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Effect of Shockwave Therapy on Low Back Pain in Primary Dysmenorrhea

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ABSTRACT

Purpose: This study was conducted to explore shockwave therapy's efficacy in managing low back pain (LBP) associated with primary dysmenorrhea (PD). Subjects: Sixty patients complaining of LBP during PD participated in this study. Participants' ages ranged from 18 to 30 years, and all subjects presented with body mass indices not exceeding 29 kg/m2.

Design: A randomized controlled methodology was employed for this study. They were divided into two equal groups: Group A, which was treated with hot packs for three consecutive menstrual cycles. Group B which was treated with hot packs in addition to shockwave therapy for three consecutive menstrual cycles.

Assessment: LBP intensity was evaluated using a visual analogue scale (VAS) and pressure algometer (PA) measurements for all participants in Groups A and B before intervention and following each of three consecutive menstrual cycles. The Oswestry disability index (ODI) was employed to assess pain-related functional limitations before and after the intervention protocol.

Results: Statistical analysis revealed significant within-group improvements in both groups, demonstrated by decreased VAS scores, increased PA values, and reduced ODI measurements following intervention. The between-group comparison demonstrated significant differences across all outcome measures, with Group B achieving superior therapeutic outcomes characterized by greater pain reduction, higher pain thresholds, and enhanced functional improvement.

Conclusion: Shockwave therapy is an effective adjunctive intervention for managing LBP in PD through reducing VAS scores, increasing PA measurements, and decreasing ODI values.

Keywords: *Shockwave therapy, Primary dysmenorrhea, Low back pain.*

1. INTRODUCTION

Dysmenorrhea represents one of the most frequently encountered gynecological disorders in the female population. Primary dysmenorrhea (PD) is identified as menstrual pain occurring with no detectable structural causes. The pain typically emerges just before or immediately following menstrual onset and generally lasts between 48 and 72 hours. Common accompanying symptoms include nausea, vomiting, diarrhea, malaise, weakness, and low back pain. The pathophysiology involves either excessive prostaglandin production or increased prostaglandin sensitivity during ovulatory cycles, which may induce myometrial contractility and nociceptor activation, thereby generating pelvic pain (1).

PD typically emerges within six to twelve months post-menarche and is distinguished by cramping, spasmodic pain in the lower abdominal area that may extend to the lumbar area and the anterior or medial thigh regions. The pain usually has a clear temporal pattern, initiating several hours prior to or coinciding with menstruation onset, reaching peak intensity at the beginning, and gradually diminishing over a two- to three-day period (2).

Research has also established connections between menstrual symptoms and musculoskeletal factors. One hypothesis suggests a correlation between abnormal pelvic positioning, lumbar vertebral alignment, and abdominal muscle contractions, which collectively alter uterine positioning and potentially increase dysmenorrhea susceptibility. Vertebral lumbar positioning may also restrict blood supply to the uterus through vascular constriction, generating painful sensations. Another theory proposes that menstrual cycle hormonal fluctuations influence the musculoskeletal system, potentially contributing to discomfort (3).

Consequently, non-pharmacological interventions, including transcutaneous electrical nerve stimulation and heat therapy, have been highlighted as important alternatives for managing PD. Among young Chinese women with PD, traditional Chinese medicine modalities like acupuncture and moxibustion are frequently preferred for pain alleviation. However, the drawback of these interventions lies in their time requirements and preparatory demands. The identification of non-invasive, more efficacious methods for managing menstrual pain and cramping in PD women requires further scientific verification (1). Among emerging conservative treatment strategies, extracorporeal shockwave therapy (ESWT) has gained clinical adoption recently (4).

ESWT delivers extracorporeal shockwaves to affected areas, promoting revascularization and activating healing responses in connective tissues and bones, resulting in pain reduction and functional improvement. ESWT provides pain management while simultaneously strengthening muscles via precise acoustic stimulation of muscular and tendinous components. ESWT is extensively utilized for addressing musculoskeletal disorders (4).

Low back pain (LBP) represents one of the most common health challenges worldwide and shows a frequent association with PD. LBP impacts a considerable portion of the world's people, and with ongoing demographic aging, its burden is expected to expand considerably in future decades (5).

Thus, this study will aim to determine the effect of shockwave therapy on relieving LBP with high efficacy, safety, and tolerability for those patients; improving their quality of life (QoL), and adding new knowledge in the physical therapy profession in the role of shockwave therapy on LBP in PD (5).

Research indicates that ESWT has demonstrated promising outcomes in treating urinary calculi, leading to its expanded application in orthopedic medicine. Therefore, this study investigates ESWT's efficacy in managing LBP and its influence on patients' QoL, aiming to provide evidence for clinical practice (6).

2. SUBJECTS, MATERIAL, AND METHODS

Subjects:

Sixty patients complaining of LBP during PD participated in this study. They were selected randomly from the Gynecology department at Minya University Hospital in Minya. Their ages ranged from 18 to 30 years. Their body mass indices were less than 29 kg/m2. All patients demonstrated regular menstrual patterns with cycles lasting between 21 and 35 days during the three months preceding enrollment. All patients didn't take oral contraceptives or drugs within 6 months before treatment. All patients have LBP intensity of 4 to 10 cm on the VAS. Patients with chronic diseases (like heart or kidney diseases) or secondary dysmenorrhea, irregular menstrual cycles, mental or neurological disorders, a history of childbirth, lumbar disc prolapses, scoliosis, a history of trauma of the back, or who had plans to become pregnant during the trial were excluded from the study.

Design of this study:

This research employed a randomized controlled design. It was implemented between June 2023 and December 2024 after the acceptance of the ethical committee of the Faculty of Physical Therapy, Cairo University NO: P.T.REC/012/004597, and clinical trial registration (NCT06762106). Research conduct strictly followed the ethical principles specified in the Declaration of Helsinki governing human research.

Randomization

Each participant was provided with detailed information about the study's aims, nature, benefits, and their right to withdraw or refuse participation at any time. Participants were then randomly allocated to two equal groups: Group A (control group) and Group B (study group).

Interventions

Group A (Control group): It consisted of thirty patients; they were treated with hot packs in the first 3 days of the menstrual cycle (follicular phase) for three consecutive menstrual cycles. Group B (Study group): It consisted of thirty patients; they were treated with hot packs in addition to shockwave therapy in the first 3 days of the menstrual cycle (follicular phase) for three consecutive menstrual cycles.

Procedures:

Prior to the study commencement, all participants in both groups were fully informed about the research protocol procedures

and provided their written consent.

Evaluation procedures:

Before initiating the study, the body mass index (BMI) was determined for all participants using a weight-height scale. Pain intensity assessment employed two measures: Visual Analogue Scale (VAS) and Pressure Algometer (PA). These assessments were conducted for all participants in Groups A and B at baseline and after each menstrual cycle throughout the three-cycle intervention period. Pain-related disability was assessed utilizing the Oswestry Disability Index (ODI) at study commencement and end.

Treatment procedures:

Hot packs:

They were utilized for managing all participants in both groups A and B. It was applied to the T10-L2 spinal region for fifteen-minute sessions, administered twice daily during the initial 3 days of menstruation over three consecutive menstrual cycles (7).

Shock wave therapy:

It was applied only to group B participants. Participants were instructed to assume a prone position. Comprehensive information regarding the procedure was provided to each participant. The treatment area was uncovered, cleansed with alcohol, and then coated with enough conductive gel over the lower back. Treatment was delivered using direct contact methodology, with the applicator head being moved continuously over the lumbar and sacral portions of the spine, focusing on regions where the patient reported maximum pain intensity. Therapeutic parameters were configured as follows: 2000 shockwaves at 2.5 bars pressure (generating an energy flux density of 0.1 mJ/mm^2), a frequency rate of 5 Hz, with each session lasting seven minutes (8). All patients underwent three treatment sessions during a single menstrual cycle, totaling nine total sessions across the intervention timeframe (9).

Statistical analysis:

Data analysis was performed using SPSS version 20.0 for Windows (SPSS Inc., Chicago, Illinois, USA). Shapiro-Wilk testing confirmed normal data distribution. Descriptive analysis included mean and standard deviation calculation for quantitative data. Two-way mixed design MANOVA was implemented to analyze between-group and within-group differences in VAS and PA measurements. The ODI values were compared within and between groups using two-way mixed design ANOVA. The alpha level of significance was set <0.05.

3. RESULTS

General Characteristics of Patients.

As observed from Table (1), statistically, there were insignificant differences in the mean values of ages, weight, height, and BMI between the two groups (A & B).

Table (1): General characteristics of patients in both groups (A and B):

	Mean ± SD		**t-value**	**p-value**
	Group (A)	**Group (B)**		
Age	**22.17±1.74**	**22.67±1.47**	**-1.2**	**.230**
Weight	**65.43±7.19**	**67.53±6.58**	**-1.18**	**.240**
Height	**160.27±2.59**	**161.90±4.29**	**-1.79**	**0.08**
BMI	**25.75±2.35**	**25.61±2.30**	**2.33**	**0.82**

Visual analogue scale (VAS) :

Within groups:

As shown in Table (2), statistical analysis using two-way mixed design MANOVA demonstrated significant decreases in VAS scores throughout the four measurement periods in both groups (A and B) ($P < 0.05$).

Between groups:

Table 2 demonstrates a statistically insignificant difference in baseline VAS mean values between Groups A and B prior to intervention (P=.297). Post-intervention analysis identified statistically significant between-group differences ($P < 0.05$),

with Group B achieving superior pain reduction outcomes.

Table (2): Comparison between visual analogue scale results within and between groups (A & B):

VAS							
Control group (A)				**Study group (B)**			
Before	**1st month**	**2nd month**	**3rd month**	**Before**	**1st month**	**2nd month**	**3rd month**
8.73±.868	**7.6±.93**	**6.3±.92**	**5.1±.97**	**8.97±.850**	**4.9±.759**	**3.5±.9**	**1.13±.819**
Within subject effect (univariate)			**F=765.2**				**P=0.000**
Between subject effect			**F=186.4**				**P=0.000**
Interaction (time*group)			**F=106.7**				**P=0.000**
Pairwise comparisons							
			Control		**Study**		
before vs. 1st month			**P=.000**		**P=0.000**		
before vs. 2nd month			**P=.000**		**P=0.000**		
before vs. 3rd month			**P=.000**		**P=0.000**		
1st month vs. 2nd month			**P=.000**		**P=0.000**		
1st month vs. 3rd month			**P=.000**		**P=0.000**		
2nd month vs. 3rd month			**P=.000**		**P=0.000**		
Experimental vs. Control			**Before**				**P=0.297**
			1st month				**P=0.000**
			2nd month				**P=0.000**
			3rd month				**P=0.000**

Pressure algometer (PA):

Within groups:

As shown in Table (3), statistical analysis employing two-way mixed design MANOVA demonstrated significant improvements in PA values throughout the four measurement periods in both groups (A and B) ($P < 0.05$).

Between groups:

As presented in Table 3, a statistically insignificant difference was detected in baseline PA measurements between Groups A and B (P=.82). Post-intervention analysis identified significant between-group differences ($P < 0.05$), with Group B achieving a superior increase in pressure pain threshold.

Table (3): Comparison between pressure algometer results within and between groups (A & B):

PA							
Control				**Study**			
Before	**1st month**	**2nd month**	**3rd month**	**Before**	**1st month**	**2nd month**	**3rd month**
1.29±.054	**2.29±.045**	**3.60±.047**	**4.91±.058**	**1.29±.064**	**3.31±.055**	**4.62±.060**	**8.29±.061**

Within subject effect	**F=90814.3**		**P=0.000**
Between subject effect	**F=44139.8**		**P=0.000**
Interaction (time*group)	**F=9260.6**		**P=0.000**
Pairwise comparisons			
	Control	**Study**	
before vs. 1st month	**P=.000**	**P=0.000**	
before vs. 2nd month	**P=.000**	**P=0.000**	
before vs. 3rd month	**P=.000**	**P=0.000**	
1st month vs. 2nd month	**P=.000**	**P=0.000**	
1st month vs. 3rd month	**P=.000**	**P=0.000**	
2nd month vs. 3rd month	**P=.000**	**P=0.000**	
study vs. Control	**Before**		**P=0.82**
	1st month		**P=0.000**
	2nd month		**P=0.000**
	3rd month		**P=0.000**

Oswestry disability index (ODI):

Within groups:

Statistical analysis using two-way mixed design ANOVA, presented in Table 4, demonstrated significant decreases in ODI values from pre- to post-intervention for participants in both Groups A and B ($P < 0.05$).

Between groups:

As shown in Table (4), the baseline comparison of ODI scores between Groups A and B showed insignificant differences (P=.978). Post-intervention analysis identified statistically significant between-group differences ($P < 0.05$), with Group B demonstrating superior functional improvement characterized by greater ODI reductions.

Table (4): Comparison between Oswestry disability index results pre- and post-treatment in both groups (A & B):

ODI			
Control		**Study**	
Before	**After**	**Before**	**After**
34.37±3.65	**31.37±3.69**	**34.3±5.5**	**13.87±3.42**
Between subject effect	**F=101.5**	**P=0.000**	
Within subject effect	**F=347.8**	**P=0.000**	
Interaction (time*group)	**F=192.7**	**P=0.000**	
Pairwise comparison tests			
Before vs. After	**Control**	**P=0.001**	
	Study	**P=0.000**	
Control vs. Study	**Before**	**P=0.978**	
	After	**P=0.000**	

4. DISCUSSION

Dysmenorrhea refers to pelvic discomfort that commences shortly before or coincident with menstruation and persists for one to three days during the menstrual cycle. Elevated prostaglandin (PG) production results from heightened peripheral pain receptor sensitivity, directly affecting uterine musculature to increase baseline intrauterine pressure and enhance both intensity and frequency of myometrial contractions (10).

PD is defined by painful menstrual periods typically emerging during adolescent years (11). LBP represents one of the most common health challenges worldwide and shows a frequent association with PD. LBP impacts a considerable portion of the world's people, and with ongoing demographic aging, its burden is expected to expand considerably in future decades (12).

The primary symptoms of dysmenorrhea are brought on by elevated prostaglandin levels during menstruation. In addition to nausea and vomiting, dysmenorrhea symptoms include discomfort in the lower back, head, legs, and abdomen (13).

The pain can initiate either before or after menstrual bleeding begins, generally lasting from several hours up to two days. It typically manifests as a diffuse discomfort that patients find difficult to localize and considerably more challenging to describe. The sensation may extend to surrounding anatomical structures, including bones, musculature, and cutaneous tissues. Although some women report mild, tolerable pain, others encounter moderate to severe discomfort predominantly concentrated in the lower abdominal region. Associated symptoms may include nausea, emesis, generalized abdominal discomfort, mastalgia, vaginal edema, and diarrhea. Additionally, certain individuals report pain radiating beyond the abdomen to the cranial region, cervical area, lower back, pelvic girdle, and thighs (3).

Treatment of dysmenorrhea varies mainly. According to (14), the three types of therapy for dysmenorrhea are pharmaceutical, non-pharmacological, and surgical. Non-steroidal anti-inflammatory drugs (NSAIDs) and oral contraceptives have been documented to cause adverse effects, including nausea, breast soreness, intermenstrual bleeding, and hearing and visual disturbances. Therefore, the literature reported that successful non-pharmacological methods for treating PD symptoms had a high potential value (15).

Numerous clinical studies have established that ESWT effectively reduces both pain severity and associated negative consequences in individuals suffering from CLBP (16). ESWT's therapeutic efficacy in managing CLBP operates predominantly through direct mechanical forces exerted by acoustic waves, supplemented by secondary mechanical effects induced through cavitation processes (17).

This study was conducted to assess the effect of shockwave therapy on LBP in PD.

Sixty patients complaining of LBP during PD participated in this study. They were selected randomly from the Gynecology department at Minya University Hospital in Minya.

This research employed a randomized controlled trial methodology. Participants were allocated into two equal groups: Group A (Control), comprising thirty patients who received hot pack treatment during the initial 3 days of menstruation (follicular phase) for three consecutive cycles, and Group B (Study), consisting of thirty patients who underwent combined hot pack and shockwave therapy during the same timeframe and duration.

LBP intensity assessment was conducted using the VAS and Pressure Algometer (PA) for both groups (A & B) prior to intervention and following each menstrual cycle during the three-cycle treatment period. The ODI was employed to assess pain-related disability for both groups (A & B) before and after the interventions.

Analysis of within-group effects using two-way mixed design MANOVA demonstrated significant improvements in both groups (A & B) following treatment, characterized by decreased VAS scores and increased PA measurements. Similarly, two-way mixed design ANOVA revealed significant reductions in ODI scores for both groups post-intervention.

Comparative analysis demonstrated no significant baseline differences between Groups A and B regarding VAS, PA, and ODI scores. However, post-treatment assessment demonstrated statistically significant differences favoring Group B, which exhibited more significant reductions in VAS and ODI scores alongside greater increases in PA measurements.

The results agreed with the research conducted by Lee et al. (2014), who examined 28 individuals (13 receiving ESWT, 15 receiving CPT) with CLBP to assess ESWT's impact on dynamic balance capabilities and pain intensity. BioRescue evaluations measured dynamic equilibrium parameters in ESWT-treated individuals. While the ESWT group demonstrated improvements across all directional parameters, the CPT group showed enhancement only in the left and posterior directions. Additionally, post-intervention VAS assessments revealed significantly better outcomes in the ESWT group compared to the CPT group (4).

Chang et al. (2023) established that ESWT treatment resulted in significant decreases in interleukin-8, tumor necrosis factor-α, and C-reactive protein levels, potentially contributing to pain alleviation (18). Zhou and Liu (2020) reported increased β-endorphin levels concurrent with notable pain diminution. The dynamic balance capabilities evaluated via the BioRescue system in Lee's research demonstrated that pain-influenced balance function enhanced following ESWT intervention (19).

Our findings corresponded with Walewicz et al. (2019), who evaluated postural stability metrics (total sway path, TSP) (8), and Elgendy et al. (2022), who utilized electromyographic assessment of muscle potentials to objectively and reliably

evaluate lumbar muscular functions. Beyond the mechanisms identified in previous studies (anti-inflammatory and pain-relieving effects), ESWT application for LBP may additionally enhance lower back vascularity and attenuate central sensitization (20).

Our investigation corroborated the findings of Walewicz et al. (2019), who determined that ESWT application produced significant pain reduction and functional status improvement among CLBP patients. Their investigation substantially reinforces our findings ($P < 0.05$), indicating significant pain alleviation, disability score enhancement, and increased lumbar flexion mobility following ESWT administration in mechanical LBP patients (8).

Our study's results were reinforced by Zimmermann et al. (2009), who revealed that low-energy ESWT application demonstrated statistically highly significant pain improvement (21).

Our findings aligned with Marwan et al. (2014), who documented that three ESWT sessions effectively alleviated pain, with maintained improvement during the subsequent year of observation (22).

The findings corresponded with Rompe et al. (2010), who examined ESWT efficacy in treating medial tibial stress syndrome (MTSS). Their research demonstrated that radial shock wave therapy constituted a valuable intervention for MTSS (23).

In concordance with our observations, SECO et al. (2011) reported that shock wave therapy produced equivalent therapeutic benefits in acute low back and leg pain patients when compared with traction, ultrasound, and laser treatment modalities (24).

Our current study was corroborated by Han et al. (2015), whose research involving 30 chronic LBP patients (15 receiving ESWT, 15 receiving CPT) revealed that ESWT had a notably stronger effect on reducing pain intensity assessed via VAS. Correspondingly, our investigation identified more significant VAS improvements following ESWT intervention (25).

Çelik et al. (2020) investigated 45 patients with CLBP (25 receiving ESWT, 20 receiving placebo ESWT) and noted that ESWT demonstrated significantly greater efficacy than placebo regarding pain reduction (26).

Nedelka et al. (2014) evaluated the comparative effectiveness of facet joint corticosteroid injections, radiofrequency neurotomy, and ESWT in 60 patients with facet joint-derived LBP. Their results indicated that both ESWT and radiofrequency neurotomy yielded significantly enhanced efficacy compared to corticosteroid injections. Correspondingly, our current study demonstrated significantly superior VAS score improvements with ESWT intervention (27).

Aligning with current results, Han et al. (2015) evaluated comparative efficacy between ESWT and CPT among CLBP patients and found that ESWT yielded significantly more beneficial outcomes than CPT concerning disability (25). Similarly, Celik et al. (2020) reported ESWT's superior effectiveness compared to placebo for disability reduction (26).

Our results contrast with those reported by Lange et al. (2021), who established that rESWT showed minimal effectiveness for pain alleviation, functional improvement, and QoL enhancement among acute LBP sufferers. While initial visual analog scale scores decreased by 60.7% ($P < 0.001$) in the treatment group versus 86.4% ($P < 0.001$) in the sham group, the treatment group exhibited progressively less significant pain reduction during follow-up examinations at four weeks and beyond, continuing through 12 weeks. EuroQoL five dimensions assessments similarly indicated inferior results for the treatment group versus the controls ($P < 0.014$) at the eight-week follow-up. Furthermore, combining ESWT with traditional physical therapy protocols failed to yield significant benefits regarding pain severity, physical capability, or QoL measures in LBP patients (28).

5. CONCLUSION

Shockwave therapy is an effective adjunctive intervention for managing LBP in PD through reducing VAS scores, increasing PA measurements, and decreasing ODI values.

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