Sig.
Group A(pre)	6.86 ±0.91	91.26	6.26	25.253	0.0001	S
Group A (Post)	0.60 ± 0.51					
Group B (Pre)	6.6 ±1.05	81.81	5.4	25.256	0.0001	S
Group B (Post)	1.2 ± 0.67					
Group A(pre)	6.86 ± 0.91	---	0.26	0.731	0.461	NS
Group B(pre)	6.6 ± 1.05					
Group A (Post)	0.6 ± 0.51	---	-0.6	-2.750	0.01	S
Group B (Post)	1.2 ± 0.67					
SPADI: Shoulder Pain and Disability Index, IR: Improvement Ratio X: Mean, SD: Stander Deviation, MD: Mean Difference, S: Significant, NS: not Significant.						

Figure (1): Inter-group difference regarding SPADI.

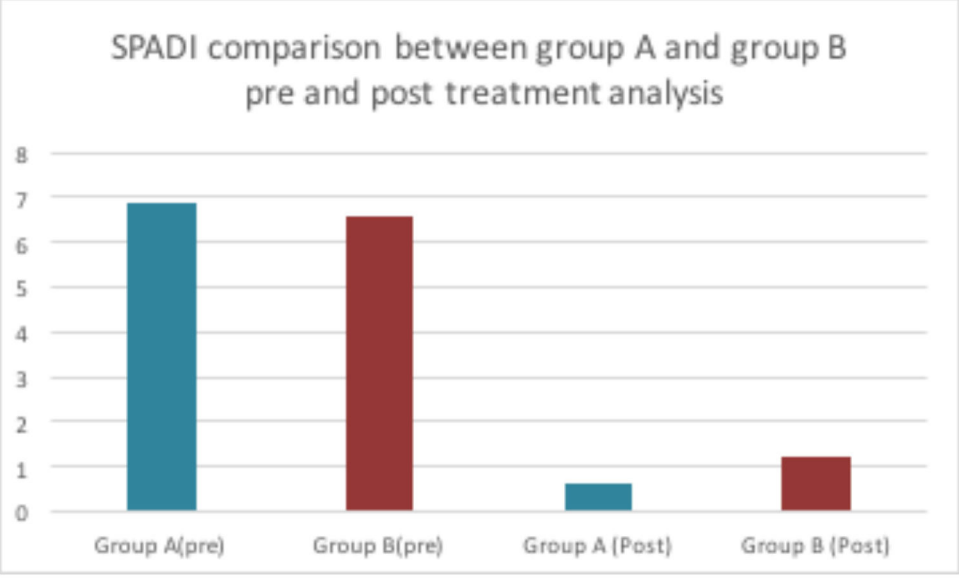


Table (3) showed the statistical analysis for the mean values of shoulder ROM for flexion, abduction and external rotation for intra-groups (with in groups) pre and post treatment. Both A and B groups were showed significant difference between the pre and post treatment measurements ($p < 0.05$). The IR for group A in shoulder flexion, abduction and external rotation was 57.95%, 73.87% and 53.10% respectively, while the IR for group B in shoulder flexion, abduction and external rotation was 44.84%, 61.34% and 51.20% respectively.

Table 3. Intra-groups comparison for pre and post ROM of shoulder joints.

Groups	ROM	Pre X ±SD	Post X ±SD	IR	MD	*t*-value	*p*-value	Sign.
Group A	Flexion	109.87±23.35	173.53±6.41	57.95	-63.67	-12.24	0.0001	S
	Abduction	100.26±7.02	174.33±5.21	73.87	-74.07	-39.22	0.0001	S
	Ext. Rotation	29±5.64	44.4±0.73	53.10	-15.4	-10.69	0.0001	S
Group B	Flexion	110±21.38	159.33±13.5	44.84	-49.33	44.84	0.0001	S
	Abduction	100.53±13.5	162.2±12.5	61.34	-61.67	61.34	0.0001	S
	Ext. Rotation	28.26±3.9	42.73±2.12	51.20	-14.47	51.20	0.0001	S

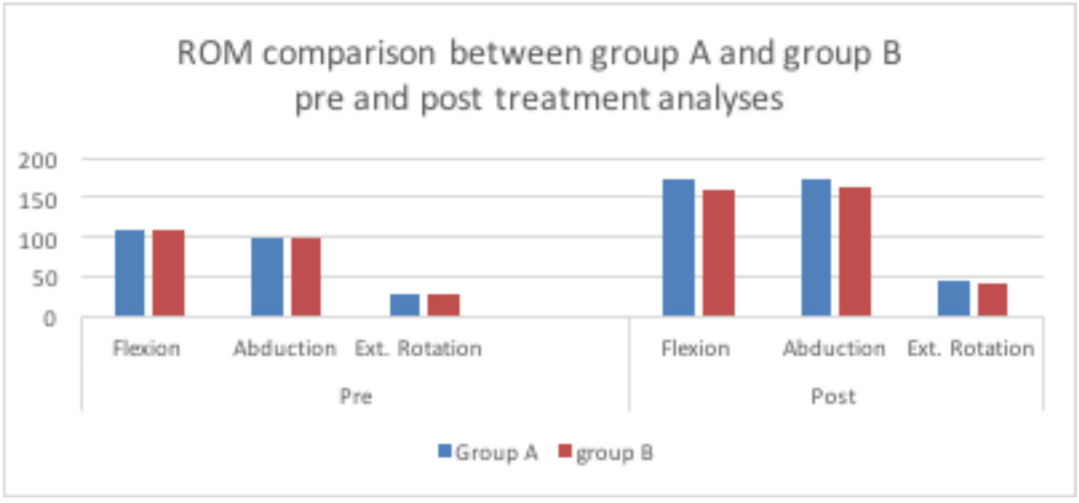
ROM : Shoulder range of motion, IR: Improvement Ratio, X: Mean, SD: Stander Deviation,
MD: Mean Difference, S: Significant

Inter-groups comparison of pre and post shoulder ROM for flexion, abduction and external rotation mean values were illustrated in table (4) and figure (2). The pretreatment values showed no significant difference between both groups ($p > 0.05$), whereas there was statistically significant difference was found in post treatment ($p < 0.05$).

Table 4. Inter-groups comparison of pre and post shoulder joint ROM.

		Group A	Group B	MD	*T* Value	*p* Value	Sign.
	Degree of ROM	X ±SD	X ±SD				
Pre	Flexion	109.87±23.35	110±21.38	- 0.14	- 0.01	0.98	NS
	Abduction	100.26±7.02	100.53±13.5	- 0.27	- 0.06	0.94	NS
	Ext. Rotation	29.00±5.64	28.26±3.86	0.74	0.41	0.68	NS
post	Flexion	173.53±6.41	159.33±13.47	14.21	3.681	0.001	S
	Abduction	174.33±5.21	162.2±12.49	12.13	3.47	0.002	S
	Ext. Rotation	44.41±0.73	42.73±2.12	1.671	2.87	0.01	S

Figure (2): Inter-group difference regarding shoulder ROM.



Discussion

DM has adverse effect in range of motion of the shoulder joint leading to increasing pain and disability of the shoulder joints. The pathology is very difficult to manage and may last for months, progressing into Frozen Shoulder. ESWT is a new technology using acoustic shockwaves to break up the shoulder adhesions, so it is a tool for physiotherapist to treat the chronic, painful conditions of musculoskeletal disorders.

Tighe et al., evaluated 88 patients with DM for detecting the presence of FS and they found FS in 34 patients (38.6%). The study revealed that the main age for occurrence of FS in diabetic patients was between 40 and

70 years .[11]

Olimpio et al., studied the effect of ESWT on twenty patients with non-calcifying supraspinatus tendinopathy NCST. They divided the patients into ESWT and sham groups. In the ESWT group, patients were received 3000 shockwaves shoots at 0 .068 mJ/mm2 of the energy flux density, with interval rest 7 days. Results showed significant improvement in the total Constant and Murley Score (CMS) and its subscales in comparison with the baseline values. The ESWT group revealed significant higher scores for CMS pain and ROM when compared to the second group. They recommended using low energy ESWT to treat patients suffering from NCST, at least in short-term.[12]

Our study showed that the treatment of diabetic frozen shoulder was improved by using ESWT in reducing the shoulder pain and disability (SPADI) from 6.86 ± 0.91 to 0.60 ± 0.51 with IR equal to 91.26%. Statistically significant improvement of IR was found in ROM of shoulder flexion, abduction and external rotation with 57.95%, 73.87% and 53.10% respectively.

The current study was supported by a prospective, randomized, controlled, single-blind clinical trial, conducted by Chen et al., found that the ESWT showed significant improvement from the fourth week in total Constant Shoulder Score (CSS) and Range of Motion (ROM) parameter of the CSS in adhesive capsulitis.[13]

Park et al. noted that when ESWT was used to treat frozen shoulder patients for two sitting in a week for six weeks with mean age 54.2±5.7 years and it was showed significant decrease pain in both Visual Analogue Scale (VAS) and Patient-Specific Functional Scale (PSFS).[14]

The other study found that ESWT was effective in reducing the pain by a sound wave effect which produces fine, repetitive stimuli that can be dispersal through soft tissues without energy dissipation.[15]

Babak et al., study found satisfactory improvement in SPADI and shoulder motion ($p < 0.05$) after four weeks and twice per week application of ESWT. They concluded that ESWT has positive effects on acceleration of the healing process of frozen shoulder.[4] As per arthroscopic findings, adhesions occur more in the descendent fold and surrounding synovium, therefore, stimulation from anterior and posterior directions is more effective rather than the lateral direction.

Coinciding with above study, the current study showed improvement in reducing the pain on anterior and posterior aspects of the shoulder joint and improving the function of shoulder joint after application of ESWT. Both groups (A and B) showed significant difference ($p < 0.05$), however the post treatment results were showed ESWT was more effect ($p = 0.01$) than traditional physical therapy.

Durante et al. evaluated patients with analogous conditions. In group A, patients received combination of ESWT plus physio-kinesiotherapy while group B received only physio-kinesiotherapy. The ESWT was done for anterior and lateral portion of shoulder

joint by 2500 shocks with intensity of 0.07 and 0.11 mJ/mm2, twice in a week, for two weeks. Follow up was done for patients after 6 months. About 30% of the patients in group A showed excellent response comparing to 10% in group B. [16]

Ludger Gerdesmeyer et al., studied the effect of high energy, low energy and placebo ESWT effect in 144 patients with chronic calcifying tendonitis of the rotator cuff. The study aimed to compare the changes inby the pain VAS and size of calcified deposits at 3, 6, and 12 months after treatment. The high-energy group received 1500 shockwaves at 0.32mj/mm2 per treatment for 2 sessions. The low energy group received 6000 shockwaves at 0.08mj/mm2 per treatment for 2 sessions. They concluded that both high and low shock wave therapy has a positive effect on improve the shoulder pain, shoulder functions and reduce the size of calcification. [17]

Conclusion and Recommendations

The study concluded that ESWT is tolerable, feasible, and effective in treatment of FS and considered to be a valid alternative method to steroids injection for treatment of Diabetic frozen shoulder patients. ESWT also more effective than traditional methods of physical therapy treatments in reducing disability and pain and increasing the shoulder joint range of motions. However, these findings need to be confirmed by more sample size, non-diabetic frozen shoulder patients and follow up assessment for function of the shoulder joints.

Source of Support: Nil

Conflict of Interest: Nil

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