Effect of Focused Shock Wave Therapy on Pain and Elbow Heterotopic Ossification Following Burns.

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Computed tomography Scan, Focused extracorporeal shock wave therapy, Visual analogue scale.

ABSTRACT
Background: Burns are devastating injuries, often resulting in significant morbidity, impairment of emotional well-being, and experienced quality of life.
Objective: to evaluate the effect of focused shock wave therapy on pain and elbow heterotopic ossification following burns.
Methods: Forty patients with elbow heterotopic ossification following burns participated in this study, they were selected from Kasr El-Aini (Cairo University hospitals and OM El-¬Masrieen hospitals (Ministry of Health). The patients were randomly assigned into two equal groups, 20 patients for each group. Group A (study Group) included twenty patients with elbow pain and heterotopic ossification following burns and they received both Focused Extracorporeal shockwave therapy plus the routine medical care (Etidronate, 300mg, twice a day, for 7 weeks). while group B (control Group) received only the routine medical care. Treatment consisted of 7 brief, non-invasive sessions given over 7 weeks, Each EWST treatment consisted of 3500 pulses at 4 Hz with an energy flux density in the range of 0.03 to 0.36 mJ/mm2. Evaluation for all patients was done before and after the treatment using Visual analogue scale (VAS) and Computed Tomography Scan (CTS) according to the Della Valle classification system.
Results: there was highly significant reduction in VAS but in spite of the occurrence of improvement in some cases of the second records of CTS in grades in the ESWT group, there was non-significant difference from the statistical point of view, between both groups.
Conclusion: The application of the focused shock wave therapy on pain and elbow heterotopic ossification following burns had only a minimal effect on some of the patient

Introduction

Burn patients suffer from many problems due to disruption of the normal protective functions of the skin, edema and low cutaneous blood flow. Burn injury can have devastating effects on the neuromuscular and the musculoskeletal systems. Patient's complaints regarding weakness or lack of sensation often are rationalized as generalized sequelae of the burn injury and healing process 1

Heterotopic ossification is defined as the presence of lamellar bone at locations where bone normally does not exist. In addition to this acquired form, hereditary causes also exist, such as fibrodysplasia ossificans progressiva and Albright's hereditary osteodystrophy 2

Increased contractures and spasticity, pressure ulcers, limitation of the range of joint motion and increasing pain further compromise the patient's capabilities. Heterotopic ossification which may develop around the elbow in patients with burns may lead to severe functional impairment 3

The prevalence of heterotopic ossification after burns is common. Along with recognized risk factors (duration of stay in the intensive care burns unit (ICU), extent and depth of burns, pulmonary and cutaneous infections), the use of curare and the use of a fluidized bed (with the duration of use) and immobilization of patients with burns in ICU could be an associated risk factor for HO development 4, 5.

In a prospective radiographic study, heterotopic ossification around joints has been reported to occur in up to 23% of patients after significant burns. Retrospective studies generally report a much lower incidence of 0.38% to 3.3%, The elbow is the most frequently involved joint in most series 6

Extracorporeal shock wave therapy (ESWT) is a noninvasive method that uses pressure waves to treat various musculoskeletal conditions. High-energy acoustic waves deliver a mechanical force to the body's tissues. Shock wave therapy may treat conditions such as degenerated tendons, heel pain and tennis elbow. The aim of shockwave is to disrupt the bone formations through either vibration or radiation 8. People who have poor sensation (neuropathy) or hypersensitivity or open sores in the target area should not have this procedure. Shock wave therapy is not used in patients with heart conditions or seizures nor during pregnancy 7.

Patients and Methods

Study participants and ethics

The study's sample size was calculated using G*Power program 3.1.9, resulting in 40 participants, with a required 20 subjects per group. Forty patients from both genders with elbow pain and heterotopic ossification following participated in this study after signing the consent form. This study extended from September 2023 and ended to October 2024. The study was approved by the Ethical Committee for Human Research at the Faculty of Physical Therapy, Cairo University, Egypt study was approved by faculty of physical therapy ethical committee, No: P.T.REC/012/003007.

Study design

This study was a Randomized controlled trial. Participants were randomly distributed into three groups using random generator (www.randomization.com). Group A (Study group): involved 20 patients and received (F-ESWT), plus the routine medical care (Etidronate, 300mg, twice a day, for 7 weeks). Group B (Control group): involved 20 patients and received the routine medical treatment only. Patients were chosen after a routine medical examination by specialist. They were selected from Kasr El-Aini (Cairo University hospitals and OM ElMasrieen hospitals (Ministry of Health), The elapsed time since burn varied from 1 to 4 years.

Design of the study:

Inclusion and exclusion criteria

- To be included in the study, subjects were evaluated using the following criteria: Patients from both genders with elbow HO secondary to burn participated in the study. All patients age ranged from 20 to 35 years old. All patients were conscious. They did not receive other physical therapy electro-modality prior to the study 9. This study excluded participants with life threatening disorders as renal failure,

myocardial infarction or other similar diseases, patients who suffered from skin diseases, diabetes, varicose veins, and peripheral vascular diseases, pregnant patients or who presented with active malignancy and Patients who suffered from, Hyperthyroidism, Hemorrhage, Acute viral diseases, acute tuberculosis, mental disorders or those with pace makers 9.

Outcome measures:

1. **Visual analog scale:** was used to measure severity of elbow pain. Patients were asked to indicate the severity of elbow pain on a visual analogue scale (VAS) graded from 0-10, where 0 means none and 10 means an intolerable level of severity 10.
2. **Computed tomography Scan (CTS) and the** Della Valle classification**:** were used to measure size of the elbow heterotopic ossification and severity of elbow stiffness in cm, but CT is able to identify lesion mineralization earlier and has good overall specificity. The **Della Valle classification** is a simple modified classification system with three grades; **grade 0:** absence of heterotopic ossification (maybe ≥1 island of bone of <1 cm in length), **grade 1:** presence of ≥1 island of bone of at least 1 cm in length; 1 cm distance between opposing bone surfaces, **grade 2:** bone spurs arising about the elbow with <1 cm between opposing surfaces or apparent bone ankylosis. The important distinction in reporting the presence of heterotopic ossification is therefore whether the space between opposing bone surfaces is greater or smaller than 1 cm 11.

Assessment procedures:

Evaluation was done before treatment (First record) and after end of 7 sessions given over 7 weeks of treatment) as a second final record).

- **Visual analog scale:** was used to measure severity of elbow pain. Patients were asked to indicate the severity of elbow pain on a visual analogue scale (VAS) graded from 0-10, where 0 means none and 10 means an intolerable level of severity 10.
- **Computed tomography Scan (CTS);** was used to measure size of the elbow heterotopic ossification in cm 11.

Treatment procedures:

F-ESWT application in the study group (A):

Before application: Information concerning the subjects name, age, sex, and address were recorded by the investigator. Only the part of the upper limb (elbow heterotopic ossification area) in which ESWT was applied and uncovered. Skin of the subjects at the area of ESWT application was cleaned using alcohol. Scheduling the subjects for the protocol of ESWT application was made at random 12.

The subject was relaxed in sitting position and the handheld probe was used to deliver high-energy pulses similar to sound waves to the elbow heterotopic ossification area. The waves were concentrated to a focal area of 2 to 8 mm using a reflector focusing on the target site. The ESWT, in the shape of cylindrical pressure waves, were localized using ultrasound imaging. Each EWST treatment consisted of 3500 pulses at 4 Hz with an energy flux density in the range of 0.03 to 0.36 mJ/mm2 delivered to the mass from the area of ossification outlined on the skin., Treatment consisted of 7 brief, noninvasive applications were given over 7 weeks, once a week 13.

Statistical analysis

Unpaired t-test was conducted for comparison of subject characteristics between groups. Chi- squared test was conducted for comparison of sex distribution between groups. Normal distribution of data was checked using the Shapiro-Wilk test. Levene's test for homogeneity of variances was conducted to test the homogeneity between groups. Unpaired t-test was conducted to compare VAS and DVCS between groups. Paired t-test was conducted for comparison between pre and post treatment in each group. The level of significance for all statistical tests was set at $p < 0.05$. All statistical analysis was conducted through the statistical package for social studies (SPSS) version 25 for windows (IBM SPSS, Chicago, IL, USA).

Results

- Subject characteristics:

Table (1) showed the subject characteristics of the group A and B. There was no significant difference between groups in age, elapsed time and sex distribution ($p > 0.05$).

Table 1. Comparison of subject characteristics between group A and B:

	Group A	Group B	MD	t- value	p-value
	Mean ±SD	Mean ±SD			
Age (years)	27.95 ± 5.55	28.00 ± 5.60	-0.05	0.10	0.92
Elapsed time	2.65 ± 0.84	2.77 ± 0.95	-0.12	-0.43	0.66
Sex, n (%)					
Females	12 (60%)	11 (55%)		($\chi2 = 0.10$)	0.75
Males	8 (40%)	9 (45%)			

SD, Standard deviation; MD, mean difference; $\chi2$, Chi squared value; p value, Probability value

Effect of treatment on VAS and DVCS:

- Within group comparison:

There was a significant decrease in VAS in group A post treatment compared with that pre treatment ($p > 0.001$). The percentage of decrease in VAS in group A was 47.83%.

There was no significant change in VAS of group B and no sibnifcant change in DVCS in both groups ($p > 0.05$). (Table 2).

- Between groups comparison:

There was no significant difference between groups pre-treatment ($p > 0.05$). Comparison between groups post treatment revealed a significant decrease in VAS of group A compared with that of group B ($p < 0.001$). There was no significant difference in DVCS between groups post treatment ($p > 0.05$). (Table 2).

Table 2. Mean VAS and DVCS pre and post treatment of group A and B:

	Pre treatment	Post treatment				
	Mean ± SD	Mean ± SD	MD	% of change	t- value	p value
VAS						
Group A	8.05 ± 0.61	4.20 ± 0.62	3.85	47.83	-23.11	0.001
Group B	8.15 ± 0.67	8.10 ± 0.72	0.05	0.61	-0.44	0.66
MD -0.10	-3.90					
t- value -0.59	-18.44					
p = 0.56	p = 0.001					
DVCS						
Group A	1.80 ± 0.41	1.65 ± 0.49	0.15	8.33	-1.14	0.27
Group B	1.90 ± 0.31	1.80 ± 0.41	0.10	5.26	-0.81	0.43
MD -0.10	-0.15					
t- value 0.87	1.05					
p = 0.39	p = 0.30					

SD, standard deviation; MD, mean difference; p-value, probability value

Discussion:

This study was conducted to detect the effects of (F-ESWT) on pain and the elbow heterotopic ossification following burns.

The results showed a highly significant decrease between the means of the second record VAS (2) (after 7 weeks of the F-ESWT application) and the first record VAS (1) (pre- the F-ESWT application) ($P< 0.0001$), with a percentage of improvement 50 %.

The results showed a non-significant difference from the statistical point of view, there was non-significant difference between the means of the second record of the CTS according to DVCS (2) (after 7 weeks of the ESWT application) and the first record of CTS according to DVCS (1) (pre-ESWT application) ($P > 0.05$) in spite of the occurrence of improvement in some cases of the second records of CTS according to DVCS in grades in the ESWT group,with a percentage of improvement 25 % .

Moya et al., (2018), Lee et al., (2011), Haake et al., (2002), Wang et al., (2002), Wang., (2012) and Reznik et al., (2013) concluded that extracorporeal shock wave therapy (ESWT) was effective in reducing patients' pain or improving ROM and quality of life and decreasing heterotopic ossification following burns.

Moya et al., (2018) concluded that extracorporeal shock wave therapy (ESWT) is a non-invasive intervention that is characterized by three-dimensional pressure pulses of microsecond duration, which could be applied to various musculoskeletal conditions, including plantar fasciitis, lateral epicondylitis, calcific tendinitis of the shoulder and fracture nonunion, etc. Several case reports and studies have described the favorable effect of ESWT on HO in the extremities, such as pain mitigation, increased ROM of joint and muscular

strengthening. However, there is no literature in regarding the effect of ESWT on alteration of the size of HO Moya et al., (2018) also concluded that in term of biomechanics, ESW has been proven to be effective in inducing angiogenesis and bone remodeling, which might be the key link in the regeneration of the diseased femoral head.

Lee et al., 2011 revealed that shock wave therapy can be effective on a wide range of soft tissue and bony conditions. Here are some examples of conditions where shock wave has effectively treated and restored normal function as plantar fasciitis. Shoulder pain, e.g. calcific lesions of the rotator cuff and bony spurs.

Haake et al., 2002 showed that ESWT affect calcium deposits and accelerates the process of calcium resorption. Therefore, the energy introduced into the focus point and susceptibility of the calcium formation to ESWT must be considered during the application.

Wang et al., 2002 mentioned that in previous studies, shock wave therapy reportedly disintegrated calcium deposits partially or completely in about two thirds of the patients, and three quarters showed clinical improvement.

Wang., 2012 showed that extracorporeal shock wave therapy (ESWT) is a generator of high-energy acoustic shockwaves, which allows for the initiation of microscopic environmental changes in the tissue where the pulse energy is propagated.

Reznik et al., 2013 concluded that Few studies have applied ESWT for the treatment of HO, and the results have indicated that ESWT was effective in reducing patients' pain or improving ROM and quality of life.

Haake et al., 2002 showed that initial studies on the effect of ESWT for management of lateral epicondylitis found little benefit over placebo treatment. Some issues, monthly frequency of treatments with a short follow-up of 3 months, low-dose ESWT as control treatment.

Conclusion

Application of the focused shock wave therapy on pain and elbow heterotopic ossification following burns had valuable effects in decreasing pain as demonstrated by the highly significant reduction in VAS while the CT results demonstrate non-significant difference between both groups.

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Conflicts of interest: For this article, none of the authors have disclosed any potential conflicts.

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Patient consent statement:

Prior to the start of data collection, all participants provided their written, informed consent.

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