

## USE OF INTRAVAGINAL ELECTRICAL STIMULATION FOR THE TREATMENT OF CHRONIC PELVIC PAIN: A RANDOMIZED, DOUBLE-BLIND, CROSSOVER CLINICAL TRIAL

### Hypothesis / aims of study

The objective of this study, therefore, was to assess the efficacy of intravaginal electrical stimulation (IVES) for pain relief in women with CPP compared to a placebo control group.

### Study design, materials and methods

This was a randomized, double-blind, crossover clinical trial. A total of 26 women with a complaint of CPP for a minimum of 6 months were included in the study. To calculate sample size, variance was estimated using the standard deviation (SD) based on an original score of 1.8 (1) with an acceptable difference of 1.3 between the mean visual analog scale (VAS) pain scores at the beginning and at the end of treatment, a type I ( $\alpha$ ) error of 0.05 and a type II ( $\beta$ ) error of 0.20. The inclusion criteria consisted of visual analog scale (VAS) pain score  $> 3$  and normal test results including negative urine analysis, urine culture, fecal parasitology, vaginal bacteriology, complete blood count and pelvic ultrasonography. Exclusion criteria consisted of the use of a pacemaker or intrauterine device, genital prolapse and having been submitted to IVES for CPP prior to admission to the study. The women were randomly allocated to their respective groups using sealed opaque envelopes prepared according to a computerized randomization program by a person who was not directly involved in the study. The women in Group I were initially submitted to intravaginal electrical stimulation (IVES) with an active electrode, while the women in Group II were initially submitted to IVES without electricity (placebo). At the end of the 10-session series of electrical stimulation or placebo, a further evaluation was performed. All women were submitted to ten 30-minute sessions of intravaginal electrical stimulation, twice weekly. After these initial sessions, the groups were then crossed over and each woman was then submitted to another 10 sessions in accordance with the therapy allocated to that group. The vaginal electrode was coated with lubricating gel and introduced into the vagina with the woman in the lithotomy position. The device used in this study has a frequency of 8Hz and a variation in intensity and frequency (VIF) of 1 ms pulse length, with adjustment in accordance with the limitations of each individual patient (in mA). To enable use of an actual device that would be able to provide either electrical stimulus or a phantom (placebo), it was developed two boxes identified with a letter, which were placed between the apparatus and the vaginal electrode. In one of these boxes, the electrical stimulus was permitted to pass through, while in the other the electricity was disconnected inside the box. Neither the patient nor the physiotherapist was able to differentiate between the two boxes. The intensity of the electrical stimuli was tested in all the women of both groups prior to connecting the active or placebo boxes. Once the intensity of the electrical stimulus was established in both groups, the equipment was switched off, the box was connected according to the randomization program and the equipment was reconnected. Pain was scored and recorded prior to and following each session (1) using a VAS. The VAS pain score was recorded daily by the women on a 10-cm ruler in the diary. These evaluations were then put into the following categories for the purpose of analysis: no pain (0), slight pain (1 to 3), moderate pain (4 to 7), and intense pain (8 to 10). An intention-to-treat analysis was conducted. The analysis was performed in a stratified manner in accordance with the sequence of treatment in the two groups. Since equations were generalized, logistic regression was used to assess the statistical significance of the differences in the proportion of the variables of dyspareunia and pain intensity in relation to the two treatment groups at the two evaluation moments (before/after treatment). The association between introital and deep dyspareunia and the time at which the interview took place was evaluated using the McNemar test. Significance was established at  $p < 0.05$ .

### Results

Only one woman discontinued the treatment, and this was due to a urinary tract infection. All the other women completed the study program. At the beginning of the study, 15 women were allocated to Group I in whom IVES was administered with an active electrode and 11 were allocated to Group II, the placebo group. The mean age ( $\pm$  SD) of the women in the cohort was  $40 \pm 12.3$  years (range 34-49 years) and mean parity ( $\pm$  SD) was  $3.0 \pm 1.2$  (range 0-4). The number of women in whom complaints of pelvic pain decreased following IVES was similar in the two groups; however, active electrical stimulation was more effective ( $p=0.0005$ ) than placebo ( $p=0.0253$ ). Dyspareunia was present at the beginning of treatment in 11.5% of the women and in 7.7% after treatment ( $p = 0.3173$ ). At the end of the first series, 5/11 women who initiated with placebo had VAS pain score  $>3$  ( $p=0.0253$ ); however, when they crossed over to active IVES, only 1 had VAS pain score  $\geq 3$  at the end of the series ( $p=0.0143$ ). In the 15 women who initiated with active IVES, 2 had a score  $>3$  at the end of the series ( $p=0.0005$ ); however, when they crossed over to placebo, 3 had VAS pain score  $>3$  at the end of treatment ( $p=0.0833$ ). After the two sessions, 54.6% who initiated with placebo and 80% who initiated with active IVES had VAS pain score  $\leq 3$ .

### Interpretation of results

Our results suggest that IVES with an active electrode was more effective than placebo IVES in alleviating pain in women with CPP. To the best of our knowledge, no studies have yet been carried out in which intravaginal electrical stimulation with an active electrode was compared to placebo IVES in women with CPP. Some studies have been conducted in which IVES was used to treat CPP and their findings confirming the effectiveness of this technique (1, 2, 3). In a previous study in our hospital, women with CPP who were submitted to IVES with an active electrode, there was a reduction in pain at the end of treatment, which persisted for as long as one year after the end of the sessions. Although all the women initiated the study with a moderate or severe pain score, almost 70% achieved pain relief by the end of the study(1). In another study that evaluated pelvic pain caused by levator ani muscle spasm, around 52% of the population reported an improvement in pain following IVES (2). These results were confirmed in a study carried out in women with urinary incontinence and pelvic pain. Around 65% of

the population reported an improvement in pain following use of IVES. These data confirm the results of the present study, since around 70% and 80% of the women in the placebo and active IVES groups, respectively, had moderate pain at the beginning of the study, while around half the women in both groups reported having no pain or only mild pain at the end of the study. Nevertheless, in a study conducted in patients with CPP, results with IVES were not encouraging. The reported rate of improvement was 20% in the patients who underwent electrostimulation; however, the poor success rate was principally due to the selection of the patients rather than to the therapy itself. The analgesic effectiveness of electrostimulation was also queried in a recent Cochrane review. Despite the widespread therapeutic use of electrostimulation, there is a paucity of controlled, methodologically rigorous studies that support its use for the relief of chronic pain. Dyspareunia is a common complaint associated with CPP. In a randomized clinical trial that compared two types of therapeutic techniques, 71% of the women investigated reported this dysfunction. In another study that evaluated pain of a sexual origin, pain decreased significantly in the women treated with IVES and there was an improvement in sexual function. Nevertheless, in the present study, no change occurred over the treatment period with respect to dyspareunia, irrespective of the group in which the woman initiated the study.

#### Concluding message

Electrostimulation is a therapeutic technique that is often used to relieve pain, constituting an inexpensive, easily applied, and relatively noninvasive option with few side effects that should be considered as one more therapeutic option for women with CPP. In the present study, active IVES was more effective than placebo in relieving pain in women with CPP.

#### References

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<b><i>Is this a clinical trial?</i></b>	<b>Yes</b>
<b><i>Is this study registered in a public clinical trials registry?</i></b>	<b>Yes</b>
<b><i>Specify Name of Public Registry, Registration Number</i></b>	<b>SISNEP/CAAE: 0248.0.146.000.05</b>
<b><i>Is this a Randomised Controlled Trial (RCT)?</i></b>	<b>Yes</b>
<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>Yes</b>
<b><i>Specify Name of Ethics Committee</i></b>	<b>Ethical Research Committee - FCM/UNICAMP</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>Yes</b>