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Impact of integrated neuromuscular inhibition technique versus electro-acupuncture stimulation of posterior tibial nerve in males with chronic pelvic pain of myofascial origin

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ABSTRACT

The aim of the study was to examine the impact of the integrated neuromuscular inhibition technique and electro-acupuncture stimulation of posterior tibial nerve in males diagnosed with chronic pelvic pain of myofascial origin. Sixty male patients with chronic pelvic pain participated in this randomized, single-blind, active-controlled trial and they were randomly divided into 3 groups of equal size**.** The group A (20 patients) received integrated neuromuscular inhibition technique (INIT) and pelvic floor exercise, the group B (20 patients) received posterior tibial nerve electroacupuncture using TENS acupuncture as a noninvasive pelvic floor muscle neuromodulation technique and pelvic floor exercise, and the control group C (20 patients) received pelvic floor exercise only. Serum cortisol level (SCL) measurement was done, and the National Institute of Health Chronic Prostatitis Symptom Index (NIH-CPSI) questionnaire score was used to assess the severity of symptoms of chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS). The measurements were done at baseline and after the next two months. Comparing the three groups post treatment, our results show that there are statistically significant differences in serum cortisol level and in the National Institute of Health Chronic Prostatitis Symptom Index (NIH-CPSI) questionnaire score in both group A and B ($p<0.05$). There are no statistically significant differences in the control group C ($p>0.05$). The findings of this research showed a significant reduction of blood cortisol level and improvement of NIH CPSI questionnaire total value in men with chronic pelvic pain who used an integrated neuromuscular inhibition technique and percutaneous posterior tibial nerve stimulation, and a non-significant difference in the control group C. The INIT has superiority over electro-acupuncture stimulation of the posterior tibial nerve in reducing pain and improving quality of life.

KEYWORDS

Male chronic pelvic pain syndrome; INIT; electro-acupuncture stimulation; SCL; NIH-CPSI questionnaire.

1. INTRODUCTION

Symptoms in men suffering from chronic pelvic pain last longer than 6 months with repeated attack of pelvic and abdominal pain and sexual dysfunction without apparent clinical pathology (Spitznagle & Robinson, 2014). Urologists have been conducting research and clinical trials for many years to determine the causes of pelvic pain and have finally classified 6 causes of male pelvic pain, The first is urinary system assessment (storage and voiding), the second is a psychosocial condition such as depression, the third cause is various organs (other than bladder and prostate infections), the fourth is infectious conditions (prostatic secretions and urine), nervous system (local and systemic), and the last cause is trigger point of pelvic floor skeletal muscles. The occurrence of chronic pelvic pain ranges between 5.7 to 26.6% around the world (Ahangari, 2014).

Male chronic pelvic pain syndrome (MCPPS) has been described as a psycho-neuromuscular condition in many previous studies, highlighting the value the value of physical therapy intervention for this musculoskeletal disorder. Good results in conjunction with cognitive behavioral therapy are achieved with techniques such as myofascial release for trigger points (Anderson, Wise & Nathanson, 2018). There are many previous studies that value the assessment of physical characteristics mainly related to the musculoskeletal system. Clinical findings show overactivity, tenderness, and impaired relaxation (dyssynergy) of the pelvic floor muscles, particularly the levator ani (FitzGerald et al., 2013).

Several findings indicate that chronic pelvic pain (CPP) may occur as a result of a neurological condition with central pain sensitization leading to nervous system dysfunction. But also, there are many treatment options for patients suffering from chronic pelvic pain. For example, neuromodulation has been explored as a therapeutic alternativ due its capacity to modify few of these dysfunctional shifts (Simis et al., 2015). Electrical stimulation is a commonly used neuromodulation technique. It is based on pain desensitisation through the ascending pathway, which results in muscle-contracting fatigue and relaxation and is recommended for the treatment of pelvic floor disorders such as overactive bladder and pelvic floor dyssynergia (Yang, 2013).

Another treatment option, is the integrated neuromuscular inhibition technique (INIT). This is a trigger point release therapy that combines ischemic compression, muscle energy technique (MET) and strain counterstrain (SCS). INIT improves pain level, range of motion, and functional mobility due to increased blood circulation after application of ischemic pressure, relaxation of the muscle by SCS, and reduction of muscle tone by MET (Jyothirmai, Kumar, Raghavkrishna & Madhavi, 2015). Also, electroacupuncture (EA) is an electrotherapy that provides pulse-type stimulation to the body through a couple of needles inserted into the area to be stimulated. It is based on conventional medical theory and is used to relieve and enhance pain and other symptoms The effect of EA is to stimulate peripheral and central nerves, which release opioids for pain relief and serotonin for an analgesic effect (Zhang, Lao, Ren & Berman, 2014). The aim of this study is to examine the impact of the integrated neuromuscular inhibition technique and electro-acupuncture stimulation of posterior tibial nerve in males diagnosed with chronic pelvic pain of myofascial origin.

2. METHODS

2.1. Study design

A randomized, single-blind, active-controlled trial was carried out on a sample of sixty male patients diagnosed with pelvic pain of myofascial origin Patients were referred by the urology department. This project was registered on the Pan African Clinical Trail and the unique identification number for the registry was PACTR202104532195177.

2.1. Participants and sample size

From June 2019 to May 2020, the clinical trial was completed. Patients were referred from the urological outpatient clinics of Haram Hospital and Sheikh Zayed Hospital to the physiotherapy outpatient clinic of Sheikh Zayed Hospital. The age of the patients ranged from 25 to 45 years. The patients were randomly divided into 3 groups, each of equal size: Group A (20 patients), received integrated neuromuscular inhibition technique (INIT) and pelvic floor exercise, group B (20 patients), received posterior tibial nerve electroacupuncture using TENS acupuncture as a noninvasive pelvic floor muscle neuromodulation technique and pelvic floor exercise, and the control group C (20 patients), received pelvic floor exercise only.

The inclusion criteria were patients with recurrent pelvic pain such as groin pain, genital pain, upper part of the lower abdomen, pelvic floor muscle spasm and perineal pain for at least 6 months without clear urological anomalies.

The exclusion criteria were patients under 25 years and over 50 years old, signs of excitation for less than 6 months, persistent urinary tract infections, stones of kidney or bladder, bacterial prostatitis, severe cardiopulmonary disease, neurological conditions such as (MS, stroke) and patients under analgesic therapy.

A preliminary power analysis [power ($1-\alpha$ error P) = 0.95, $\alpha = 0.05$, effect size = 1.36] was performed to prevent type II error. In this study, a sample size of 21 was determined for the three groups (7 subjects for each group) with suggested 40% drop rate. Effect size was measured using the primary outcome of a pilot study and the effect size of the study group.

G*Power 3.1.9.2 software (G power programmer version 3.1, Heinrich-Heine-University, Düsseldorf, Germany) was used for power analysis, with the test family as F-tests and the statistical test as a fixed ANOVA effect for three groups. With a failure rate of 40%, our power analysis predicts 20 participants for each group as the sample size.

2.2. Randomization

Written informed consent was obtained from each participant. Male patients with chronic pelvic pain were randomly divided into 3 equal groups (the experimental A, B groups & the control group C) using block randomization.

2.3. Interventions

2.3.1. Group A

This group was treated with INIT, which includes ischemic compression technique, Strain-Counterstrain and muscle energy technique.

1) Ischemic compression technique: Participants were placed in the supine position to reduce spasm and relax the levator ani and quadratus lumborum muscles. The investigator determined the trigger points by pincer palpation after asking the subjects about the pain region. After the trigger points were established, intermittent ischemic compression began with the thumb and index

using pincer grip of the trigger point. The pressure was turned on for five seconds and off for five seconds in a disrupted path The procedure was repeated three times per session for a total of 90 seconds, depending on the subjects' tolerance (Hains & Hains, 2000).

2) Strain-Counterstrain technique: To treat trigger points in muscle, the Strain-Counterstrain is a type of indirect osteopathic manual therapy known as a highly efficient approach to improve pain and function of muscles, bones and fascia. It is used to treat somatic dysfunction where the therapist must identify the location of the trigger point in the muscle The patients' limb is shifted in such a way that at least 70 percent of the pain associated with the stress on the tender points is alleviated to find a position of ease (Wong & Schauer, 2004). 90 seconds is the minimum time required to maintain a position of ease. The mechanism used for therapeutic treatment of shortening of affected soft tissue is achieved by both nociceptive and proprioceptive mechanisms.

-The SCS technique for the levator ani muscle: The patient is vulnerable to this tender point in the midline of the sacrum just above the shiatus sacralis. The anterior pressure to the sacral base in the midline is exerted by the therapist. Rotation is produced around a transverse axis (Ambrogio, 1997).

-The SCS technique for the quadratus lumborum: Trigger points occur on the tip of the LI to L5 transverse processes. With the hips and knees flexed to about 90°, the patient is lateral recumbent on the unaffected side. The therapist holds the ankles and lifts them to cause mild side bending of the torso. The patient was asked about the level of pain of trigger point. This position was held for 90 seconds and repeated 3 times per session when pain reduced by 70% from the beginning of session (Ambrogio, 1997).

3) Muscle energy technique for the quadratus lumborum muscle: The patient lies supine, both hands are behind the head, the feet are crossed at the lower leg, and there is a lateral flexion of the trunk towards affected side. The therapist stands on the contralateral side, one hand holds the patient's shoulder at the axilla side and the other hand stabilizes the pelvis at the ASIS of the affected side. The patient was advised to produce an isometric contraction of the quadratus lumborum with a very light sideband towards the treated side. The patient was advised to fully relax after 7 seconds and then move to the untreated side while the therapist partially leaned backward at the same time to side band the patient (Ellythy, 2012).

2.3.2. Group B

Transcutaneous electrical nerve stimulation by acupuncture (TENS) had been supplied to the posterior tibial nerve using an electrode-generator combination. Acupuncture needles (diameter 0.25, length 25 mm;) were sited unilaterally at the spleen (SP) 6 and kidney (KI) 2 points behind the medial malleoli (Chesler & Heald, 2017).

The location of the acupuncture points:

- SP 6:3: cun on the inner side of the calf, directly to edge of the medial malleolus, posterior border of the medial tibia (Chesler & Heald, 2017).

- KI 2: These are elements of the tibial nerve, located in the groove between the medial malleolus and the Achilles' tendon. The tibial nerve supplies the whole foot plantar sensation. The tibial nerve ramification occurs inside tarsal tunnel, behind the medial malleolus (Lee et al., 2019).

The TENS device is then connected to the needles. The device model is DH-808, made by DAE Han in Korea. The intensity of the device is low voltage (9 volts) and is modulated according to the sensitivity of the patient. 200 microseconds is a fixed pulse width and a frequency of 10Hz for 30 minutes. The stimulator produces a variable electrical impulse that passes through tibial nerve to sacral nerve plexus through the acupuncture needle. In order to evoke sensory or motor response in the tibial nerve, subjects were advised to gradually increase the intensity. A total of 8 weekly sessions were performed by the participants.

2.3.3. Group C (control group)

The pelvic floor muscles exercise program focused on a 6-second contraction of the muscles accompanied by a 6-second rest, equivalent to a contraction of 5 cycles/min. During the 8-week treatment period, the number of contraction cycles should be gradually increased. The first week starts with 25 cycles per day for 5 minutes; in the second week, cycles are increased to 50 cycles per day for 10 minutes; in the third week, to 75 cycles per day for 15 minutes; the fourth week, to 100 cycles per day for 20 minutes (Cammu, Nylen & Amy, 2000).

2.4. Outcome Measures

1) The National Institute of Health Chronic Prostatitis Symptom Index (NIH-CPSI) Questionnaire

The primary outcome measure used in this study is the Arabic version of the National Institutions of Health - Chronic Prostatitis Symptom Index (NIH-CPSI), which is widely used among men to assess the severity of symptoms of chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS). The questionnaire consists of 3 subscales; for pain (parts 1a, 1b, 1c, 1d, 2, 3, and 4), urinary symptoms (parts 5 and 6), and quality of life (parts 7, 8, and 9). Each patient answered to this questionnaire with 9 items.The score of NIH-CPSI was the summation of the total scores of each domain, with the total score of NIH-CPSI ranging from 0 to 43 points (Davis et al., 2013).

2) Serum cortisol level (SCL) measurement

Cortisol is referred to as a stress hormone that is released in the body in response to inflammatory, physical, or mental stress. The elevated cortisol's natural function is to stimulate the body's immune defense mechanism and encourage healing to eliminate the source of pain and stimulate tissue regeneration (Khoromi et al., 2006).

Blood samples were collected at 8-10 a.m. after subjects had fasted and rested overnight to avoid any changes in serum cortisol levels. Samples were obtained in EDTA prechilled test tubes and held at -20ºC before analysis. Radioimmunoassay was used to determine the level of in serum. The morning cortisol reference range (from 8 a.m. to 12 p.m.) is 6.2-19.4 g/dl for average adults.

2.5. Data analysis

The One-way ANOVA test was used to analyze the mean value of BMI, height, body mass and age among all studied groups. Also, descriptive statistics with mean ± standard deviation (SD) and Post Hoc tests were used for all dependent variables. For all statistical tests, a p-value < 0.05 was considered statistically significant.

3. RESULTS

The subject characteristics of groups A, B and C are shown in Table 1. There was no statistically significant difference between groups in age, body mass, height and BMI ($p>0.05$).

The numerous pair wise comparison tests revealed statistically significant decreases in NIH-CPSI and SCL at both group A and group B ($p<0.05$) but there were no statistically significant differences at C group after treatment ($p>0.05$) (Table 2). There were statistically significant improvements in NIH-CPSI and SCL within group A more than group B and C ($p<0.05$). Furthermore, there were statistically significant improves in group B compared to group C.

Table 1. Basic characteristics of participants.

	Group A Mean±SD	Group B Mean±SD	Group C Mean±SD	F-value	p-value
Age (years)	41.47±3.292	41.73±2.789	42.27±3.105	1.3488	0.27055
Body mass (kg)	76.93±6.85	77.4±5.501	75.87±5.502	0.6287	0.53818
Height (cm)	175.67±7.394	175.47±6.3	173.4±4.657	0.9009	0.41390
BMI (Kg/m^2)	24.97±1.309	25.14±0.783	24.16±1.629	1.6866	0.19744

Table 2. Before and after treatment mean values of NIH-CPSI and SCL of groups A, B and C (within and among groups).

Variables	Group A		Group B		Group C	
	Before	After	Before	After	Before	After
NIH-CPSI	32.35±3.1	22.26 ±2.08	31.26±3.04	26.95±1.36	32.86 ±1.34	30.71±1.53
SCL	36.17±3.5	23.67 ±1.56	36.3±2.9	24.54 ±1.9	36.1 ±2.83	35.02±1.76

Within groups (Before vs After)

p-value	NIH-CPSI	SCL
Group A	0.0001*	0.0001*
Group B	0.0001*	0.0001*
Group C	0.984	0.97

Among groups

	NIH-CPSI		SCL	
	Before treatment	After treatment	Before treatment	After treatment
Group A vs. B	0.999	0.006*	0.999	0.004*
Group A vs. C	0.999	0.0001*	0.999	0.0001*
Group B vs. C	0.999	0.0001*	0.999	0.0001*

**NOTE: * (level of significance).*

4. DISCUSSION

Our results demonstrated that both the integrated neuro-muscular inhibition technique and electro-acupuncture stimulation of the posterior tibial nerve have a large effect on CPP in men, with

INIT producing much greater improvement than electro-acupuncture in pain levels assessed by SCL and NIH-CPSI.

According to some evidence, neural inflammation and muscle impairment of the pelvic floor may play a role. This can set off a vicious cycle of immunological inflammation and/or neurogenic injury, setting the stage for acute and chronic pain (Nickel et al., 2007).

The influence of three manual therapy techniques could be attributed to the impact of INIT. For example, intermittent ischemic compression reduces pain by stimulating A-beta fibres, which inhibit the pain pathway while under pressure and improve circulation when pressure is released (Nambi et al., 2016). According to the proprioceptive theory, SC-S corrects abnormal neuromuscular behavior caused by muscle spindle and local circulation, as well as inflammatory responses mediated by the sympathetic nervous system, which explains technique's efficacy. According to the proprioceptive hypothesis, the neuromuscular imbalance caused by repetitive excitation of the muscle spindles can be minimized by passive shortening of the dysfunctional agonist muscle. SCS can also restore normal muscle spindle activity. After the agonist muscle spindle activity is already restored, the activity of antagonist muscle spindle can also be reset, decreasing excessive neuromuscular activity and restoration of function (Wong, 2012).

The clinical efficacy of SCS may be supported by the in vitro SCS model. SCS has been shown to induce secretions of pro-inflammatory, fibroblast proliferation and anti-inflammatory interleukins (Meltzer & Standley, 2007).

The effect of MET on Golgi tendon organs that are triggered during muscle stretch has a negative effect on motor neuronal discharges, thus reducing the reflex contraction induced by the stretch reflex. This allows the musculotendinous unit to relax, allowing the sarcomere to regain its original length, and the muscle fiber to lengthen from its shortened position to its normal length (Dagenais et al., 2010). The effect of isometric muscle contractions during MET is thought to cause a shift in blood flow and static lymphatic pressure, resulting in paraspinal muscle decongestion (Dagenais et al., 2010). This finding is consistent with Nagrale et al. (2010), who investigated the effect of INIT on trigger point release of upper fiber trapezius using VAS, ROM and NDI. The researchers divided the participants into 2 groups MET was applied in one group and INIT in the other. Their findings showed that both groups progressed, but the second group exceeded the first in all variables (Nagrale et al., 2018).

According to the gate control theory, electroacupuncture decreases pain by stimulating large somatic fibers that occupy the thinner afferent A delta or C fiber, resulting in a reduction in pain perception related to the activation of pain-inhibitory neurotransmitters such as endorphins and monoamines (serotonin and noradrenaline) (Brown & Jones, 2010), and activation of μ and δ-opioids by secretion of enkephalins & β-endorphins and stimulation of κ-opioid receptors by dynorphins (Lin & Chen, 2008).

In a study of 63 patients divided into three classes, that was aimed to examine the therapeutic benefits of electroacupuncture (EA) for chronic pelvic pain syndrome, electroacupuncture was found to be superior to sham treatment, guidance and exercise only (Lee & Lee, 2009). Another randomized clinical research comparing once-weekly acupuncture treatment (n=50) with sham treatment (n=50) over a 6-month period found significant long-term improvement in response rate and improvement in various values after 24 weeks (Sahin et al., 2015).

5. CONCLUSIONS

The findings of this study showed a significant reduction of blood cortisol and an improvement of NIH-CPSI questionnaire total value in men with chronic pelvic pain who used an integrated neuromuscular inhibition technique and percutaneous posterior tibial nerve stimulation, and a non-significant difference in the control group C. The INIT has superiority over electro-acupuncture stimulation of the posterior tibial nerve in reducing pain and improving quality of life.

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CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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