Improvement of somatic cervical/shoulder pain and disability after the application of TENS device (TANIX®)

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BACKGROUND: Cervical facet joints and neck muscles have been well established in the literature as a common nociceptive pain generator, with an estimated prevalence that ranges from up to 66% of chronic axial neck pain[1]. The most common symptom is pain without radiation to the arm, however associated with neck and shoulder muscles pain, while rotation and retroflexion are frequently painful or limited[1,2].

OBJETIVES: We tested the hypothesis that the new TENS device (TANYX®) would relieve cervical pain, both facet and muscle pain (examples of nociceptive somatic pain).

METHODS: The local Ethics Committee approved the study, and informed consent was obtained. In this prospective, randomized, double-blinded, controlled study we studied 44 chronic cervical pain patients without radicular symptoms with insufficient pain relief (visual analogue scale >4) treated with standardized analgesic therapy, with diagnosis of painful neck muscle combined with cervical facet pain. Either the new, very small and light, high frequency TENS device (TANYX®), or placebo device was placed centrally above and below the space between the C7 and T1 spinous processes, perpendicular to the spine, for 20-min at 12-hour interval during 3-days[3]. Patients were randomly divided into two groups (n=22). For the placebo group (PG), the device did not transmitted electrical stimulus, although it was externally similar to the active one. The other patients applied the active TENS device (TG), which produced a mixed (85 Hz) frequency of stimulation: 1) conventional (not pulsated, constant), or 2) burst. 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 and reduction in use of rescue analgesics and capability of rotation, lateral extension and retroflexion of the neck.

MAIN RESULTS: Patients were demographically similar. The active TENS device induced gradually release of pain relief after its first application, which persisted during the 3-day treatment. By the end of the TENS application, the capability of rotation, lateral extension and retroflexion were improved ($p<0.05$). The pain score was significantly reduced in the TG compared to the PG ($p < 0.01$), and the mean pain score dropped from 8 to 3 points ($p <0.01$) to the TG. Concurrent use of analgesic tablets was also reduced ($p<0.05$) in the TG compared to the PG and 6 patients stopped taking analgesics while using the active device ($p<0.05$). The PG did not resulted in cramp pain relief, although 18% of patients consumed less rescue analgesic during the period of the study, however it was not statistically significant. All the participants subjectively found the device useful. There were no adverse events. The treatment schedule of repeated daily TENS administration (3-days) did not result in a tolerance effect. On follow-up 1-month post study, patients from the TG still referred improvement in neck pain and disability.

CONCLUSIONS: We found that patients suffering from cervical articular facet and neck muscle pain improved pain and disability after TENS daily application during the three

consecutives days which persisted at the 1-month reevaluation. The mechanism of action involved in TENS efficacy appears to be mediated by the release of mu- or delta-opioids[3], and involve its ability to increase the vibration threshold probably due to distraction or antidromic block of large-diameter nerve fibres[4]. This TENS device appears to be a useful treatment alternative for nociceptive somatic cervical/neck pain, in accordance to others[5].

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