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Effect of Shockwave Therapy on Postmenopausal Sacroiliac Joint Pain: A Randomized Controlled Trial

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ABSTRACT

Background: Sacroiliac joint pain is a common complaint among women and old-aged people, affecting their life quality. **Objective:** To examine the effect of shockwave therapy on postmenopausal sacroiliac joint pain.

Subjects and Methods: Thirty postmenopausal women with sacroiliac joint pain were randomly chosen and divided into 2 groups of equal number. Group (A) received muscle energy technique for 8 weeks, whereas group (B) received the same muscle energy technique in addition to shockwave therapy for 8 weeks. The outcome measures were the mean values of pressure pain thresholds (PPT) at five chosen points in the sacroiliac joint region to assess pain sensitivity, visual analog scale (VAS) to evaluate pain intensity, and Oswestry disability index (ODI) to evaluate the functional disability. All of them were evaluated before and after treatment.

Results: A comparison of the two groups after treatment showed statistically significant increases in the mean values of PPT at the five chosen points ($p<0.05$), as well as significant reductions in the scores of VAS and ODI ($p<0.05$) in favor of group (B).

Conclusion: Shockwave is effective in treating postmenopausal sacroiliac joint pain through decreasing pain sensitivity and intensity, as well as improving functional ability.

Keywords: Shockwave, Sacroiliac joint pain, Postmenopause, Pressure pain threshold.

INTRODUCTION

Contemporary women spend about one-third of their lives in the postmenopausal period due to increased life expectancy. Chronic pain affects women more than men, and it worsens with aging. The transition from pre-menopause to post-menopause is associated with reduced estrogen production, resulting in enhanced pain experience. In addition, menopause-related fatigue, insomnia, and mood changes have all been shown to increase pain perception. One of the most common symptoms connected with this stage of life is joint pain [1,2].

Sacroiliac joint pain represents a major leading cause of lumbo-pelvic pain. It has a prevalence of 15–38% and causes around 13% of persistent low back pain conditions. It affects women more than men and is more common among elderly people due to decreased ligamentous flexibility [3-6].

Numerous physical therapy interventions, such as patient education, bracing, massage, mobilization, manipulation, therapeutic exercises, aerobic conditioning, and electrotherapeutic modalities like transcutaneous electrical nerve stimulation and ultrasound are effective in treating sacroiliac joint pain [7]. Additionally, using the force exertion of the muscles to cure joint problems is another option offered by the muscle energy technique [8].

Shockwave therapy is a novel conservative method of treatment for musculoskeletal pain produced by a range of illnesses [9]. Since it inhibits pain transmission and suppresses the inflammatory response, it is considered a good choice for alleviating lumbo-pelvic pain and enhancing its function in recent years [10-12]. Although menopause is a difficult time for most women and its symptoms have a significant influence on their well-being and life quality [13], research regarding the benefit of physical therapy interventions on postmenopausal sacroiliac joint pain is lacking. Therefore, this study was conducted to examine the effect of shockwave therapy on pain sensitivity, intensity, and functional disability in postmenopausal women with sacroiliac joint pain.

SUBJECTS AND METHODS

Study Design

The study was designed as a prospective, randomized, controlled trial.

Ethical approval:

Before the study began, ethical permission was received from the institutional review board at the Faculty of Physical Therapy, Cairo University [No: P.T.REC/012/002792]. Every patient signed an informed written consent for acceptance of participation in the study. The study conformed to the Helsinki Declaration Guidelines for conducting human research. It took place from December 2021 to March 2022.

Study Subjects

A sample of thirty postmenopausal women, suffering from chronic sacroiliac joint pain for at least 6 months, was recruited from the Physical Therapy Outpatient Clinic, Agouza Police Hospital, Giza, Egypt. Participants in the trial were required to be

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sedentary, ambulatory, non-smoking women who had reached natural menopause at least one year preceding the study and had no history of bilateral surgical removal of the ovaries and/or the uterus.

They had moderate to severe unilateral sacroiliac joint pain (visual analog scale (VAS) ≥ 5) and positive results in three out of five provocation sacroiliac joint tests (i.e., compression test, distraction test, Faber sign, Gaenslen test, and thigh thrust test). Their age varied from 54 to 58 years, their body mass index (BMI) was ≤ 30 kg/m^2 and the maximum parity number was 4 times. The exclusion criteria were spinal or hip joint disease or surgery, having a positive straight leg raising test, acute pelvic bacterial or viral infections or tumor, leg length discrepancy, or receiving nonsteroidal anti-inflammatory drugs, hormonal therapy, or corticosteroid injections.

Randomization

Each participant was informed about the study's nature, objective, and usefulness, her freedom to reject or leave the study anytime, and the privacy of all information gathered. A computer-based randomization program was used to randomize participants into two equal groups (A and B). After randomization, there was no subject withdrawal from the research (Figure 1).

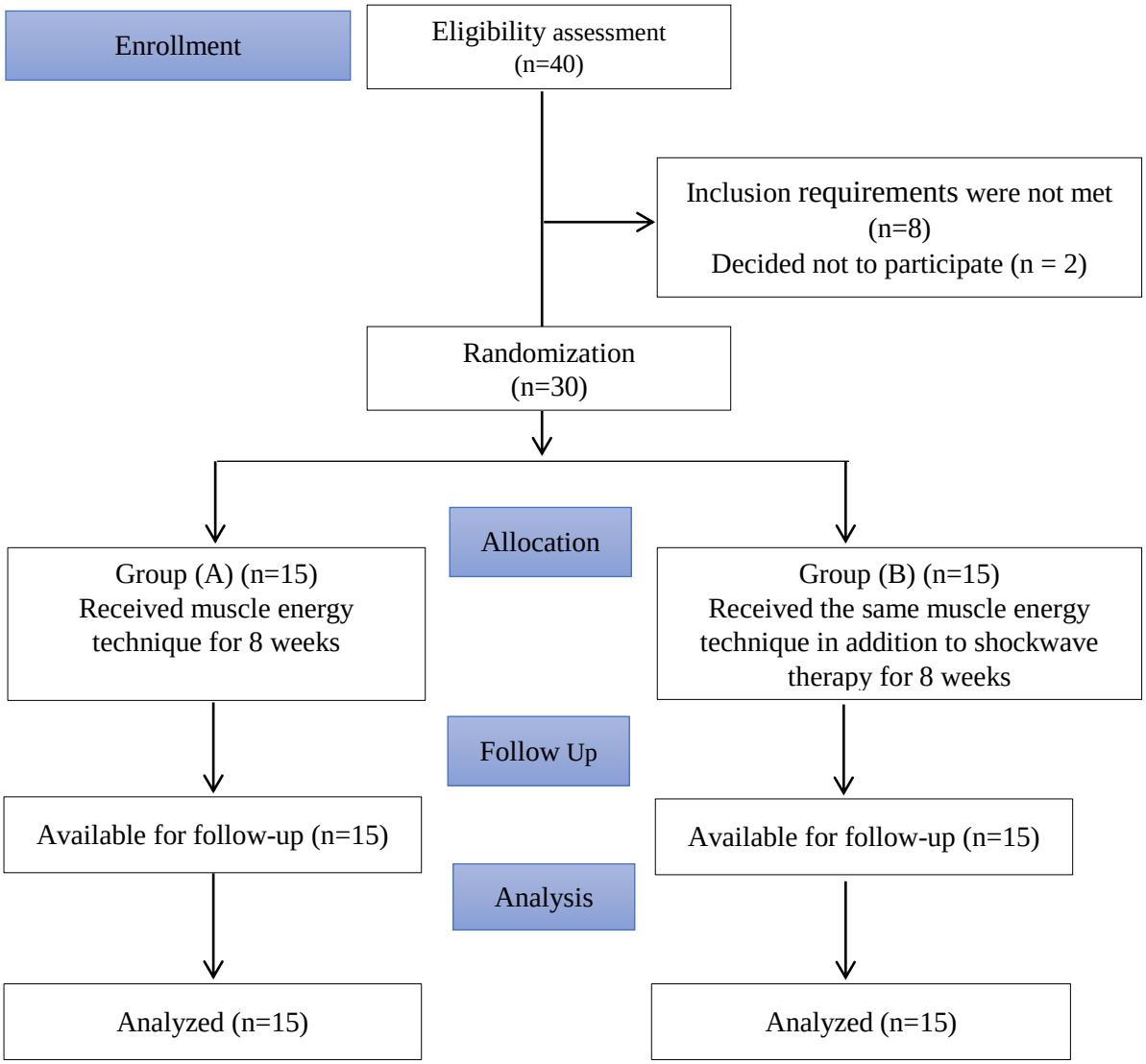

Figure (1): The study's flow chart.

Interventions

Group (A) included 15 postmenopausal women who received muscle energy technique for 8 weeks, while group (B) included 15 postmenopausal women who received the same muscle energy technique plus shockwave therapy for 8 weeks.

Muscle Energy Technique

All postmenopausal women in both groups (A) and (B) received muscle energy technique, twice a week, for eight weeks. It was performed as post isometric relaxation techniques for the muscles of iliopsoas, hamstrings, erector spinae, and quadratus lumborum. Following the identification of the restriction barrier, each participant was asked to perform a contraction at 20–30% of her maximal voluntary isometric contraction, maintain it for 7–10 seconds, and then relax for 2–3 seconds. Appropriate breathing guidelines were given. The limb was then moved just a little bit beyond the restriction barrier on expiration and kept there for 10 to 30 seconds.

Regarding iliopsoas, each woman was positioned supine with her affected lower extremity hanging freely at the plinth's edge, while the other lower extremity was flexed at the knee and hip. The affected leg was taken from the distal anterior thigh beyond the barrier by the therapist's hand after the muscular energy technique was performed with gentle downward pressure and held for 10 to 30 seconds. Regarding hamstrings, each woman was asked to lie on her back with her leg hanging over the therapist's shoulder. The participant's leg was held just above the knee, by the therapist, to avoid bending. The participant was instructed to perform an isometric contraction before relaxing, and her leg was then moved beyond the barrier and kept there for half a minute. Regarding erector spinae, each woman was positioned in sitting with her back to the therapist. The therapist slid her arm to be in front of the participant's axilla before flexing, bending to the side, and rotating the participant to the barrier. The participant was then instructed to look in the opposite direction for 7–10 seconds before relaxing. The therapist took the participant further beyond the barrier. Regarding the quadratus lumborum, each woman was positioned supine trying to bend toward the un-treated side (forming a banana shape), while the therapist grasped the participant's shoulder of the treated side from the axilla. The woman was instructed to side bend toward the treated side and to hold it for 7 seconds then relax and move toward the untreated side [14].

Shockwave Therapy

Each woman in group (B) received shockwave therapy (Gymna ShockMaster 500, Germany), for 10 minutes/session, one session/week, for 8 weeks. The participant was instructed to lie on her abdomen with the treated side toward the physiotherapist. A coupling gel was applied to the treated area to lower tissue resistance and enhance energy transmission. The probe was moved upward and downward along the posterior sacroiliac joint line while being held perpendicular to the joint line (Figure 2). The parameters were 2400 pulses, frequency of 8 Hz, and an energy density of 0.11 mJ/mm^2 [11].

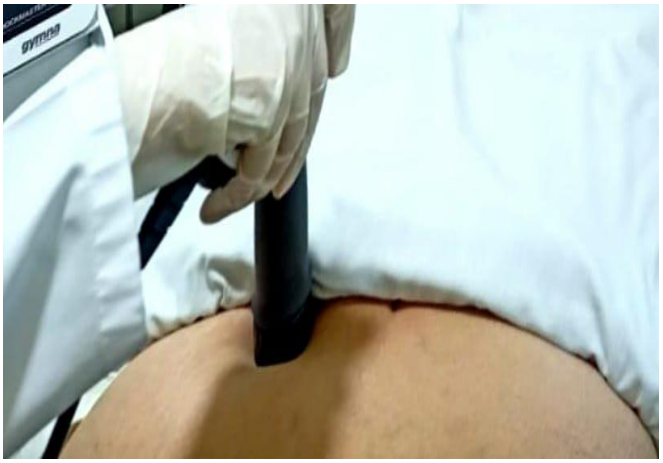

Figure (2): Shockwave application on the sacroiliac joint.

Outcome measures

Pressure pain threshold

Each woman in both groups (A & B) was assessed prior to and following the completion of the study, by measuring pressure pain thresholds (PPT) at five selected points in the sacroiliac joint region of the affected side, using a pressure algometry (Force Dial model FDK 20 Push Pull Force Gage, Wagner Instruments, Greenwich CT, USA) to assess her pain sensitivity. All participants received the same detailed instructions regarding the evaluation process. Each woman was asked to lie face down on the plinth, with both arms alongside the body. The researcher marked the chosen examined points with an anthropologic pencil. The first examined point was 1 cm medial and inferior to the posterior superior iliac spine, while the other four examined points were 2 cm lateral, medial, superior, and inferior to the first point. From an anatomical point of view, the location of the second examined point (2 cm laterally) was near the posterior superior iliac spine where the gluteus maximus attached to the iliac crest. The third (superior) point was overlying the erector spinae muscle, while the fourth (medial) point was overlying the deep posterior sacroiliac ligament. The location of the fifth (inferior) point was where the gluteus maximus was attached to the posterior sacral facies and posterior sacroiliac ligament [15].

The PPT was then measured, via a pressure algometry with a probe area of 1 cm^2, through the application of a constant pressure axially on each point until the pain was reported by the participant. The algometry could measure 10 kg/cm^2 and be accurate to 0.1 kg/cm^2. Each point was measured three times with

a ten-second interval between them; the mean of them was then calculated for each point to be utilized for statistical analysis.

Visual analog scale (VAS)

The VAS was utilized to evaluate the intensity of pain at the sacroiliac joint for each woman in the two groups (A & B) before and following the completion of the treatment program. It is the best scale for evaluating pain intensity because it is simple, valid, and reliable, in addition to its ratio scale characteristics. It is a horizontal line whose length is 10 cm; its left end (zero) indicates no pain, while its right end (ten) reveals the worst imaginable pain. Each woman was requested to score her pain level by marking a point on the VAS line that reflected her pain intensity. Then, to get the VAS score for sacroiliac joint pain severity, the distance between the left end of the line to the marked point was measured in centimeters [8].

Oswestry Disability Index (ODI)

It was utilized to evaluate the functional disability level of each woman in the two groups (A & B) before and after the treatment program. It is a valid tool for assessing disability related to sacroiliac joint pain.

It includes 10 questions concerned with pain level, self-care, lifting, abilities to walk, sit, and stand, quality of sleep, sexual life, social life, and travels [16]. Each question has a score range from 0 to 5, with the lowest value indicating the best health condition.

To calculate the percentage of functional disability, the scores were added together and multiplied by 2. Scores between 0 and 20 percent showed minor disability, 21 to 40 percent suggested disability of moderate degree, 41-60 percent reflected disability of severe degree, 61 to 80 percent revealed crippling back pain, and 81 to 100 percent indicated bed ridden [17].

Sample size calculation and statistical analysis

G*POWER statistical software (version 3.1.9.2; Franz Faul, Universitat Kiel, Germany) was utilized to calculate sample size depending on PPT data from a pilot study conducted on five subjects per group, revealing that the required sample size for this research was 15 participants in each group. Calculation was performed with α=0.05, power = 80% and effect size = 1.1.

Data presentation was in the form of mean ± standard deviation. Data normal distribution was checked through the Shapiro-Wilk test, while group homogeneity was tested through Levene's test for variance homogeneity. The t-test was used to compare baseline characteristics between groups.

Mixed MANOVA was performed for comparing the time effect (pre versus post) and the treatment effect (between groups), as well as the interaction between time and treatment on mean values of PPT, VAS, and ODI. For subsequent multiple comparisons, post-hoc tests with the Bonferroni correction were performed. The statistical package for social studies (SPSS) version 25 for Windows (IBM SPSS, Chicago, IL, USA) was used for all statistical analyses. The significance level was set at $p<0.05$ for all statistical tests.

RESULTS

Baseline characteristics, including age, BMI, years after menopause, and parity, as well as all outcome variables, did not differ significantly between the two groups at the beginning of the study ($p>0.05$) **(Tables 1-2).**

Table (1): Baseline characteristics of women in both groups

	Group (A) (n = 15)	**Group (B) (n = 15)**	**P-value**
Age (yrs.)	55.33 ± 1.75	55.8 ± 1.37	0.42 ^{NS}
BMI (Kg/m^2)	28.61 ± 1.62	28.28 ± 0.82	0.49 ^{NS}
Years after menopause	6.4 ± 1.18	6.93 ± 1.22	0.23 ^{NS}
Parity	2.6 ± 0.98	2.66 ± 0.61	0.82 ^{NS}

^{NS} $p > 0.05$ = non-significant, p = Probability.

The mean values of PPT at the five chosen points (point I, point II, point III, point IV, and point V) revealed statistically significant increases within both groups ($p<0.05$). Comparing both groups after treatment revealed statistically significant increases in the mean values of PPT at the five chosen points in favor of group (B) ($p<0.05$). The VAS scores showed statistically significant reductions within both groups ($p<0.05$). Comparing both groups after treatment revealed a statistically significant decrease in the VAS scores in favor of group (B) ($p<0.05$). The ODI scores showed statistically significant reductions ($p=0.001$) within both groups (A & B). Comparing both groups after treatment revealed a statistically significant decrease in the ODI scores in favor of group (B) ($p<0.05$) (Table 2).

Table (2): The mean values of PPT at the five chosen points, VAS, and ODI for both groups

		Group (A) (n = 15)	Group (B) (n = 15)	p-value*
PPT at point I (kg/cm^2)	Pre-treatment	7.67 ± 1.79	8.1 ± 2.01	0.53 ^{NS}
	Post-treatment	10.64 ± 1.64	13.38 ± 1.94	0.001 ^{S}
	p-value**	0.001 ^{S}	0.001 ^{S}	
PPT at point II (kg/cm^2)	Pre-treatment	7.71 ± 1.98	8.04 ± 1.84	0.63 ^{NS}
	Post-treatment	10.26 ± 1.71	12.67 ± 1.94	0.001 ^{S}
	p-value**	0.001 ^{S}	0.001 ^{S}	
PPT at point III (kg/cm^2)	Pre-treatment	7.01 ± 1.83	7.7 ± 1.34	0.25 ^{NS}
	Post-treatment	10.98 ± 0.98	12.91 ± 1.97	0.002^{S}
	p-value**	0.001 ^{S}	0.001 ^{S}	
PPT at point IV (kg/cm^2)	Pre-treatment	7.16 ± 1.86	7.5 ± 2.06	0.64 ^{NS}
	Post-treatment	11.05 ± 1.23	12.32 ± 1.66	0.02^{S}
	p-value**	0.001 ^{S}	0.001 ^{S}	
PPT at point V (kg/cm^2)	Pre-treatment	7.17 ± 1.45	7.58 ± 1.9	0.51^{NS}
	Post-treatment	10.38 ± 0.98	12.8 ± 1.67	0.001 ^{S}
	p-value**	0.001 ^{S}	0.001 ^{S}	
VAS (cm)	Pre-treatment	7.33 ± 0.81	7.26 ± 0.79	0.82 ^{NS}
	Post-treatment	3.26 ± 0.7	2.6 ± 0.63	0.01^{S}
	p-value**	0.001 ^{S}	0.001 ^{S}	
ODI	Pre-treatment	64.86 ± 3.96	63.4 ± 5.94	0.43 ^{NS}
	Post-treatment	23.86 ± 4.94	18 ± 3.29	0.001^{S}
	p-value**	0.001 ^{S}	0.001 ^{S}	

* Inter-group comparison; ** intra-group comparison of the results pre-and post-treatment.
^{NS} $p>0.05$ = non-significant, ^{S} $p<0.05$ = significant, p = probability.

DISCUSSION

Sacroiliac joint pain represents a very high illness burden due to its likely high prevalence and its negative consequences on health-related quality of life. This burden exceeds several widespread medical conditions, is comparable to osteoarthritis of the hip and knee, spinal stenosis, and degenerative spondylolisthesis, and is only slightly less than the burden of serious diseases like ankylosing spondylitis, severe parkinsonism, and decompensated cirrhosis. Sacroiliac joint pain is a prime candidate for therapeutic intervention optimization due to its enormous burden [18]. Therefore, this study aimed to investigate the effect of shockwave therapy on postmenopausal sacroiliac joint pain.

Regarding group (A), the results of this study showed statistically significant increases in the mean values of PPT at all measured points, as well as statistically significant reductions in scores of VAS and ODI between pre-and post-treatment.

The positive effect of the muscle energy technique on postmenopausal women with sacroiliac joint pain could be supported by recent studies that reported the effectiveness of the muscle energy technique in reducing pain and enhancing the functional status of postnatal women having sacroiliac joint dysfunction [19,20].

The analgesic and functional enhancing findings in group (A) after 8 weeks of muscle energy technique can have several explanations. The first explanation can be related to the post-isometric relaxation produced in the agonist's muscle following its isometric contraction because of Golgi tendon organ stretching and Ib-afferent stimulation, resulting in motor neuron inhibition and subsequent muscle relaxation. The second explanation concerns the indirect effect of the muscle energy technique on the sacroiliac joint through influencing myofascial tissues, correcting the muscular imbalance, realigning the pelvis, and so enhancing functional symmetry. The third explanation involves the neurophysiological pain-relieving mechanisms such as gate control theory and supra-spinal mechanisms. Finally, the muscle energy technique produces muscular blood increase, lymphatic fluid improvement, as well as inflammatory cytokines reduction, and peripheral nociceptors desensitization [8,21,22].

Regarding group (B), the results of the current study showed statistically significant increases in the mean values of PPT at all measured points, as well as statistically significant reductions in scores of VAS and ODI after treatment compared to the baseline, reflecting that a combination of muscle energy technique and shockwave therapy for 8 weeks had a beneficial impact on postmenopausal women with sacroiliac joint pain.

These results agreed with **Kansagara and Patel [23],** who found that the muscle energy technique, in conjunction with traditional or other physical therapy methods, can be beneficial in lowering pain and increasing functional capacity in individuals having sacroiliac joint dysfunction.

Regarding the comparison between both groups post-treatment, the results revealed that there were

statistically significant increases in the mean values of PPT at all measured points, in addition to statistically significant reductions in scores of VAS and ODI in favor of group (B). These results revealed that the combination of muscle energy technique plus shockwave therapy had a better therapeutic effect on postmenopausal sacroiliac pain than the muscle energy technique alone.

These findings could be reinforced by **Elhosary *et al.*** [11], who found that 8-week of combined application of shockwave therapy and a program of posture correction exercise had superior effects on lowering VAS scores of sacroiliac pain and enhancing the function of postnatal women with sacroiliac joint pain than did the exercise program alone. Additionally, **Saleh *et al.*** [24] reported that the addition of shockwave therapy to Mulligan mobilization for 8 weeks resulted in significantly greater PPT increase, ODI scores reduction, and mobility improvement when compared to only Mulligan mobilization in female and males patients with sacroiliac joint dysfunction. Moreover, a recent systematic review and meta-analysis of randomized controlled trials concluded that shockwave treatment is valuable in relieving pain and increasing overall functional status in people suffering from low back pain [10]. Furthermore, a narrative review by **Reilly *et al.*** [25] revealed that shockwave is a well-tolerated therapeutic method for a variety of clinically painful musculoskeletal diseases in the upper and lower limbs.

Extracorporeal Shockwave therapy is made up of biphasic pulsed acoustic waves that are produced extracorporeally and travel in three dimensions through the tissue to cause a fast pressure rise. Shock waves, for instance, are composed of quickly increasing positive pressure impulses with a range of 5-120 MPa in 5 ns, and after that a negative pressure of around 20 MPa. Both positive and negative pressure impulses provoke physical/mechanical consequences like absorption, reflection, refraction, and cavitation in the underlying treated tissues that are followed by numerous molecular and biological consequences, because of mechano-transduction. Indeed, shockwaves can activate various cell signaling pathways and induce the production of a variety of biomolecules[26].

In the current study, the advantageous effect of shockwave therapy on reducing pain sensitivity and intensity along with recovering functional disability could be attributed to several mechanisms of action. shockwave therapy can relieve pain in musculoskeletal tissues via selectively destroying unmyelinated fibers, reducing neuropeptides related to pain, hyper-stimulating nociceptors, modulating neurotransmission of pain, and reducing the levels of mediators of inflammation such as interleukins and matrixins [26,27]. Moreover, the shock waves produce micro-destruction, which causes micro-tearing of tissues with minimal or insufficient vascularization to promote revascularization via local growth factors production and stem cells mobilization, resulting in blood flow increase to these tissues and a subsequent reduction in muscular tension and tissue adhesions [28,29]. Furthermore, the application of shockwave therapy on the posterior sacroiliac joint line might stimulate ligamentous regeneration between the sacrum and ilium by promoting the synthesis of collagen, inducing neovascularization, and boosting blood flow, thus increasing stability, minimizing the motion type that produces sacroiliac pain, and improving the functional status [30].

FUTURE RESEARCH RECOMMENDATIONS

The current study presents objective data with statistically significant differences regarding the antinociceptive and functional enhancing effects of shockwave therapy on postmenopausal sacroiliac pain. However, it lacks the underlying mechanisms explaining these results. Therefore, future research is needed to investigate the effects of shockwave therapy on different inflammatory mediators, pain markers, and imaging outcomes in postmenopausal women suffering from sacroiliac joint pain.

CONCLUSION

Eight-week shockwave therapy is a safe, non-invasive, and effective method for raising pressure pain threshold, minimizing pain intensity, and boosting functional ability in postmenopausal women with sacroiliac joint pain.

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