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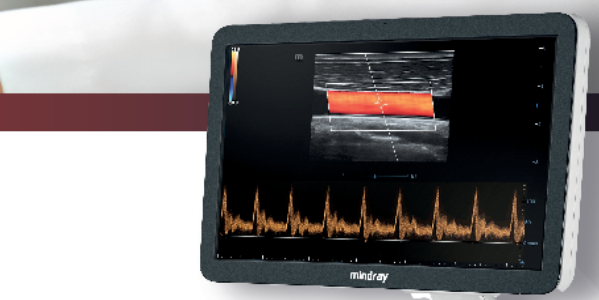

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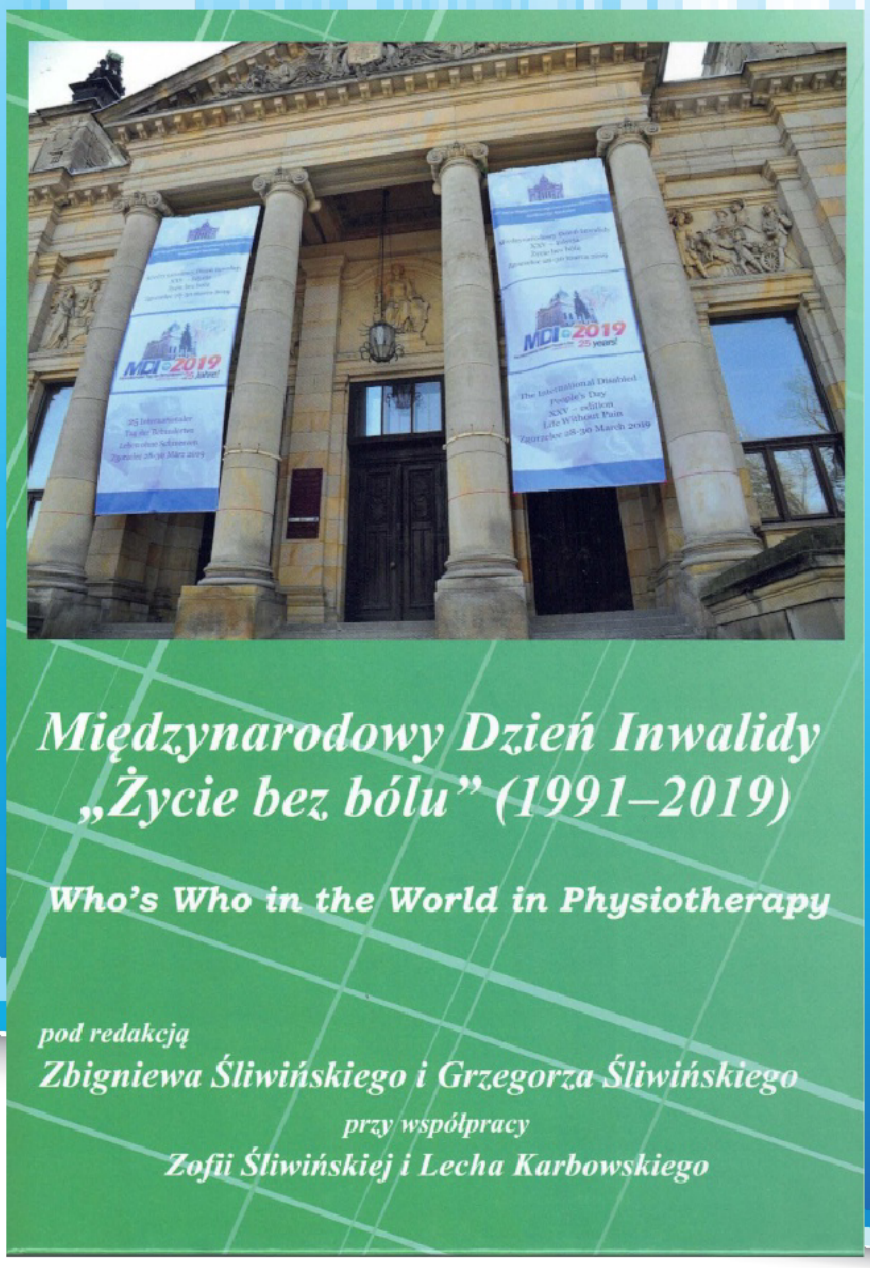

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Effect of shock wave therapy on primary dysmenorrhea: a randomized controlled trial

Wpływ fali uderzeniowej na pierwotne bolesne miesiączkowanie: randomizowane badanie

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Abstract

Purpose. Primary dysmenorrhea is a cramping aching pain in the lower abdominal that affects nearby 90% of adolescent females. The purpose of this study was to investigate the impact of the shock wave therapy on primary dysmenorrhea.

Methods. Fifty females with primary dysmenorrhea aged 18 –25 years were randomly allotted into two equivalent groups, study group (A) or a control group (B). Group (A) received shock wave about 5000 shock/session for three sessions for the first three days of the menstrual period in addition to the in addition to the dietary modifications for three successive menstrual period. The control group (B) received dietary modifications for 3 months. The numerical rating scale (NRS) and prostaglandin F2α level were used to evaluate females before and after intervention.

Results. Within- and between-group analysis revealed a significant difference in all variables after the intervention in favor of group A, as p-value < 0.05.

Conclusion. Shock wave therapy is an effective method for alleviating primary dysmenorrhea pain.

Key words:

primary dysmenorrhea, prostaglandin f2α, shock wave, dietary modifications, numerical rating scale

Streszczenie

Cel. Pierwotne bolesne miesiączkowanie to skurczowy ból w podbrzuszu, który dotyka około 90% dorastających kobiet. Celem pracy było zbadanie wpływu fali uderzeniowej na pierwotne bolesne miesiączkowanie.

Metody. Pięćdziesiąt kobiet z pierwotnym bolesnym miesiączkowaniem w wieku 18-25 lat zostało losowo przydzielonych do dwóch równych grup, grupy badanej (A) lub grupy kontrolnej (B). Grupa (A) była poddawana działaniu fali uderzeniowej około 5000 wstrząsów/sesję przez trzy sesje przez pierwsze trzy dni miesiączki, oraz modyfikacji diety przez trzy kolejne miesiączki. Grupa kontrolna (B) została poddana modyfikacji diety przez 3 miesiące. Do oceny kobiet przed i po interwencji zastosowano numeryczną skalę ocen (NRS) i poziom prostaglandyn F2α.

Wyniki. Analiza wewnątrzgrupowa i międzygrupowa wykazała istotną różnicę we wszystkich zmiennych po interwencji na korzyść grupy A, jako wartość p < 0,05.

Wniosek. Terapia falą uderzeniową jest skuteczną metodą łagodzenia pierwotnego bólu związanego z bolesnym miesiączkowaniem.

Słowa kluczowe

pierwotne bolesne miesiączkowanie, prostaglandyny F2α, fala uderzeniowa, modyfikacje diety, numeryczna skala oceny

Introduction

Primary dysmenorrhea is identified as cramping aching pain in the lower abdominal region prior to or during the menstrual cycle without any pelvic pathology [1]. It is identified as the most issue that affects nearby 90% of adolescent females and more than 50% of the menstruating ladies [2].

A high level of the endometrium prostaglandin F2α of females with primary dysmenorrhea seems to be consequence from the overabundance of PGF2α or the raise in the proportion of PGF2α to PGE2. Prostaglandins initiating for severe uterine contractions, anxiety, dizziness, headache, exhaustion, and other side effects [3].

These indications are well-thought-out the most reasons for teenage visiting the gynecologist [4].

Shock wave therapy (SWT) is non-surgical conventional therapy of numerous musculoskeletal conditions. Shock wave therapy is deliberated as the modest and low adversative effect [5].

Shock wave therapy has an extraordinary impact in the therapy of inflammatory circumstances, for example, low back pain, diabetic ulcers, Achilles tendinopathy, and chronic pelvic pain disease/chronic prostatitis (CPPS/CP) due to its pain relieving, anti-spastic, and anti-inflammatory effects [6, 7, 8, 9].

Shock wave (SW) could have an immediate and circuitous impact, generating a virtual biological reaction in the treated tissues. Mechanobiologically, SW growths the density of the soft tissue and send direct mechanical distresses, with special effects on the polarization of the cell membrane and the radical development. In view of this, SWT could create therapeutic profits via the proliferation of the cell and tissue recovery in the therapeutic aim [10].

Female's daily diet was related with the severity of dysmenorrhea. dysmenorrhea was greater in girls who consumed tea, Pepsi or Coca-cola, and too much intake of sugar [11]. The diet that increases the prostaglandins levels in the body, comprising processed vegetable oils; fried foods; prepared meats; dairy items; alcohol; high-glycemic nourishments, for example, refined flour; and sugar [12].

In conformity with the author's information, it was the principal study to investigate if shock wave therapy is a potent method for primary dysmenorrhea pain. So, the current study was conducted to determine the impact of shock wave therapy on pain of primary dysmenorrhea.

Material and Methods

Design

This study is a randomized controlled study, conducted through the period between (September 2019 to November 2020) at the outpatient center of the Faculty of Physical Therapy, Modern University for Technology and Information. The study was ethically accepted by the ethical committee of the Faculty of Physical Therapy, Cairo University, Egypt with number NO: P.T.REC/012/002358 and registered at Clinical Trials (ID / NCT04662814).

Participants

Fifty virgin females diagnosed as having primary dysmenorrhea by the physician were selected randomly from students of the Faculty of Physical Therapy, Modern University for Technology and Information. Their ages were between 18 to 25 years old, their body mass index (BMI) did not surpass 30kg/m2. The females had secondary dysmenorrhea as well as mental illnesses, irregular or infrequent menstrual cycle and taking aspirin, indomethacin, or anti-inflammatory tablets were excluded from this study [13].

Randomization

Randomization was done by the wrapped envelopes as prior to the beginning of the study. The physiotherapist gathered 50 females who met the inclusive characteristics and afterward everyone was told to choose one of the wrapped envelope, were 50 wrapped envelopes 25 of them contain the letter (A) and 25 of them contain the letter (B). Group A: received shock wave therapy in conjunction with dietary modifications for three successive menstrual periods. Group B: received dietary modifications for three successive menstrual periods.

Interventions

Shock wave application

SW was utilized for all females in the group (A) only. The female assumed the comfortable supine lying position, the therapist stride standing at the level of the female waist. Preceding the intervention, the therapist determine the abdominal muscles myofascial trigger points, and then a coupling gel was applied to the skin surface of the lower abdomen [14]. At that point, the therapist held the shock wave head (EME srl) serial number (EM12681015- Italy) definitely on the area of the lower abdomen. The application of the treatment was on the area of lower abdomen on six points as the following: attachment point of rectus abdominis above the symphysis pubis (bilateral), intersection of the anterior superior iliac spine with the outer margin of the rectus abdominis (bilateral), and the anterior superior iliac spine shifts inward by approximately 2 cm along the line (bilateral) [14].

Group A received shock wave therapy (5000 shock/ session, 12 Hz and 1.5 bar at a rate of 10–14 impulses per second for each female) [15].

The intervention was one session preceding the expected day for the monthly cycle and three sessions for the initial three days of the monthly cycle for three successive periods alongside with dietary modifications [16].

Diet modifications

Diet adjustment was accustomed for all females in both gatherings (A&B): sufficient liquid consumption and diet was well off in complex starches and fibers and low fat meals and cut off the junk food take up ought to be portrayed for three months [17].

Each female trained momentarily and clearly about the significance of diet adjustment and its impact to calm the menstrual pain. Females were followed by telephone calls twice weekly by the therapist all through the time of this investigation (three months).

Outcome measures

Numeric rating scale (NRS)

The pain was estimated by the numeric rating scale (NRS)

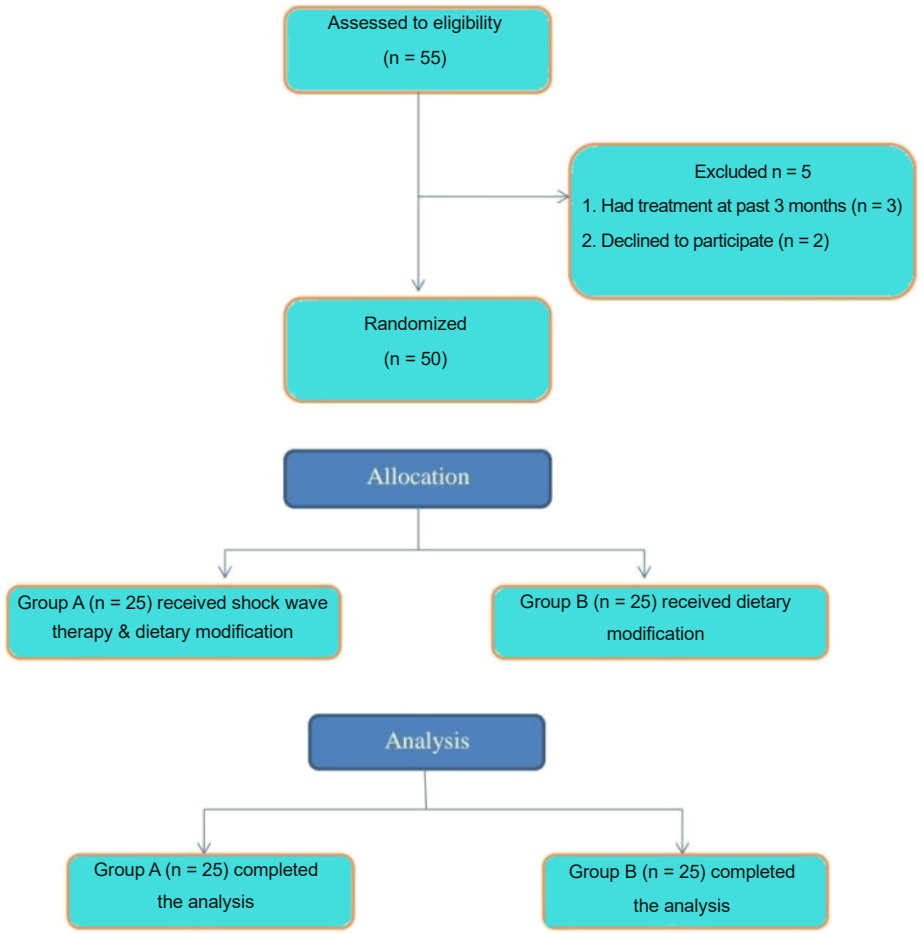

Figure 1. CONSORT Flow chart for patients in the study

which is a valid and reliable patient-reported outcome instrument. The NRS is ten cm aligned line with zero addressing no pain and 10 addressing worst pain, was utilized to assess pain subjectively[18]. An assistant requested each female of the two gatherings (A&B) to stamp on the line that tends to her pain level before the intervention and at the third period after intervention.

Prostaglandin F2α (PGF2α) level

Blood tests were gathered by the technicians from every female pre and post the intervention to quantify the serum PGF2α utilizing ELISA kit (USA). It were handled in copy on a completely mechanized ELISA framework (Human Diagnostics), and as indicated by the maker's directions. It is utilized to survey the pain degree before and after intervention for all females in the two gatherings (A&B).

Records were acquired from NRS and blood tests were gathered twice, the first on the second day of the first menstrual cycle before the intervention. The second record on the second day of the third menstrual cycle after the intervention [19].

Sample size calculation

Sample size calculation was performed prior to the study using G*POWER statistical software (version 3.1.9.2; Universitat Kiel, Germany) and revealed that the required size of each group was 25. The Calculations were made using $\alpha = 0.05$, $\beta = 0.2$ and large effect size = 0.82.

Statistical analysis

All statistical examination was constituted via the Statistical Package For The Social Studies (SPSS) version 22 for windows (IBM SPSS, Chicago, IL, USA). Descriptive statistics and unpaired t-test were constituted for comparison of the subject characteristics between both gatherings (A&B). Shapiro-Wilk test was used to check the normal distribution of the data. Levene's test for homogeneity of variances was constituted to confirm the homogeneity between the gatherings (A&B). The mean values of NRS and PGF2α between the gatherings (A&B) were analyzed using an unpaired t-test. Paired t-test was constituted for comparison before and after intervention in each gatherings. The significance level was set at $p < 0.05$.

Informed consent

Informed consent has been obtained from all females included in this study.

Results

Females characteristics

As shown in Table 1, There was no statistically significant difference between the two groups (A&B) in the mean age, weight, height, and BMI ($p = 0.69$, 0.52, 0.58 and 0.4 respectively).

Table 1. Comparison of subject characteristics between the study and control groups (A&B)

	Study group Mean ± SD	Control group Mean ± SD	MD	t-value	P-value
Age [years]	21.16 ± 1.77	20.44 ± 1.87	0.72	−0.39	0.69
Weight [kg]	64.16 ± 7.85	65.36 ± 8.68	−1.2	0.64	0.52
Height [cm]	161.84 ± 4.5	163 ± 3.87	−1.16	−0.55	0.58
BMI [kg/m^2]	24.48 ± 2.65	24.6 ± 3.07	−0.12	0.84	0.4

SD: Standard deviation; MD: Mean difference; p value: Probability valu

Effect of intervention on NRS and PGF2α

Within-group analysis

There was a significant decrease in NRS and PGF2α after intervention in both groups (A) and (B) compared with that before intervention (p > 0.001). The percent of decrease in NRS and PGF2α in the group (A) were 66.12 and 55.81% respectively and that of the group (B) were 38.64 and 19.06% respectively, as showed in table 2.

Table 2. Mean NRS and PGF2α pre and post treatment of the study and control groups (A&B)

		Study group Mean ± SD	Control group Mean ± SD	MD (95% CI)	t- value	p value
NRS	Pre treatment	7.32 ± 0.98	7.04 ± 0.93	0.28 (−0.26: 0.82)	1.02	0.3
	Post treatment	2.48 ± 0.77	4.32 ± 0.74	−1.84 (−2.27: −1.4)	−8.56	0.001
	MD (95% CI)	4.84 (4.41: 5.26)	2.72 (2.2: 3.23)			
	% of change	66.12	38.64			
	t- value	23.54	10.94			
		p = 0.001	p = 0.001			
PGF2a (Pg/ml g)	Pre treatment	664.08 ± 111.63	654.84 ± 104.62	9.24 (−52.28:70.76)	0.3	0.76
	Post treatment	293.46 ± 64.3	530.05 ± 84.42	−236.59 (−279.26: 193.91)	−11.14	0.001
	MD (95% CI)	370.62 (349.08: 392.15)	124.79 (110.92:138.66)			
	% of change	55.81	19.06			
	t- value	35.52	18.57			
		p = 0.001	p = 0.001			

SD: Standard deviation; p-value: Level of significance

Between-groups analysis

There was no significant difference in the NRS and PGF2α between both groups (A&B) before intervention (p > 0.05). Comparison between the two groups (A&B) after intervention revealed a significant decrease in NRS and PGF2α of the group (A) compared with that of the group (B) (p < 0.001) as showed in (table 2).

Discussion

This study was conducted to determine the impact of shock wave therapy on primary dysmenorrhea. According to the current results, there was a statistical significant difference in pain, prostaglandin f2 alpha level after shock wave application.

Our data suggested that the NRS score and PGF2α level were significantly decreased in the groups A (Table.2). However, the major decrease was in group A after shock wave therapy alongside dietary modifications in compared to the group B who treated by dietary modifications only. Consequently, this trial implied that the mediation diminished pain was illustrated by the prostaglandin F2α decreases and that a greater pain reduction with the SW treatment in groups A than with the dietary modifications in group B.

As reported in our study, the mechanism of causing menstrual pain is associated with the levels of prostaglandins during menstruation [20].

Shock wave may stimulate the muscle nodules by activating myofascial release, modifying peripheral sensory nerve fibers and

their conduction, and thereby decreasing dysmenorrhea to the uterus and alleviating menstrual pain. Furthermore, the process of the SW intervention could increase uterine blood flow [21].
SW could increase the declaration of angiogenesis-related growth and proliferation factors, prompting collagen formation, neovascularization, fibroblastic proliferation, and lessening the inflammatory period and the wound infection. SW was also established to relieve pain by directing substance-P positive sensory nerve fibers [21].
In the current study there was superior effect of shock wave on primary dysmenorrhea; this result are supported by study done by Xing et al., who revealed that the ESWT reduced menstrual cramps when applying treatment during the proliferative phase or secretory phase of the menstrual period [22].
Hurt et al. [23] revealed that extracorporeal shock wave therapy has an incredible impact on the vulvodynia treatment and they discovered significant improvement in the treatment gathering. Diminishes in visual analogue scale (VAS $P < 0.01$) and cotton-swab test (CST $P < 0.01$) were seen at all 3 follow-ups. At all outcomes, pain lessening was each time > 30%. In the placebo gathering, there were no statistically significant alterations between pre and post treatment.
A single-blinded examination conducted to survey the impact of shock wave therapy (SWT) in the back pain patients, and establish that a strong analgesic effect through improving local circulation and reduce the muscle spasm [24].
Moreover, SW application produces low-to-medium energy with a penetrative depth of up to 3 to 5 cm, and effectively stimulates the trigger points and reduces pain [25]. Likewise, Aydin et al., reasoned that SWT gave a compelling pain control in the coccydynia patients [26].
Salama & Abouelnaga [27]. affirmed that SWT is a powerful strategy for chronic pelvic pain disease/chronic prostatitis CPPS treating, through A statistically critical reduction was resolved in the pain, urine score, personal satisfaction, and the Chronic Prostatitis Symptom Index (NIH-CPSI) score.
The present trial selected the dietary modifications which could lead to decrease in NRS and PGF2α in the group (B) were 38.64 and 19.06% respectively who treated by dietary modifications only. There were numerous investigations which show that there is a critical relationship between dysmenorrhea and diet [28].
As reported by Fujiwara [29] who expressed that Junk food is considered as one of the variables that reason primary dysmenorrhea since junk food has unequal healthful content, high fat, great calories intake, too much sugar, and less fibers. The unsaturated fat substance in junk food affects with the metabolism of the progesterone in the luteal phase of the menstruation. The outcome is an increment in the levels of prostaglandin which reason dysmenorrhea.
The study also found that females who don't eat up breakfast expressively more experiencing dysmenorrhea, when contrasted with females who eat up breakfast and a high admission of fiber diet [30].
As per the discussion of last studies in scopes related to our study, the application of SW combined with dietary modifications had a positive effect on alleviating pain in females with PD.

Study Limitation

The limitations of this study were a lack of opportunity for further long-term investigations are required to clarify the relationship. Another study limitation of the study is that time was not dispensed to the sessions appropriately, because the students' school program was very intensive and they had to leave the city regularly when the study was conducted.

Conclusion

Utilizing shock wave (SW) combined with dietary modifications had a significant positive effect on alleviating dysmenorrheic pain.
Shock wave was very effective noninvasive method for decreasing the menstrual pain without causing any side effect.

Recommendations

Further studies are required with a large sample, longer follow-up, and more objective measures to clarify the potential mechanisms.

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