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Effect of microcurrent stimulation on interstitial cystitis/painful bladder syndrome.

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To determine the effect of micro current electrical neuromuscular stimulation (MENS) on interstitial cystitis/painful bladder syndrome. Measurement of the visual analogue scale (VAS) and estimation of the clomipramine medicament intake (CMI).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, and 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 micro current electrical neuromuscular stimulation (MENS) in addition to the traditional physical therapy and medical care for 3 months. Control group (B): received only the traditional physical therapy and medical care for 3 months, each treatment session was conducted for 20 minutes, two electrodes were positioned supra pubically, 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 showed a highly significant reduction in VAS and CMI at the end of the treatment program in group (A) only. So MENS was effective in improving the interstitial cystitis/painful bladder syndrome as manifested by the highly significant reduction in VAS and CMI.

Keywords: (Interstitial cystitis/painful bladder syndrome, Micro current electrical neuromuscular 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'sulcers, this is also referred to as the "classic IC" due to a finding in 1978 by Messing and Stanley of a "non-ulcer IC" L.K.) Carr, et al., (2009), Dasgupta and Tincello (2009), Davis, et al., (2014), T.E. Dawson

and J.A. Jamison (2007).

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, Dell (2007), Andersen (2012),

Evans(2002),French and Bhambore (2011) Associated symptoms are dyspareunia (pain with intercourse), chronic constipation, slow urinary stream, food sensitivities that worsen symptoms, radiating pain in the groin, vagina, rectum, or sacrum. Associated co-morbidities are anxiety, depression, migraine, chronic fatigue syndrome, dysmenorrhea, vulvodynia, fibromyalgia, irritable bowel syndrome (IBS), urethral burning and pelvic floor dysfunction, MacDiarmid and Sand (2007), Moutzouris and Falagas (2009), Rosenberg et al., (2007) 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 penetrating the subepithelial layer of the bladder. It is reported that it could take up to 6 months for individuals to receive the desired effect, Carr, et al., (2009), Davis, et al., (2014), Andersen (2012), Moutzouris and Falagas (2009)10, M.T. Rosenberg et al., (2007) 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, Becker (2008), Byl and McKenzie (2009), Byl (2008).

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, J.D. Chapman and D.Z. Hill (2002), Gersh (2009), Haar (2002).

Micro current electrical neuromuscular stimulation (MENS) is a new physical therapy

modality and its current at micro ampere which has advantage of whispering to the body instead of shouting with milliampere. Micro current increase in muscle metabolism, oxygen uptake and carbon dioxide and other metabolites production, as well as raised local temperature and greater local blood flow and intramuscular blood flow and as a consequence of regular muscle contraction and relaxation which provides muscle pumping action and lead to raising the rate of flow in venous and lymphatic vessels. Micro current improves blood flow, inhibits bacterial growth, and enhances phagocytosis by attracting macrophages, and neutrophils. Thus, the influence of stimulation goes beyond events occurring at the skin cell level, Hooker (2005),

Kjartansson and Lundeberg (2006), Leffmann and Cornwall (2010), Lennox (2002) and Prentice(2005)

MATERIALS AND 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 microcurrent electrical neuromuscular stimulation (MENS) in addition to the traditional physical therapy and medical care for 3 months. Control group (B): received only the traditional physical therapy and medical care for 3 months, each treatment session was conducted for 20 minutes, two electrodes were positioned suprapubically, while the other two electrodes were applied under the lower back (T10L1) with the patient in comfortable supine hook-lying position with abducted hips, Andersen (2012), Evans (2002), Schaeffer (2000), Steven (2006), Becker (2008), Byl and McKenzie (2009), Byl (2008), Chapman and Hill(2002).

Instrumentation:

Micro current stimulator: BTL – 5000 manufactured by BTL Industries Limited London United Kingdom. The Micro current device composed of the following: Electrodes: The number of active pad varies from two to four. The size of each active pad range from 5 to 7 cm.

Adhesive tape: An adhesive tape was used to hold the electrodes in its position. On / off timer control: this switch turns the power on and current flows through the patient circuit, and sets the duration of the treatment. Polarity switch: the polarity switch sets the polarity of the active electrode, Gersh (2009), Haar (2002), Hooker (2005), Kjartansson and Lundeborg (2006), Leffmann and Cornwall (2010), Lennox (2002), Prentice(2005)

Procedures

Evaluation

Visual Analogue Scale (VAS):

The pain level was assessed by visual analogue scale (VAS) before starting treatment (first record) then after 3 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" incenimeters.

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 3 months from the starting of the study, .French and Bhambore (2011), Rosenberg et al., (2007), Schaeffer (2000), Steven (2006), Becker (2008) , Byl and McKenzie (2009)

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. MENS treatment protocol including position of patient and position of electrodes: The MENS was applied once daily, three times per week for 3 months as a total period of treatment.

Each treatment session was conducted for 20 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 MENS electrode Surface area was equal to or greater than 4 cm² 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 MENS application in the first study group were the following: The parameters were, modified square DC biphasic pulses of frequency usually 0.3 – 80 Hz provides the best pain relief with changing polarity at intervals of 1 seconds, while MENS application for the control group (B) was placebo MENS in the same position of subject and MENS electrodes placement,

Chapman and Hill (2002), Gersh (2009), Haar (2002), Hooker (2005), Kjartansson and Lundeborg (2006) , Leffmann and Cornwall (2010).

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, Hinton(2004)

RESULTS

In the present study, effects of micro current electrical neuromuscular stimulation (MENS) on interstitial cystitis/painful bladder syndrome were investigated. As shown in table (1) and figure (1), the mean values of VAS before treatment was (9.550 ± 0.322) degrees in the study group, while after treatment was (3.700 ± 0.221) degrees. These results revealed a highly significant reduction in VAS (P < 0.0001). While the mean value of VAS before treatment was (9.555± 0.324) degrees in the control group, while

after treatment was (9.552 ± 0.321) degrees, these results revealed non-significant difference in VAS ($P > 0.05$).

Also as shown in table (2) and figure (2), the mean value of CMI before treatment was (75.00 ± 10.40) mg in the study group (True MENS group), while after treatment was (20.44 ± 6.66) mg.

These results revealed a highly significant reduction in CMI ($P < 0.0001$). The mean value of CMI before treatment was (74.99 ± 10.34) mg in the control group (False MENS group), while after treatment was (74.95 ± 10.30) mg, these results revealed non-significant difference in CMI ($P > 0.05$).

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 MENS group)	9.550	0.322	3.700	0.221	5.85000	58.01	< 0.0001
Control group (False MENS group)	9.555	0.324	9.552	0.321	0.003000	0.03	0.980

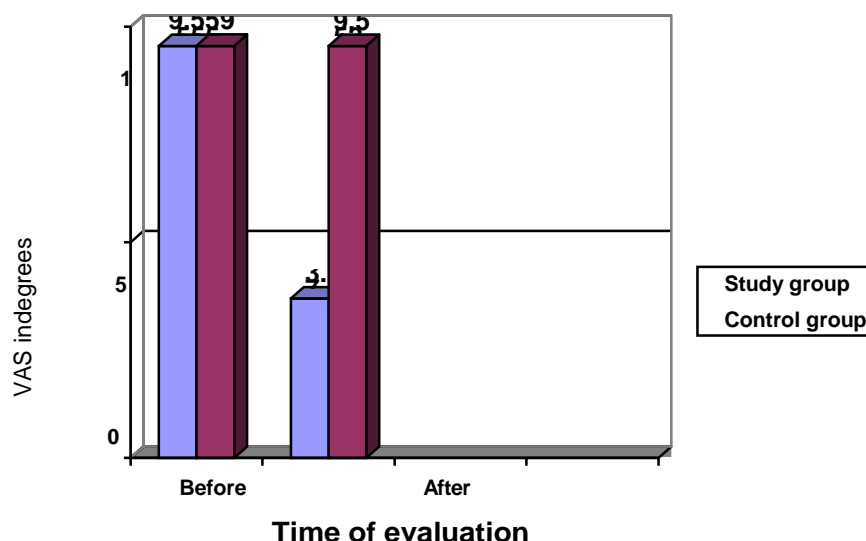


Figure (1): Mean values of the VAS before and after treatment in the two groups.

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 MENSgroup)	75.00	10.40	20.44	6.66	54.5600	17.11	< 0.0001
Controlgroup (False MENS group)	74.99	10.34	74.95	10.30	0.04000	0.01	0.992

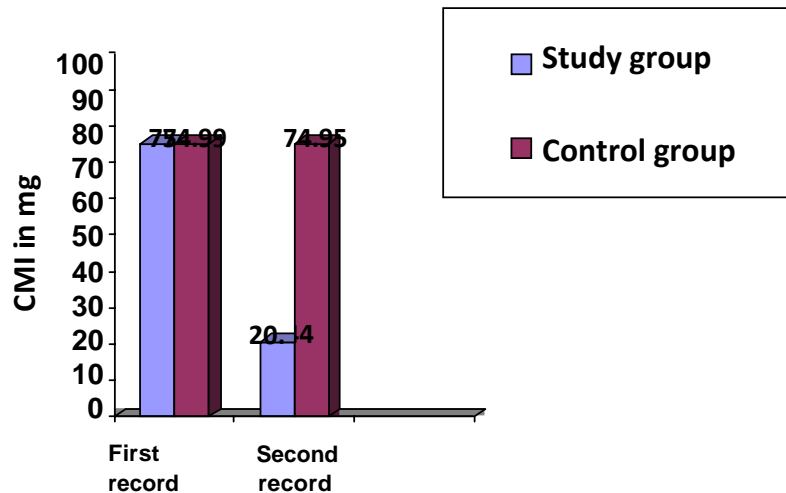


Figure (2): Mean values of the CMI in mg before and after treatment in the two groups.

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, Carr, et al., (2009), J.A. Dasgupta and Tincello (2009), Davis, et al., (2014), Dawson and Jamison (2007), Dell (2007), Andersen (2012)

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, Evans (2002), French and Bhambore (2011) MacDiarmid and Sand (2007), Moutzouris and M.E. Falagas (2009), Rosenberg et al., (2007),.

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, Andersen (2012), MacDiarmid and Sand (2007), Moutzouris and Falagas (2009), Rosenberg et al., (2007).

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, Davis, et al., (2014), Dawson and Jamison (2007), J.R. Dell (2007), L.M. French and .Bhambore (2011) and, Moutzouris and Falagas (2009).

Micro current electrical neuromuscular stimulation (MENS) is a new physical therapy modality. The "micro" in micro current reflects the level of amperage delivered by the unit. In the conventional physical therapy electrical modalities, the current is in milli amperes, while micro current is at microampere (thousandth of a milli ampere) levels. Micro current is available in both high and low volt devices, but low volts most frequently is used and is delivered below the normal level of sensory perception. The principle supporting the use of MENS is that the current is similar to normal physiologically existing electric currents and can thereby produce beneficial therapeutic effects, Becker (2008), Byl and McKenzie (2009), Byl (2008), Chapman and Hill (2002).

Low intensity stimulator currents are defined as those of less than 1 mA or 1000 μ A. Generators that produce low intensity stimulator (LIS) were originally called micro current electrical stimulator (MES). Low intensity stimulator is the most recent and currently used term in an ongoing evolution of terminology relative to this type of stimulator. If the current generator can be adjusted to allow increases of intensity above 1000 μ A, the current becomes like the standard equipment. Micro current electrical neuromuscular stimulation (MENS) is better in enhancing cellular physiology processes than other current of higher amplitude, micro current is effective in the management of open wounds micro current therapy uses extremely small amounts of electrical current to help in relieving pain and healing of the soft tissues of the body, and is an alternate, noninvasive approach for healing of the acute and chronic medical conditions, Gersh (2009), Haar (2002), Hooker (2005), Kjartansson and Lundeberg (2006), A.S. Leffmann and R.R. Cornwall (2010), Lennox (2002), Prentice (2005).

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 MENS, 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 MENS 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 Evans, 2002; Becker, 2008; Byl and McKenzie, 2009; Byl et al., 2008; Chapman and Hill, 2002; Gersh, 2009; Kjartansson and Lundeberg, 2006; Leffmann and Cornwall, 2010 and Lennox et al., 2002.

Results of this study support the expectation that application of MENS 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 MENS 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).

CONFLICT OF INTEREST

The authors declare no conflict of interest regarding this study.

AUTHOR CONTRIBUTIONS

All authors contributed in collecting and analyzing data. All authors participated in writing every part of this study. All authors read and approved the final version.

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