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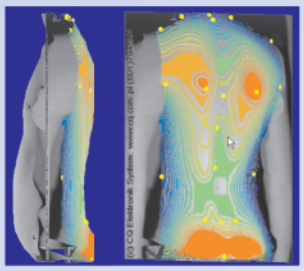

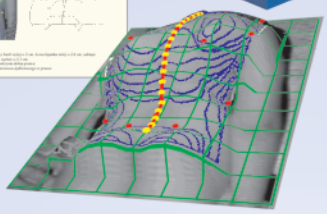

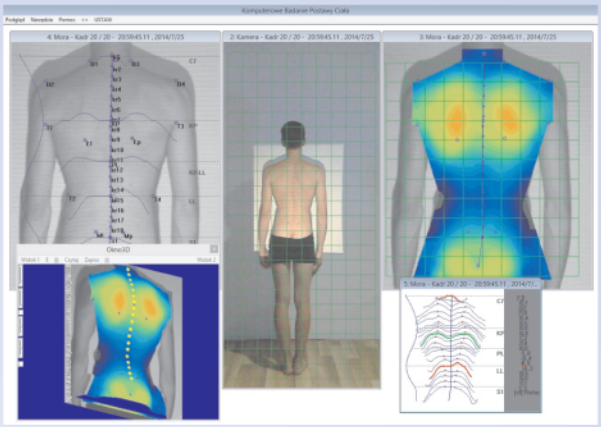

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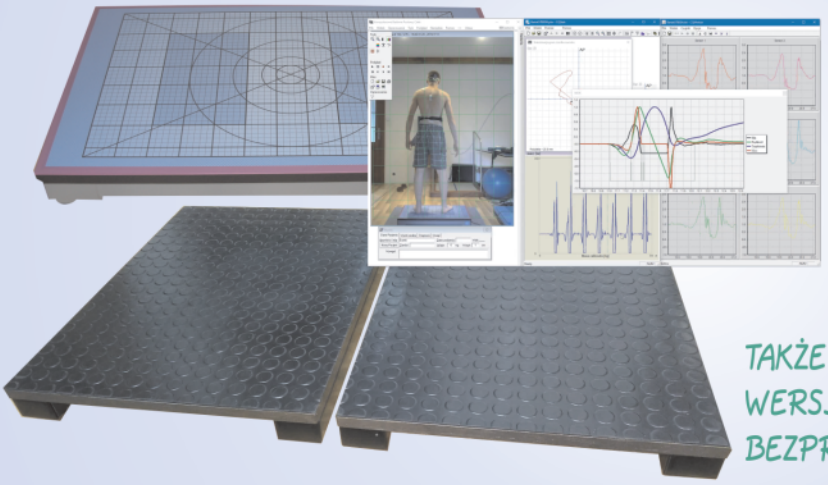

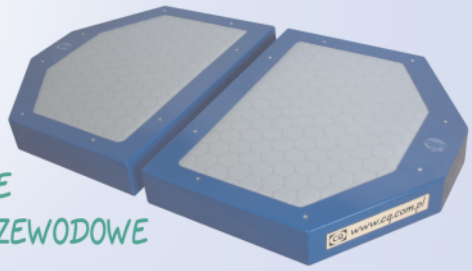

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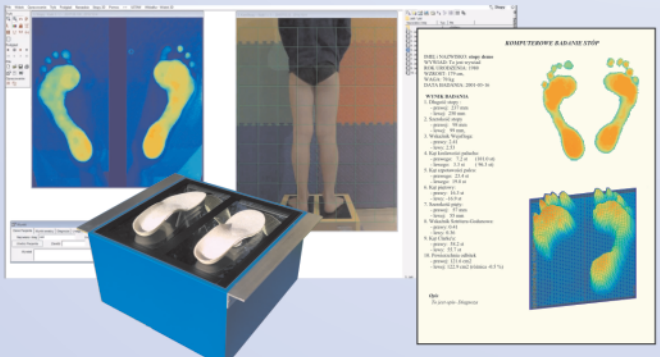

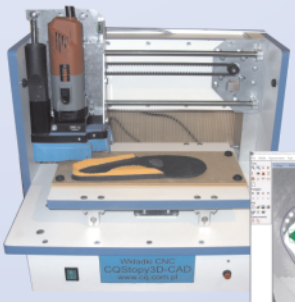

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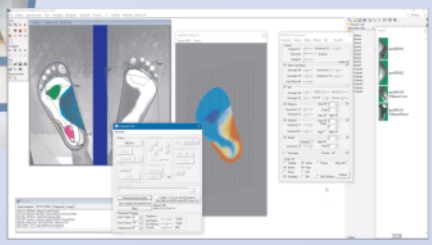

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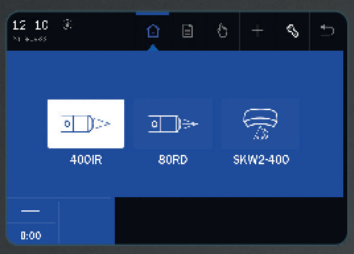

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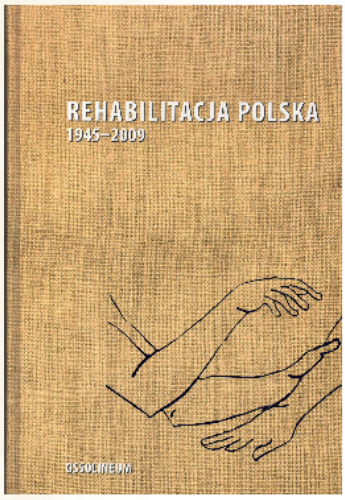

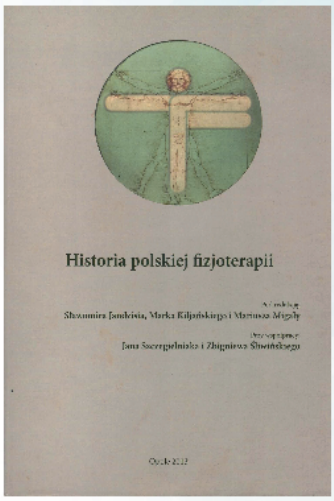

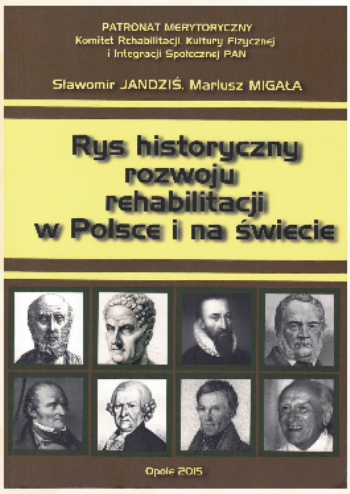

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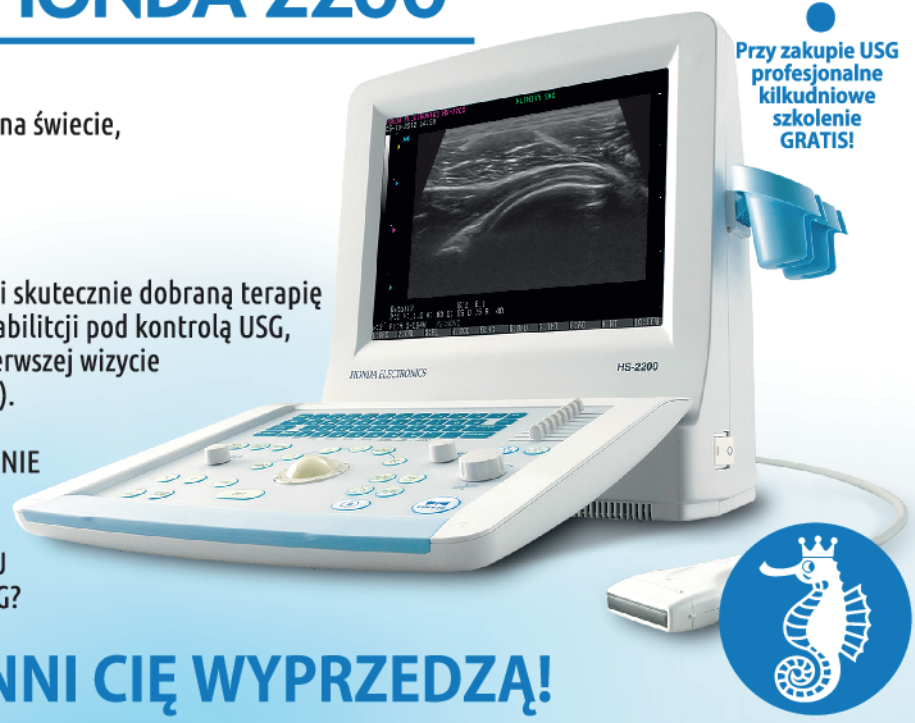

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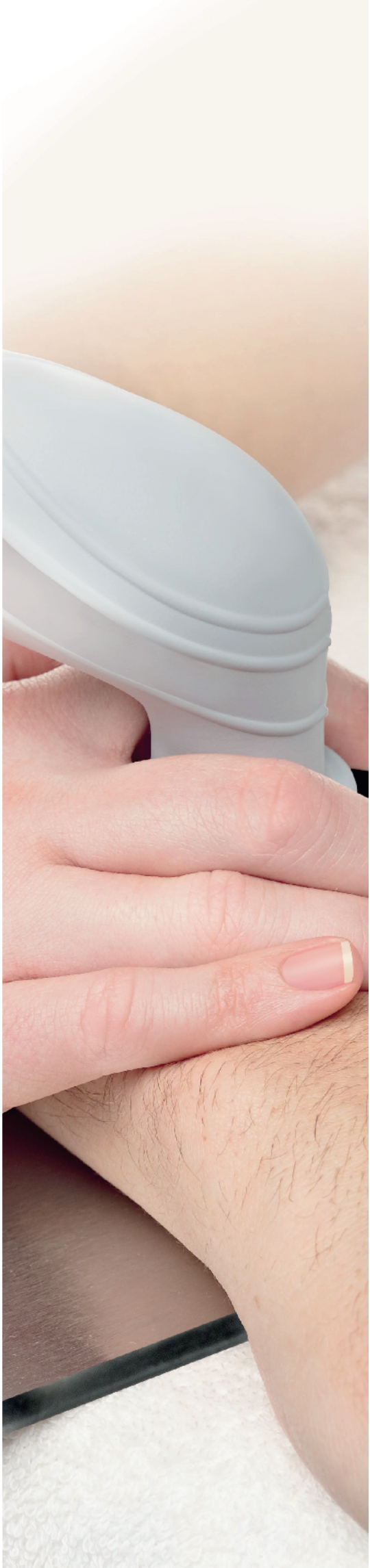

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Effect of interferential Electrical Stimulation on pain perception and disability level on Interstitial Cystitis: a randomized controlled trial

Wpływ elektrostymulacji interferencyjnej na odczuwanie bólu i poziom niepełnosprawności u pacjentów ze śródmiąższowym zapaleniem pęcherza moczowego: Randomizowane badanie kontrolowane

Ghada Ebrahim El Refaye[1,2(A,B,C,D,E,F)], Hamada A. Hamada[3(A,C,D,E,F)], Ibtissam M. Saab[4(A,C,D,E,F)], Najlaa Fathi Ewais[5(A,D,E,F)]

[1]Department of Physical Therapy for Women's Health, Faculty of Physical Therapy, Cairo University, Egypt
[2]Department of Physical Therapy for Women's Health, Faculty of Physical Therapy, Pharos University of Alexandria, Egypt
[3]Department of Biomechanics, Faculty of Physical Therapy, Cairo University, Egypt
[4]Physical Therapy Departmen, Faculty of Health Sciences, Beirut Arab University, Lebanon
[5]Department of Basic Science, Faculty of Physical Therapy, Cairo University, Egypt

Abstract

Background. Interstitial cystitis is a range of urological manifestations that are characterized by bladder, pelvic and urethral pain, just as irritative voiding side effects. It is characterized by the International Continence Society as the protest of suprapubic pain, identified with bladder filling combined by different manifestations, for example, expanded day time and evening time recurrence, without demonstrated urinary contamination or different evident pathology of the lower urinary tract. Objective. To investigate the effect of interferential electrical stimulation on pain perception and disability level on interstitial cystitis. Participants and methods. A total of 40 volunteering women diagnosed with interstitial cystitis. Their ages were ranged between 25 to 40 years old and their body mass index was > 30 kg/m^2. Participants were randomly assigned to two equally numbered groups; group (A) receiving interferential current at the lower abdomen, in addition to a routine medical intervention, or group (B) receiving solely routine medical intervention for 8 successive weeks. Participants were assessed for pain using visual analog scale (VAS), related disability index using levels using O'Leary–Sant Symptom Index or Interstitial Cystitis Index (ICSI), and blood cortisol concentration. Measurements were taken before and after eight weeks of intervention. Results. The analysis of the results revealed a significant reduction in VAS score ($P < 0.0001$), ICSI scores ($P < 0.0001$), and the plasma cortisol concentration ($P < 0.0001$) in the participants of group (A) at the end of the treatment, compared to group (B). Conclusion. These results concluded that adding IC therapy to routine medical intervention had an excellent effect on the management of interstitial cystitis associated signs and symptoms particularly pain, plasma cortisol levels, related disabilities.

Key words:

Interferential current, pain perception, disability level, interstitial Cystitis

Streszczenie

Informacje wprowadzające. Śródmiąższowe zapalenie pęcherza moczowego to szereg objawów urologicznych, które charakteryzują się bólem pęcherza, miednicy i cewki moczowej oraz irytującymi skutkami ubocznymi związanymi z oddawaniem moczu. International Continence Society scharakteryzowało chorobę jako protest na ból nadłonowy, utożsamiany z wypełnieniem pęcherza w połączeniu z różnymi objawami, na przykład nawrotami w ciągu dnia oraz w porze wieczornej, bez wykazanego zanieczyszczenia dróg moczowych lub innej widocznej patologii dolnych dróg moczowych. Cel. Zbadanie wpływu elektrostymulacji interferencyjnej na odczuwanie bólu i poziom niepełnosprawności w śródmiąższowym zapaleniu pęcherza. Uczestnicy i metody. W sumie 40 ochotniczek, u których zdiagnozowano śródmiąższowe zapalenie pęcherza. Ich wiek wahał się od 25 do 40 lat, a wskaźnik masy ciała wynosił >30 kg/m^2. Uczestniczki zostały losowo przydzielone do dwóch równych grup; grupa (A) poddawana stymulacji interferencyjnej w dolnej części brzucha oprócz rutynowej interwencji medycznej lub grupa (B) poddawana wyłącznie rutynowej interwencji medycznej przez kolejnych 8 tygodni. Uczestniczki były oceniane pod kątem bólu za pomocą wizualnej skali analogowej (VAS), powiązanego wskaźnika niepełnosprawności przy użyciu poziomów wskaźnika objawów O'Leary-Sant lub wskaźnika śródmiąższowego zapalenia pęcherza moczowego (ICSI) oraz stężenia kortyzolu we krwi. Pomiary wykonano przed i po ośmiu tygodniach interwencji. Wyniki. Analiza wyników wykazała istotne obniżenie wartości VAS ($P < 0,0001$), ICSI ($P < 0,0001$) oraz stężenia kortyzolu w osoczu ($P < 0,0001$) u uczestniczek z grupy (A) na koniec leczenia w porównaniu z grupą (B). Wniosek. Z tych wyników wynika, że wprowadzenie elektrostymulacji interferencyjnej do rutynowej interwencji medycznej miało bardzo dobry wpływ na leczenie objawów przedmiotowych i podmiotowych związanych ze śródmiąższowym zapaleniem pęcherza, zwłaszcza bólu, poziomu kortyzolu w osoczu i związanych z tym niepełnosprawności.

Słowa kluczowe:

Prąd interferencyjny, odczuwanie bólu, stopień niepełnosprawności, śródmiąższowe zapalenie pęcherza moczowego

Introduction

Interstitial cystitis (IC) is a condition resulting in bladder repeated distress and/or pain and the encompassing pelvis. The side effects vary from case to case and even in a similar person. Individuals may encounter mild distress, pressure sensation, tenderness, or extreme pain in the bladder and pelvic area in addition to an urge and incessant need to urinate. Pain may result in alterations in the intensity of the bladder filling with urine or its emptying. The sign and symptoms usually deteriorate during the menstrual cycle. Ladies affected with IC complain also from painful during vaginal intercourse [1].

IC often has deceptive beginning and stays undiscovered for quite a long time especially that not the majority of the underlying manifestations show up at the same time yet rather present gradually. Manifestations incorporate pain [considered as basic demonstrative basis criterion by all grouping plans], urgency, urinary frequency, and nocturnal. Earlier in the disease, side effects might be mild and discontinuous, yet they will in general wind up steady and serious after some time [2].

IC is usually diagnosed based on constant pelvic pain, pressure, or distress associated with no less than one other urinary manifestation, for example, steady desire to void or urinary recurrence [3].

IC is commonly designated also as painful bladder syndrome [PBS] with a non-well defined etiology and clinical characteristics fluctuating among patients. Early identification of IC is critical that the manifestations are very debilitating, influencing personal satisfaction and leading patients to visit by different medical specialists [4].

Diagnostic tests that help in ruling out different disorders consist of urinalysis, cystoscopy, urine culture, biopsy of the bladder wall and urethra, and bladder distention under anesthesia [5].

In light of the absence of conclusive diagnostic tests and clinical standard criteria, the diagnosis of IC is a done by exclusion; therefore, the randomized controlled trials designs [RCTs] for its treatment are very troublesome. In this way, information's with respect to the viability of treatments are restricted and regularly dependent on uncontrolled examinations or case arrangement. It is reported that 180 various treatments have been proposed in managing PBS/IC [6].

An acceptable tool often used to monitor the patient's progress is the O'Leary/Sant Voiding and Pain Indices. Reviewing patient responses to this questionnaire, with its precise numerical system, at each follow-up appointment, has been claimed to be mostly helpful [7].

The multifaceted nature of IC disorder leads to a challenging management planning. Patient education beginning shortly after diagnosis is crucial, as treatment regimens may involve complex multimodal therapy over long periods of time with a very gradual response.

Lifestyle changes for patients with IC are considered an important component of treatment. Dietary changes specifically including reducing intake of foods with high acidic content [citrus fruits, tomatoes], alcoholic beverages, spices, and potassium have been reported to be helpful. Reducing stress and anxiety, whenever possible, has also been noted to alleviate symptoms [4].

Interferential current [IFC] has been extensively used in the management of urinary stress incontinence [USI]. It was revealed that, for the treatment of incontinence, after exercises the IFC was the most widely advised treatment. Interferential current as one of the medium frequency currents is generally utilized in the management of USI. IFC can be applied using two or four electrodes with a rationale to enhance the pelvic floor muscles. Simplicity of use and noninvasive application are the fundamental points of interest of this strategy. The current induces positive bodily reactions and the intensity is considered well tolerated by the patients [8].

Managing USIs, different electrode placements were described. One placement is to use a quadripolar technique, where the electrodes are placed over the lower abdomen and the inner thighs. A second method is a bipolar technique placing one electrode under both ischial tuberosities and the other over the anterior perineum, immediately inferior to the symphysis pubis. The theory behind the use of IFT is based on the intersection of two medium frequency currents, between 2 and 10 KHz, considered as carrier frequencies and generating what is called beating low-frequency current between 0 and 150 Hz in the deep tissues [9].

These created beat frequencies, depending on the frequency chosen, are accused to modulate pain in the applied region and foster the reduction of edema and improvement of joint range of motion (ROM) [10].

The choice of amplitude modulated frequency (AMF) is dependent to the desired physiological and therapeutic response whether the target is the nerve or other tissues. General recommendations are the use of 80 to 130 Hz AMF for modulation of pain through the gate control theory, or the use of AMF 25 Hz or less for targeting descending pain mechanisms. Additionally, the use of variable AMF throughout the session has been proven to be beneficial in various clinical settings including chronic pain, musculoskeletal conditions, and urogenital disorders [11].

In referral to what has been stated before, the main purpose of this study was to explore the effect of interferential electrical stimulation on pain perception and disability level in interstitial cystitis.

Materials and methods

Study Design

This was a randomized clinical trial abiding to the Guidelines of Declaration of Helsinki on the conduct of human research and approved, before subject's recruitment, by the institutional review board of the Faculty of physical therapy, Cairo University. The clinical trial registry number is NCT03844581.

Participants

Forty volunteering women diagnosed clinically by gynecologist as painful bladder syndrome were included in this study. They were selected randomly from the gynecological outpatient clinic, at Al-Zahra Universal Hospital and Al Azhar University. Age range of participants was from 25 to 40 years and body mass index was > 30 kg/m2. All participants reported complains of suprapubic pain while bladder filling, combined with other signs such as repetitive frequency of voiding at day- and night-time. Exclusion criteria were as follows: Participant suffering from acute viral disease, acute tuberculosis, mental disorders, benign or malignant tumors of the pelvic region, active endometriosis. Additionally, patient having artificial pacemaker, cardiac arrhythmia, or having sensory disturbances were also excluded.

Participants were assigned randomly, using sealed envelope technique, into two equally numbered groups (A&B).

Group (A): twenty participants receiving interferential current at the lower abdomen, in addition to the already prescribed anticholinergics (propiverine hydrochloride 20 mg/once per day in the morning) for 8 weeks.
Group (B): twenty participants receiving solely prescribed anticholinergics (propiverine hydrochloride 20 mg/once per day in the morning) for 8 weeks.

Methods
Before the start of the first session, the purpose of the study and the treatment procedures were explained to all participants to obtain their confidence and cooperation and informed consent form was signed from each woman. This study was conducted at from January 2017 to October 2018.

Application of the interferential current
Before the application of IFC, each patient was instructed briefly and clearly about the nature of IFC and its value. IFC was administered while the patient was lying in relaxed comfortable crock lying position. Treatment was applied using four vacuum electrodes with wet sponge, two of them were put under the patient lumbar region 5 cm from lumbar spinous process on each side and the other two were applied over the suprapubic region parallel to iliac crest.
Treatment frequency: Starting the treatment session with a constant frequency of 100Hz (5 min) for pain relief, then using rhythmic frequency of 1-100 Hz to disperse infiltration and adhesions [12].
Treatment duration: Twenty four "20 min" sessions were applied three times/week for 8 weeks [12].
Treatment intensity: The intensity was adjusted according to the individual tolerance until the patient reported tingling sensation [13].

Outcome measures
The assessment of the participants in the 2 groups (A and B) was done before and after the end of the treatment program. Researchers assessed the pain intensity and disability level using Visual analogue scale, O'Leary–Sant Symptom Index/Interstitial Cystitis Index (ICSI) and blood cortisol concentration.
1. Visual analogue scale
It is a 10 cm horizontal line with one end depicted as (no pain = 0) and the other end depicted as (worst pain = 10). Visual analog scale is considered as a valid way of assessing pain and provides graphic representation and numerical analysis of the collected information [14].

2. O'Leary–Sant Symptom Index/Interstitial Cystitis Index (ICSI)
ICSI is a validated symptom score. It is useful in assessment the main symptoms (as pain, impact on daily activities, frequency and nocturia) and the treatments effectiveness [15].
ICSI includes 2 parts, the index of symptom, which assesses the urgency and pain in patients with PBS or IC, and a problem index, which evaluates the degree of each symptom the patient is complaining of. When the score outshoots 6 points on each symptom index it is considered as indication of IC or PBS [16].

3. Plasma cortisol concentration
5 ml of venous blood were taken from each participant at 9 am, put into a tube to measure the blood cortisol level. Cortisol is a steroid (glucocorticoid) hormone produced by the adrenal gland. Plasma cortisol level was evaluated before starting and after the end of the treatment program (8 weeks) for all patients in both groups (A&B) [17].
At the morning, normal level of serum cortisol is usually between 9 to 25 μg/dl and patients with painful conditions usually have a higher serum cortisol level. The serum cortisol level estimation was done before and after 8 weeks of the treatment program. The 5 ml venous blood sample were drawn at the morning, centrifuged and put away at 200 C for further examination [17].

Statistical analysis
Results were recorded in regards of the mean ± standard deviation (SD) or median (interquartile range) of measured variables. According to the normality test, comparison the VAS and plasma cortisol concentration between and within groups was performed using 2x2 mixed design MANOVA. The comparison the O'Leary–Sant symptom index or interstitial cystitis index (ICSI) between groups was performed by Mann-Whitney U test while within the same group was performed using Wilcoxon Signed Ranks test. Data analysis was performed using the Statistical Package for Social Sciences (SPSS) computer program (version 23 windows). Significance was considered significant at P value ≤ 0.05 and highly significant at P < 0.01.

Results
Table 1 highlights the general characteristics of all subjects in both groups (A & B) at the beginning of the study. Inferential statistics showed no significance in mean comparison for all measured parameters and for both groups.

Table 1. General characteristics of both groups A&B (Mean ± SD)

Variables	Group A (n = 20)			Group B (n = 20)
Age (years)	33.85 ± 2.17	32.50 ± 3.58	−1.704	0.097
Weight (kg)	73.50 ± 4.19	74.60 ± 4.03	−0.618	0.542
Height (cm)	162.60 ± 4.75	163.70 ± 3.92	−0.706	0.484
BMI (kg/m^2)	27.62 ± 1.31	27.56 ± 1.57	−0.130	0.896

Significance considered at p < 0.05

Table 2. and 3. present descriptive statistic, Within and between groups differences at 95% CI for the effects of interventions for the VAS and plasma cortisol concentration. In the same context regarding within subject effect, the multiple pairwise comparison tests revealed that there was significant reduction ($p < 0.05$) in VAS and plasma cortisol concentration at both groups in the post treatment condition compared with the pretreatment. Regarding between subject effects multiple pairwise comparisons revealed that there was significant difference of VAS and plasma cortisol concentration between both groups ($p < 0.05$) and this significant reduction in favor to group (A).

Table 2. Descriptive statistics for the all VAS and plasma cortisol concentration for both groups at different training periods

Variables	Group A		Group B	
	Pre	Post	Pre	Post
VAS	4.93 ± 0.54	2.20 ± 0.78	4.65 ± 0.71	2.65 ± 0.61
plasma cortisol concentration (mg/dl)	37.15 ± 0.71	24.73 ± 1.26	36.78 ± 0.86	29.68 ± 1.83

Values of all dependent variables are expressed as mean ± SD

Table 3. Within and between groups differences at 95% CI for the effects of interventions

Variables	Within groups		Between groups	
	Group (A) Mean difference (95% CI)	Group (B) Mean difference (95% CI)	Mean difference (95% CI)	MCID
VAS	2.73 (2.44 to 3.02)*	2 (0.5 to 3.5)*	0.73 (0.53 to 0.93)*	0.02
plasma cortisol concentration (mg/dl)	12.42 (11.99 to 12.85)*	7.1 (6.51to 7.69) *	5.32 (4.96 to 5.68)*	0.233

*CI: Confidence Interval, MCID: Minimal Clinically Important Difference, * the mean difference is significant at the 0.05 level.*

Table 4. represents ICSI before and after treatment program for both groups. Using the Wilcoxon Signed Ranks test, the comparison between the ICSI before and after treatment program revealed a highly statistical significant decrease ($p < 0.05$) in the measured index at both groups. To determine the difference in the median value of the ICSI, Mann-Whitney U test was performed, and revealed that there was no statistical significant difference among the two groups before treatment ($p > 0.05$). While there was a highly significant statistical difference ($p < 0.05$) at the end of the treatment as the median value of the O'Leary–Sant symptom index or interstitial cystitis index (ICSI) in group A is lesser than its corresponding value in group B.

Table 4. Descriptive statistics and non-parametric tests of the O'Leary–Sant symptom index for both groups at different training periods

	Pre treatment			Post treatment			Repeated measures (group A)	Repeated measures (group B)
	Group A	Group B		Group A	Group B			
	Median (IQR)	Median (IQR)	p- value	Median (IQR)	Median (IQR)	p- value	p-value	p- value
O'Leary–Sant symptom index	11 (2)	11 (2)	1.00	6 (4)	7 (3)	0.001*	0.001*	0.001*

IQR: Interquartile range, level of significance: Significant.*

Discussion

This study aimed to investigate the effect of adding interferential current [IC] intervention to routine medical treatment in managing signs and symptoms associated with interstitial cystitis. As statistically proven, it appears that eight weeks of IC did decrease pain scores measured by VAS. The same statistical observation was also recorded in ICSI index as well as for cortisol concentrations.

Our results were in line with others [18] who analyzed the clinical effects of low frequency interferential current in elder patients with

overactive bladder syndrome and who did not respond to three months of anticholinergics alone. They observed clinical effectiveness after a median of 8 sessions in many measured parameters. It has been postulated that overactive bladder is caused by activation of certain afferent fibers. This activation is routed by either hypogastric nerve, the pelvic nerve in the sacral region, or the supraspinal over reactivity of the detrusor and that the main effect induced by IC is through all or one of these routes [19]. The same researchers reported promising positive effects in inhibiting the detrusor reflex.

A study investigating the effect of IC on urgent urinary incontinence and involving sixty-four patients with irritative voiding manifestations reported significant improvement in absence of any pharmacological intervention [20]. In our study, both groups were on medications treatment prescribed by physicians for ethical reasons, and the addition of IC intervention was performed in order to detect the value of adding such noninvasive and low cost intervention on selected interstitial cystitis related signs and symptoms.

The results from this study were also supported by others [21] who examined the additional effect of interferential treatment in decreasing the manifestations of stress urinary and urge incontinence. They concluded that interferential therapy has an evident additional effect in the management of urinary stress and urge incontinence when applied together with pelvic floor exercises. In their study, the measured outcomes were perineometer readings, pad weighing test and start/stop test. However, they stated that they had a major limitations regarding the relative reduced sample size used [24 participants]. In our study, the measured outcomes consisted of VAS and a functional assessment scale namely the ICSI index. Additionally, the present study had a larger and consequently a more representative sample. Altogether, it seems that interferential therapy can have multidimensional arrays of benefits for patients with bladder dysfunctions.

When comparing the effect of IC in comparison with other types of electrical stimulation particularly Transcutaneous Electrical Nerve Stimulation [TENS], it was found that IC application significantly reduced pain [22], they also explained the reported results by the fact that IC have the potential to enter deeply into the targeted tissues, due to the low tissue impedance resulting from the carrier frequency. In other context, IC has been also proven effective in managing many reported dysfunctions particularly pain, edema, and limited range of motion [10].

A systematic review discussing the effectiveness of IC in various musculoskeletal conditions concluded that such non-invasive intervention appears to have an additional analgesic effect for reducing pain than control treatment and more effective than placebo treatment at the 3-month follow-up [23]. However, they pointed on the fact that IC alone was not significantly better than placebo or other therapy at discharge or follow-up. These conclusions partially meet our findings, as the observed beneficial effect on functional disturbances associated with interstitial cystitis were significantly improved and consequently this might be due not only to the reduction of pain but possibly from a positive effect on deep muscles that responded well to such non-invasive intervention.

Other contradictory reports stated that IC did not offer any clear benefits in the management of pain, range of motion and strength losses associated with delayed onset of muscle soreness [DOMS] [24]. In their study, researchers studied the effect of 5 days IC current on induced DOMS and reported no significant decrease in pain levels. Such conclusions along with our study raise a possible explanation, that IC might have provoked physiological changes over prolonged period of application and that the effect of such intervention is possibly inducing physiological changes at the deep disturbed structures. This was evident in the observed improvement in the functional scale used. Additionally, the comparison between induced DOMS and interstitial cystitis might not be consistent especially when considering the underlying pathophysiological disorder.

Conclusion

From the obtained results, it could be concluded that the addition of interferential current therapy (IFC) to medical treatment is beneficial in addressing pain and functional impairment associated with interstitial cystitis.

Adres do korespondencji / Corresponding author

Ghada Ebrahim El Refaye

E-mail: ghada2008@cu.edu.eg

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