Lauretti GR, Mattos AL, Pacchioni A, Paccola CAJ. Efficacy of the use of two simultaneously TENS devices for Fibromyalgia pain (TANYX®).

BACKGROUND: Fibromyalgia is characterized by a range of symptoms that include muscle pain, fatigue and sleep disorders. Anxiety and depression are often also present, and the cause is unknown. Worst pain is normally felt during bedtime, at night and before waking up in the morning, and pain is normally widespread at the low back and cervical area. Transcutaneous electrical nerve stimulation (TENS) is an established method for pain relief, which does not involve the use of medication and can be advantageous, as adjuvant, for pain control[1,2].

OBJECTIVES: The purpose of the study was to evaluate the effectiveness and safety of the use of two simultaneously new TENS devices for Fibromyalgia pain (TANYX®).

METHODS: The local Ethics Committee approved the study, and informed consent was obtained. This prospective, double-blind randomized study evaluated the clinical utility of a new, very small and light, high frequency TENS device (TANYX®) in 39 patients suffering from Fibromyalgia. Two TENS device were applied simultaneously in each patient: 1) at the lower back (perpendicular to the vertebrae canal, at the level of the 5^{th} lumbar vertebrae), and 2) centrally above and below the space between the C7 and T1 spinous processes, perpendicular to the spine. The two devices were applied during 20-min at 12-hour interval during 7 consecutive days (Before bed-time and just after waking up in the morning). Patients were randomly divided into three groups: For the placebo group (PG), the two devices did not transmitted electrical stimulus, although they were externally similar to the active ones. The single-TENS group (STG) (n=13) had applied one active TENS device at the worst area of pain (low back or cervical), which produced a mixed (2- and 100-Hz) frequency of stimulation, and the placebo device at the less painful area. The third group (DTG) applied both active TENS devices at the low back and cervical areas. Diclofenac (50 mg) up to three times daily was used as rescue analgesic if necessary for pain control. The efficacy measures were pain relief evaluated on a VAS scale, reduction in use of daily analgesic tablets, quality of sleep, and fatigue.

MAIN RESULTS: Patients were demographically similar. 36 patients completed the study. Three patients from the PG give up the study on the fourth day for absence of any pain relief. The evaluation within groups revealed that patients from DPG refereed no pain relief when compared to their previous VAS pain score (8-cm, $p>0.05$), while patients from the STG refereed improvement of 2.5 cm in the pain VAS (previous 8.5 cm compared to 6-cm after treatment) ($p<0.05$); and the DPG refereed daily maintained reduction of 4 cm in the VAS-pain (previous 8.5-cm to 4.3-cm) ($p<0.02$). Concurrent daily consumption of analgesic tablets was reduced in both STG ($p<0.05$) and DTG ($p<0.02$). Comparison among groups revealed that analgesia, as well as quality of sleep and disposition was: DTG > STG > PG ($p<0.05$). Participants subjectively found the active device useful. There were no adverse events. No adverse effects were observed.

CONCLUSIONS: while the application of one active TENS device at either the lower back or cervical area improved pain relief in patients suffering from Fibromyalgia pain, the pain

and fatigue were further improved when two actives devices were simultaneously applied at the low back and cervical area, reflecting this new device an useful adjuvant for Fibromyalgia pain.

REFERENCES:

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2. Ricci NA, Dias CN, Driusso P. The use of electrothermal and phototherapeutic methods for the treatment of fibromyalgia syndrome: a systematic review Rev Bras Fisioter 2010;14(1):1-9.