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Effect of Connective Tissue Manipulation on Primary Dysmenorrhea: A Randomized Clinical Trial

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Abstract: *Background*: Primary dysmenorrhea is the most common gynecological condition among women of reproductive age. Connective tissue manipulation (CTM) is one of the specific manual therapy techniques which stimulate autonomic responses via cutaneous-visceral reflexes. *Purpose of this study*: To investigate the effect of connective tissue manipulation on primary dysmenorrhea. *Subjects and methods*: This study was carried upon 30 females suffering from primary dysmenorrhea. Their age ranged from 18 to 25 years and their BMI was less than 30 kg/m^2. They were selected from Abu-kabir central hospital- Al Sharquia. The participants were randomly distributed in two groups equal in number. Control group (A) consisted of 15 females, they received TENS during the first three days of menstrual cycle and this was repeated on the second consecutive menstrual cycle. Study group (B) consisted of 15 females, they received connective tissue manipulation for 20 minutes/session, 5 session/week for a total of 10 sessions per cycle for two consecutive cycles (The sessions start before menstruation by two weeks) in addition to TENS treatment as described for group A. All females in both groups (A and B) were assessed pre and post treatment by using, visual analogue scale and serum cortisol level. *Results*: The results revealed that pre-treatment, there was a non- statistical significant difference between two groups in mean value of VAS and cortisol level with p-value was (P=0.889) & (P=0.293) respectively. Post-treatment, there was statistical significant reduction between two groups in mean value of VAS and cortisol level with p-value was (p=0.0001) & (p=0.029) respectively, in favor to group B. *Conclusion*: Connective tissue manipulation could be used as an effective treatment in reducing the amount of pain associated with primary dysmenorrhea as it is a safe and non-invasive therapeutic technique.

Key words: Connective Tissue Manipulation · Primary Dysmenorrhea · TENS · Visual Analogue Scale · Cortisol Level

INTRODUCTION

Dysmenorrhea, defined as painful menstrual cramps of uterine origin, is the most common gynecological condition among women of reproductive age. Dysmenorrhea can be sub-classified as either primary or secondary dysmenorrhea. Primary dysmenorrhea is defined as painful, spasmodic cramping in the lower abdomen, just before and/or during menstruation, in the absence of any discernable macrosco Physical Therapy for Women's Health Department, Faculty of Physical Therapy, Cairo University, Giza, Egypt pic pelvic pathology. The pain typically lasts for 8-72 h, is most severe during the first or second day of menstruation and may radiate to the back and thighs. In addition, systemic symptoms such as nausea, vomiting, diarrhea, fatigue and insomnia frequently accompany the pain [1].

Primary dysmenorrhea occurs more frequently in unmarried compared to married women (61% vs. 51%). 88% of adolescents experience their first painful menstruation within the first 2 years after menarche [2]. Primary dysmenorrhea is a common cause of sickness

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absenteeism from both classes and work by the female student community due to the negative effects of dysmenorrhea on an individual's psychological status and health-related quality of life [3]. The cause of pain at, or around, the time of menses is believed to be due to the production of prostaglandins in the endometrium in an ovulatory cycle. Prostaglandins cause uterine contractions, which result in the expulsion of sloughed endometrial lining [4].

Physiotherapy may be indicated to treat women with primary dysmenorrhea for being a low cost and noninvasive alternative. For such, there are several therapeutic resources, such as thermotherapy, cryotherapy, kinesio-therapy, TENS and connective tissue massage, acupuncture and Pilates, among others [5].

Connective tissue manipulation (CTM) is a soft tissue manipulative technique used by physiotherapists whose stimulus is directed at the fascial interfaces and forms general body relaxation, reduces muscle spasm and connective tissue tenderness and increases circulation and plasma B-endorphins through reflex ways. The technique aims to stimulate the autonomic nervous system to rebalance the parasympathetic and sympathetic systems usually by means of moving in a parasympathetic direction [6].

Transcutaneous electrical nerve stimulation (TENS) is a non-invasive analgesic technique that is used to relieve nociceptive, neuropathic and musculoskeletal pain [7]. TENS reduces pain through both peripheral and central mechanism. Centrally, sites in the spinal cord and brainstem that utilize opioid, serotonin and muscarinic receptors are activated by TENS. Peripherally, at the site of TENS application, opioid and α-2 nor adrenergic receptors are involved in TENS-induced analgesia [8].

Consequently, the purpose of this randomized controlled study was to investigate the effect of connective tissue manipulation in addition to TENS on primary dysmenorrhea.

MATERIALS AND METHODS

Design of Study: Two groups pre- test and post- test experimental design. The participants were randomly distributed in two groups equal in number. Control group (A): This group consisted of 15 females with primary dysmenorrheal, they received TENS only. Study group (B): This group consisted of 15 females with primary dysmenorrhea, they received connective tissue manipulation, in addition to TENS.

Participant: This study was carried upon thirty females suffering from primary dysmenorrhea. They were selected randomly from Abu-kabir central hospital- Al Sharquia, on the following criteria: (1). Their ages ranged from 18 to 25 years old; (2). Their body mass index (BMI) were less than 30 kg/m^2; (3). They were suffering from primary dysmenorrhea with regular menstrual cycles; (4). All participants were conscious and free from any medical disease (detailed medical history was obtained to screen for other pathological conditions and all subjects underwent pelvic ultrasonography to exclude any pelvic pathological problems such as endometriosis, adenomyosis, or pelvic adhesions).

Measurement Procedures: All participants were given a full explanation for the evaluation and treatment procedures and informed constant form was signed by each participant. All information including name, age, address, occupation, date of last menstrual cycle and duration of menstruation was recorded at a recording data sheet.

The Visual Analogue Scale (VAS): Severity of pain was assessed through VAS for each female in both groups A & B before and after treatment. It is usually a horizontal line 10 cm long whose ends are labeled as the extreme (no pain and worst pain). The patient was asked to put a mark on the line indicating their pain intensity [9].

Serum Cortisol Level: It would be used to objectively measure pain level for each participant before and after treatment.

Treatment Procedures

Control Group (Group A): This group consisted of 15 females, they treated by TENS (high frequency) device that was adjusted at: a) Frequency (50-100Hz), b) Pulse width: 95 microseconds, c) Intensity: Until patient feel tingling sensation. A pair of the adhesive electrodes was placed 10cm from the umbilicus on either side, the second pair placed on either side of the pubic symphysis close to each anterior superior iliac spine [10].

The participants received TENS for 30 minutes/session once per day during the first three days of menstrual cycle and the procedure repeated on the second consecutive menstrual cycle.

Study Group (Group B): This group consisted of 15 females with primary dysmenorrhea, they received CTM in addition to TENS treatment as described fore group A.

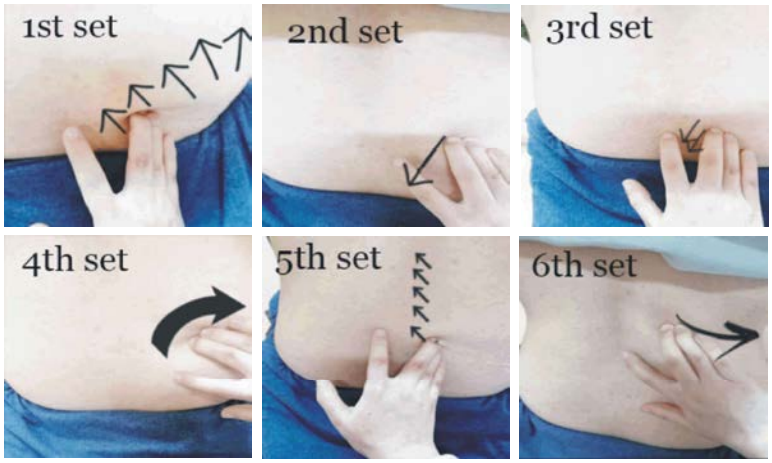

Fig. 1: Application of CTM.

All participants in group (B) received CTM for 20 minute/ sessions, 5 sessions / week for a total of 10 sessions per cycle for two consecutive cycles (The sessions started before menstruation by two weeks). During manipulation, the pad of the middle finger was in contact with the patient's skin. The finger was placed on the skin at 45 degree angle with distal interphalangeal joint in flexion and moved to cause traction. The treatment position is generally seated to take advantage of the gravitational effects placed on the soft tissue during the strokes. CTM was applied to the basic section. The basic section of CTM consists of the manipulation of the following regions: sacral, lumbar, last thoracic vertebrae and subcostal region. Six different sets of strokes were used. The strokes were short (approximately three cm) and long (approximately 10 cm). Each set of strokes was repeated three times, first on the right and then on the left lumbosacral and dorsal regions.

The first set consisted of short strokes starting from the anal cleft and end at the edge of sacroiliac joint of the iliac crest. *The second set* consisted of long strokes descending along the border of the sacroiliac joint, towards the gluteal cleft. *The third set* consisted of short strokes perpendicular to the spine and ending at the joint of L5 with the S1 vertebrae. *The fourth set* consisted of three long strokes starting from the external border of the sacrum and moving outwards (The first stroke passes close to the iliac crest, starting at the transverse process of L5 and moving towards the anterior superior iliac spine, where it comes to an end. The second starts at the widest part of the sacrum, passes laterally and forward and finishes in the same manner as the first stroke. The third stroke starts at the gluteal cleft and passes forward above the great trochanter and ends in same way as the first and second strokes). *The fifth set* consisted of five short strokes, approximately, which move from lateral to medial over the erector spinae area, following the space between the transverse processes of the lumbar vertebrae. *The sixth set* consisted of one long stroke, moving from medial to lateral following the lower edge of the last rib (Fig. 1).

Data Analysis: Statistical analysis was conducted using SPSS for windows, version 23 (SPSS, Inc., Chicago, IL). 2x2 Mixed MANOVA test was used to compare the tested variables of interest at different measuring periods at both groups. With the initial alpha level set at 0.05.

RESULTS

The current study was conducted on 30 participants. They were assigned into two equal groups. Control group (A) consisted of 15 participants who treated by TENS. Study group (B) consisted of 15 participants who received connective tissue manipulation in addition to TENS treatment. There were no significant differences ($p>0.05$) in the mean values of age, body mass, height and BMI between both tested groups (Table1).

As presented in Table (2), Multiple pairwise comparison tests revealed that there was significant reduction of VAS at post treatment in compare to pre-treatment in both groups A & B with (P-value =0.026*) & (P-value =0.0001*) respectively. Considering the effect of the tested group on VAS, Multiple pairwise comparison tests revealed that there was no significant differences in mean value (P=0.889)of "pre" test between both groups while, there was significant difference in mean value of the "post" test between both groups with (p=0.0001*) and this significant reduction in favour to group B.

Table 1: Physical characteristics of participants in both groups (A&B).

	Group A	Group B	Comparison		
Items	Mean ± SD	Mean ± SD	t-value	P-value	S
Age (years)	20.33±1.39	19.93±1.83	0.673	0.507	NS
Body mass (Kg)	64.06±7.38	62.2±6.81	0.72	0.478	NS
Height (cm)	160.86±5.84	159±5.51	0.9	0.376	NS
BMI (kg/m^2)	24.66±1.39	24.54±1.45	0.244	0.809	NS

*SD: standard deviation, P: probability, S: significance, NS: non-significant.

Table 2: Mean ±SD and p values of VAS pre and post-test at both groups

	Pre test	Post test			
VAS	Mean± SD	Mean± SD	MD	% of change	p- value
Group A	7.66±1.34	6.8 ±0.94	0.88	11.48%	0.026*
Group B	7.6 ±1.24	4.2±1.37	3.4	44.73%	0.0001*
MD	0.067	2.6			
p- value	0.889	0.0001*			

SD: standard deviation p-value: probability value MD: Mean difference *Significant level is set at alpha level <0.05

Table 4: Mean ±SD and p values of cortisol level pre and post-test at both groups.

	Pre test	Post test			
Cortisol level (ug/dl)	Mean± SD	Mean± SD	MD	% of change	p- value
Group A	16.22±2.02	15.84 ±1.91	0.37	2.28%	0.098
Group B	17 ±1.95	14.3±1.74	2.7	15.88%	0.0001*
MD	-0.78	1.54			
p- value	0.293	0.029*			

SD: standard deviation MD: Mean difference

*Significant level is set at alpha level <0.05 p-value: probability value

As presented in Table (3), Multiple pairwise comparison tests revealed that there was no significant difference of cortisol level at post treatment in compare to pre-treatment (P-value =0.098) in group (A). While, there was significant reduction of cortisol level at post treatment in compare to pre-treatment (P-value =0.0001*) in group (B). Considering the effect of the tested group on cortisol level, Multiple pairwise comparison tests revealed that there was no significant differences in mean value of the "pre" test between both groups with (P=0.293). While, there was significant difference in the mean value of the "post" test between both groups with (p=0.029*) and this significant reduction in favour to group B.

DISCUSSION

This study was conducted to determine the effect of connective tissue manipulation on primary dysmenorrhea. This study demonstrates that the study group which received connective tissue manipulation in addition to TENS showed more improvement in pain level than the control group which received TENS only.

The results of this study were in agreement with Akbaş *et al.* [11] who found that CTM has an immediate reducing effect on sympathetic activity in healthy young women independently from the physical activity level. The results of this study also lie in the same line with Özgül *et al.* [12] who proved that CTM seems to be an effective physiotherapy approach for improving menstrual pain, menstrual pain catastrophization, menstruation-related symptoms and menstrual perception in patients with primary dysmenorrhea.

Celenay *et al*. [13] suggested that exercises with CTM might be superior in improving pain, fatigue, sleep problem and role limitations due to physical health compared to exercise alone in patients with fibromyalgia syndrome.

The results of this study were agreed with Kaur *et al.* [14] who found that kinesio-taping and CTM techniques are effective non-pharmacological interventions to reduce the premenstrual symptoms and menstrual pain. As they showed that CTM able to reduce the cramps in the lower abdominal area and the associated complains like low back pain, thigh pain immediately after the first session of treatment. Also, the results of this study were in agreement with Demirtürk *et al.* [6] who proved that CTM and foot reflexology are found to be effective in alleviating menstrual pain and associated symptoms in young adults.

Regarding the mechanism of CTM in reducing menstrual pain and associated symptoms the results may be related to producing general body relaxation, decreasing muscle spasm and increasing plasma β-endorphins and vascularization throughout the CTM applications. CTM appears to work via a reflex effect on the autonomic nervous system which is induced by manipulating the fascial layers within and beneath the skin [15].

Regarding the effect of TENS in reducing menstrual pain. The results of our study agreed with Jakhar *et al.* [16] who found that conventional TENS is effective in relieving pain and improving quality of life in moderate degree of disability due to primary dysmenorrhea. Majority of subjects have shown relief of pain and improvement in quality of life in next 2 menstrual cycles and didn't need any analgesic after one-time TENS treatment. Also, our results agreed with Kanwal *et al.* [17] who concluded that TENS is more effective for pain improvement on Primary dysmenorrhea.

Parsa and Bashirian [18] conclude that TENS method seems to be effective in managing primary dysmenorrhea. It is free from the adverse effects of analgesics, gives immediate pain relief and had no adverse effects.

The results of our study contradicted with Fagevik Olsén *et al.* [19] who studied the effects of high-intensity high-frequency transcutaneous electric nerve stimulation in primary dysmenorrhea with a randomised cross-over pilot study and found that there was no significant difference in pain intensity, limitations in physical function, consumption of analgesics and associated symptoms between the groups but a significant lower limitation in physical function during the wash-out period in comparison to the treatment period within the whole group.

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