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Abstract:	Objectives: Cervical facet joints and neck muscles are common nociceptive pain generator, with neck and shoulder muscles pain, and limited retroflexion. We tested the hypothesis that the new TENS device (TANYX®) would relieve cervical somatic pain. Design: prospective double-blind randomized. Settings: Teaching Hospital, School of Medicine of Ribeirão Preto, university of São Paulo Subjects: 44 patients with chronic cervical pain patients with somatic pain, but without radicular symptoms. Interventions: TANYX® or placebo device was placed above C7-T1 spinous process, perpendicular to the spine, for 20-min at 12-hour interval during 3-days. The two groups were: placebo group (PG), with a sham device and the active TENS group (TG), which produced a mixed (85 Hz) frequency of stimulation, conventional, and burst. Diclofenac up to three times daily was available. Outcome measures: Efficacy measures were pain relief, rescue analgesics and neck disability. Results: The active TENS device induced 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 and rescue analgesics consumption reduced in the TG ($p<0.01$, $p<0.05$, respectively), and the mean pain score dropped from 8 to 3 points ($p <0.01$). There were no adverse events. Conclusions: Somatic cervical pain and disability improved after active TENS application during the three consecutive days, which persisted upon

	the 1-month reevaluation.

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

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Running head: Cervical pain relief after TENS

Key-words: cervical somatic pain, neck disability, TENS

Abstract

Objectives: Cervical facet joints and neck muscles are common nociceptive pain generator, with neck and shoulder muscles pain, and limited retroflexion. We tested the hypothesis that the new TENS device (TANYX®) would relieve cervical somatic pain.

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Results: The active TENS device induced 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 and rescue analgesics consumption reduced in the TG ($p<0.01$, $p<0.05$, respectively), and the mean pain score dropped from 8 to 3 points ($p <0.01$). There were no adverse events.

Conclusions: Somatic cervical pain and disability improved after active TENS application during the three consecutive days, which persisted upon the 1-month reevaluation.

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

Introduction

Cervical facet joints and neck muscles have been well ascertained in the literature as a customary nociceptive pain producer, with a projected prevalence that ranges from up to 66% of chronic axial neck pain[1]. The most ordinary symptom is pain without radiation to the arm, however linked with neck and shoulder muscles pain, while turning and retroflexion are habitually painful or narrow.[1,2] We tested the hypothesis that the new TENS device (TANYX®) would relieve cervical pain, both facet and muscle pain, examples of nociceptive somatic pain.

Materials and Methods

The local Ethics Committee approved the study protocol, and informed consent was obtained from all patients. 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 (VAS) >4) treated with standardized analgesic therapy, with diagnosis of painful neck muscle combined with cervical facet pain.

All patients rated pain on average ≥ 4 cm on a VAS, taking no other drugs apart analgesics such as metamizol, paracetamol or cyclobenzaprine, enrolled at the Center for Pain Treatment- Teaching Hospital were potentially qualified for inclusion. Diagnosis of nonappearance of radicular neuropathic and proof of nociceptive somatic pain was settled based on the clinical history and examination, combined with cervical magnetic resonance to reject any pathologies. Patients were unqualified for the study if they had experienced surgery for radiculopathy within the last 3 months; if they had been once treated with TENS, suffered from dizziness, if they used non-steroidal anti-inflammatory drugs for the last 14-day prior to entrance into the study protocol, if they had agonized cervical pain for less than 3 months; if cervical pain was coupled with radiculopathy; if any surgery was anticipated within the next 6 months; if they had a pacemaker; if they were naive of non-pharmacological treatments including physiotherapy, acupuncture, mesotherapy, manipulations, wearing a corset, or psychological support; if their cervical was indicative of another condition (i.e., compression fractures or progressive inflammatory, neoplastic or infectious conditions); if the physician had appraised their life expectancy to be less

than 3 months; and finally if articular, median branches, epidural or foraminal blocks were planned during the study period, or if the patient was involved in an ongoing medico-legal dispute.

Either the new, very small and light, high frequency TENS device (TANYX®), or placebo device was placed centrally at 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 conventional TENS characterized by continuous stimulation at high frequency (85 Hz), wave duration of 75 μs and intensity of up to 30 mA, potentially achieving painless paraesthesia only in the cervical region or tingling sensation. It was explained to patients not to obtain cervical muscle contraction, but only paresthesia feeling. 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: 1) a VAS scale, 2) reduction in use of rescue analgesics, 3) capability of rotation, lateral extension and retroflexion of the neck, and 4) capacity of performing routine physical activities, defined as maintained, improved, or worsened.

Statistics

We hypothesized that 100% of the patients receiving TENS twice daily would achieve a decrease of at least 50% on the pain VAS compared with baseline pain. On this basis, with an alpha of 5%, it was calculated that at least 18 evaluable patients would be

needed to achieve an 80% power to detect any effect of TENS. Data was compared between groups by Kruskal Wallis when evaluating numerical data, and chi-squared test for qualitative variables. $P<0.05$ was considered significant.

Results

Patients were demographically similar related to age, American Society of Anesthesiology status (ASA), weight, height and gender ($p>0.05$, Table 1). One patient from the PG failed to complete data collection and was withdrawn from the final data evaluation.

The active TENS device induced gradually pain relief in 20 of 22 patients after its first application, which persisted during the three-day treatment. Two patients from the TG turned the active TENS device on until obtaining cervical muscle contraction, instead of obtaining only paresthesia, and were more painful after the first day. 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 ($p<0.01$, Table 2) to the TG.

Concurrent use of analgesic tablets was also reduced ($p<0.05$) in the TG compared to the PG and six patients stopped taking analgesics while using the active device ($p<0.05$, Table 2).

There were no difference between two groups in cervical activity in all directions before treatment ($P > 0.05$). By the end of the TENS application, the capability of rotation, lateral extension and retroflexion were worldly improved in the TG ($p<0.05$). The capacity of performing routine physical activities during these three day-evaluation were defined as improved in 20 of 22 patients in the TG ($p<0.05$, Table 3). In the PG, 19 of 21 patients referred maintenance of worsening of cervical disability and capacity of performing routine daily activities, while two patients the PG described as improved, although they maintained the daily rescue analgesic consumption ($p<0.05$, Table 3).

Twenty TG participants subjectively found the device useful. There were no adverse events. On follow-up 1-month post-study, the twenty patients from the TG still referred improvement in neck pain and disability. Apart from local cervical muscle pain after inappropriate device application in the two patients from the TG, three patients observed itching sensation on the local of application. No other adverse effects were observed in any of the groups.

Discussion

A literature search regarding neck pain revealed inconsistent results and low quality evidence for cervical TENS up to date[4]. One of the reasons could be the lack of separation of the neuropathic and somatic type of pain, as it has been demonstrated that active TENS was effective only after somatic, but not neuropathic pain.[5,6] Another reason could be the intensity of the neck pain. The TENS treatment was demonstrated to be effective for neck pain due to musculoskeletal disorders with subjects who have a mild neck pain rather than those with severe symptoms.[7] In this actual study we found that patients suffering from cervical articular facet and neck muscle pain, that are examples of pure somatic type of pain, improved pain and disability after the active TENS daily application during the three consecutive days, which persisted at the one-month revaluation, combined to a lesser rescue daily analgesic consumption during the three-day evaluation, maintained up to one month evaluation. All patients from both groups reported a VAS pain qualified as 8-cm, which was considered strong, although not the strongest, probably in accordance to others[7]

Among the mechanisms involved, 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[8]. In addition, TENS analgesia appears to be caused mainly by differentially blocking the activation of large diameter primary afferents from deep somatic tissues, and not cutaneous afferents.[9] High frequency-TENS, as the device we used, was described capable of inducing analgesia, which was most likely related to increased serotonin release and

also to block the adverse cardiovascular and respiratory changes induced by pain.[10] A superior mechanism of action was also identified through the periaqueductal gray that sends projections through the rostroventralmedial medulla to the spinal cord to produce an opioid-mediated analgesia.[11]

In the actual study, all patients used the TENS device for three-days, twice daily, during 20-min, where patients from the TG applied 85 Hz frequency, wave duration of 75 μs and intensity of up to 30 mA. Tolerance to the TENS have been suggested before, although with much higher currents with pulse duration (110 μs), and pulse frequencies in healthy volunteers, during two consecutive days. However the authors found no ideal frequency *versus* time interaction and time-dependent for the outcome measures.[12.] Other authors demonstrated that in rats, repeated administration of modulating frequency TENS lead to the development of opioid tolerance, which was delayed by approximately 5 days after low- or high-frequency TENS independently.[3] Because we used the device for only three days with good results, we did not expect any tolerance effects development.

Recent trial revealed a better therapeutic effect obtained by combining traction with TENS in cervical spinal pain.[13] However neither neck manipulation, wearing neck collar, nor neck rehabilitation exercises were applied in the actual study during the one-month evaluation, in order to not interfere with the final results. Manipulation of miofascial trigger points were also not done as interactive neurostimulation therapy associated with myofascial trigger points in adults with mechanical neck pain was

demonstrated effective[14] or at least similar when comparing manual therapy to TENS.[15] Again, no manual neck handling was included in the study protocol, in order to avoid bias.

Although the active TENS device was extremely effective in 20 of 22 patients, two patients applied the device with such an increased intensity that caused cervical muscles contraction and pain. Any TENS device is always supposed to be applied with enough intensity to obtain paresthesia only which recruits β-fibers, and Aα-fibers recrutation[16], what would result and muscle contraction and resultant pain. These patients continued the evaluation up to one month and complained of worse pain, although the device was correctly applied on the second and third days. Another interesting aspect is the itching sensation after TENS, observed by three patients in the TG, as described by other[17], although, controversially, TENS was also used to treat pruritus[18], with unfortunately unknown mechanisms.

Regarding he capability of rotation, lateral extension and neck retroflexion, and capacity of performing routine physical activities, all patients who correctly applied the TENS device at C7-T1 improved, in accordance to others.[4] Few patients with cervical pain may complain of dizziness, what was not our case because of the exclusion criteria. TENS was found to influence cardiovascular responses by alleviating sympathetic activity[10,19], to enhance visuospatial abilities and postural control[19], what would benefit patients. In our study, device was applied over C7-T1 dorsal spine, as the location of TENS electrodes is crucial for obtaining the strongest pain relief[20] Significant tinnitus suppression was described after lower frequency TENS applied for 30 min at the C2 level.[21]

Conclusions

In conclusion, this active TENS device resulted in effective treatment alternative for nociceptive somatic cervical/neck pain, with no serious adverse effects when correctly applied.

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Table 1. Demographic data.

	Age (years)	ASA I/II	Weight (kg)	Height (cm)	Gender (M/F)
PG	42±6	9-I 12-II	72±12	172±6	13-M 8-F
TG	44±8	8-I 14-II	78±9	175±7	12- M 10-F

PG- placebo group; TG- TENS group

ASA- American Society of Anesthesiology ($p>0.05$).

Table 2. Pain measurements.

	Prior VAS (cm)*	VAS after TENS*	Prior n°. of diclofenac tablets*	N°. diclofenac tablets after TENS*
PG	8(7-9)	8(6-9)	2(2-3)	2(2-3)
TG	8(7-9)	3(2-4)	2(2-3)	1(0-2)
p (between groups)	p>0.05	P<0.01	p>0.05	P<0.05

*Data expressed as mean (25%-75% percentile); VAS- visual analog scale

Table 3. Neck disability and capacity of performing routine daily activities after 3-day TENS device.

	Capability of neck rotation	Capability of neck lateral extension	Capability of neck retroflexion	Capacity of performing routine activities
PG	15- maintained 4- worsened 2- improved	14- maintained 5- worsened 2- improved	15- maintained 4- worsened 2- improved	15- maintained 4- worsened 2- improved
TG	20- improved 2- worsened	20- improved 2- worsened	20- improved 2- worsened	20- improved 2- worsened

PG- placebo group; TG- TENS group; $p<0.05$ between groups