The new portable transcutaneous electrical nerve stimulation device (TANYX®) was efficacious in the control of primary dysmenorrea cramp pain

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Abstract

Introduction. Transcutaneous electrical nerve stimulation (TENS) is an established method for pain relief in dysmenorrhea. However, the greatest disadvantage is the absence of a portable device for commodity. The purpose of the study was to evaluate the effectiveness and safety of a new portable, disposable TENS device (TANYX®) for menstruation cramps.

Materials and Methods. 40 women were evaluated in a double-blind prospective randomized way and divided into two groups. TENS was applied at the lower pelvis during 30-min at 8-hour interval for up to 7-days. The placebo group (PG) received sham device. The TG group applied an active high-frequency TENS. Efficacy measures were pain relief evaluated on a VAS scale and diclofenac intake, and quality of life represented by: 1)

capacity to get out of the bed, 2) food or drink intake, 3) missing routine daily activities such as work or school and, 4) quality of sleep.

Results. The active TENS device induced a prompt onset (2-min) of pain relief in a strictly segmental manner, and there was a drop in mean pain score from 7 to 2 points ($p < 0.001$). Diclofenac consumption was also significantly reduced ($p<0.01$), compared to the PG. Quality of life improved int the TG compared to the PG ($p<0.05$). On follow-up 3-months post study, 14/20 of the women were still using the active device regularly. No adverse effects were observed.

Conclusions. The portable disposable active TENS device induced a prompt onset of pain relief and improved quality of life, without adverse effects in dysmenorrhea cramp pain.

Key words. TENS, portable, dysmenorrhea

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Introduction

Primary dysmenorrhea is a common gynecological problem consisting of painful cramps accompanying menstruation, without any evident pathology to account for them, and it occurs in up to 50% of menstruating females and causes significant disruption in quality of life and work or school nonappearence[1]. The uterus is induced to contract frequently and disrhythmically, with increased basal tone and increased active pressure[2]. Transcutaneous electrical nerve stimulation (TENS) is an established method for pain relief in dysmenorrhoea[3-6], which does not involve the use of medication and can be advantageous, as therapeutic for this the monthly cramp pain. However, the greatest disadvantage until now was the absence of a portable device for commodity of patients. The purpose of the study was to evaluate the effectiveness and safety of a new portable, disposable Brazilian TENS device (TANYX®) for menstruation cramps.

Materials and Methods

The local Ethics Committee approved the study protocol, and informed consent was obtained from patients. This prospective, double-blind randomized study evaluated the clinical utility of a new, very small and light, high frequency TENS device (TANYX®) in 40 women during the menstrual cycle. All patients had past history of painful cramps associated to the menstruation cycle and regularly took rescue analgesics such as N-butyl-scopolamine combined to the non-steroidal anti-inflammatory diclofenac for pain control. Patients with any disease that could justify cramps such as endometriosis, uterine myoma, uterine malformations, other uterine disease, pelvic inflammatory disease, congenital mullerian anomalies, ovarian cysts, or any inflammatory bowel disease were excluded from the study.

Patients were computer randomized into two groups. All patients were interviewed before starting the use of either TENS device (active or sham), and classified their habitual cramp pain by the visual analog scale pain score (VAS 0-10cm), where “zero” meant “no pain at all” and 10-cm meant “worst possible pain”. Symptoms were evaluated by and function questionnaire related to dysmenorrhea, quality of life and satisfaction after TENS application. Patients classified their quality of life based on a simple questionnaire which included: 1) capacity to get out of the bed, 2) food or drink intake, 3) missing routine daily activities such as work or school and, 4) quality of sleep. Patients ranked capacity to get out the bed, food/drink intake, to sleep and capacity to work and as: 1) disabling, 2) reasonable, 3) no effect at all or 4) the best. Missing routine activities

was defined as “yes” or “no”. The daily number of rescue analgesics while felling menstruation cramp pain prior to the study was noted.

The TENS device was applied at the referral dermatome skin for the uterus (lower pelvis)[7] during 30-min at 8-hour interval for up to 7 days. The first day to apply the device was defined as the first felling of cramps by the patients, what could or not coincide with the first day of menstruation or the day before. For the placebo group (PG), the sham device did not transmitted electrical stimulus, although it was externally similar to the active one. The other 20 patients applied the active TENS device (TG), which produced a mixed (85 Hz) frequency of stimulation: 1) conventional (not pulsated, constant), and 2) burst. Diclofenac (50 mg) up to four times daily was used as rescue analgesic if necessary for pain control. If necessary, N-butyl scopolamine up to three tablets daily was also available. The efficacy pain measures after using the TENS device were pain relief evaluated on a VAS scale and reduction in use of analgesic tablets. Outcome pain measures included self-reported pain intensity measured by the VAS pain scores (0-10 cm) and mean daily rescue diclofenac and N-butyl scopolamine consumption. Quality of life questionnaire was also applied at the end of the treatment and referred to the time while using the TENS device. Patients classified symptoms and quality of life after the TENS treatment following the same protocol applied prior to the study. Patients were free to complain and/or refuse to continue the study. Three months follow up was done for efficacy evaluation and usefulness of the active and sham TENS devices.

Statistical analysis

The power of the study was based upon preliminary data. We hypothesized that the active TENS device would decrease cramping pain by 80% compared to the PG in the population studied, and further decrease the number of daily rescue analgesic tablets by at 50% compared to the Dexamethasone group. If a standard deviation was estimated, an 80% and an alpha value of 0.05, these assumptions would require at least 13 patients in each group.

The normality of the distributions was assessed using the Shapiro-Wilk's test. Groups were compared for demographic data (*i.e.*, age, weight and height), analgesic consumption and duration of surgery by Kruskall-Wallis. Incidence of adverse events, quality of life, religion, profession, nonappearance at work or school and American Society of Anesthesiology (ASA) status were compared among groups by Chi-square and $P<0.05$ was considered significant. Data are expressed as median(25%-75%), unless otherwise stated.

Results

No patients were excluded from the study. Patients were demographically similar related to age, ASA status, weight, height, profession and religion (Table 1, $p>0.05$). Table 2 describes the quality of life of the groups prior to the treatment. The two groups were similar between them prior to the treatment ($p<0.05$).

All patients had past history of monthly devastating cramps (VAS 7-10 cm) prior to the study (Table 3, $p>0.05$). The active TENS device induced a prompt onset (2-min) of pain relief in a strictly segmental manner, and there was a statistically significant drop in mean pain score from 7 to 2 points ($p <0.001$). The pain score was significantly reduced in the TG compared to the PG ($p<0.001$), and none patients from the TG needed N-butyl scopolamine tablets. Concurrent daily use of diclofenac was also significantly reduced ($p<0.05$) and 9 women stopped taking it while using the active device. The PG did not resulted in cramp pain relief, although 20% of patients consumed less rescue analgesic during the first three days of the study, however it was not statistically significant ($p>0.05$).

Table 4 describes the quality of life while wearing the TENS device. The capacity to get out of the bed, food or drink intake and quality of sleep improved in the TG ($p<0.05$). In addition, fewer patients missed routine daily activities such as work or school in the TG compared to the PG ($P<0.05$).

Both groups used the TENS device for 3-5 days ($p>0.05$). None patients from the TG refused to continue the treatment, however, 15/20 patients from the PG dropped the sham device way by the third day of the study due to apparent lack of effectiveness on

this day (Table 3). Differently, patients from the TG application of the TENS device varied from 3 to 5 days and they stopped using it due to improvement of pain and felling of confidence they would carry on with absence or controlled low level pain.

On follow-up 3-months post study, 14/20 of the active TENS women were still wearing the active device regularly. All participants from the TG subjectively classified the active device as useful, compared to 2 patients from the PG. There were no adverse events.

Discussion

TENS is an established method for pain relief in primary dysmenorrhoea[3-6], which does not involve the use of medication. This prospective study evaluated the clinical utility of a new, very small and light, high frequency TENS device in 40 women suffering from chronic menstruation cramps during the menstrual cycle. We demonstrated that the portable active device used was effective in all patients, resulting in a prompt onset of pain relief, and maintained analgesia in accordance to others[3-5]. Patients from the TG also referred improved quality of life and a high degree of satisfaction after its use.

Routinely, young women suffering from menstruation cramps take a great quantity of analgesics such as N-butyl-scopolamine and diclofenac, in Brazil. Non-steroidal anti-inflammatory drugs and oral contraceptives are commonly used treatments for menstrual pain, but are associated with relevant side effects[8,9], including gastritis and renal insufficiency. N-butyl-scopolamine administration was previously demonstrated to act peripherally as an effective complement for treatment of visceral pain through anticholinergic effects[10], and therefore patients suffering from uterine cramp would benefit from its use. In this actual study, patients receiving the active TENS did not take the peripheral anticholinergic N-butyl-scopolamine. If TENS would act through cholinergic pathways as electroacunpucture does[11] is not known.

The TENS device represents an alternative for pain control, and would act as adjuvant in menstruation cramp pain. The application of TENS induced a prompt onset of pain relief which persisted during and after its use, and the rescue analgesics consumption was very scarce, without adverse effects. The analgesia observed by the patients following

the active TENS application had a prompt onset in a strictly segmental manner, simultaneously to a significant drop in mean pain score from 7 to 2 points (VAS pain score). The beneficial and prompt effect of TENS in menstruation cramps have been demonstrated before[6]. The authors also demonstrated that TENS significantly changed the degree of autonomic symptoms (p= 0.048); but not after placebo TENS[6]. Possible mechanisms for the pain relief include decreased uterine ischemia, opioid-sparing effect than either low (2-Hz) or high (100 Hz) frequencies alone[12], decrease of prostanoids and possibly eicosanoids released from the endometrium during menstruation[13], distraction or antidromic block of large-diameter nerve fibres[14]or glial activation[15]. In this actual study, the active TENS device is a high frequency one. Recently, it was reinforced that high frequency TENS analgesic effect indeed includes opioid receptors, when an higher naloxone dose is applied[16]. This finding suggests that analgesia following Tanyx® would be in part secondary to release of endogenous opioids.

Previously it was demonstrated that in arthritic rats, the repeated application of TENS produced analgesic tolerance through cholecystokinin receptors by the fourth day and a concomitant cross-tolerance at spinal opioid receptors[17]. However, in our study, patients used the active TENS device for 3 to 5 days, which probably was not enough for developing tolerance or spinal cross-tolerance. Whether this would appear in patients deserves further investigation. Other thinking includes the possibility of peripheral edema in the skin to which the uterine β-fibers refers to. However, it was previously demonstrated that neither low- nor high-frequency TENS inhibited 5-serotonin-induced edema[18] Another interesting point was that transcutaneous neuromuscular electrical

stimulation modified the order of motor unit recruitment and had a profound influence on the metabolic demand associated with producing a given muscle force, involving neural adaptations through reflex inputs to the spinal cord and supraspinal centers[19]. Nevertheless, although any TENS device can in theory exert a contraction in pelvic muscles, this is not desirable and was explained to the patients. The intensity of high frequency should be enough to result mostly in paresthesia, and not muscle contractions when one is looking for pain relief.

In this actual study, apart from efficacious analgesia, we demonstrated improvement in quality of life, in agreement to others[6], when the parameters namely: capacity to get out of the bed, food or drink intake, missing routine daily activities such as work or school and, quality of sleep were evaluated. Recently, the occurrence of insomnia was suggested to be associated to more severe dysmenorrhea pain and causing interference with daily activities[20]. Whether there was an automatic maintaining feedback between insomnia and severity of dysmenorrhea did not affect these actual results, as all selected patients already complained of both. In this actual study the severity of menstruation cramps before treatment was averaged similar between groups (VAS 7-10 cm) and this would not have interfered with final results. In the previous study[20] the authors also demonstrated that sleep onset latency was longer and sleep efficiency was lower in participants with severe dysmenorrhea than in those with mild dysmenorrhea.

Conclusions

In conclusion, the portable TENS device Tanyx® demonstrated to be efficacious for pain relief and improvement of quality of life with no adverse effects for control of menstruation cramp pain, as demonstrated elsewhere for other chronic pain[21].

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