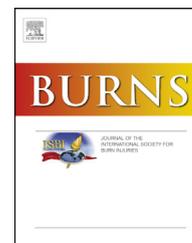


Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.elsevier.com/locate/burns

Impacts of low-energy extracorporeal shockwave therapy on pain, pruritus, and health-related quality of life in patients with burn: A randomized placebo-controlled study

Ahmed Fathy Samhan^{a,b,*}, Nermeen Mohamed Abdelhalim^{a,b}

^a Department of Physical Therapy, New Kasr El-Aini Teaching Hospital, Faculty of Medicine, Cairo University, Egypt

^b Department of Physical Therapy and Health Rehabilitation, College of Applied Medical Sciences, Prince Sattam Bin Abdulaziz University, Saudi Arabia

ARTICLE INFO

Article history:

Accepted 7 February 2019

Keywords:

Low-energy extracorporeal shockwave therapy

Burn

Pain

Pruritus

Health-related quality of life

ABSTRACT

Background: The management of post-burn pain and pruritus remain a potent challenge because of their bad effects on health-related quality of life (HRQOL). The main purpose of this study was to evaluate the impacts of low-energy extracorporeal shockwave therapy (low-energy ESWT) in the management of pain, pruritus, and HRQOL in patients with burn. **Methods:** Forty-five adult patients with burn, their age ranged from 18 to 55 years, were included in the study, they randomly assigned into 22 patients in the study group (low-energy ESWT) and 23 patients in the placebo group. The study group received low-energy ESWT (0.05–0.20mJ/mm², a frequency of 4Hz with total shocks from 1000 to 2000 shocks) once per week for 4 successive weeks, while the placebo group received ESWT without energy. Both groups received traditional physical therapy program of selective different exercises (respiratory, range of motion, endurance, strengthening, balance, mobilization, stretching, and gait training) 3 days per week for 4 weeks. Numerical Rating Scale (NRS) for pain and for pruritus, Pressure Pain Threshold (PPT), 12-Item Pruritus Severity Scale (12-PSS), and Burn Specific Health Scale-Brief (BSHS-B) were measured before and after treatment procedures in both groups.

Results: NRS were decreased significantly in the study group than in the placebo group ($P < 0.05$). PPT, 12-PSS, and BSHS-B scores were improved more significantly in the study group than in the placebo group ($P < 0.05$) while body image and burn associated issues were improved at the same level in both groups ($P > 0.05$).

Abbreviations: HRQOL, health-related quality of life; ESWT, extracorporeal shockwave therapy; mJ, mill Joule; mm², mill meter square; Hz, Hertz; NRS, Numerical Rating Scale; PPT, Pressure Pain Threshold; 12-PSS, 12-Item Pruritus Severity Scale; BSHS-B, Burn Specific Health Scale-Brief; QoL, quality of life; ADL, activity of daily life; TBSA, total body surface area; \bar{x}_1 , mean 1; \bar{x}_2 , mean 2; SD, standard deviation; IBM Inc., International Business Machines Incorporation; USA, United States of America; n, number; ROM, range of motion; Q, question; SPSS, statistical package for the social sciences; P-value, the probability that the study results are due to chance; M, male; F, female; ST, split-thickness; FT, full-thickness; UL, upper limb; LL, lower limb; min., minimum; Max., maximum; eNOS, endothelial nitric oxide synthase; HSP, heat shock protein.

* Corresponding author at: Department of Physical Therapy, New Kasr El-Aini Teaching Hospital, Faculty of Medicine, Cairo University, Egypt.

E-mail address: ahmedsamhan44@yahoo.com (A.F. Samhan).

<https://doi.org/10.1016/j.burns.2019.02.007>

0305-4179/© 2019 Elsevier Ltd and ISBI. All rights reserved.

Conclusion: The findings suggest that low-energy ESWT with traditional regular physical therapy may relieve post-burn pain and pruritus, and improve HRQOL, particularly in adult patients with burn.

© 2019 Elsevier Ltd and ISBI. All rights reserved.

1. Introduction

Burn wounds have destructive effects, uncertain and unexpected types of trauma that influence the physical and psychosocial state of patients with burn. Fortunately, new medical modalities reduced mortality rates in the burn. The effective controlling of infections and the advances of health care are rescue the life of patients with burn [1]. The depth and extent of burn wounds which are consider as the basic factors which decide the severity of the burns' wound. The burned patient is suffering from troubling in body image, and reduction of functional ability, social, sexual, and economic conditions. Evaluating physical and psychosocial circumstances of patients with burn are very important to improve multidisciplinary therapy and to regain quality of life (QoL) [2].

Burn wounds can be considered as an extended traumatic stress disturbance [3]. The pain after burn is described as the most severe pain felt by the patients [4]. Post-burn pain is one of the most severe and sustained type of pain as it begins from the onset of burn injury, and throughout the treatment duration. Pain disturbs the burned patient as a common manifestation in addition to as a challenging curative complication. Pain results from burn itself and/or their therapies as replacement of dressing, surgical debridement, and physical therapy interventions [5]. Life adaptation with pain is very difficult, and chronic pain has a harmful influence on health-related quality of life (HRQOL) [6].

Another common and upsetting problem of burn wounds is post-burn pruritus. It is described as an undesirable perception that induces the need to scrape. It is an impairment and common characteristic during the healing phase, post-healing phase or wound of the donor site [7]. The rate of intolerable pruritus is elevated up to 100% in burned children and 87% in mature patients with burn. Acute itching usually starts in the first 2 weeks after burns' wound while chronic itching may persist up to 2 years post-healing [8]. The mechanism of post-burn pruritus is considered to be due to the destruction of the nerve endings, substance P, and histamine liberated from mast cells, as well as the production of inflammatory prostaglandins and/or opioids-induced itching [9]. Pruritus is a QoL complication of patients with burn. Pruritus disturbs patients during activity of daily living (ADL) and rests [10]. Despite pain and pruritus are different phenomena, they participate same recurrent reactions, such as exaggeration of pain or pruritus further raises the bad negative effect of perception [11].

The QoL in patients with burn may concern with physical, psychological and psychosocial manifestations, it also can lead to emotional troubles [12]. The HRQOL concerns with health, sickness and health aid or the health condition associated with the physical status which determines the precise situation of the patients [13]. In patients with burn, it is

the health condition which is responsible for reactivity and adjustment to impairments or alterations caused by burning, regarding the patient, family, and social concerns [14]. The assessment of the HRQOL can help the burn members in to decide the necessities of patients with burn and distinguishing the areas of QoL influenced with burns [15].

Extracorporeal shock wave therapy (ESWT) has reinforced its situation as supplementary modality choice in numerous soft tissue disorders [16]. The underlying mechanisms of ESWT are not obvious, while it has been revealed to improve blood supply [17], stimulate the inflammatory processes, enhance fibroblasts which enhance damaged tissues repair [18], assist the healing of tendons and ligaments [19], reduce pain, and stimulate the immune system. Shock wave therapy is classified into 2 types according to its intensity degrees: low-intensity (0.05–0.20mj/mm²), and high-intensity (0.2–0.6mj/mm²) [20]. Low-energy ESWT used to accelerate wound healing, and high-intensity ESWT treats musculoskeletal disorders [21].

Clinical studies concentrate on facilitating the functional abilities and cosmetic appearance of burned areas with less attention to improve the psychosocial state. The development of pain and pruritus in patients with burn disturb activity of daily life (ADL) and HRQOL. However, it is very important to find modality which can relieve pain and pruritus, and also it may improve HRQOL. We hypothesized that low-energy ESWT will reduce pain symptoms; low-energy ESWT will reduce pruritic symptoms associated with burn and HRQOL will be higher in patients with burn following use of low-energy ESWT. Thus, this study was designed to evaluate the impacts of low-energy ESWT in the management of pain, pruritus, and HRQOL in patients with burn.

2. Patients and methods

This study was a randomized, placebo-controlled, double-blind study; it was carried out on adult burned patients with a partial to full thickness burns that were cured in a spontaneous manner without surgery or received skin graft (split or full-thickness graft). Forty-five outpatients with burn (males and females) were referred from burn department and enrolled in the study between March 2017 and October 2018 at department of physical therapy, New Kasr El-Aini Hospital, Cairo University, Egypt.

The study protocol was approved by Cairo University Hospitals Ethics Committee. The procedures of the study followed the ethical standards of the institutional research committee and the guidelines of Helsinki Declaration with its later comparable ethical standards. All Patients signed a written informed consent for participation in the study.

The patients with burn aged 18–55years, their total body surface area (TBSA) was more than 10% with a partial or full

thickness burns of the upper or lower extremities which received skin graft or healed in a spontaneous manner and completely healing one month before the study, excluding hands and feet because both need specific intervention and different outcome measures. The patients suffered from severe pain and pruritus with a minimal score 5 on the NRS, and the ability to finish the whole questionnaires and received the same standard treatments (drugs or physical therapy) at hospitalization time. The patients were excluded from the study if they had malignancy, diabetes, pregnancy, fracture around burned areas, psychiatric disorders if the burn was due to a suicide attempt, anticoagulant medications, and blood clotting diseases or possibility for extra skin injury such as blisters due to the application of ESWT.

To avoid type II error, a preliminary sample size calculation was applied. Estimates of means and a common standard deviation were collected from a pilot study included eight patients with burn who received the same treatment for the same duration ($\bar{x}_1=3.55$, $\bar{x}_2=4.75$, and a common $SD=1.14$). Independent t-test, power of 95%, $\alpha=0.05$, and effect size=1.05 created a sample of 42 subject (21 for each group). We recruited up to 50 patients to account for the dropout rates.

Patients were randomized using SPSS (IBM, Inc., New York, USA) into the study group ($n=25$) and the placebo group ($n=25$). Post-treatment outcome measures were unavailable from all patients, 3 patients were excluded from the study group (one patient discontinued the study, 2 patients had blisters after ESWT application), also 2 patients did not complete the trial in the placebo group. Finally, 45 patients (25 male and 20 female)

were involved in the study; 22 patients in the study group, and 23 patients in the placebo group (Fig. 1). Patients and the examiner who conduct the outcome measures were blinded to the treatment procedures (study or placebo).

The study group was treated by low-energy ESWT (Storz Duolith Li-ESWT system, Storz Medical AG, Switzerland) with probe's diameter of 30mm at 100shocks per cm^2 depending on the TBSA with an energy flux density of 0.05-0.20mJper mm^2 according to the patient tolerance, and frequency of 4Hz [22]. The total shocks per session were ranged from 1000 to 2000 shocks started from 1000 shocks in the first session until 2000 shocks in the last session and/or according to the size of the treated area. The treatment session was once per week for 4 consecutive weeks (4 sessions). The time of low-energy ESWT application did not exceed 10min.

Patients were informed to detect the most pruritic and painful areas to apply the ESWT probe, and then medical ultrasound gel without any anesthetics was applied between the probe and the treated area. The probe placed with sufficient pressure to ensure complete contact between it and the skin without air interference.

The placebo group was treated by the same low-energy ESWT device and the same protocol as the study group without any energy output on the treated area by placing a thin foam pad on the probe [23]. The thin pad was placed before the treatment session to keep the patient blinded about the procedure. The pad was replaced by a new one before every session because the used pad became too thin to withstand the new shocks.

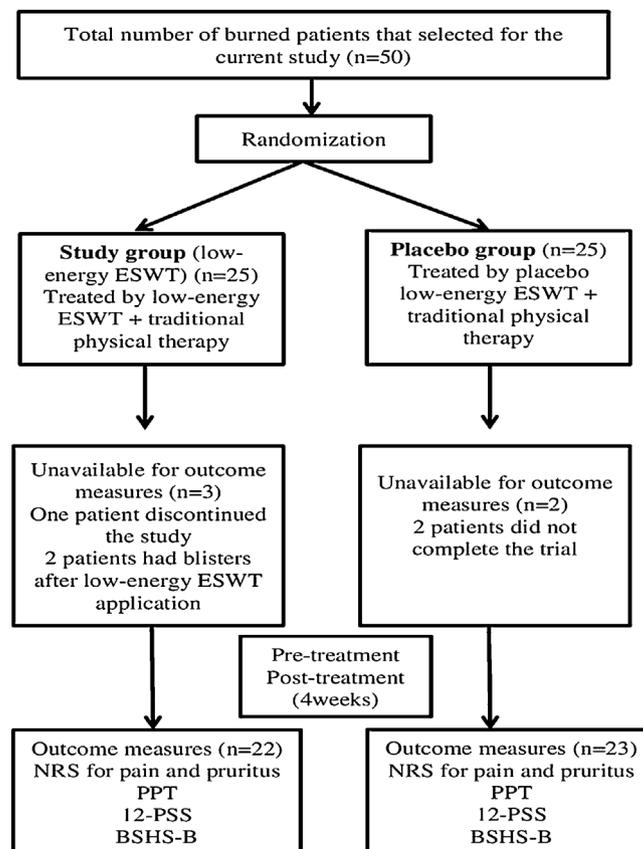


Fig. 1 – Flow chart of the study.

All patients in both groups received the traditional physical therapy program under supervision of trained physical therapists in addition to low-energy ESWT. The duration of each session one hour including 10min warming up, 40min of selective different exercises (respiratory, ROM, endurance, strengthening, balance, mobilization, stretching, and gait training), and finally 10min cooling down 3days per week for 4 weeks [24]. In addition to pressure garments, controlling of edema, moisturizing emollient, humectant creams for scar moisture, maintaining the skin pliable, avoiding sunlight and using sunscreens continuously with an ultraviolet protection factor more than 50 for reducing hyperpigmentation [25].

The NRS was utilized to assess the extent of perception of post-burn pain and pruritus pre and post-treatment procedures. For pain; 0 described no pain and 10 described severe pain [26], also for pruritus; 0 stands for no pruritus and 10 represents intolerable itching [22].

Pressure Pain Threshold (PPT) as the smallest quantity of pressure that produces pain was examined with digital pressure algometer (Commander Algometer, JTECH Medical, USA) which used to determine pain tolerance levels in a non-invasive technique. The pressure sensor of the digital algometer was calibrated under the producer's guidelines prior to gathering the data. The digital pressure algometer was placed perpendicularly on the treated area then pressure applied in a steady manner with a sustained rate, expressed in pounds, and starting from 0 to 25 pounds. The compression was applied slowly as much as possible to provide the patient with sufficient time to respond when the pain was felt. When the patient felt pain the pressure was stopped [27]. The PPT procedure was performed 3 times, and the mean was recorded.

The 12-Item Pruritus Severity Scale (12-PSS) was applied to assess the extent of subjective pruritus and Burn Specific Health Scale-Brief (BSHS-B) was utilized to evaluate outcome measure, giving a precise data for practitioners and simple comparison between patients with burn. Both questionnaires were collected by trained interviewers of physiotherapists using a set of structured questionnaires. No open answer questions were included. Any question required a frequent response, was answered in a numerical form. The family members or caregivers were allowed when desired by the participants as they may have felt more confident.

The 12-PSS is a simple self-reported questionnaire made up of 12 items that evaluate various directions of itching. The 12-PSS includes 12 individual questions that include 5 domains: recurrence and periods of pruritus (Q1), influence of pruritus on ADL and emotion (Q2-Q5), and scraping evaluation as a reaction to pruritus (Q6-Q8 and Q12), pruritus severity (Q9, Q10), and pruritus extent (Q11). The final score of 3 denoted mild pruritus while the final score of 22 denoted severe pruritus [28].

The Burn Specific Health Scale-Brief (BSHS-B) composed of 40 items was extracted in 2001 from the first 80 item BSHS created in the USA. The BSHS-B includes 3 domains inspecting physical, psychosocial performance and body image and burn associated issues. The comprised questions (maximum score of 160) investigated the answers to the BSHS-B concerned with physical capabilities (items 1-9; maximum score of 36), psychosocial issues (items 10-30; maximum score of 84), and the last 10 questions were too definite to body image due to

burn (items 31-40; maximum score of 40). As customary, the burned patient was asked to rate each question from 0 to 4; extreme(ly) (0), quite a bit (1), moderate(ly) (2), a little bit (3), and none (not at all) (4), with 4 referring that the point was 'not at all' a trouble and zero revealing an "excessive" trouble [29]. All outcome measures were performed before starting the first session of treatment procedure (pre-treatment) and after finishing the last session (post-treatment).

Data analysis was performed utilizing IBM SPSS Statistics for Windows, version 23 (Armonk, New York: IBM Corporation). All variables were assessed for normality using the Shapiro-Wilk test. Paired and unpaired t-test were used to calculate the differences between normally-distributed measures within and between groups respectively. While NRS for pain and pruritus were not normally-distributed measures so, Wilcoxon signed rank test and Mann Whitney U test were used to calculate the differences of measures within and between groups respectively. Data were considered significant if $P < 0.05$.

3. Results

Forty-five patients with burn completed the procedure according to the study design. Table 1 showed the baseline characteristics of the patients (age, gender, TBSA, type of skin graft, duration, and burned areas), which were identical between both groups with no significant differences ($P > 0.05$).

The measures of NRS for pain in the study group reduced significantly ($P < 0.05$), while in the placebo group reduced non-significantly from pre to post-treatment ($P > 0.05$). The post-treatment difference in NRS for pain between both groups was significant ($P < 0.05$) as presented in Table 2. Therefore, the pain was significantly decreased greater in the study group than in the placebo group.

The values of NRS for pruritus in the study group reduced significantly ($P < 0.05$), while in the placebo group reduced non-significantly from pre to post-treatment ($P > 0.05$). The post-treatment difference in NRS for pruritus between both groups was significant ($P < 0.05$) as presented in Table 2. Thus, pruritus

Table 1 – Baseline characteristics.

Variables	Study group (n=22)	Placebo group (n=23)	P-value
Age, years	35.18±10.23	32.78±10.15	0.432
Gender (M/F), n	12/10	13/10	0.962
TBSA, %	18.54±4.52	19.56±4.32	0.443
Type of skin graft (ST/FT/none), n	10/7/5	12/5/6	0.923
Duration from injury, days	42.50±5.19	39.87±8.07	0.134
Affected area (UL/LL), n	9/13	8/15	0.921

Data were presented as the mean±standard deviation, statistically significant at $P < 0.05$, M: male, F: female, TBSA: total body surface area, ST: split-thickness, FT: full-thickness, UL: upper limb, LL: lower limb.

Table 2 – Numerical Rating Scale (NRS) changes for pain and pruritus between the study group and the placebo group pre and post-treatment.

Variables	Study group (n=22)	Placebo group (n=23)	P-value
Pain rating, median (min.-max.)			
Pre-treatment	7 (6-10)	7 (6-9)	0.833
Post-treatment	2 (0-4)	6 (5-9)	0.012
P-value	<0.001	0.173	
Pruritus rating, median (min.-max.)			
Pre-treatment	7 (6-9)	7 (6-10)	0.913
Post-treatment	3 (0-5)	6 (4-10)	<0.001
P-value	<0.001	0.211	

Statistically significant at $P < 0.05$, n: number, min.: minimum, max.: maximum.

was significantly decreased greater in the study group than in the placebo group.

Mean score of Pressure Pain Threshold (PPT) measured in pounds was increased significantly in the study group ($P < 0.05$), while in the placebo group increased non-significantly from pre to post-treatment ($P > 0.05$). The difference in PPT between both groups post-treatment was significant ($P < 0.05$) as presented in Table 3. However, the improvement of PPT was significantly greater in the study group than in the placebo group.

Means of the final score of 12-Item Pruritus Severity Scale (12-PSS) in the study group and the placebo group reduced significantly ($P < 0.05$). The differences in 12-PSS scores in both groups post-treatment were statistically significant ($P < 0.05$) as presented in Table 4. Therefore, the improvement of the 12-Item Pruritus Severity Scale (12-PSS) was significantly greater in the study group than in the placebo group.

Mean scores on the Burn Specific Health Scale-Brief (BSHS-B) including physical capabilities, psychosocial issues, body image and burn associated issues, and total score increased significantly from pre to post-treatment in the study group ($P < 0.05$). Mean scores on BSHS-B (physical capabilities, body image and burn associated issues, and total score) increased significantly from pre to post-treatment in the placebo group ($P < 0.05$), but mean scores of psychosocial issues was non-significantly increased ($P > 0.05$). The differences in BSHS-B (physical capabilities, psychosocial issues, and total score) scores between both groups post-treatment were statistically

Table 3 – Pressure Pain Threshold (PPT) changes in pounds between the study group and the placebo group pre and post-treatment.

Variables	Study group (n=22)	Placebo group (n=23)	P-value
Pre-treatment	4.72±0.95	4.23±0.83	0.072
Post-treatment	7.83±2.57	4.87±1.31	<0.001
P-value	<0.001	0.058	

Data were presented as the mean±standard deviation, statistically significant at $P < 0.05$, n: number.

Table 4 – 12-Item Pruritus Severity Scale (12-PSS) scores changes between the study group and the placebo group pre and post-treatment.

Variables	Study group (n=22)	Placebo group (n=23)	P-value
Pre-treatment	17±2.64	18.3±2.08	0.071
Post-treatment	11.1±4.56	16.52±3.58	<0.001
P-value	<0.001	0.045	

Data were presented as the mean±standard deviation, statistically significant at $P < 0.05$, n: number.

significant ($P < 0.05$), while scores of body image and burn associated issues were statistically non-significant ($P > 0.05$) as presented in Table 5. However, BSHS-B scores were improved more significantly in the study group than the placebo group in physical capabilities, psychosocial issues, and total score but body image and burn associated issues was improved at the same level in both groups.

4. Discussion

Post-burn pain and pruritus had a remarkably bad effect on patients' HRQOL. Thus, any treatment modalities which decrease pain, control pruritus, and improve HRQOL in the patients with burn should be investigated and executed. This study aimed to evaluate the impacts of low-energy ESWT in the management of pain, pruritus, and HRQOL in patients with burn. The findings of this study revealed that low-energy ESWT decreased post-burn pain, increased PPT, and improved 12-PSS

Table 5 – Burn Specific Health Scale-Brief (BSHS-B) scores changes between the study group and the placebo group pre and post-treatment.

Variables	Study group (n=22)	Placebo group (n=23)	P-value
Physical capabilities			
Pre-treatment	10.73±1.83	11.04±1.55	0.543
Post-treatment	17.27±8.56	13.13±2.67	0.032
P-value	<0.001	0.002	
Psychosocial issues			
Pre-treatment	26.41±6.10	24.78±7.03	0.411
Post-treatment	31.54±8.59	27.09±5.24	0.041
P-value	0.027	0.213	
Body image and burn associated issues			
Pre-treatment	15.50±4.14	16.17±4.87	0.622
Post-treatment	21.64±6.62	20.48±6.54	0.557
P-value	<0.001	0.015	
Total scores			
Pre-treatment	52.64±10.51	51.99±12.94	0.854
Post-treatment	70.45±17.19	60.7±10.21	0.025
P-value	<0.001	0.015	

Data were presented as the mean±standard deviation, statistically significant at $P < 0.05$, n: number.

scale in form of decreasing post-burn pruritus recurrence, periods, influence on ADL and emotion, reaction to pruritus, severity, and extent. Simultaneously, HRQOL was improved in the study group including a total score, especially in physical capabilities domain, and psychosocial issues domain while body image and burn associated issues slightly improved at the same level within both groups because they need long time to be better. The little improvement in the placebo group may be attributed to the impacts of the traditional physical therapy program. On the other hand, the definitive improvement in the study group may be due to the combined impacts of low-energy ESWT with the traditional physical therapy program.

Earlier studies had examined the influences of ESWT on patients with burn to hasten re-epithelialization [30], hypertrophic and contracture of scars [31], post-burn pain [32], and pruritus after burn [22]. The lack of previous studies investigated the impacts of ESWT in post-burn pain, pruritus and disturbed HRQOL. This randomized placebo-controlled study was the first attempt to evaluate HRQOL in patients with burn with pain and pruritus following low-energy ESWT.

Shockwaves are a form of sound waves with elevated positive pressure magnitude that augments rapidly, similar to circumferential pressure as it is an existent applied science that has been utilized in different kind of diseases. The precise physiological effects of ESWT are still unclear [33]. ESWT generated kinetic intensity which transformed into biochemical or microscopic power in human tissues to produce different particular intracellular alterations and maybe decrease pain and improves tissue reformation. Various trials revealed that ESWT was efficient in reducing pain by the discriminative deprivation of C nerve fibers. Another hypothesis is elevation the level of endothelial nitric oxide synthase (eNOS) and/or increasing heat shock protein (HSP) [34].

Cho et al. applied ESWT at 100impulses/cm² (0.05-0.15mJ/mm²) on the scar in patients with burn to measure its effect on pain. They proved that ESWT group revealed significantly higher pain relief than the control group, this improvement could be probably due to ESWT-induced angiogenesis that improve blood flow to accelerate tissue reformation and prevent nociceptors presented in burn scar that close pain signals to central nervous system in addition to reduce the formation of substance P in the posterior root ganglion and restrain neuronal hyper-excitability [32].

The main cause of itching is histamine liberation, beside histamine, other inflammatory chemicals, like substance P, and a platelet activating factor. The input signals from histamine receptors are transferred through activated unmyelinated C nerve fibers [35].

Pruritus is believed to be the same as the pain underlying mechanism. Itching and pain transmitted through C fibers nerve endings from the spinal cord to the brain in the anterolateral spinothalamic tract course. When the pain course is disturbed, pruritus also absents. Though, pruritus and pain stimuli have a different threshold. As a result of the light stimulus to the external layer of skin leads to itching, although a profound stimulus to the deeper layer of skin causes pain. Activation of the small afferent C fibers induces pruritus while stimulation of the large afferent C fibers felt as pain [36]. The existence of histamine in the superficial layer of skin leads to severe pruritus, and when histamine is presented

deeply it feels pain. If the painful stimulus is used in the same region, pain is felt more than pruritus [37].

Pain and pruritus are uncomfortable symptoms in post-burn patients and contribute the same underlying mechanism. From this point of view, low-energy ESWT was applied to patients with burn to evaluate their impacts on pain, pruritus, and HRQOL.

The utilization of ESWT may be increased blood supply and hinder the presence of ischemia which caused by stasis zone post-burn injury [30]. Joo et al. implemented low-energy ESWT with flux density (0.05-0.20mJ/mm²) once per week for 3 successive weeks to investigate its effect on burn scar pruritus; they reported that the time, intensity, and total marks of pruritus using the Leuven Itch Scale were reduced significantly in low-energy ESWT group. They explained that low-energy ESWT was efficient in decreasing post-burn itching and increase blood flow [22].

Evaluation of HRQOL in patients with burn should be considered since post-burn pain and pruritus appear. It can be result in limitations of functional capabilities, a serious problem in the psychosocial aspects and body image of patients with burn. Assessments of HRQOL have been greatly accepted in research and practical concerns and many HRQOL forms have been created [38]. Based on the findings of this study, more attention should be presented between burn team members in concerning the vitality to assess HRQOL in post-burn pain and pruritus, to help in identification of optimal diagnosis and treatment. To our knowledge, it was the first time to apply BSHS-B, which was valid and reliable HRQOL form [29] to evaluate the impacts of low-energy ESWT on pain and pruritus in burn patients.

More than one method of the evaluation was implemented to assess impacts of low-energy ESWT on post-burn pain. Subjective prognosis of pain perception was measured by NRS, while PPT measured by an objective algometer. Also, NRS was used to measure the severity of post-burn pruritus, while the valid and reliable 12-PSS questionnaire was applied to measures post-burn pruritus recurrence [28], periods, influence on ADL and emotion, reaction to pruritus, severity, and extent. Both the NRS and the 12-PSS scale were carried out to assess different aspects of pruritus.

This study has some strength's points. Firstly, the findings after application of low-energy ESWT are encouraging and having minimal side effects. Secondly, low-energy ESWT was time-efficient simplicity of use as the total treatment session did not exceed 10min and cost efficiency. Thirdly, placebo treatment protocol considered as a significant ethical method of the treatment as it can be utilized in the medical field to supplement common treatment modalities [39]. On the other hand, the placebo treatment persists disputable in the health care [40]. In the present study, patients in the placebo group were advised to be treated with low-energy ESWT after finishing the study procedures to get benefits from its positive impacts. Further studies should be concerned with the long-term effects and different dosage of low-energy ESWT on post-burn pain, pruritus, and HRQOL. Although low-energy ESWT was implemented after a split or full-thickness skin graft or after healing of burn wound without surgical interference during chronic stage, future studies are suggested to ascertain the effects of low-energy ESWT at the acute stage for post-burn pain and pruritus.

5. Conclusions

The finding of the study indicates that low-energy ESWT is a new, noninvasive, and practicable modality. Clinically, low-energy ESWT with traditional physical therapy program may relieve pain, decrease pruritus, and improve HRQOL in adult patients with burn.

Conflict of interest

The authors declare no conflict of interest.

Acknowledgments

The authors would like to gratitude all the study participants for cooperation as well as the Department of Physical Therapy staff for their support and encouragement.

REFERENCES

- [1] LonCar Z, Bras M, Mickovic V. The relationships between burn pain, anxiety and depression. *Coll Antropol* 2006;30(2):319-25.
- [2] Druery M, Brown TL, Muller M. Long term functional outcomes and quality of life following severe burn injury. *Burns* 2005;31(6):692-5.
- [3] Gilboa D, Friedman M, Tsur H. The burn as a continuous traumatic stress: implications for emotional treatment during hospitalization. *J Burn Care Rehabil* 1994;15(January-February (1)):86-91.
- [4] Kursun S. Burn pain and nursing care. *Florence Nightingale Nurs Rev* 2007;15(60):195-9.
- [5] Guloglu R, Aksoy M. Prevention from burns: to who, how? *Turkiye Klinikleri J Surg Med Sci Gen Surg* 2007;3(1):70.
- [6] Bernfort L, Gerdle B, Rahmqvist M, Husberg M, Levin LA. Severity of chronic pain in an elderly population in Sweden – impact on costs and quality of life. *Pain* 2015;156:521-7.
- [7] Yosipovitch G, Goon A, Wee J, Chan YH, Goh CL. The prevalence and clinical characteristics of pruritus among patients with extensive psoriasis. *Br J Dermatol* 2000;143:969-73.
- [8] O'Donoghue M. Antihistamines and their role as antipruritics. *Dermatol Ther* 2005;18:333-40.
- [9] Nelson RD. Post-burn itch. In: Yosipovitch G, Greaves MW, Fleischer AB, McGlone F, editors. *Itch: basic mechanisms and therapy*. New York: Marcel Dekker, Inc.; 2004. p. 247-54.
- [10] Goutos I. Burns pruritus – a study of current practices in the UK. *Burns* 2010;36:42-8.
- [11] Woo KY. Exploring the effects of pain and stress on wound healing. *Adv Skin Wound Care* 2012;25(1):38-44.
- [12] Wasiaak J, Lee SJ, Paul E, Mahar P, Pfitzer B, Spinks A, et al. Predictors of health status and health-related quality of life 12 months after severe burn. *Burns* 2014;40(June (4)):568-74.
- [13] Stavrou D, Weissman O, Tessone A, Zilinsky I, Holloway S, Boyd J, et al. Health-related quality of life in burn patients – a review of the literature. *Burns* 2014;40(5):88-96.
- [14] Xie B, Xiao S, Zhu S, Xia Z. Evaluation of long term health-related quality of life in extensive burns: a 12-year experience in a burn center. *Burns* 2012;38:348-55.
- [15] Elsherbiny OE, Salem MA, El-Sabbagh AH, Elhadidy MR, Eldeen SM. Quality of life of adult patients with severe burns. *Burns* 2011;37(5):776-89.
- [16] Di Meglio F, Nurzynska D, Castaldo C, Miraglia R, Romano V, De Angelis A, et al. Cardiac shock wave therapy: assessment of safety and new insights into mechanisms of tissue regeneration. *J Cell Mol Med* 2012;16(4):936-42.
- [17] Wang CJ, Wang FS, Yang KD, Weng LH, Hsuet CC, Huang CS, et al. Shock wave therapy induces neovascularization at the tendon-bone junction: a study in rabbits. *J Orthop Res* 2003;21:984-9.
- [18] Haupt G, Chvapil M. Effect of shock waves on the healing of partial-thickness wounds in piglets. *J Surg Res* 1990;49:45-8.
- [19] Chen YJ, Wang CJ, Yang KD, Kuo YR, Huang HC, Huang YT, et al. Extracorporeal shock waves promote healing of collagenase-induced Achilles tendinitis and increase TGF- β 1 and IGF-I expression. *J Orthop Res* 2004;22:854-61.
- [20] Verstraelen FU, in den Kleef NJHM, Jansen L, Morrenhof JW. High-energy versus low-energy extracorporeal shock wave therapy for calcifying tendinitis of the shoulder: which is superior? A meta-analysis. *Clin Orthop Relat Res* 2014;472:2816-25.
- [21] Davis TA, Stojadinovic A, Amare K, Anam M, Naik S, Peoples GE, et al. Extracorporeal shock wave therapy suppresses the acute early proinflammatory immune response to a severe cutaneous burn injury. *Int Wound J* 2009;6:11-21.
- [22] Joo SY, Cho YS, Seo CH. The clinical utility of extracorporeal shock wave therapy for burn pruritus: a prospective, randomized, single-blind study. *Burns* 2018;44:612-9.
- [23] Shaheen AA. Low-energy radial extracorporeal shock wave therapy for chronic plantar fasciitis: a randomized control trial. *World Appl Sci J* 2011;12(1):10-5.
- [24] Tang D, Li-Tsang CWP, Au RKC, Li K, Yi X, Liao L, et al. Functional outcomes of burn patients with or without rehabilitation in mainland China. *Hong Kong J Occup Ther* 2015;26:15-23.
- [25] Middelkoop E, Monstrey S, Teot L, Vranckx JJ, editors. *Scar management practical guidelines*. Maca-Cloetens; 2011. p. 1-109.
- [26] Downie WW, Leatham PA, Rhind VM, Wright V, Branco JA, Anderson JA. Studies with pain rating scales. *Ann Rheum Dis* 1978;37(4):378-81.
- [27] Fernández-de-las-Pefias C, Alonso-Blanco C, FernándezCarnero J, Miangolarra-Page JC. The immediate effect of ischemic compression technique and transverse friction massage on tenderness of active and latent myofascial trigger points: a pilot study. *J Bodyw Mov Ther* 2006;10:3-9.
- [28] Reich Adam, Božek Agnieszka, Janiszewska Katarzyna, Szepietowski Jacek C. 12-Item Pruritus Severity Scale: Development and Validation of New Itch Severity Questionnaire. *BioMed Res Int* 20172017: Article ID 3896423, 7 pages.
- [29] Kildal M, Andersson G, Fugl-Meyer AR, Lannerstam K, Gerdin B. Development of a brief version of the Burn Specific Health Scale (BSHS-B). *J Trauma* 2001;51(4):740-6.
- [30] Ottomann C, Stojadinovic A, Lavin PT, Gannon FH, Heggeness MH, Thiele R, et al. Prospective randomized phase II trial of accelerated re-epithelialization of superficial second degree burn wounds using extracorporeal shock wave therapy. *Ann Surg* 2012;255:23-9.
- [31] Fioramonti P, Cigna E, Onesti MG. Extracorporeal shock wave therapy for the management of burn scars. *Dermatol Surg* 2012;38:778-82.
- [32] Cho YS, Joo SY, Cui H, Cho S, Yim H, Seo CH. Effect of extracorporeal shock wave therapy on scar pain in burn patients: a prospective, randomized, single-blind, placebo-controlled study. *Medicine* 2016;95(32):7.
- [33] Meirer R, Kamelger FS, Huemer GM, Wanner S, Piza-Katzer H. Extracorporeal shock wave may enhance skin flap survival in an animal model. *Br J Plast Surg* 2005;58:53-7.
- [34] Wang CJ, Wang FS, Yang KD, Weng LH, Hsu CC, Huang CS, et al. Shock wave therapy induces neovascularization at the tendon-bone junction: a study in rabbits. *J Orthop Res* 2003;21(6):984-9.

-
- [35] Mendham JE. Gabapentin for the treatment of itching produced by burns and wound healing in children: a pilot study. *Burns* 2004;30:851-3.
- [36] Fischer HB, Scott PV. Spinal opiate analgesia and facial pruritus [letter]. *Anaesthesia* 1982;37:777-8.
- [37] Yosipovitch G, Greaves MW, Schmelz M. Itch. *Lancet* 2003;361:690-4.
- [38] Garratt A, Schmidt L, Mackintosh A, Fitzpatrick R. Quality of life measurement: bibliographic study of patient assessed health outcome measures. *BMJ* 2002;324(7351):1417.
- [39] Tilburt JC, Emanuel EJ, Kaptchuk TJ, Curlin FA, Miller FG. Prescribing "placebo treatments": results of national survey of US internists and rheumatologists. *BMJ* 2008;337:a1938.
- [40] Miller FG, Colloca L. The legitimacy of placebo treatments in clinical practice: evidence and ethics. *Am J Bioethics* 2009;9:39-47.