Effect of Radial Extracorporeal Shockwave Therapy on Pain Intensity Level in Patient with Calcaneal Spur

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KEYWORDS

Radial extracorporeal shockwave; Heel Pain; Calcaneal spur; Visual analogue scale.

ABSTRACT

Background: Heel pain is a common musculoskeletal issue that significantly impacts patient daily activities and, consequently, their quality of life. This clinical study aims to evaluate the effectiveness of radial extracorporeal shockwave therapy in reducing pain intensity in patients with calcaneal spurs.

Objective: To investigate the effects of radial extracorporeal shockwave therapy on pain intensity in patient with calcaneal spur.

Methods: A total of 60 patients diagnosed with calcaneal spurs based on clinical examination and lateral radiography between September 2022 and June 2023 were included in this study. Participants were randomly assigned to two groups: Group A (radial extracorporeal shockwave therapy) and Group B (traditional physical therapy). All participants followed an exercise program; however, those in Group A received six sessions of radial extracorporeal shockwave therapy (10 Hz, 2000 pulses, at 2.4 bar). The Visual Analog Scale (VAS) was used to assess pain intensity both before and after treatment in all participants.

Results: No significant differences were observed between Group A and Group B regarding gender, affected side, condition distribution, age, weight, height, or BMI ($p > 0.05$). Both groups experienced significant reductions in VAS scores post-treatment ($p < 0.001$); however, Group A demonstrated a greater improvement, with a percentage reduction in pain of -50.65%, compared to -28.17% in Group B. Additionally, post-treatment VAS scores were significantly lower in Group A than in Group B ($p = 0.003$), indicating that shockwave therapy yielded a more substantial reduction in pain

Conclusions: Both radial extracorporeal shockwave therapy and traditional physical therapy programs significantly reduced pain intensity in patients with calcaneal spurs, with a favorable effect observed for radial extracorporeal shockwave therapy. These methods can be considered effective, safe, and conservative treatment options for managing calcaneal spurs.

1. Introduction

Heel pain is a common condition affecting approximately 10% of the population [1, 2] Calcaneal spur is a common cause of localized heel pain, that represent around 15-20% of heel pain cases [3, 4]. It can lead to localize irritation and restriction of daily living activities [4] Calcaneal spur develop due to abnormal calcium deposits building up on the medial tubercle of the calcaneus [1, 3, 5]. Symptoms include heel pain which worsens during activities such as walking or rising after extended periods of rest, and experiencing morning stiffness

The incident of the calcaneal spur is more common in female than male and increase with age and being overweight [6] Calcaneal spur has been found in 45% to 85% of patients with plantar fasciitis [7, 8]. Endoscopic removal of calcaneal spurs in patients with plantar fasciitis has demonstrated high success rates, suggesting that calcaneal spurs may play a significant role in the pathology of plantar fasciitis [2] the diagnosis of calcaneal spur is typically based on clinical examination , such as tenderness upon palpation of the medial tubercle of the calcaneus, and confirmed with lateral plain radiographs [5, 9]. The treatment options include local injection [10], surgical interventions [2], and conservative treatment methods such as cold application, rest [5], orthotic shoes [8], LASER [4], ultrasound [11], exercise [12], kinesio taping [13], and extracorporeal shockwave therapy [3, 12].

Previous studies have demonstrated that radial extracorporeal shockwave therapy is effective in treating musculoskeletal pain [14]. The pressure waves generated by radial extracorporeal shockwave travel through body fluids and soft tissues to reach the target area, where they produce both mechanical and cellular effects.

These effects include transient disturbance of the neuronal cell membrane, increase in the tissue permeability, encourage tissue regeneration and neovascularization, all of which contribute to the analgesic effect of radial extracorporeal shockwave [15]. Radial extracorporeal shockwave presents a viable alternative to surgical intervention and steroid injections for treating heel pain but research on its effect on calcaneal spur pain remains limited [16]. The aim of this study was to investigate the effects of radial extracorporeal shockwave on pain intensity level in patients with calcaneal spurs.

2. Subjects and methods:

2.1. Study design:

The current study design is a randomized, controlled, double-blinded trial. Participants were recruited from El-Sahel hospital and El-Khazendara hospital, both located in Cairo governorate, Egypt. The research was conducted at El-Sahel hospital between September 2022 and June 2023. All patients were thoroughly informed about the intervention procedures, potential benefits, and their right to withdraw from the study at any time. Informed consent was obtained from all participants prior to their involvement in the study.

2.2. Participants:

All patients referred from the orthopedic department to the physical therapy department with a diagnosis of calcaneal spur were screened for eligibility to participate in this study. A total of 60 patients were selected based on the following inclusion criteria which required them to be between 20 and 70 years old, with a calcaneal spur confirmed via lateral plane radiography. Moreover, patients were required to have at least one month since their last medical intervention, such as injections or physical therapy sessions. Exclusion criteria included the presence of lower extremity neurological diseases, inflammatory joint disorders (e.g., rheumatoid arthritis or ankylosing spondylitis), fractures, severe osteoporosis, recent foot or ankle surgery, cardiac pacemakers, coagulation blood disorders, anticoagulant therapy, wounds, or ulcers in the heel area.

2.3. Sample size calculation:

This study included 60 patients who were medically diagnosed with calcaneal spur. The sample size was calculated using G*POWER statistical software (version 3.1.9.2, Germany). based on paired-samples T-tests Type I error (α) of 0.05, a power of 85%, and an effect size of 0.79. The sample size was estimated using unpublished data from a pilot study conducted by the same investigator with six subjects.

2.4. Randomization:

A total of 60 participants with heel spurs were randomly assigned to either the treatment group (group A) or the control group (group B) using computerized randomization.

2.5. Intervention:

After the initial assessment, Group A received radial extracorporeal shockwave using the Chattanooga Intelect RPW device with the following parameters 2000 pulse, 2.4 bar, 10 Hz. The treatment consisted of six sessions, administered twice per week over a three week. Group B managed by a traditional physical therapy program which included stretching exercise for the plantar fascia and strengthening exercise for the leg & intrinsic foot muscles. Each subject was individually instructed about the treatment protocol and asked to report any adverse incidents following each session of shockwave therapy. The same therapist applied shockwave sessions over the the medial tubercle of the calcaneus without any analgesic or local anesthetic medication administrated before or during the treatment.

2.6. Outcome measures

Pain intensity level was measured using the visual analogue scale, a self-reported scale consisting of 100 mm horizontal line. The left end of the line is labeled "no pain," while the right end is labeled "worst possible pain." Patients were asked to mark the point on the line that best reflected their pain intensity level. The visual analogue scale is a valid, reliable and appropriate for use in clinical practice [3, 17]

2.7. Statistical analysis:

In this study, all statistical analyses were conducted using IBM SPSS version 25.0 software (SPSS Inc., Chicago, IL, USA). Descriptive statistics were calculated for all study variables across all participants. A paired-samples t-test was employed to compare the Visual Analogue Scale (VAS) scores before and after treatment within the same group, while an independent (unpaired) t-test was used to compare VAS scores between the treatment groups. A p-value of ≤ 0.05 was considered statistically significant.

3. Results:

A chi-square test was conducted to compare the distribution of gender, side affected, and condition between Group A and Group B. The gender distribution showed that Group A consisted of 22 females (73.3%) and 8 males (26.7%), while Group B had 23 females (76.7%) and 7 males (23.3%). The chi-square test result was 0.089 with a significance level (p-value) of 0.766, indicating no significant difference in gender distribution between the groups.

Regarding the side affected, in Group A, 13 participants (43.3%) had the right side affected, and 17 (56.7%) had the left side affected. In Group B, 17 participants (56.7%) had the right side affected, while 13 (43.3%) had the left side affected. The chi-square test yielded a value of 1.067 and a p-value of 0.302, showing no statistically significant difference in the affected side between the groups.

For the condition status, Group A had 2 participants (6.7%) with an acute condition, none with a subacute condition, and 28 participants (93.3%) with a chronic condition. Group B had 1 participant (3.3%) with an acute condition, 3 participants (10%) with a subacute condition, and 26 participants (86.7%) with a chronic condition. The chi-square test result was 3.407 with a p-value of 0.182, indicating that the difference in the distribution of conditions across the groups was not statistically significant.

The comparison of demographic characteristics between Group A and Group B revealed no statistically significant differences. The mean age was 50.47 ± 7.31 years for Group A and 50.33 ± 8.04 years for Group B, with a mean difference of 0.13 (95% confidence interval: -3.84 to 4.11), and a t-value of 0.067 (p = 0.947). The mean weight was 88.9 ± 16.39 kg in Group A and 87.57 ± 13.58 kg in Group B, yielding a mean difference of 1.33 (-6.45 to 9.11), with a t-value of 0.343 (p = 0.733). The mean height was 161.33 ± 8.06 cm for Group A and 161.17 ± 9.09 cm for Group B, with a mean difference of 0.17 (-4.27 to 4.6), and a t-value of 0.075 (p = 0.94). The BMI was 34.34 ± 7.16 kg/m² in Group A and 34.02 ± 6.64 kg/m² in Group B, resulting in a mean difference of 0.31 (-3.26 to 3.88), with a t-value of 0.176 (p = 0.861). These results indicate no significant differences between the two groups in terms of age, weight, height, or BMI.

Table 1 shows that both Group A and Group B experienced significant reductions in VAS scores from pre- to post-treatment (p < 0.001 for both). Group A showed a greater percentage change (-50.65%) compared to Group B (-28.17%). Post-treatment, Group A had significantly lower VAS scores than Group B (p = 0.003), with a mean difference of -8.67.

Table (1): Descriptive and inferential statistics of VAS within and between groups

	Group (A)	Group (B)	MD (LL-UL)	t	Sig
Pre_VAS	51.33±11.67	47.33±16.8	4(-3.48-11.48)	1.071	0.289
Post_VAS	25.33±10.17	34±11.63	-8.67(-14.31--3.02)	-3.07	0.003
MD	DE-26	DE-13.33			
% of change	-50.65%	-28.17%			
t	12.490	12.042			
Sig. (2-tailed)	0.000	0.000			

4. Discussion:

The main findings of the current study demonstrated that both radial extracorporeal shockwave and traditional physical therapy program significantly decreased pain intensity level in patients with calcaneal spur (p < 0.001). While the precise biological mechanisms underlying the analgesic effects of radial extracorporeal shockwave remain under debate, several hypotheses have been proposed in the literature. These inducing of release of fascial tissue by the mechanical stimulation [16], analgesia by overstimulation [3], modulation of macrophage activity, reduction of cellular inflammation, reduction of the leukocyte infiltration, and down-regulation of the cytokine production [18]. Additionally, radial extracorporeal shockwave promotes angiogenesis by enhancing the release of nitric oxide which in turn accelerate the healing process [15, 16, 19, 20].

However, the mechanism behind the analgesic effects of a traditional physical therapy program involves several key factors. Foot and leg exercises help reduce fascial contracture, improve flexibility, and enhance foot mechanics, thereby alleviating stress on the calcaneus bone. By reducing this stress, the excessive tension exerted by the plantar fascia on the heel is minimized, potentially controlling the development of calcaneal spurs.

Additionally, the increased blood flow resulting from exercise promotes healing and reduces inflammation, while neuromuscular adaptations help desensitize pain receptors, further alleviating discomfort [21–23].

The findings of the current study is in consensus with the previously conducted studies on patients with calcaneal spur [16, 19] and heel pain [12]. Radial extracorporeal shockwave significantly reduced pain intensity level in patient with calcaneal spur in short term [19] and over long term duration[16]. Furthermore, the combination of radial extracorporeal shockwave therapy with exercise resulted in significant improvements in VAS pain scores, both clinically and statistically [12]. Compared to ultrasound therapy, Radial extracorporeal shockwave required fewer sessions to achieve effective pain relief [24]. It also reduced the recurrence rates of pain [19]. However, the current results differ from findings from previous studies on calcaneal spur [13], and in different population [25–27]. Radial extracorporeal shockwave showed nonsignificant difference in pain intensity level compared to Kinesio tape in a previous study [13]. This difference may be attributed to the variation in the shockwave dosage and parameters.

Radial extracorporeal shockwave showed non-significant difference in pain intensity level compared to shame shockwave therapy in patients with plantar fasciitis [25–27]. This inconsistency with the current study findings may be attributed to the differences in study population, the shockwave dosage, and frequency of the sessions [25–27]. Also, the shame shockwave therapy group received low dose of shockwave which might influence the results [26]. Furthermore, both shockwave group and placebo group received local anesthesia prior to intervention which may affect the results [27].

This study has a few limitations; first, the short duration of the study. Further studies should be conducted with longer follow-up duration to show the long-term effects. Second, the study didn't explain the mechanism of current results. Further studies should be conducted to investigate the mechanism of pain and pain reduction following treatment with radial extracorporeal shockwave.

5. Conclusion:

In conclusion, both radial extracorporeal shockwave therapy and traditional physical therapy programs have proven to be effective, non-invasive options for reducing pain intensity in patients with calcaneal, with a notable advantage for radial extracorporeal shockwave therapy. The findings of this study support previous research, confirming the analgesic benefits of both treatments and their safety in managing heel pain. These conservative modalities provide a viable alternative to more invasive procedures such as surgery or steroid injections, offering effective short-term pain relief. As non-invasive interventions, radial extracorporeal shockwave and traditional physical therapy are valuable options for patients seeking to alleviate discomfort caused by calcaneal spurs without the need to use an invasive treatment.

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