



# TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION VERSUS PULSED ELECTROMAGNETIC FIELD THERAPY ON INTERSTITIAL CYSTITIS

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## Abstract

**Objective:** to determine the effect of transcutaneous electrical nerve stimulation (TENS) versus pulsed electromagnetic field therapy (PEMFT) on interstitial cystitis.

**Setting:** outpatient setting.

**Methods of evaluation:** visual analogue scale (VAS) and estimation of the clomipramine medicament intake (CMI).

**Subjects:** Forty male patients who had interstitial cystitis 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.

**Interventions:** 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 20 minutes 3 times /week in addition to the traditional physical therapy and medical care for 4 months. Group (B): received PEMFT in addition to the traditional physical therapy and medical care for 4 months, each treatment session was conducted for 10 minutes for each area 3times /week.

**Results:** Results showed a highly significant reduction in VAS and CMI at the end of the treatment program in groups (A) and (B). So, both TENS and PEMFT were effective in improving the interstitial cystitis.

**Conclusion:** TENS was more fruitful than the PEMFT

**Keywords** (Interstitial cystitis, Transcutaneous electrical nerve stimulation, Pulsed electromagnetic field therapy, Visual analogue scale (VAS) as well as Clomipramine medicament intake).

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## Introduction

Interstitial cystitis (IC) means bladder wall inflammation. Urinary symptoms of IC include a significantly diminished bladder capacity as well as the presence of Hunner's ulcers on cystoscopic examination, which is also denoted to as the "classic IC" due to a conclusion in 1978 by Messing and Stanley of a "non-ulcer IC" [1]

There are nine times as many women as men diagnosed with IC in the United States, and most patients are in their 30s or 40s. Jewish women appear to be at increased risk; 90% of those affected are Caucasian; the black population has a low prevalence; and it can affect both young children and the elderly. urine frequency (including frequent urination during the night), urine urgency, as well as suprapubic pelvic pain associated with a

full bladder are the most often reported symptoms [2]

Dyspareunia (pain during sexual activity), chronic constipation, a weak urine stream, dietary sensitivities that make symptoms worse, as well as radiating pain in the groin, vagina, rectum, either sacrum are all symptoms that may accompany this condition. Depression, anxiety, migraine, persistent fatigue, dysmenorrhea, vulvodynia, fibromyalgia, irritable bowel syndrome (IBS), urethral burning, as well as pelvic floor dysfunction are some of the co-morbidities that might occur [3]

Most oral drugs for IC are taken "off-label," meaning they have not been evaluated particularly for people with IC. The only FDA-approved oral medication for IC is Pentosanpolysulfate (Trade name: Elmiron). The medicine is intended to improve the thickness of the bladder's protective

layer of glycosaminoglycan (GAG). The idea is that this barrier blocks the penetration of the subepithelial layer within the bladder by toxic as well as inflammatory chemicals present in urine. According to some reports, it may take up to six months for people to feel the full benefit [4]

In order to reduce pain that is acute as well as chronic, transcutaneous electrical nerve stimulation is frequently utilized. This method works by decreasing dorsal horn neuron sensitization, increasing gamma-aminobutyric acid as well as glycine levels, also decreasing glial activation [5] Due to a lack of good quality and unbiased evidence, however, several systematic reviews as well as meta analyses of clinical studies examining the efficacy of utilizing TENS to relieve diverse types of pain have come to contradictory conclusions [6][7] TENS treatment may be advantageous because it is risk-free, inexpensive, easy to use, and available without a doctor's prescription.

The term "pulsed electromagnetic field" (PEMF) is used to describe electromagnetic induction, the process by which a magnetic field interacts with an electric circuit to generate an electromotive force. Normal and diseased states are influenced by endogenous as well as Exogenous signaling during cellular communication. Pain and inflammation can be affected by exogenous influences like PEMF through the following mechanisms: (1) modulating pain-associated molecules like G protein coupling receptors (GPCRs); (2) decreasing cyclooxygenase-2 (Cox-2) activity; as well as (3) inhibiting the production of inflammatory proteins like tumor necrosis factor alpha (TNF-), interleukin-1 beta (IL-1), as well as the transcription factor nuclear factor kappa B (NF-B). [8].

It has been hypothesized that PEMF have a direct impact on plasma membrane phospholipids, stimulating the generation of second messengers and so triggering a variety of intracellular signal transduction pathways [9].

Using Faraday's rule of electromagnetic induction, exogenously applied PEMF is hypothesized to improve microcirculation, modulate inflammatory activity, as well as alleviate pain by interacting with the most fundamental cellular-level biological processes. Low frequency PEMFs as well as TENS have been shown to be effective in reducing pain in fibromyalgia as well as chronic low back pain, two chronic pain syndromes that are often co-occurring with IC but whose precise molecular pathways are not well understood [10,11], this implies that PEMF as well as TENS may help with pain management for those having IC.

#### Material and Methods:

The research was a double-blinded (both patients as well the assessor), Parallel-group, randomized

controlled trial Forty male patients with IC were took part in the study. They were gathered from the urology units of hospitals Cairo University. Each participant was given a thorough explanation of the study's purpose, methods, and potential benefits before signing a signed consent form.

#### Inclusion Criteria:

Patients met all of the following criteria to be included in the study:

They were between the ages of 30 and 50.

Males.

All patients exhibited symptoms of interstitial cystitis.

All participants would be required to give their informed consent before taking part in the study.

#### b. Exclusion Criteria:

Patients did not participate in the study if they met any of the following conditions:

Cardiovascular disorders.

Chronic pulmonary diseases.

Current or past smoking habit.

#### Intervention

**1-Subjects:** Forty male patients suffering from IC took part in the research. They were chosen from university hospital urology departments in Cairo. They were all between the ages of 30 and 50. They were divided into two equal groups at random. **study group (A):** included 20 patients who, in addition to conventional physical therapy along with medical care, received TENS for a total of 4 months.

**study group (B):** included 20 patients who, in addition to conventional physical therapy along with medical care, received PEMFT for a total of 4 months [12,13]

#### Ethical Approval:

The study was approved by the Ethics Board of Cairo University (Reference number P.T. REC/012/003043) and the patients were given all the information they need about the trial. An informed written consent was taken from each participant in the study. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

#### 2-Procedures:

##### A. Measurement procedures:

- 1- Visual Analogue Scale (VAS) for pain assessment:** included a line, typically 10 cm in length, with no pain and extreme pain labels at either end. Patients were asked to indicate where on a line (ranging from "no pain" to "worst pain") they were experiencing pain the most, and the distance from "no pain" was assessed in centimeters.

- 2- Estimation of the Clomipramine Medicament Intake (CMI):**

It was used to measure the reduction of symptoms associated with IC

- 3- Both parameters (VAS as well as the CMI) were measured twice; first before beginning of the study (as a baseline) then again four months later (as a final measurement) [14,15]

**B. Treatment procedures:**

Before beginning the initial evaluation, each patient was given a thorough explanation of the experimental protocol and asked to sign a written consent form. Patients receiving treatment were asked to report any adverse effects immediately. Both Group A and Group B got the same medications as well as physical therapy treatments.

**TENS treatment protocol:** TENS was used for a total of 4 months, once per day, three times each week. The length of each therapy session was 20 minutes, two electrodes were placed above the pubis, while the other two were placed beneath the lower back (T10-L1), with the patient in a relaxed supine hook-lying position with the hips abducted. The TENS electrodes surface area was equal to or greater than 4 cm<sup>2</sup> to avoid heat from building up under the electrodes as well as prevent skin burns. Heat generated either below or between electrodes must not exceed safe limits to prevent skin burn, and the interelectrode distance must be greater than the electrode's cross-sectional diameter, each of the four electrodes was an adhesive type. 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.

**PEMFT application:** For a total of four months, the patient was treated with a PEMFT unit

**Results:**

In the current study, impacts of TENS on IC were examined. As presented in table (1) also figure (1), the mean values of VAS pre-treatment were (8.600 ± 0.445) degrees regarding the TENS group, whereas post-treatment was (2.400 ± 0.505) degrees. These findings showed a

(JAMAVA® S Magneto therapeutic apparatus) that had the following specifications: a maximum induction of magnetic field of 70 mT, dimensions of 55 mm in diameter as well as 160 mm in length, an active surface area of 30 cm<sup>2</sup>, gentle impulses, a soothing North polarity of the magnetic pulses, and a frequency of 12.5 Hz. Patients were treated for a total of twenty minutes. at a time, ten minutes suprapubically while lying in a relaxed supine hook-lying position while hips abducted, as well as ten minutes paravertebrally over the thoracolumbar region (lower back; T10-L1) while lying in a relaxed prone position with the active surface of the apparatus anchored directly over the treated area [16,17]

**Traditional physical therapy:**

Conventional pelvic floor exercises include kegal exercise, squats, bridging, and squeeze and release exercises. Patients performed a home exercise of 60 contractions per day. gradually increasing to 60 contractions per day, in addition, patients were instructed to execute the exercises daily at home, as well as while engaging in everyday activities such as picking things up, squatting, coughing, as well as sitting or standing up from a chair. Patients did daily home exercises consisting of 60 repetitions. gradually increasing to 60 contractions per day. [18]

**Data analysis:**

Descriptive statistics such as mean, standard deviation, minimum, as well as maximum were determined for each group based on VAS and CMI measurements taken prior to and following the treatment program. Mean differences between the two groups as well as within each group were compared using the t-test. The significance threshold chosen was 0.05 at the alpha level [19]

highly substantial decrease in VAS (P < 0.0001). Whereas the mean values of VAS pre-treatment was (8.630± 0.460) degrees for the PEMFT group, whereas post-treatment was (3.100 ± 0.755) degrees, The findings showed a substantial reduction in VAS as well (P < 0.0001).

**Table (1): Comparison of the mean values of VAS pre- as well as post- treatment in the two groups in degrees.**

	Pre- treatment		Post- treatment		Mean difference	T.value	P.value
	Mean in degrees	± SD	Mean in degrees	± SD			
First study group (TENS group)	8.600	0.445	2.400	0.505	6.20000	41.19	0.0001
Second study group (PEMFT group)	8.630	0.460	3.100	0.755	5.53000	27.97	0.0001

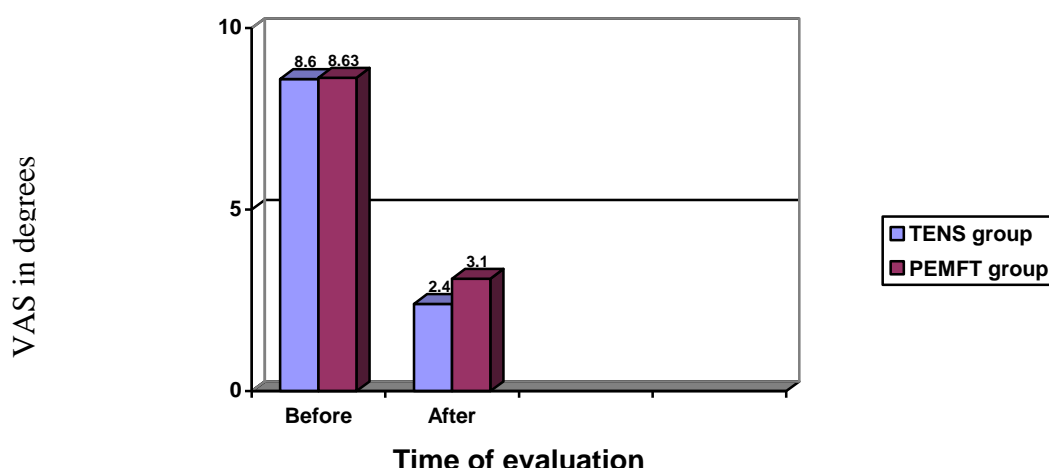


Fig (1): Mean values of the VAS pre- as well as post- treatment in the two groups.

Also, as presented in table (2) as well as figure (2), the mean value of CMI pre- treatment was (70.00 ± 11.12) mg regarding the TENS group, whereas post- treatment was (25.00 ± 10.25) mg. These findings showed a highly substantial decline in

CMI (P < 0.0001). The mean value of CMI pre- treatment was (72.00 ± 11.65) mg regarding the PEMFT group, whereas post- treatment was (30.00 ± 15.60) mg, these findings showed a highly substantial decline in mg (P < 0.0001).

Table (2): Comparison of the mean values of CMI in mg pre- as well as post- treatment in the two groups.

	Pre- treatment		Post- treatment		Mean difference	T.value	P.value
	Mean in mg	± SD	Mean in mg	± SD			
First study group (TENS group)	70.00	11.12	25.00	10.25	45.0000	13.31	0.0001
Second study group (PEMFT group)	72.00	11.65	30.00	15.60	42.0000	9.65	0.0001

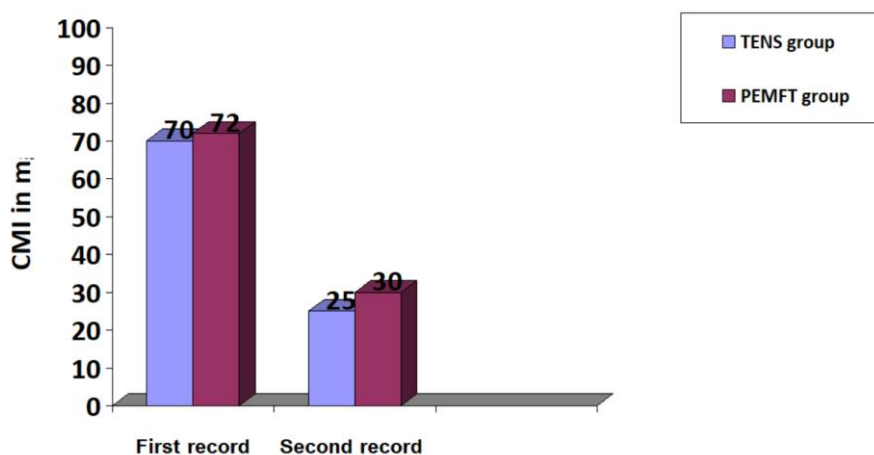


Fig (2): Mean values of the CMI in mg pre- as well as post- treatment in the two groups.

### **Discussion:**

In the current investigation, impacts of TENS on IC were the mean values of VAS pre-treatment were  $(8.600 \pm 0.445)$  degrees regarding the TENS group, whereas post-treatment was  $(2.400 \pm 0.505)$  degrees. These findings showed a highly substantial decline in VAS ( $P < 0.0001$ ). Whereas the mean values of VAS pre-treatment were  $(8.630 \pm 0.460)$  degrees regarding the PEMFT group, whereas post-treatment was  $(3.100 \pm 0.755)$  degrees, these findings showed a highly substantial decline in VAS ( $P < 0.0001$ ). In addition, the mean value of CMI pre-treatment was  $(70.00 \pm 11.12)$  mg regarding the TENS group, whereas post-treatment was  $(25.00 \pm 10.25)$  mg. These findings showed a highly substantial decline in CMI ( $P < 0.0001$ ). The mean value of CMI pre-treatment was  $(72.00 \pm 11.65)$  mg regarding the PEMFT group, whereas post-treatment was  $(30.00 \pm 15.60)$  mg, these findings showed a highly substantial decline in mg ( $P < 0.0001$ ).

There is currently no viable treatment for IC because its cause is unknown. Patients having IC frequently report with co-occurring non-urological diseases, including fibromyalgia as well as chronic pelvic pain, despite the fact that the syndrome is defined by pelvic bladder pain and urine symptoms. Many treatments therefore focus on reducing distressing signs and sensations.

Acute and chronic pain can be treated with TENS by placing transcutaneous electrodes over the affected areas [20]. The gate control hypothesis of pain, which supports the idea that a counter stimulation of the neural system can alter the perception of pain, is the theoretical foundation for this application. It has been documented that higher frequency treatments (i.e., 75-100 Hz) have a more positive effect on pain effects as well as tolerance for female patients [21]

Muscle guarding and malfunction of the pain cycle, as well as the internal alterations that accompany the pain cycle, can be treated or at least minimized by administration of TENS because it is beneficial, noninvasive, no unpleasant, as well as nonaddictive. Since pain causes muscle tension, blood flow to the painful area decreases, resulting in ischemia, a rise in metabolites, a reduction in oxygen supply, a reduction in lymphatic drainage, a reduction in food supply, a rise in muscle fatigue, inflammation, as well as oedema. TENS can prevent or lessen the worsening of the pain cycle that results from all these internal alterations [22,23]

With a frequency of between 80 to 100 (Hz), traditional TENS activates the largest low

threshold cutaneous nerve fiber A-delta, which prevents unpleasant impulses from being transmitted through the small unmyelinated C-fiber. In addition, the gate control theory of pain is triggered, which prevents nociceptive transmission by activating the A-beta large myelinated fibers. Traditional TENS typically begins relieving pain within 10 minutes and maintains its effects for up to 30 minutes after stimulation has stopped. Its analgesic effects are not reversed when the opioid antagonist naloxone hydrochloride is given to the patient. [24,25]

Because of its potential efficacy in relieving chronic pain, PEMF therapy is currently being investigated as a potential addition to standard treatments for IC. The anti-pain effects of PEMF have been hypothesized to result from the modification of inflammatory cytokines, growth factors, as well as membrane receptors using in vitro & animal examinations [26]. Moreover, various clinical research has shown that PEMF has both effective and safe properties. In the first study of its kind, Jorgensen et al. found alleviation for 17 women suffering from persistent pelvic pain. [27].

Numerous RCTs have also shown that low-frequency PEMF therapy is superior to a sham treatment in reducing pain along with other symptoms. In a group of 56 women with fibromyalgia, Sutbeyaz et al. found reductions in functional impairment, pain, as well as other symptoms. [28], and also Shupak et al. showed statistically substantial decreases in pain in individuals with rheumatoid arthritis ( $n = 13$ ) as well as fibromyalgia ( $n = 18$ ), as measured by the McGill Pain Questionnaire as well as the Visual Analog Scale. [29].

Since fibromyalgia and IC share diagnostic criteria and are frequently co-occurring [30], it is logical to assume that PEMF may also be helpful for those suffering from both chronic pain conditions. Indeed, Overholt et al. published a case study of a woman having IC who, despite not responding to conventional treatments, claimed considerable symptom relief while using PEMF [31].

Patients with IC could benefit greatly from a randomized, double-blind, placebo-controlled clinical trial assessing the efficacy as well as the safety of PEMF therapy for the treatment of pain and also non-urological symptoms.

PEMF has been proved to be effective in the treatment of different pain problems, and its side impact profile is rather modest. As a result, it would suggest that the use of PEMF for managing



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