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Transcutaneous electrical nerve stimulation for treatment of spinal cord injury neuropathic pain

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Abstract—The aim of the study was to assess the short-term effects of high- and low-frequency (HF and LF, respectively) transcutaneous electrical nerve stimulation (TENS) for neuropathic pain following spinal cord injury (SCI). A total of 24 patients participated in the study. According to the protocol, half of the patients were assigned to HF (80 Hz) and half to LF (burst of 2 Hz) TENS. Patients were instructed to treat themselves three times daily for 2 weeks. After a 2-week wash-out period, patients switched stimulation frequencies and repeated the procedure. Results were calculated on an intent-to-treat basis. No differences between the two modes of stimulation were found. On a group level, no effects on pain intensity ratings or ratings of mood, coping with pain, life satisfaction, sleep quality, or psychosocial consequences of pain were seen. However, 29% of the patients reported a favorable effect from HF and 38% from LF stimulation on a 5-point global pain-relief scale. Six of the patients (25%) were, at their request, prescribed TENS stimulators for further treatment at the end of the study. In conclusion, TENS merits consideration as a complementary treatment in patients with SCI and neuropathic pain.

Key words: high frequency, low frequency, neuropathic pain, pain, pain intensity, pain relief, rehabilitation, SCI, spinal cord injury, TENS, transcutaneous electrical nerve stimulation.

INTRODUCTION

Nearly half of those suffering from a spinal cord injury (SCI) are at risk of developing neuropathic pain [1–2]. SCI-related neuropathic pain is often difficult to relieve [3–4]; our knowledge about the underlying mechanisms is unsatisfying, and few randomized controlled intervention studies have been carried out within this patient group [5], thus limiting our knowledge of how to best treat this condition. Treatment algorithms for neuropathic pain in general [6] and SCI-related neuropathic pain in particular [5] have been presented. In the treatment of neuropathic pain, a pharmacological approach is often recommended, mainly because this approach has been extensively studied in peripheral neuropathic pain conditions. Unfortunately, few studies have reported favorable pharmacological effects in patients with SCI who, to a large extent, suffer from central neuropathic pain [2]. In addition, the side effects of these drugs may be considerable, which can make therapeutic doses unmanageable.

Abbreviations: Borg CR-10 = Borg Category Ratio-10 scale, HADS = Hospital Anxiety and Depression Scale, HF = high-frequency, LF = low-frequency, LiSat-9 = Life Satisfaction Instrument-9, MPI-S = Multidimensional Pain Inventory-Swedish language version, NRS = numerical rating scale, RP = relative change in position, SCI = spinal cord injury, SD = standard deviation, TENS = transcutaneous electrical nerve stimulation.

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Patients with an SCI and pain have often tried numerous pharmacological as well as nonpharmacological treatments in their search for pain relief [7]. Patients with physical disabilities and pain have reported preferences for alternative treatment—e.g., relaxation and massage—compared with conventional treatment [8], and in patients with SCI and pain, nonpharmacological treatments—e.g., physical therapy, relaxation, and acupuncture—were preferred to the use of opioids [9]. This preference might be associated with the severity of the side effects experienced, the limited pain relief provided by pharmacological treatment, or both. Treatment with transcutaneous electrical nerve stimulation (TENS) is rarely associated with negative side effects and has been reported to be effective in patients with peripheral neuropathic pain [10], e.g., patients with diabetic neuropathy [11], and patients with pain of differing origin [12] but less effective in patients with central neuropathic pain [12].

TENS has been assessed for SCI-related chronic pain in a handful of studies with diverse results. Complete or almost-complete short-term pain relief was reported in around 50 percent of patients in one study [13], but worse results were seen after 3 months. Other studies have defined success as an effect large enough to motivate patients to continue use of the stimulator. One of these studies reported that one-third of the patients were successfully treated [14] and another that 7/11 experienced useful analgesia [15]. In yet another study, 11 percent of those with pain due to spinal cord disorders (n = 17) reported an improvement of 20 percent or more in pain intensity ratings [16]. Whether all patients had neuropathic pain is difficult to know based on the descriptions.

The large variation in results, also seen in patients with pain from other etiologies, may be a direct consequence of not only our limited knowledge of the parameters of choice—such as stimulation frequency, intensity, duration, and electrode sites—but also the outcome measures used to evaluate improvement.

Most studies have assessed the effect of either high- or low-frequency (HF or LF, respectively) TENS. A recent review on electrostimulation for neuropathic pain concluded that making conclusive recommendations for treating neuropathic pain with TENS is still difficult because of the low number of patients studied; however, those authors stated that HF TENS is possibly better than placebo and worse than LF TENS (referred to as acupuncture-like TENS in that study) [10]. We still have very little support for the choice of frequency, even though basic research has provided us with more information on the mechanisms involved during the last few years, with support for the hypothesis that LF and HF TENS act through partly different physiological mechanisms.

In our study, we chose to evaluate the short-term effects of both modes of stimulation (LF vs HF) for treating neuropathic pain following SCI.

METHODS

Patients

Patients were recruited to participate in the study through advertisements at the Karolinska University Hospital spinal unit, on our Web site, and through our clinical work. Patients were required to have been between 18 and 70 years, have had an SCI for more than 6 months, have pain classified as neuropathic, have a pain intensity of at least 4 on the Borg Category Ratio-10 scale (Borg CR-10) [17] (general or worst), and be fluent in Swedish. Exclusion criteria were known cognitive impairment, previous systematic experience of TENS, and ongoing treatment with acupuncture. Patients were allowed to continue on stable medication but asked to refrain from changes in analgesic doses during the trial.

Patients needed a good range of motion in their shoulder joints in order to place the electrodes on the paraspinal site of stimulation, or they needed a personal assistant to help with the placement.

Of those interested in participating, 24 patients fulfilled the inclusion criteria and were included in the study.

Procedures

Patients signed a written consent on their first visit. Enrolled patients were assessed and assigned to either LF or HF TENS stimulation according to the protocol (every other patient enrolled was assigned to start with HF TENS) and sent home with operating instructions. After 2 weeks, at the period 1 follow-up, the patients returned the stimulator and evaluated the treatment. In order to avoid carryover effects, we followed the first treatment period with a 2-week wash-out period, after which patients switched stimulation frequency and repeated the procedure. Once again, the patients completed a baseline assessment before taking the stimulator home for 2 weeks of self-treatment. After the second 2-week period, patients were once more evaluated (**Figure 1)**. CEFAR Dumo stimulators (CEFAR Medical AB; Malmö, Sweden) were

used. During HF stimulation, the pulse frequency was 80 Hz, and during LF stimulation, the pulse frequency was 2 Hz bursts (8 pulses at 80 Hz/burst). Pulse duration in both groups was 180 µs. The stimulation site was an area with intact or decreased but preserved sensibility at and directly above the level of the lesion.

After electrode placement was determined, the patients tested the stimulation frequency while at the SCI unit. Patients were instructed to use the highest intensity that did not cause discomfort or pain. When stimulation site, frequency, and intensity had been tested, the patients were sent home with the stimulator and four self-adhesive electrodes (40 × 60 mm) together with written operating instructions for the stimulator and a treatment plan describing self-treatment. Patients were instructed to place the four electrodes paraspinally and to use the stimulator three times a day at evenly spaced intervals, 30 to 40 minutes per session, for 2 weeks. Patients were asked to keep a diary and record the treatment duration and their pain intensity on the Borg CR-10 [17] before and after each treatment.

Instruments

Patients were assessed at each occasion regarding pain intensity, pain unpleasantness, coping with pain, mood, quality of sleep, life satisfaction, and psychosocial consequences of pain. Patients also rated their global pain relief at both follow-ups.

Primary Outcome Measures

Patients rated their pain during the last week at each occasion using the Borg CR-10 [17], a combined numerical rating scale (NRS) and verbal rating scale. The Borg CR-10 ranges from 0 to 11, but any number can be chosen, including decimals, in order to avoid ceiling effects. The numbers 0, 0.5, 1, 2, 3, 5, 7, and 10 have verbal expressions, such as 0 = none, 3 = moderate, 5 = strong, 7 = very strong, and 10 = extremely strong/maximal. When patients had more than one painful area, the highest scores for pain intensity and pain unpleasantness were noted.

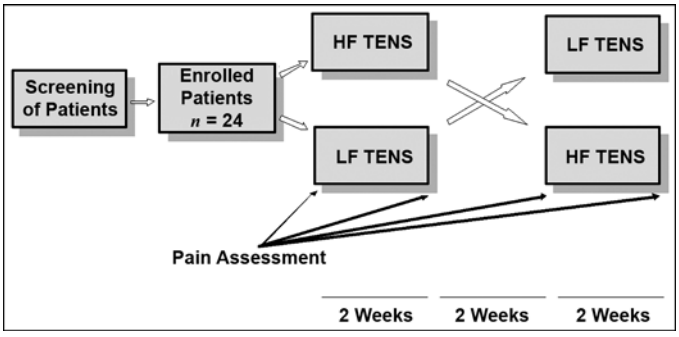

Figure 1.
Study design. HF = high-frequency, LF = low-frequency, TENS = transcutaneous electrical nerve stimulation

The patients rated the global pain-relieving effect of each 2-week treatment session at both follow-ups on a 5-point global pain-relief scale: no effect, insufficient, rather good effect, good effect, or very good effect.

Secondary Outcome Measures

The Multidimensional Pain Inventory-Swedish language version (MPI-S), part I, was used to assess the psychosocial consequences of pain [18]. This section of the MPI-S is composed of 22 items rated on a 0- to 6-point scale, with each endpoint described separately. The MPI-S consists of five subdomains: pain severity, interference (pain-related interference in everyday life), perceived life control, affective distress, and social support (perceived support from a spouse or significant other).

The Hospital Anxiety and Depression Scale (HADS) was used for rating mood [19–20]. This instrument consists of seven questions on anxiety and seven on depression. Each item has outcome values ranging from 0 to 3.

The Nordic Basic Sleep Questionnaire assesses quality of sleep [21]. In this study, we only analyzed the global item (question 6), “How well have you been sleeping?”

The Life Satisfaction Instrument-9 (LiSat-9) by Fugl-Meyer et al. [22] is a self-rating instrument that consists of a global life satisfaction item and eight domain-specific items rated on an ordinal scale from 1 to 6, where 1 represents “very dissatisfying” and 6 “very satisfying.” In the analysis, only the global rating of life satisfaction was considered.

Further, patients rated how well they were able to cope with their pain on a 0-to-10 NRS, with the anchors “not at all” and “very good.”

The MPI-S, HADS, and LiSat-9 have all been frequently used in SCI pain research. The Nordic Basic Sleep Questionnaire has been used in a couple of SCI studies in Scandinavia.

The study was approved by the Regional Ethics Approval Board in Stockholm, Sweden (KI registration No. 01-386).

STATISTICS

Standard descriptive statistics—i.e., number of observations, median and range (minimum to maximum), and interquartile range—were used to present data at baseline and after the interventions.

The rank-invariant method introduced by Svensson was used to estimate the systematic change in outcome variables after 2 weeks of HF and LF TENS [23]. Outcome measures after 2 weeks were compared with initial levels before stimulation.

Systematic group changes are explained by relative change in position (RP), i.e., the proportion of individuals with an increased level minus the proportion of patients with a decreased level within outcome variables. Values of RP range from –1 (all patients decreased) to 1 (all patients increased), and a value close to 0 indicates a negligible systematic change. When RP ≠ 0, the values at the 2-week follow-up are systematically higher or lower than the initial levels for the group. Estimates of RP were calculated together with the corresponding 95 percent confidence interval. Differences between HF and LF TENS concerning the proportion of patients with increased and decreased levels of outcome variables were tested using the chi-square test. Also, differences between the orders of assessment of HF and LF TENS were tested using the chi-square test. Tests were two-sided, and a significance level of 5 percent was chosen.

RESULTS

The results in this study were calculated on an intent-to-treat basis. All differences between patients assigned to start with LF TENS and those assigned to HF TENS were nonsignificant. No carryover effect between the two modes of stimulation was found.

Descriptive Data

Twenty men and four women were included in the study. Subjects were a mean ± standard deviation (SD) 47.2 ± 11.2 years old (range 29–68). Mean ± SD time since injury was 6.8 ± 8.4 years (range 0.5–28). Sixteen had had a traumatic injury. Thirteen had a cervical, eight a thoracic, and three a lumbar injury. Seven patients had pain located at the lesion level, six below the lesion level, and eleven both at and below the lesion level.

Dropouts

Nine patients (38%) did not complete the entire study protocol, i.e., two 2-week treatment periods including assessments. Five patients withdrew from the study during the first treatment period and three during the second period. One patient who completed both treatment periods did not show up for the second follow-up.

Reasons behind withdrawal during the first treatment period were gastrointestinal problems, bladder infection, more severe pain (n = 2), and a desire to undergo acupuncture treatment instead; during the second treatment period, reasons for withdrawal were the study protocol was too time-consuming, the stimulation frequency used during the first treatment period gave better results, and no effect was noted.

Stimulation

Patients in the first treatment period (n = 18; missing diary on one patient) underwent self-treatment a mean ± SD of 33 ± 11 times (range 12–47), and patients in the second treatment period (n = 15; missing diary on one patient) underwent self-treatment a mean ± SD of 32 ± 10 times (range 13–44). During both treatment periods, each session was reported to last a mean of 34 minutes (for period 1, the SD was 6.7 and the range 20–52; for period 2, the SD was 5.8 and the range 25–47).

Side Effects

Few side effects were reported. Three patients experienced discomfort or increased pain during treatment, and one patient experienced local muscle spasms. Positive side effects were increased relaxation (n = 2), use of fewer analgesics, increased mobility in the shoulders, ability to work more than usual, and improved sleep.

Primary Outcome Measures

Pain intensity rated on the Borg CR-10 and the MPI-S was unchanged compared with baseline values on a group level (**Figure 2** and **Table**). Also, no differences were found between the two modes of stimulation.

A reduction of 1.8 steps on an 11-point NRS [24] has been regarded as a significant reduction in clinical pain intensity in patients with SCI (defined as “my pain decreased to a meaningful extent”). In our study, five individuals (21%) reported a reduction of ≥2 units in general pain intensity, seven (29%) in worst pain intensity, and eight (33%) in pain unpleasantness. No differences were seen between HF and LF stimulation.

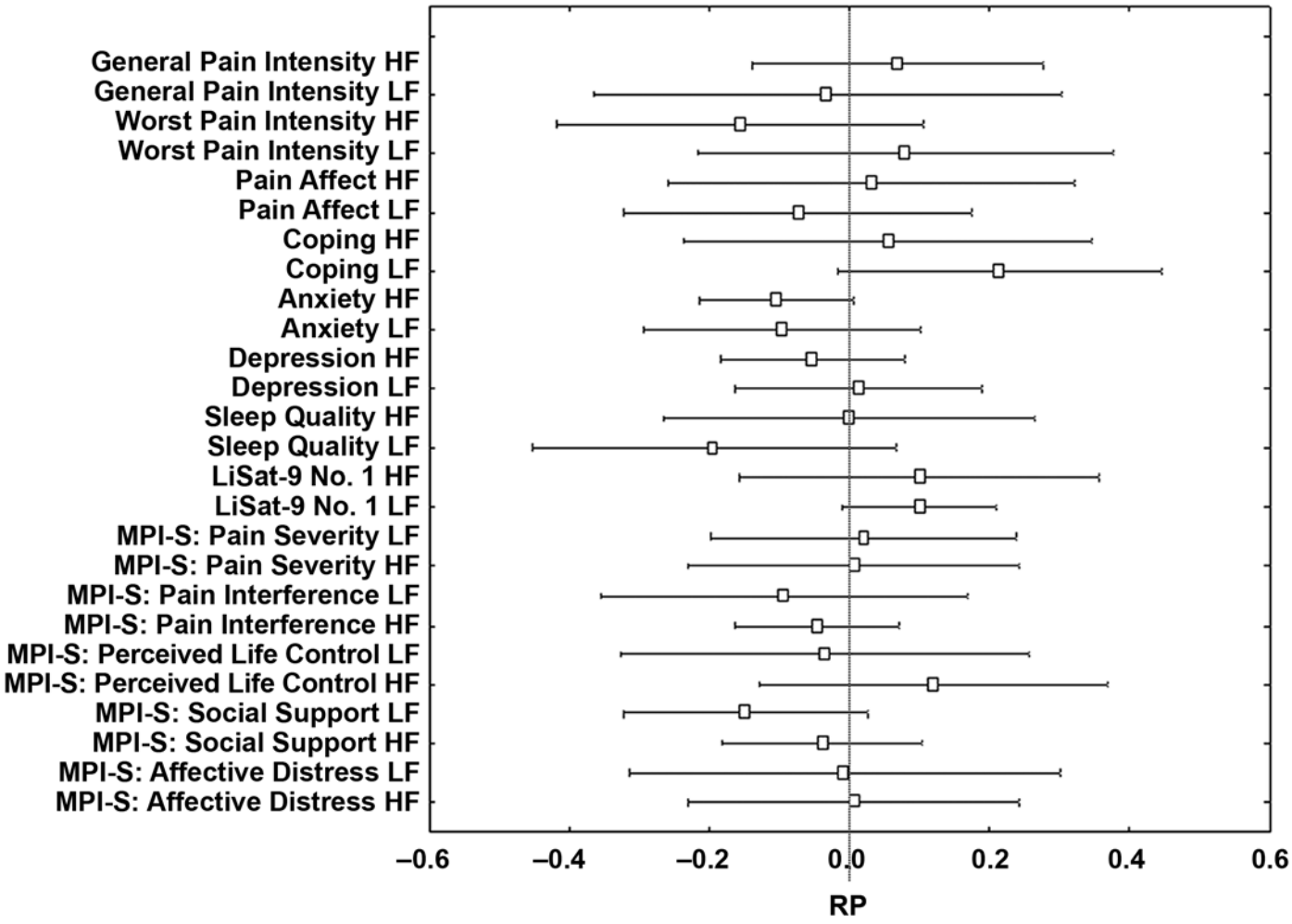

Figure 2.
The relative change in position (RP), i.e., the proportion of individuals with a higher level minus the proportion of patients with a lower level within outcome variables. Error bars are corresponding 95% confidence intervals. HF = high-frequency, LF = low-frequency, LiSat-9 = Life Satisfaction Instrument-9, MPI-S = Multidimensional Pain Inventory-Swedish language version.

Median values of pain intensity reported in the pain diaries were 4 at baseline and 3.8 after the last HF TENS session. The corresponding figures for LF TENS were 4 and 3.9.

Rating of improvement was made on a 5-point global pain-relief scale (**Figure 3**). Of the 15 patients who completed both treatment periods, 5 rated one of the treatment modes and 5 rated both modes to be rather good to very good. Five patients reported no treatment effect from either stimulation frequency. Of the four patients who completed only one 2-week treatment session, three reported insufficient or no effect and one a good effect.

Secondary Outcome Measures

No significant changes in secondary outcome measures were detected after either LF or HF stimulation compared with baseline values (**Table**).

Prescription of TENS Stimulators

Six patients (25%) were prescribed TENS stimulators on demand for continuing pain treatment after the study ended. Of these, five reported a good to very good effect on the global pain-relief scale after at least one of the treatment periods (one report was verbal, in a telephone interview, and not in writing) and one patient a rather good effect from both stimulation frequencies. Of

Table.
Primary and secondary outcome measures presented with median and interquartile range (IQR) before and after each treatment period with high-frequency (HF) and low-frequency (LF) transcutaneous electrical nerve stimulation (TENS).

Rating	HF TENS				LF TENS			
	Baseline		Follow-up		Baseline		Follow-up	
	Median	IQR	Median	IQR	Median	IQR	Median	IQR
General Pain Intensity	4.0	4–6	5.0	4–7	5.0	4–5	4.5	3–7
Worst Pain Intensity	7.0	6–9	7.0	5–8	7.0	6–7	7.0	7–8
Pain Unpleasantness	5.0	4–7	5.0	4–7	5.0	3–7	4.0	4–6
Coping	6.5	3–8	7.0	5–7	6.0	4–7	6.0	6–7
Anxiety	4.0	2–9	5.0	2–7	6.0	3–9	4.0	3–7
Depression	3.0	2–7	4.0	1–6	4.0	3–8	5.0	2–7
Global Sleep Quality	3.0	2–4	3.0	2–4	4.0	2–4	3.0	2–4
LiSat-9: No. 1 “Life as a whole”	4.0	3–5	4.0	3–5	4.0	2–5	4.0	3–5
MPI-S								
Pain Severity	3.5	3–5	3.5	3–4	3.5	3–4	3.5	2–4
Pain Interference	2.6	2–3	2.5	1–3	2.5	2–3	2.5	2–3
Perceived Life Control	3.0	3–5	3.5	3–5	3.5	3–5	3.5	3–4
Affective Distress	2.0	1–3	2.0	0.3–3	1.3	1–3	2.7	1–3
Social Support	5.0	4–5	4.5	3–6	4.5	3–5	3.0	2–5

LiSat-9 = Life Satisfaction Instrument-9, MPI-S = Multidimensional Pain Inventory-Swedish language version.

the six patients who were prescribed TENS stimulators, three reported a decrease in general pain intensity ratings of ≥2 units following one of the treatment frequencies.

DISCUSSION

Neither LF nor HF TENS had any statistically significant effect on either the primary or the secondary parameters as assessed in this group of patients with SCI and neuropathic pain on a group level. However, 7 of the 24 patients (29%) reported a favorable effect on the global pain-relief scale from HF stimulation and 9 (38%) from LF stimulation; 6 patients (25%) were prescribed TENS stimulators on demand for continuing treatment at home after completing the study. Twenty-one percent of the patients reported a decrease in general pain intensity ratings of ≥2 units, and twenty-nine percent reported a decrease in worst pain intensity ratings of ≥2 units for one of the stimulation modes.

More patients seemed to rate a rather good to very good effect on the global pain-relief scale than was found in analyses of the decrease in pain intensity. However, five of the six patients who chose to continue the treatment after the study reported a good to very good effect from the treatment, indicating that evaluating TENS with an effect scale might be more appropriate than evaluating it with a decrease in pain intensity. Jensen and collaborators discuss the fact that ratings of pain relief and changes

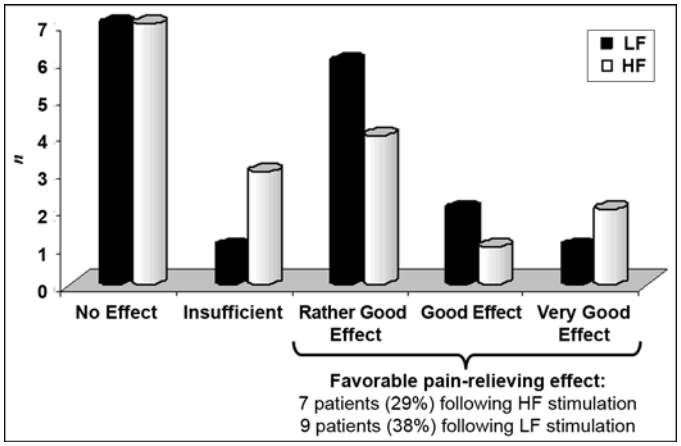

Figure 3.
Rating of pain-relieving effect on a global pain-relief scale. Frequency and cumulative percentage of patients with high-frequency (HF) and low-frequency (LF) transcutaneous electrical nerve stimulation (TENS) by categorized effect. Cumulative percentage is calculated on an intent-to-treat basis. In addition, one person who did not show up for the final evaluation reported a good effect over the telephone from LF TENS. LiSat-9 = Life Satisfaction Instrument-9, MPI-S = Multidimensional Pain Inventory-Swedish language version.

in pain intensity are not necessarily the same and that pain relief is "something more than just change in pain intensity" [25]. Yet we do not know what this improvement consists of. It might include improvement in ratings of least and worst pain intensity, as well as improvements in pain affect, or it might be a decrease in the size of the pain area or a change in the quality of the pain [25]. Also, side effects, positive and negative, might be considered when patients rate their global pain relief. In patients with SCI, worse results from TENS treatment have been reported when outcomes refer to pain intensity ratings [16]; when outcomes are described as "useful analgesia," equated with patients desiring to continue treatment, the result is a more positive effect [15].

When long-term effects of TENS were assessed in patients with chronic pain [26], positive results were found regarding interference with work, home, and social activities; increased activity level and pain management; and lower use of drugs and other therapies. In the interviews at follow-up in our study, patients reported increased relaxation, decreased use of analgesics (despite being asked to refrain from changes in analgesic drugs), increased ability to work, improved mobility in shoulder joints, and improved sleep. Unfortunately, we did not use systematic questions in the interview to evaluate these effects.

Another limitation in our study is the lack of a control group. Sham TENS is not an option at present because most patients are aware of the nature of the stimulation and recruiting patients to be part of an inactive control group is difficult, which is why we chose the present crossover design. Nonspecific effects, i.e., placebo effects, cannot be ruled out in a setting like this.

Studies in the literature on the effect of TENS in patients with chronic pain are sparse. Possible factors for the variation in results could be the use of different outcome measures, as discussed previously, and evaluation of single- or multidose treatment. Another important issue is the use of different stimulation parameters, e.g., frequency. TENS has long been considered to exert its pain-relieving effect primarily through activation of the gate-control mechanisms and the descending inhibitory pathways [27]. Higher concentrations of the endogenous opioid enkephalin, as well as gamma-aminobutyric acid, have been measured after HF stimulation; higher concentrations of β-endorphin and serotonin have been found after LF stimulation [28–29]. When antagonists have been administered, the analgesic effects have been reversed, suggesting that analgesia is mediated at least partly through these neurotransmitters. HF and LF TENS might therefore target different pain mechanisms, and frequency choice would be individual.

But frequency is not the only parameter that affects the release of transmitters. Apparently, nondisabled subjects respond differently to electrostimulation than subjects with neuropathic pain [30]. Somers and Clemente reported that the concentration of excitatory amino acids in the dorsal horn of rats that had a chronic constriction injury and responded to HF TENS was lower than in intact rats [30], suggesting that TENS might have different effects depending on the underlying pathology.

In the present study, the self-adhesive electrodes were placed paraspinally at the level of the injury in an area with preserved or intact sensibility with disregard for the completeness of injury. This placement was chosen in order to stimulate nerves at and above the area of the lesion. In patients with neuropathy of different etiologies, placing the electrodes directly over the affected nerve trunk produced the best pain relief [31]. Whether the electrode placement was optimal in the present study and whether the effect might have been greater if other stimulation sites had been chosen remain unknown.

The treatment effect in our study was quite "poor" but not exclusive to this patient group. As observed in many pharmacological studies on SCI-related neuropathic pain, we found no significant treatment effect on a group level, but some patients still seemed to experience an effect that made continuation of the stimulation worthwhile. The low number of participants in this study probably resulted in statistical power that was too low to detect possible significant changes, but unfortunately, we had difficulties enrolling participants in this study.

CONCLUSIONS

Until treatment options for SCI-related neuropathic pain become adequate, all interventions that might help a patient should be considered. TENS may be tried as a complement to the pharmacological approach in patients with SCI and neuropathic pain.

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The author has declared that no competing interests exist.

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