



Effect of Myofascial Trigger Point Release on Pelvic Pain in Pudendal Nerve Entrapment: A Single Blind Randomized Controlled Trial

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ABSTRACT

Purpose: this study was to investigate the effect of myofascial trigger point release on pelvic pain in pudendal nerve entrapment syndrome. **Design:** A prospective, randomized, single-blind, pre-post-test, controlled trial. **Setting:** outpatient Clinic for Gynaecology, Faculty of Medicine, Ain Shams University (El Demerdash Hospital). **Participants:** Forty married females suffering from pudendal nerve entrapment. **Interventions:** Participants were randomly assigned into; group A receiving medical treatment and myofascial trigger point release and group B receiving medical treatment only subscribed by their gynaecologist. **Main Outcome Measure:** The primary outcome was present pain intensity scale to assess pelvic pain severity before starting and after the end of treatment program. **Results:** Comparing both groups post-program revealed that there were statistically significant differences in pain scale ($P < 0.05$) and this significant reduction in favour of group A. **Conclusion:** Myofascial trigger point release and medical treatment yield improvement in pain scale more than medical treatment alone

Key Words: Myofascial Trigger Point Release, Pelvic Pain, Pudendal Nerve Entrapment

eIJPPR 2017; 7(1): 22-25

HOW TO CITE THIS ARTICLE: Marwa Fakhry Aly, Amal Mohamed Youssef, Adly Sabor, Amr Abdel Aziz Nadim. (2017). "Effect of Myofascial Trigger Point Release on Pelvic Pain in Pudendal Nerve Entrapment: A Single Blind Randomized Controlled Trial", *International Journal of Pharmaceutical and Phytopharmacological Research*, 7(1), pp: 22-25.

INTRODUCTION

Pudendal nerve entrapment (PNE) syndrome is an unwell identified condition and consequently rarely involved in the differential diagnoses. Described firstly by Amarenco in 1987 [1]. Pudendal nerve entrapment may cause pelvic discomfort and pain in wholly or part of the nerve distribution, specifically, the saddle area between the legs involving the rectum, genitalia, and terminal urinary tract [2]. Symptoms of PNE may have sexual and urinary dysfunction in addition to painful bowel movements and constipation.[3] Beginning of PNE may be insidious with no clear precipitant but a history of

trauma, infection, a pulled muscle in pelvis, child birth, and iatrogenic injury [2]. The effect of the symptoms of PNE may be severely devastating, influence quality of life and restrictive patients' capability to participate in normal daily activities.[3]. Though there are a number of reports covering different aspects of diagnosis and management [4]. The rate of success in managing PNE has been restricted [5]. One issue has been that there have all the earmarks of being a few subtypes with various anatomical destinations of entrapment and clinical presentation [6]. Furthermore, the surgical anatomy of the pudendal nerve itself is complex and subject to significant

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Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Received : 11 July 2016; **Revised:** 18 January 2017; **Accepted:** 26 February 2017



individual variation [7]. Myofascial pain is often ignored by first line healthcare providers moreover a primary or causal source of pain for disorders such as urgency, interstitial cystitis, irritable bowel syndrome, dyspareunia, urge incontinence, endometriosis, constipation, coccygodynia, vulvodynia, proctalgia fugax, post-surgical pelvic pain, and pudendal entrapment [8]. So, the purpose of this study was to investigate the effect of myofascial trigger point release on pelvic pain in pudendal nerve entrapment syndrome.

MATERIALS AND METHODS

Study Design

The study was designed as a prospective, randomized, single-blind, pre-post-test, controlled trial. Ethical approval was obtained from the institutional review board at Faculty of physical therapy, Cairo University before study commencement. The study was followed the Guidelines of Declaration of Helsinki on the conduct of human research. The study was conducted between June 2014 and August 2016.

Participants

A convenient sample of forty married females suffering from pedundal nerve entrapment was recruited from the Outpatient Clinic for Gynecology, Faculty of Medicine, Ain Shams University (El Demerdash Hospital). They were enrolled and assessed for their eligibility to participate in the study. To be included in the study, the participants were married females, experiencing pudendal nerve entrapment syndrome. Their ages ranged from 25 to 35 years old and their BMI was $20 < \text{BMI} < 25 \text{ Kg/m}^2$. The participants were excluded if they were any gynecological diseases as vulvar vestibulitis, vulvar pain, clitrodynia, and vulvar dysesthesia or any pelvic inflammatory diseases, as well as lower urinary tract infection, neurological problems, and psychological disability.

Randomization

Informed consent was obtained from each participant after explaining the nature, purpose, and benefits of the study, informing them of their right to refuse or withdraw at any time, and about the confidentiality of any obtained information. Anonymity was assured through coding of all data. The forty married females suffering from pedundal nerve entrapment were randomly assigned into two groups (group A and group B) by a blinded and an independent research assistant who opened sealed envelopes that contained a computer generated randomization card. No subjects dropped out of the study after randomization.

Interventions

Participants were randomly assigned into; group A receiving medical treatment and myofascial trigger point release and group B receiving medical treatment only subscribed by their gynecologist.

Patients in group (A) were treated by myofascial release and trigger point massage combined with

pelvic floor exercises plus medical treatment. The patient was asked to concentrically contract (squeeze) and eccentrically contract (push out) the levator ani muscles and voluntarily relax or “drop” the pelvic floor muscles for count of 10 and then contract for 5 counts and hold.

Myofascial Release: Release restrictions in deeper layers of fascia, stretch cross-link, change viscosity of ground substance multidirectional myofascial release. External connective tissue manipulation involves the therapist ‘pinch-rolling’ the affected tissue (below the skin and above the muscle) between her thumb and other four fingers, with both hands. The therapist palpated to feel where the tissue is thick and restricted and mobilize the tissue using the thumb and forefinger to improve blood flow, decrease thickness, and restore mobility. There are two manual techniques the physical therapist can use to eliminate them. In the first technique, the therapist manually compresses the trigger point for 60 to 90 seconds or until feeling the trigger point ‘release.’ The second technique requires the therapist compressed the trigger point and instruct the patient to very gently contract the involved muscle 10 to 15 times, or until the therapist feels the trigger point release. The choice of technique depends on the preference of the individual therapist and the tolerance of the patient. Patients in group (B) will only have medical treatment subscribed by their gynecologist.

Outcome measures

Present Pain Intensity scale

Intensity of pain was measured by mean of present pain intensity scale to help patients to determine the intensity of pelvic pain on a line from 0 to 4 on which pain intensity was scored as follows: no pain = 0, mild pain = 1, moderate pain = 2, severe pain = 3, and unbearable pain = 4. The Present Pain Intensity scale is reported to be a reliable outcome measure for pain evaluation [9].

Sample size and Statistical analysis

To avoid a type II error, a preliminary power analysis [power $(1-\alpha \text{ error } P) = 0.80$, $\alpha = 0.05$, effect size = 0.91, with a two-tailed for a comparison of 2 independent groups] determined a sample size of 20 for each group in this study. This effect size was calculated according after a pilot study on 12 participants (6 in each group) considering pain scale as a primary outcome. Statistical analysis was conducted using SPSS for windows, version 20 (SPSS, Inc., Chicago, IL). The current test involved two independent variables. The first one was the tested group that had two levels (group A receiving medical treatment and myofascial trigger point release and group B receiving medical treatment only). The second one was the treatment periods, within subject factor which had two levels (pre-treatment, post treatment). In addition, this test involved one tested dependent variable (pain scale). Prior to final analysis, data were screened for normality assumption,

homogeneity of variance, and presence of extreme scores. This exploration was done as a pre-requisite for parametric calculations of the analysis of difference. Descriptive analysis using histograms with the normal distribution curve showed that the pain scale was not normally distributed and violates the parametric assumption for the measured dependent variable. Additionally, testing for the homogeneity of covariance revealed that there was significant difference with p values of < 0.05. Normality test of data using Shapiro-Wilk test was used, that reflect the data was not normally distributed for motor latency. All these findings allowed the researchers to conduct non parametric analysis. So, non-parametric statistical

tests in the form of Wilcoxon Signed Rank tests was used to compare between pre and post treatment for each group and Mann-Whitney U test was used to compare between both groups. The alpha level was set at 0.05.

RESULTS

Baseline and demographic data

There were no statistically significant differences (P>0.05) between subjects in both groups concerning age, body mass, height, and BMI (Table 1).

Table 1: Descriptive statistics and unpaired t-tests for the mean age of the patients with pudendal nerve entrapment for both groups.

Items	Group A	Group B	Comparison	
	Mean ± SD	Mean ± SD	t-value	P-value
Age (yrs)	28.5±3.56	28.45±3.41	0.045	0.964
Body mass (Kg)	62.4±6.27	64.65±5.05	-1.249	0.219
Height (cm)	156.15±3.55	157.1±2.14	-1.022	0.313
BMI (Kg/m ²)	25.56±2.07	26.18±1.86	-0.992	0.328

*SD: standard deviation, P: probability

Pain scale:

The median score of pain scale in the "pre" and "post" treatment of both groups illustrated at table (1). " statistical analysis using the non-parametric Wilcoxon Signed Rank tests" revealed that there was a significant decrease in the pain scale in the "post" test (p <0.05) at both groups. Considering the effect of the tested group (first independent variable) on pain scale, " Mann-Whitney tests" revealed that the median

score of the "pre" test between both groups revealed that there was no significant difference between the both groups (p>0.05). as well as, the median score of the "post" test between both groups showed there was significant difference between the both groups (p<0.05) and this significant reduction in favor to group A (Table).

Table (1): Median score, U, Z, and P values of the pain scale pre and post treatment in both groups.

Pain scale	Median score		Z-value	P- value
	pre	post		
Group A	4	0	-3.988	0.0001*
Group B	4	1	-4.021	0.0001*
U-value	193.5	112		
Z-value	-0.187	-2.623		
P- value	0.852	0.009*		

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

DISCUSSION AND CONSOLATION

Trigger point release therapy, also known as myofascial trigger point release, is an alternative treatment for pudendal nerve entrapment syndrome. "Myo" means muscle and "fascia" refers to the connective tissue that is in and around the muscle [10]. Myofascial release (MFR) is a therapeutic treatment of the biological part of the pain; it adds more effect of reducing pain with stretching and strengthens exercises. Myofascial release uses gentle pressure and stretching to facilitate the release of fascial restrictions caused by accidents, injury, stress, repetitive use, and traumatic or surgical scarring [11].

The TPs pressure release is based on the technique of ischemic compression and can provide effective pain relief especially with stretching exercises. The clinician uses palpatory pressure on each myofascial TP, until a state of tension relief is reached and, thus, inactivates the TP so enhance stretch response to decrease pain [12] The result of the current study revealed that trigger point release with medical treatment is beneficial for treating myofascial pain associated with pudendal nerve entrapment syndrome than medical treatment alone. The results showed a significant decrease in pelvic pain at the end of



treatment program of group A. This comes in agreement with Jacobson et al. [13] and Mense [14] that revealed significant pain relief due to application of myofascial trigger point release as part of nociceptive or physiological part of pain management. This improvement attributed firstly to the relaxation effect of shortened muscles after stretch. On the other hand, the local stretch after myofascial trigger point release reduces actin and myosin overlap, which reduces, the release of noxious substances, contractile activity, energy consumption, and ischemia-all of which tend to break the trigger point feedback cycle Simons [15]. There are some limitations of this study. Firstly, the lack of follow-up for patients with pudendal nerve entrapment syndrome in group A for several months' post rehabilitation program to evaluate the long lasting effect of additional effect of myofascial trigger release on pelvic pain. Secondly, certain secondary outcome variables such as functional activity, and muscle strength were not assessed. In conclusion, this study shows that myofascial trigger point release has favourable effects on pelvic pain on the pudendal nerve entrapment syndrome.

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