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Research Article,

Comparison of Burst Type Tens and Conventional Tens Therapy in Patients with Neuropathic Pain after Spinal Cord Injury

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Abstract:

Background: Neuropathic pain, which is very common after SCI, is confronted as a problem that affects the quality of life negatively and restricts the functional capacity of the patient

Objective: The aim of this study was to compare the efficacy of burst type transcutaneous electrical nerve stimulation (TENS) and conventional TENS therapy on pain, quality of life and disability in neuropathic pain following spinal cord injury (SCI).

Methods: The patients were randomly divided into two groups. Group 1 (n=20) received conventional-TENS therapy and group 2 (n=20) received burst-TENS for 15 sessions. Before and after the treatment, neuropathic pain was assessed with Douleur Neuropathique en 4 Questions (DN-4), pain severity was assessed with visual analogue scale (VAS), quality of life and functional status were evaluated with short form 36 (SF-36) and functional independence measure (FIM) scales.

Results: After the treatment VAS and DN-4 scores were significantly decreased in both groups ($p<0.05$). However, in group 2 (burst type TENS) reduction of the VAS scores was significantly higher than group 1 (conventional TENS) ($p<0.05$). After the treatment there were statistically significant improvements in physical function and body pain scores of SF-36 in both groups ($p<0.05$). There were significant improvements in FIM total scores in both groups ($p<0.05$) however the difference between the groups was not statistically significant ($p>0.05$).

Conclusions: TENS is a nonpharmacologic treatment modality which is useful in reducing neuropatic pain level, increasing quality of life and functional independence of the patient. In addition, we decided that burst-TENS is more effective than conventional-TENS for pain severity and neuropathic pain in patient with neuropathic pain syndrome due to SCI.

Keywords: Spinal cord injury, neuropathic pain, TENS

Introduction:

Neuropathic pain, which is very common after SCI, is confronted as a problem that affects the quality of life negatively and restricts the functional capacity of the patient. Siddall et al. reported that the incidence of neuropathic pain after SCI was 41% [1], and NorrBrink et al. reported similarly as 40% [2]. It has been suggested that neuropathic pain developed after SCI may be a combination of anatomic and humoral changes in the medulla spinalis [3]. Pharmacologic, non-pharmacologic, interventional and surgical treatment options are recommended in the treatment of neuropathic pain syndrome. In a study conducted by Nepomuceno et al. 38% of SCI patients with neuropathic pain are treated with medical treatment, however the analgesic activity could be achieved only for 22% of them [4]. In addition, due to side effects, patients seem to have difficulty to control the therapeutic dose level of the drugs. Physical therapy agents, acupuncture, relaxation technics, massage, cognitive and behavioural therapy are recommended as non-pharmacologic treatment options. Transcutaneous electrical nerve stimulation is a noninvasive, inexpensive, safe and self-administered physical therapy agent that stimulates the skin surface with pulsed electrical currents and activates peripheral nerves. The analgesic effect of TENS can be explained by gate-control theory which is defined by Melzack and Wall, increased spontaneous opiate release, induction of local vasodilatation, and pain relief via stimulation of acupuncture points that could influence energy flow [5]. TENS also inhibits nociceptive transmission in central nervous system. It may interact some of the physiological processes involved in neuropathic pain [6]. In a study conducted by Richardson et al, TENS was administered to chronic musculoskeletal pain of 20 SCI patients and a significant decrease in the pain was observed. No side effect was observed in TENS administration; there was a decrease in the use of narcotic analgesics [7]. Rarely adverse side effects have been reported in the treatment of pain with TENS and have been reported to be effective in the treatment of neuropathic pain [8]. Kılınç et al. reported improvements on pain intensity in both peripheral and central neuropathic pain patients however more improvements were detected in peripheral neuropathic pain patients [9]. Another study demonstrated that low-frequency TENS is more effective than placebo in the treatment of neuropathic pain in patients with SCI [10]. The evidence of the effectiveness of TENS therapy in neuropathic pain syndrome is conflicting and there is no consensus about which TENS mode, frequency and duration provide the most beneficial effect [6]. In this study, we aimed to investigate the efficacy of burst-TENS and conventional-TENS therapy on pain, quality of life and disability in patients with neuropathic pain syndrome due to SCI.

Patients and Methods:

Patients with SCI between the ages of 18-60 who admitted to our inpatient physical therapy and rehabilitation clinic between 01.05.2014 - 01.11.2014 were included in the study. Patients were informed about the study and signed informed consent was obtained from all patients. The human Research Ethic Comitee approved the study (approval number: 81266704). The inclusion criteria for the study was determined as being 18 to 60 years of age, volunteering, good cognitive status and being able to cope, and having a stable clinical status. General physical examination, neurological examination and pain questionnaires of the patients were performed. 40 patients who described neuropathic pain and who were diagnosed as neuropathic pain with DN-4 were included in the study.

Design of the Study:

This study is a prospective randomised-controlled study. The patients were randomly divided into two groups of 20 persons each as prospective and open labeled. Randomization method was performed by randomly distributing to 2 groups

with a closed envelope method. Group 1 (n = 20); Conventional-TENS was applied for fifteen sessions once a day for thirty minutes (pulse frequency: 100 Hz and pulse duration: 100 μs). Group 2 (n=20); the burst-TENS was applied for fifteen sessions, once a day for thirty minutes (pulse frequency: 1-10 Hz and pulse duration: 75-100 μs). TENS electrodes were placed to the proximal and distal of the areas where the patient located his/her pain. TENS administration of both groups of patients was performed by the same physician and on the same device (ChattanoogaGroupMedical; Hixson, USA).

Assessments:

Sociodemographic characteristics, history of injury, etiology, duration of illness, complications of the patients have been recorded. The 2011 American Spinal Injury Association (ASIA) Scale was used for the neurological examination and classification criteria of the patients [11]. The spasticity of the patients was assessed with modified Ashworth Scale.

Neuropathic pain:

The DN4 scale was used for the diagnosis of neuropathic pain. The Turkish validity and reliability study of the DN4 questionnaire was conducted by Çevik et al [12]. The DN4 questionnaire is a pain questionnaire in which 7 pain types are questioned and pain is described by a simple sensory examination, scored between 0 and 10, and neuropathic pain is diagnosed with a score of 4 and above. Pain severity: VAS (Visual Analogue Scale) was used to measure the severity of the pain. (0-10 cm, 0: no pain, 10: severe pain)

Quality of Life:

SF-36 scale was used to assess the quality of life. SF-36 is a questionnaire used to assess the quality of life, comprised of 36 items in total, including physical function, physical role, body pain, general health, vitality, social function, emotional state and mental health subgroups. Koçyiğit et al. have performed the Turkish validity and reliability study of SF-36 scoring [13].

Functional status:

As for functional status, the FIM was used. FIM is a test of independence scale consisting of 18 questions, where each question is scored between 1 to 7 (1: fully dependent, 7: fully independent). Kucukdeveci et al. have performed the Turkish validity and reliability study of FIM scoring [14]. All assessments were done before and after the treatment.

Statıstıcal Analysıs:

Mean, standard deviation, median, ratio and frequency values were used in the descriptive statistics of the data. The distribution of the variables were checked by the Kolmogorov Smirnov test. The values were not normally disributed. Non-parametric Wilcoxon test was used for determining the differences before and after the treatment for all groups and Mann-Whitney U test was used to analyze the difference between the groups. Chi-square test was used to analyze qualitative data. SPSS 22.0 program was used in the analyzes. $P < 0.05$ was considered as statistically significant level.

Results:

40 SCI patients who were diagnosed with neuropathic pain have been included in our study. The mean age of our patients was 43±13.3 (18-60) years. 35% (n=14) of the participant patients were females and 65% (n=26) were males. When the etiologic reasons were examined, falling from high was at the first rank with a rate of 47.5% (n=19). The patients have express that the neuropathic pain was mostly felt in the thigh and distal region with 42.5% (n=17), followed by low back and distal with 27.5% (n=11), knee and distal with 15% (n=6), foot and distal with 7.5% (n=3) and the cervical region and distal with the same ratio. The sociodemographic and clinical characteristics of the patients are shown in Table 1.

Table 1. Sociodemographic and Clinical Properties of All Patients.

		Med (Min-Max)	Ave.±s.d./n-%	
Age		46 (18 - 60)	43.0 ±	13.3
Gender	Female		14	35
	Male		26	65
Traumatisation Period (Month)		3 (1 - 132)	12 ±	27.6
Education	None		3	7.5
	Primary		10	25
	Secondary		12	30
	High School		11	27.5
	Collage		4	10
Marital Status	Married		30	75
	Single		8	20
	Widow		2	5
Etiology	Traffic Accident		6	15
	Fall From Height		19	47.5
	Neoplasia		5	12.5
	Degenerative		10	25
Complete Incomplete	Complete		12	30
	Incomplete		28	70
Paraplegia tetraplegia	T6 High P.		8	20
	Tetraplegia		3	7.5
	T6 Low P.		29	72.5
ASIA	A		12	30
	B		4	10
	C		8	20
	D		16	40
Spasticity	Yes		10	25
	No		30	75
Spasticity level	*I*		4	10
	II		6	15
Location of Pain	Foot		3	7.5
	Knee and Distal		6	15
	Thigh and Distal		17	42.5
	Low back and Distal		11	27.5
	Cervical and Distal		3	7.5

There was no significant difference in VAS score before treatment in both groupsI ($p > 0.05$). VAS score after treatment in Group I was significantly higher than Group II ($p < 0.05$). In both groups, the VAS score was shown statistically significant decrease after the treatment ($p < 0.05$). However, the decrease in VAS score after treatment in Group II was significantly higher than Group I ($p < 0.05$) (Table 2).

Table 2. Intergroup Comparison of VAS and DN4 values before and after treatment.

		GROUP I	GROUP II	P
		Ave.±s.d. Med (Min-Max)	Ave.±s.d. Med (Min-Max)	
VAS	Before Treat.	7.1 ±1.6 7 (3-10)	7.8 ±1.5 8 (5-10)	0.220†
	After Treat.	3.7 ±1.3 4 (0-6)	2.6 ±1.7 2 (0-6)	***0.010**†***
Before After Treat. Variance		-3.4 ±1.0 -3 (-5--2)	-5.2 ±2.0 -5 (-9--1) †	***0.001*****
Variaep		***<0.001*****‡	***<0.001*****‡	
DN4	Before Treat.	6.4 ±1.9 7 (4-9)	5.8 ±1.3 6 (3-8)	0.363†
	After Treat.	3.8 ±1.5 4 (0-7)	2.9 ±1.5 3 (0-6)	***0.036**†***
Before After Treat. Variance		-2.6 ±1.4 -3 (-5-0)	-2.9 ±1.6 -3 (-6-0)	0.570
Variaep		***<0.001*****‡	***<0.001*****‡	

p < 0.05, DN4: Douleur Neuropathique en 4 Questions, VAS: Vizuel Analog Scale Wilcoxon test, Mann-Whitney U test

Before the treatment DN4 scores were not differ significantly in both groups ($p > 0.05$). After the treatment DN4 score in Group I was significantly higher than Group II ($p < 0.05$). In both groups, after the treatment DN4 score was shown a significant decrease compared to before the treatment state ($p < 0.05$). The decrease in DN4

score after treatment did not show a statistically significant difference in Group I and Group II ($p > 0.05$) (Table 2). The body pain score of SF-36 before treatment was significantly lower in Group I ($p < 0.05$). There was no significant difference between the other subcategories of SF-36 before treatment ($p > 0.05$). Physical function and body pain scores were determined as significantly lower in both groups after treatment ($p < 0.05$). In Group I, unlike Group II, the general health and social function scores after the treatment were found significantly lower comparing to before the treatment scores ($p < 0.05$). (Table 3)

Table 3. Before and After Treatment Comparison of SF-36 Sub-groups.

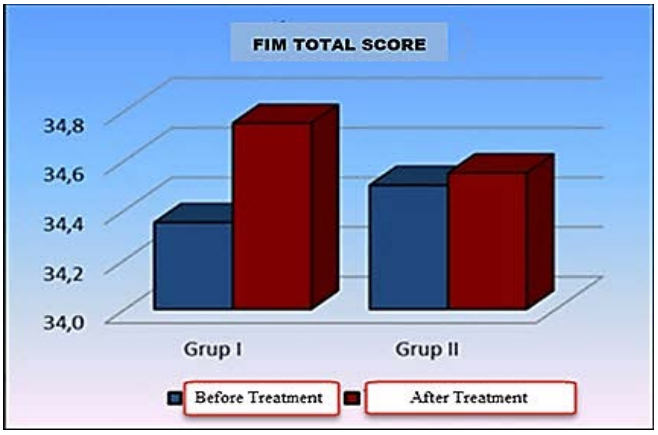
		Group I				Group II				p
		Ave.±s.d.	Med(Min-Max)			Ave.±s.d.	Med(Min-Max)			
SF 36 Physical Function	Before Treat.	8.0±14.8	30	0	-57	6.0±11.2	0	0	-37	0.406†
	After Treatment	20.3±20.2	15	0	-67	22.3±14.1	23	0	-50	0.398†
	Before After Treat. Variance	12.3±11.3	13	0	-33	16.0±11.6	17	0	-33	0.346†
	Variance p	***<0.001*****‡				***<0.001*****‡				
SF 36 Physical Role	Before Treat.	5.0±15.4	0	0	-50	6.9±14.3	0	0	-38	0.486†
	After Treatment	5.0±15.4	0	0	-50	11.3±19.4	0	0	-50	0.151†
	Before After Treat. Variance	0.0±0.0	0	0	-0	4.4±12.4	0	13	-50	0.081†
	Variance p	1.000‡				0.096‡				
SF 36 Body Pain	Before Treat.	56.4±21.0	59	9	-100	70.9±12.4	73	36	-82	***0.007**†***
	After Treatment	33.2±19.6	36	0	-64	40.5±19.7	41	18	-73	0.282†
	Before After Treat. Variance	23.2±19.9	18	6	-9	30.5±21.3	24	6	-18	0.186†
	Variance p	***<0.001*****‡				***<0.001*****‡				
SF 36 General Health	Before Treat.	45.2±13.2	42	16	-76	44.2±12.4	44	20	-72	0.838†
	After Treatment	40.6±12.3	40	8	-64	44.0±14.7	44	12	-80	0.367†
	Before After Treat. Variance	4.6±10.5	4	24	-28	0.2±10.3	4	16	-24	0.137†
	Variance p	***0.023****‡				0.775‡				
SF 36 Vitality	Before Treat.	34.4±14.6	33	0	-58	39.6±10.1	42	17	-54	0.274†
	After Treatment	35.4±16.0	35	0	-58	39.6±9.2	38	25	-58	0.446†
	Before After Treat. Variance	1.0±11.1	0	25	-25	0.0±8.8	0	17	-17	0.733†
	Variance p	0.801‡				0.849‡				
SF 36 Social Functions	Before Treat.	42.5±10.7	40	20	-70	41.5±7.5	40	30	-60	0.774†
	After Treatment	35.0±14.3	40	0	-50	41.5±9.9	40	20	-60	0.164†
	Before After Treat. Variance	7,5±14,5	5	40	-20	0.0±9.7	0	20	-20	0.089†
	Variance p	***0.036****‡				0.951‡				
SF 36 Emotional	Before Treat.	6.7±16.6	0	0	-50	2.5±8.2	0	0	-33	0.556†
	After	9.2±18.0	0	0	-50	12.±20.0	0	0	-5	0.692

Condition	Treatment	3			5	1		0	†		
Before After Treat. Variance		2.5	±6.10	0	-17	10.00	±16.60	0	-50	0.165†	
Variance p		0.083‡			***0.024**‡***						
SF 36 Mental Health	Before Treat.	42.8	±15.37	47	0 -67	38.8	±11.5	40	17	-57	0.169†
	After Treatment	41.0	±16.4	45	0 -60	40.3	±9.8	43	20	-57	0.414†
Before After Treat. Variance		1.8	±8.30	23	-13	1.5	±9.52	20	-23		0.210†
Variance p		0.266‡				0.476‡					

p < 0.05,SF-36: Short Form-36,

Wilcoxon test, Mann-Whitney U test In group I and group II, before treatment and after treatment FIM total score did not show any significant difference (p > 0.05). After the treatment FIM total score was shown a significant increase in both groups (p <0.05). There was no significant difference between the groups (p > 0.05). (Figure 1)

Figure 1. FIM Total Score:



Discussion:

In our study, we determined that both TENS types showed a significant healing in pain, functional status and quality of life in the treatment of neuropathic pain for the patients with SCI, but there was more pain relief and improvement in general health and social function subgroups of SF-36 at the end of therapy in the burst-TENS.

After SCI, pain is a very common complication. Although the most important consequence of SCI is known as loss of function, one of the most important factors in achieving the optimal activity level of the patient is the patient's pain. Rose at al. reported that the reason which prevents 11% of those who participated in the survey from working was pain, rather than the loss of function. Many patients stated that the reduction in pain is more important than gaining ability to walk [15,16]. From 47% to 96% of the SCI population can develop severe neuropathic pain which reduce quality of life [17]. In a study by Felix ER et al. evaluating chronic pain after SCI, patients reported neuropathic pain as the most disturbing pain and it was found to be more intense than the musculoskeletal system pain [18]. The treatment of neuropathic pain due to SCI is quite difficult. Underlying neuropathic pain mechanism and pathophysiology is unclear [16,19,20]. In a study conducted by Widerström et al. it was seen that various physical therapy methods have reduced pain complaints in SCI by about 50% [21]. In a study by Alvaro et al. patients with diabetic neuropathic pain were divided into three groups, first group was administered with TENS only, second group was administered with TENS and amitriptyline, and the third group was administered with amitriptyline only. In the group administered with TENS only, there was a 52% reduction in pain in the first 3 weeks, a 26% reduction in the group administered with amitriptyline only, and a 66% reduction in the group administered with both of them. After 1 year a 44% reduction was observed. The authors concluded that long term TENS administering maintained the effect of reducing pain [22]. The effects of the current types by which mechanism is unknown due to lack of researches and studies regarding effective frequency, amplitude and duration of the current to be selected [20,23,24].

The literature is not clear in which case and for which patients and what kind of TENS should be administered. However, researchers found that the use of high-frequency TENS in neuropathic pain treatment is more effective than placebo, but less effective comparing to the use of low-frequency TENS [8]. Norbrinkk C reported similar pain relief in patients with SCI with conventional and burst TENS therapy [20]. In a study conducted by De Ridder et al. they used spinal cord stimulation in 12 patients via laminectomy and compared conventional-TENS and burst-TENS therapy on patients with neuropathic pain, and found more statistically significant reductions in pain scores on patients receiving burst-TENS [25]. In a study conducted by Claydon et al. the effect of TENS was investigated on experimental pain in healthy volunteers who were administered with burst type TENS compared with placebo and conventional TENS. As a result, the reduction in pain scores was not found to be statistically significant compared with placebo, and the rate of reduction was found to be higher in conventional TENS [26]. In literature some of the studies indicated that there is no difference in pain relief among the different frequencies of TENS [27-29]. In our study, we administered conventional TENS to 1st group and burst type TENS to the 2nd group. No significant difference was observed in mean VAS values of both groups before the treatment. When the mean values of VAS and DN4 were compared after 15 sessions, a significant decrease was detected in both groups. However, there was a statistically significant decrease in VAS scores in Burst type TENS group. The decrease in DN4 scores was similar between the two groups. High levels of serotonin and β- endorphin release were reported with low frequency TENS and endogen opioids such as enkephalin with high frequency TENS [20,6]. Different effects of different frequency and mode of TENS application on pain relief can be explained by their effect on different pain mechanisms. Neuropathic pain significantly reduces the quality of life of patients and affects the patients' ability to cope with the current status of inability and disability [30]. In a systematic review by Khadilkar et al. it was stated that the use of both high and low frequency TENS significantly improves quality of life in patients with chronic pain compared to placebo [31]. Also in our study, both groups showed a significant improvement in physical function and general body pain subgroups of SF-36 after the treatment. In our study, there was no significant difference between the two groups in terms of functional status before treatment. In both groups, after the treatment significant improvements were observed and no statistically significant difference was found between the groups. Healing in disability was observed with the treatment of pain also. This result is consistent with the literature [15,32]. Limitations of our study were the absence of placebo group. Additionally the number of patients participating in the study was low. Besides, the fact that we did not administer the TENS treatment at the same time period within the day, it could affect the results of the study.

Conclusion:

In SCI, the neuropathic pain is a condition, which prevents the functional independence and disrupts the life quality of the patient. For this reason, after SCI, patients' pain assessment should be done in detail, the characteristic of the pain should be determined, the quality of life should be examined and the neuropathic pain treatment should be done as a multidisciplinary approach in an early and appropriate manner. The use of TENS is a non-pharmacological, inexpensive and a safe treatment option that is useful in reducing the level of neuropathic pain, increasing quality of life and functional independence of the patient and can be considered as a complementary treatment option amongst multidisciplinary approach in the management of patients with neuropathic pain.

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