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Effect of Transcutaneous Electrical Nerve Stimulation on Interstitial Cystitis/Painful Bladder Syndrome

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Abstract: Purpose: to determine the effect of transcutaneous electrical nerve stimulation (TENS) on interstitial cystitis/painful bladder syndrome. **Methods of evaluation:** Measurement of the visual analogue scale (VAS) and estimation of the clomipramine medicament intake (CMI). **Methods:-** Thirty male patients who had interstitial cystitis/painful bladder syndrome were participated in the study. They recruited from the urology department of Cairo university hospitals, their ages were ranged from 30 to 50 years, they were randomly divided into 2 equal groups in number, one study group (A) and a control one (B). All patients in the 2 groups (A) and (B) received the same traditional physical therapy and home exercises in the form of pelvic floor exercises. Also all patients received the same medical care and medications. Group (A): received the transcutaneous electrical nerve stimulation in addition to the traditional physical therapy and medical care for 4 months. Control group (B): received only the traditional physical therapy and medical care for 4 months, each treatment session was conducted for 15 minutes, two electrodes were positioned suprapubically, while the other two electrodes were applied under the lower back (T10-L1) with the patient in comfortable supine hook-lying position with abducted hips. **Results and conclusion:-** Results showed a highly significant reduction in VAS and CMI at the end of the treatment program in groups (A) only. So TENS was effective in improving the interstitial cystitis/painful bladder syndrome as manifested by the highly significant reduction in VAS and CMI..
Key words (Interstitial cystitis/painful bladder syndrome, Transcutaneous electrical nerve stimulation, Visual analogue scale (VAS) and Clomipramine medicament intake).

Introduction

Interstitial cystitis (IC) is a defined by its characteristics due to lack of a standardized diagnostic criteria globally. Both the definition and the diagnosis name have evolved with time, the term IC means "inflammation of the bladder wall". IC is a condition characterized by urinary symptoms of severely reduced bladder capacity and cystoscopic findings of Hunner's ulcers, this is also referred to as the "classic IC" due to a finding in 1978 by Messing and Stanley of a "non-ulcer IC"[1,2,3,4].

In the United States, approximately 1 million individuals are affected. The prevalence of IC is higher in the USA than in United Kingdom and Europe, female: male ratio is ~9:1, the average age is between 30-50. It appears to be more common in Jewish women, 90% Caucasian, low prevalence in the black population, may occur in pediatric and geriatric populations. Most common symptoms are urinary Frequency (includes multiple nighttime voids), urinary urgency, suprapubic pelvic pain related to the bladder filling [5,6,7,8].

Associated symptoms are dyspareunia (pain with intercourse), chronic constipation, slow urinary stream, food sensitivities that worsen symptoms**, r**adiating pain in the groin, vagina, rectum, or sacrum. Associated co-morbidities are anxiety, depression, migraine, chronic fatigue syndrome, dysmennorrhea, vulvodynia, fibromyalgia , irritable bowel syndrome (IBS), urethral burning and pelvic floor dysfunction[9,10,11].

Most of the oral medications used to treat IC are used in an "off-label" manner without being studied specifically for patients with IC/PBS. The only FDA-approved oral medication for IC is Pentosanpolysulfate (Trade name: Elmiron). The drug is designed to enhance the glycosaminoglycan (GAG) layer of the bladder. The theory is that it prevents toxic/inflammatory agents of urine from pentrating the subepithelial layer of the bladder. It is reported that it could take up to 6 months for individuals to receive the desired effect [4,8,10,11].

Since the discovery of electricity, and before, current has been applied to the human flesh by a variety of methods to cure a multitude of afflictions. Electrical discharges from the black torpedo fish (Electric eels) were known to the Ancient Egyptians as well as to Hippocrates, for the treatment of headache and gout. The word electric was first used by William Gilbert (1544-1603), who was the first to classify and generalize the phenomenon of electricity in his book De Magnete. Kratzenstein (1746) wrote the first report on the use of electricity in medical therapy, so William Gilbert considered as the electricity father, while Kratzenstein considered as the electrotherapy father [12,13,14,15] .

In the course of the nineteenth century, electrical and mechanical stimulation were employed as a therapy for many diseases by a large number of practicing physicians, but in the twentieth century, with the increased number of efficient analgesics, turned interest away from peripheral stimulation as a pain relieving mode until Melzack and wall (1965) published their gate-control theory of pain, which reawakened interest in the use of peripheral stimulation as a mode of pain control, again, [16,17,18] .

Transcutaneous electrical nerve stimulation (TENS) was introduced as a test for the gate-control theory of pain by (Melzack and wall, 1965). Wall went to recruit Sweet, who was head of neurosurgery at Harvard medical school to propose an experiment about the temporary abolition of pain, first on themselves and then, if that worked, on patients, Wall and Sweet published their work in 1967 (Wall and Sweet, 1967). TENS has rapidly been accepted as a standard modality in the treatment of pain and was introduced to the profession in the early 1970th. Practitioners, who have utilized TENS, properly have reported excellent results in many aspects of practice as pre and postoperative pain, non-united fracture pain and healing, obstetrics, dental and tempro-mandibular joint pain and other aspects [14,15,16,17,19] .

Material and Methods

Subjects:

Thirty male patients who had interstitial cystitis/painful bladder syndrome were participated in the study. They recruited from the urology department of Cairo university hospitals, their ages were ranged from 30 to 50 years, they were randomly divided into 2 equal groups in number, one study group (A) and a control one (B). All patients in the 2 groups (A) and (B) received the same traditional physical therapy and home exercises in the form of pelvic floor exercises. Also all patients received the same medical care and medications. Group (A): received the transcutaneous electrical nerve stimulation in addition to the traditional physical therapy and medical care for 4 months. Control group (B): received only the traditional physical therapy and medical care for 4 months, each treatment session was conducted for 15 minutes, two electrodes were positioned suprapubically, while the other two electrodes were applied under the lower back (T10-L1) with the patient in comfortable supine hook-lying position with abducted hips[1,8,14,15,20,21,22] .

Instrumentation:

A dual channel TENS stimulator: Model DH-808, made by DAE Han in Korea was utilized; Dimension: 170 (height) □ 58 (width) □ 26 thickness in mm, weight: 170 grams, power voltage: 9 volts direct current supplied by a DC adaptor (new general made in USA), power consumed: 600 mw (maximum), frequency: 1 Hz- 100 Hz Amplitude: 10 mA - 100 mA, pulse width: 50 □sec. - 400 □sec, wave form: Asymmetrical biphasic square pulse. Accessories: 4 body electrodes with 2 plugs and 2 adhesive belts. Self adhesive electrodes: Dura-Stick II self adhesive round electrodes (for use with most muscle stimulator, clinical

electrotherapy, and transcutaneous electrical nerve stimulator) were used. The electrodes were two inches (about 5 cm) in diameter and their part number is 42042. Modulation: Intermittent changes in the TENS parameters of stimulation (frequency and intensity) were programmed by the manufacturer to vary about 10 percent periodically to overcome the accommodation process [12,13,14,15,17,18].

Procedures

Evaluation:

1- Visual Analogue Scale (VAS): The pain level was assessed by visual analogue scale (VAS) before starting treatment (first record) then after 4 months (as second final record). The visual analogue scale (VAS) consisted of a line, usually 10 cm long, whose ends are labeled as the extremes of pain (e.g., no pain to unbearable pain). Patient was asked to place a mark at the point on the line which best represent his experience of pain between two "no pain" to "worst pain", then the operator measured the distance from the zero "no pain" in centimeters.

2- Estimation of the Clomipramine Medicament Intake (CMI): it was used to evaluate the improvement in the interstitial cystitis/painful bladder syndrome. All the aforementioned parameters (VAS and the CMI) were measured 2 times; the baseline record that was taken before starting of the study, the second final record was taken after 4 months from the starting of the study[7,10,15,21,22].

Treatment:

The experimental protocol was explained in details for every patient before starting the initial assessment, and a written consent form was signed by each patient before starting. The treated patients were instructed to report any side effects during the treatment sessions. All patients in the 2 groups (A) and (B) were received the same traditional physical therapy and same medications. TENS treatment protocol including position of patient and position of electrodes: The TENS was applied once daily, three times per week for 4 months as a total period of treatment. Each treatment session was conducted for 15 minutes, two electrodes were positioned suprapubically, while the other two electrodes were applied under the lower back (T10-L1) with the patient in comfortable supine hook-lying position with abducted hips, the TENS electrode surface area was equal to or greater than 4 cm^2 to minimize heat produced beneath electrodes to prevent skin burns. Also the interelectrode distance must not be less than the cross-sectional diameter of the electrode, to minimize current density between electrodes, so heat produced either beneath or between must not exceed the safe limits to avoid skin burn, the 4 electrodes were of the adhesive type and if not of the adhesive type they were moistened with jelly and firmly fixed by a relevant adhesive tapes over the recommended areas**.** Stimulation parameters of the conventional TENS mode application in the study group (A) were the following: The parameters were, square wave form, frequency from 80-100 Hz and an intensity from 10-30 mA, associated with a pulse width from 50-60 μsec, producing a comfortable perceptible paraesthesia (tingling) without significant muscle contractions or fasciculations, while TENS application for the control group (B) was placebo TENS in the same position of subject and TENS electrodes placement[12,13,15,16,17,18].

Data analysis:

VAS and CMI were measured before and after the treatment program and the collected data were fed into computer for the statistical analysis; descriptive statistics as mean, standard deviation, minimum and maximum were calculated for each group. The t-test was done to compare the mean difference of the two groups before and after application and within each group. Alpha point of 0.05 was used as a level of significance [23,24].

Results

In the present study, effects of transcutaneous electrical nerve stimulation (TENS) on interstitial cystitis/painful bladder syndrome were investigated. As shown in table (1) and figure (1), the mean values of VAS before treatment was (9.442 ± 0.232) degrees in the study group, while after treatment was (2.600 ± 0.132) degrees. These results revealed a highly significant reduction in VAS ($P < 0.0001$). While the mean

values of VAS before treatment was (9.440± 0.221) degrees in the control group, while after treatment was (9.437 ± 0.210) degrees, these results revealed non-significant difference in VAS (P > 0.05).

Table (1): Comparison of the mean values of VAS before and after treatment in the two groups in degrees.

	Before treatment		After treatment		Mean difference	T.value	P.value
	Mean in degrees	± SD	Mean in degrees	± SD			
Study group (True TENS group)	9.442	0.232	2.600	0.132	6.84200	99.28	< 0.0001
Control group (False TENS group)	9.440	0.221	9.437	0.210	0.003000	0.04	0.970

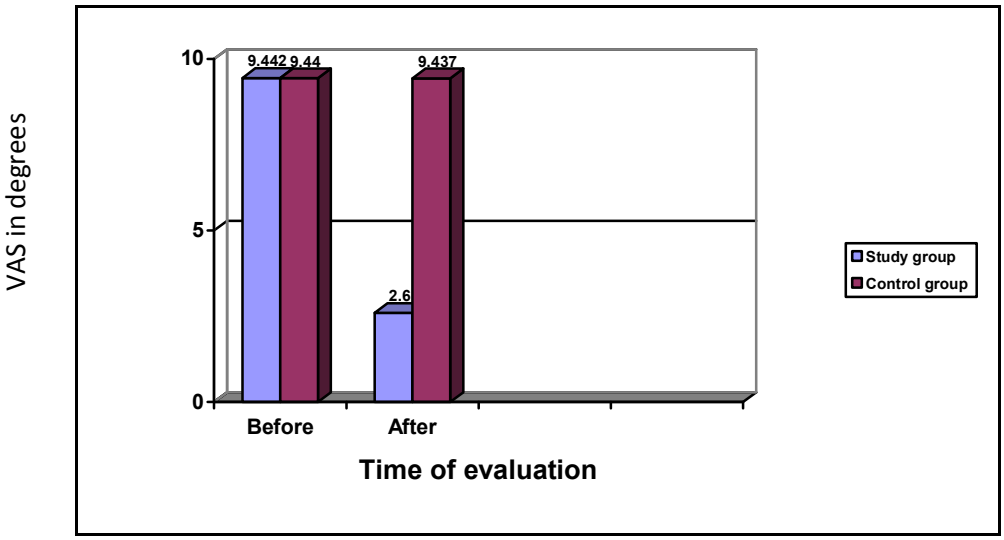

Fig (1): Mean values of the VAS before and after treatment in the two groups.

Also as shown in table (2) and figure (2), the mean value of CMI before treatment was (72.00 ± 10.35) mg in the study group (True TENE group), while after treatment was (18.33 ±11.44) mg. These results revealed a highly significant reduction in CMI (P < 0.0001). The mean value of CMI before treatment was (73.33 ± 6.45) mg in the control group (False TENS group), while after treatment was (72.99 ± 5.87) mg, these results revealed non-significant difference in CMI (P > 0.05).

Table (2): Comparison of the mean values of CMI in mg before and after treatment in the two groups.

	Before treatment		After treatment		Mean difference	T.value	P.value
	Mean in mg	± SD	Mean in mg	± SD			
Study group (True TENS group)	72.00	10.35	18.33	11.44	53.6700	13.47	< 0.0001
Control group (False TENS group)	73.33	6.45	72.99	5.87	0.34000	0.15	0.881

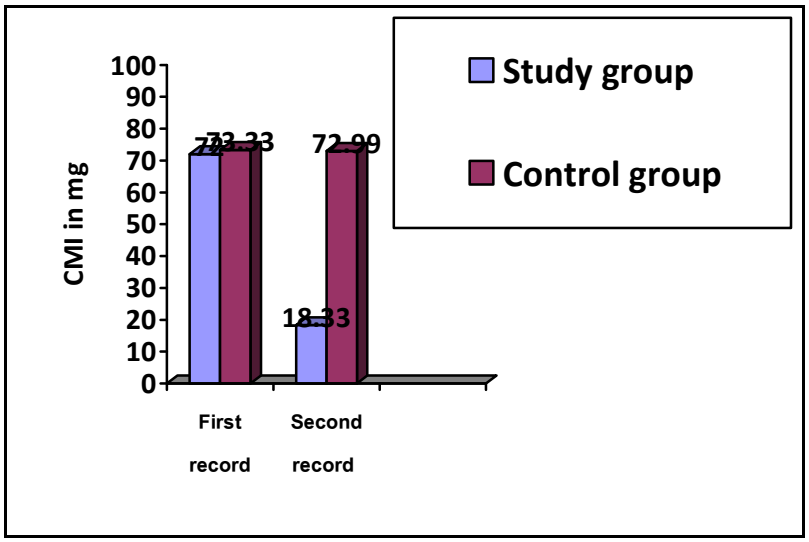

Fig (2): Mean values of the CMI in mg before and after treatment in the two groups.

Discussion

Interstitial cystitis/painful bladder syndrome (IC/PBS) is a chronic debilitating condition characterized by pelvic pain, urinary urgency, and urinary frequency. The condition takes a significant toll on patients' quality of life. People who have IC/PBS suffer from a "silent affliction," often appearing healthy but experiencing unrelenting pain that requires frequent trips to the bathroom, both day and night. Although curing IC/PBS is not yet possible, the high toll that IC/PBS exacts can be mitigated with currently available therapy once the disease is diagnosed [1,4,5,8].

Unfortunately, people who have IC/PBS often suffer needlessly because of delays in diagnosis, misdiagnosis, and lack of awareness of the disorder. On average, patients experience a lag time of five to seven years before they receive a diagnosis of IC/PBS. Primary care providers can play an essential role in reducing such suffering by identifying persons whose symptoms are consistent with IC/PBS, promptly diagnosing and treating the disorder, and referring patients to specialists as necessary. For this reason, it is important for primary care providers to be aware of IC/PBS and become familiar with the presentation and recommendations for diagnosis and management of IC/PBS [7,9,10].

This quick reference guide for clinicians is designed to help health care providers more easily identify patients for whom a diagnosis of IC/PBS should be considered and, depending on their level of experience and comfort, begin the process of diagnosis and treatment, referring for specialty care when needed. Considering the possibility that a patient's symptoms may represent IC/PBS is the crucial first step in uncovering previously undiagnosed and untreated IC/PBS. This quick reference guide for clinicians allows health care providers to confidently take that first step, preventing unnecessary and prolonged suffering for the many people whose condition remains undiagnosed and therefore inadequately treated [3,4,10,11].

Symptoms and characteristic of IC/PBS are bladder pain (or pressure or discomfort), pain or discomfort often increases with bladder filling and may diminish during voiding, bladder pain or discomfort is associated with a persistent urge to void, urinary frequency, or both, urinary urgency, often a progressive course of urgency that may be relieved by voiding. Urgency is caused by increasing pain, unlike overactive bladder (OAB), in which urgency waxes and wanes and is due to concern about impending incontinence. Persistence of urgency often is useful in differentiating IC/PBS from acute urinary tract infection (UTI) or OAB, urinary frequency, common in IC/PBS, with voiding 10 to 15 times or more within 24 hours, may be severe, with voiding more than once an hour, other symptoms includes nocturia is common and may cause sleep deprivation, dyspareunia is common in women with IC/PBS. Incontinence is uncommon. Symptoms range from very severe, described as a sharp pain, to less severe, described as feeling similar to a persistent urinary tract infection. Symptoms can be intermittent or constant, symptoms can wax and wane over time. Among women, symptoms may flare during the premenstrual week. Comorbid conditions are more common in patients with IC/PBS than in the general population, some of these conditions have an immunologic or allergic basis [1,4,7,8,10].

TENS is an effective, noninvasive, nonaversive, nonaddictive method of managing pain, muscle guarding and dysfunction of the pain cycle as well as the internal changes that accompanied the pain cycle can be managed or at least reduced by TENS application. As pain produces a state of muscle tension that results in a diminished blood supply within the painful area (or a state of ischaemia), increased metabolites, decreased oxygen supply, decreased lymphatic clearing, decreased nutrient supply, increased muscle fatigue, inflammation and oedema. All these internal changes can lead to the progressive amplification of the pain cycle which can be prevented or reduced by TENS [5,12,14,15].

In the conventional TENS, the frequency is high because it ranges from 80-100 pulses per second (Hz) and low intensity as it activates the largest low threshold cutaneous nerve fibre A-delta that blocks the transmission of noxious stimuli by the small unmyelinated C-fibre. Also it activates the A-beta large myelinated fibres that block the nociceptive transmission via the gate control theory of pain. The onset of analgesia in conventional TENS is less than 10 minutes and continues for approximately 30 minutes after the termination of the stimulation. Its analgesic action is not blocked by the administration of the opioid antagonist, naloxone hydrochloride (no reversal by naloxone) [14,15,16,17,18].

Findings of the present study showed non-significant difference in the pre-treatment records of the VAS and CMI, between the mean values of the study and the control groups. Results of this study revealed a highly significant reduction in the mean values of VAS and CMI in the study group after the application of the conventional true TENS, also comparing second records of the VAS and CMI, between the mean values of the study and the control groups showed highly significant reduction indicating that the conventional true TENES was fruitful and beneficial in improving the interstitial cystitis/painful bladder syndrome as evidenced by the highly significant reduction in VAS and CMI in the study group (A).

Significant differences showed in this study were consistent with those observed and recorded by Andersen et al., 2012; Barr and Soderberg, 2006; Chen et al., 2008; Dell, 2007; Johnson and Ashton, 2007; Lampe, 2004; Liggett et al., 2005; Roberts, 2007; Schaeffer, 2000; Solomon and Long, 2008; Somers and Clemente, 2006 and Steven, 2006.

Results of this study supports the expectation that application of the conventional true TENES was fruitful and beneficial in improving the interstitial cystitis/painful bladder syndrome as evidenced by the highly significant reduction in VAS and CMI in the study group (A).

Conclusion

Application of the conventional true TENES was fruitful and beneficial in improving the interstitial cystitis/painful bladder syndrome as evidenced by the highly significant reduction in VAS and CMI in the study group (A).

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