Original Article

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A Comparative Study of the Efficacy between Self-controlled Energo-Neuro-Adaptive Regulator and Transcutaneous Electrical Nerve Stimulation for Whiplash Injury

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Objective: Self-Controlled Energo-Neuro-Adaptive Regulator (SCENAR) device was introduced in 2006 as an alternative electrotherapy for pain in Korea. The aim of this study is to investigate the efficacy of SCENAR standing for SCENAR in patients with subacute neck pain following a rear-end collision.

Methods: A randomized and controlled prospective study was conducted on 60 patients with neck pain following rear-end collision between the ages of 20 to 50 years. Written informed consent was obtained and participants were randomly allocated to transcutaneous electrical nerve stimulation (TENS) and SCENAR therapy. The treatment regimen included 20-min treatment sessions for 4 weeks (3 times per week). Therapeutic effects were evaluated at each of the assessment points (0, 4, 8, 12 and 16 weeks) using a visual analogue scale (VAS) pain scores and neck disability index (NDI) scores.

Results: Eligible participants (n=70) were recruited between March 2014 and July 2015. Final trial sample (n=60) compromised 32 within the SCENAR group and 28 TENS group. The SCENAR group showed superior pain reduction compared with TENS (SCENAR: initial mean VAS score; 6.3, final mean VAS score; 2.1, TENS: initial mean VAS score; 6.2, final mean VAS score; 3.7). Sixteen week NDI scores showed the disability level of the SCENAR group (9.5) was significantly lower than that of the TENS group (14.3).

Conclusion: SCENAR therapy provided a significant reduction in the intensity of neck pain (VAS) and disability (NDI) compared with TENS group. SCENAR therapy is superior to the TENS therapy in reducing and disability for whiplash injury.

Key Words: Whiplash · Pain · SCENAR · TENS

INTRODUCTION

Whiplash occurs as the result of acceleration-deceleration mechanism of energy transfer to the neck. It is a symptom complex which has no pathological or radiological correlates[2,11,13]. The most common cause is a motor vehicle accident such as rear-end or side-impact collisions. The most common symptom is neck pain. In addition to neck pain, there may be pain in one or both arms and interscapular area and arm pain. The most common treatment options include physiotherapy, acupuncture, or a neck collar[2,11,13]. However, the recovery is often incomplete and 30% to 40% of people who get neck pain following motor vehicle accident continue to complain of constant severe pain even after 12 month[13,15].

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Electrotherapies such as transcutaneous electrical nerve stimulation (TENS) are one of popular treatment options for whiplash patients[12]. The Self-Controlled Energo-Neuro-Adaptive Regulator (SCENAR; ZAO, OKB RITM, Russia) standing for SCENAR is a hand held, battery powered, electrotherapy device. It was first invented in Russia in mid-80s under space and military research program. The SCENAR device combines Western electrical biofeedback with Eastern energy medicine[14]. This is the first time that SCENAR therapy is used in the treatment of whiplash. The aim of this study was to investigate the short-term efficacy of SCENAR therapy in patients with subacute neck pain after rear-end collision.

MATERIALS AND METHODS

1. Subject

In the period March 2014 to July 2015 consecutive patients who presented to the spine center at our hospital after a motor vehicle accident were evaluated for recruitment into our study. The study was approved by the Institutional review board of

our institute and informed consent was obtained from all the participants.

Whiplash injury can be categorized into 4 different grades according to clinical symptoms and radiologic findings. Our study included 1, 2 grade of whiplash injury patients, 20 to 50 years of age who had been exposed to a rear-end car collision experienced neck pain for more than 1 month. The following patients were excluded from the study: (1) patients aged below 20 or above 50 years; (2) patients with neurological deficits, whiplash injury grade 3; (3) patients with fractures or dislocation of the cervical spine, loss of consciousness after accident, and injuries other than the whiplash injury. Furthermore, we also excluded patients presenting contraindications for the SCENAR therapy, which compromised those having cardiac pacemaker.

2. Intervention Protocol

1) TENS

Electrodes were applied to the skin overlying the posterior surface of the neck and upper thorax regions. Dosage was set to a level that the participant described as strong but comfortable. Participants received TENS therapy (100 Hz, 200 sec, 2 mA) according to the schedule (for 20 min, 3 times per week for 4 weeks).

2) SCENAR

SCENAR device weighs approximately 208.5 g is 180 mm in length and 60 mm width, with an electrical contact at one end and runs off a 4.5 V battery (Fig. 1). The practitioner applies it onto the skin overlying the posterior surface of the neck and upper thorax regions in an identical manner to the TENS therapy. The SCENAR device provides slightly uncom- fortable but not painful sensation. Participants received SCENAR therapy for 20 min, 3 times per week, for 4 weeks.

The dimensions, application to skin regions, and overall potential treatment sensations of each group had similar properties to facilitate a blinded comparison.

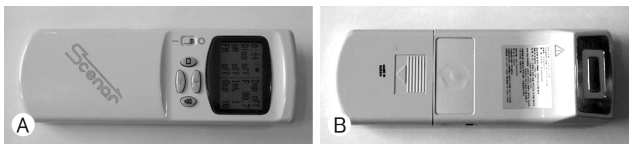

Fig. 1. The photo of Self-Controlled Energo-Neuro-Adaptive Regulator (SCENAR) device; anterior part of the device (**A**) and posterior part (**B**). Posterior part of the SCENAR shows a fixed and constant distance between electrodes.

3. Outcome Measures

Participants scored their average neck pain using a visual analogue scale (VAS) pain scores (0=no pain and 10=worst pain)[8]. Neck disability was measured by neck disability index (NDI) scores (0=no neck disability and 30=extremely disabled)[9]. VAS pain scores and NDI scores were collected during weeks 4, 8, 12 and 16 of the trial. The administrators were blinded as to which therapy each participant received.

4. Statistical Analyses

Data analysis was performed using StatsDirect software version 2.4.4 (StatsDirect Ltd., Altrincham, UK) and GraphPad Prism 4.0 (GraphPad Software, Inc., San Diego, CA, USA). Variableare presented as mean±standard deviation compared using a Student t test for continuous variables and the Chi-square test for categorical variables between SCENAR and TENS groups. Logistic regression analyses were to adjust possible confounders, including age, gender, hypertension and diabetes mellitus (DM). A p-value of 0.05 was considered to indicate statistical significance.

RESULTS

A total of 70 participants were included in the present trial. The clinical characteristics of all the subjects are summarized in Table 1. There was no statistically significant difference for age and gender. Additionally, the prevalence of hypertension and DM did not differ between SCENAR and TENS groups (Table 1). In the TENS group, 7 participants were lost during follow-up compared with 3 in the SCENAR group. No adverse affects were registered in any of intervention groups.

Pain and neck disability scores at each follow-up are shown

Table 1. Baseline characteristics in participants who completed the trial

Characteristics	TENS	SCENAR	p-value
Subject number	28	32	
Male (%)	16 (57.1)	22 (68.8)	0.264
Age (years, mean±SD)	43.58±9.45	44.63±9.70	0.268
Hypertension	9 (32.1)	10 (31.3)	0.621
DM	4 (14.3)	5 (15.6)	0.273

Values are the mean±standard deviation or n (%) of participants. p-values are chi-square test for the categorical data, and the Student t-test for the continuous data. TENS: transcutaneous electrical nerve stimulation; SCENAR: Self-Controlled Energo-Neuro-Adaptive-Regulator; SD: standard deviation; DM: diabetes mellitus.

in Table 2 and Table 3, respectively. The SCENAR group showed superior pain reduction compared with TENS group (SCENAR: initial mean VAS score; 6.3, final mean VAS score; 2.1, TENS: initial mean VAS score; 6.2, final mean VAS score; 3.7). Compared with the TENS group, the SCENAR group presents a reduction of mean VAS scores to the first follow-up measurement at four weeks. This improvement continued during the 16 week follow-up period. Similarly, the 16 week NDI score showed the disability level of the SCENAR group (9.5) was significantly lower than that of the TENS group (14.3).

DISCUSSION

Most patients who suffer neck pain following a rear-end collision will recover after a few weeks. However, approximately 30% of patients who have neck pain following a rearend collision continue to complain of constant severe pain and need active physical therapies including electrotherapy[13]. In the present study, we investigate whether largely untested electrotherapy (SCENAR therapy) can reduce subacute neck pain following whiplash.

It has been reported that TENS can be an important method of pain control because of its effect on large-diameter nerves. However, published reports on the effectiveness of TENS vary widely[6]. In this study, SCENAR therapy was used due to the similarity of its sensory stimulus compared to the TENS. The results of the present study show the possible therapeutic effects of SCENAR in the treatment of whiplash. In the TENS group, more participants were lost for follow-up than in the SCENAR group. This could be due to dissatisfaction with feeling of lacking treatment effect of the TENS.

The use of SCENAR for neck pain following whiplash is new. There are few reports investigating its mechanism of action[5,14]. The SCENAR is a hand held, electric stimulation therapeutic medical device. The device sends out electrical im-

Table 2. The mean pain visual analogue scale scores

Intervention	Assessment	Mean	Standard error	95% confidence interval	
				Lower bound	Upper bound
SCENAR	Initial	6.3	0.769	1.391	6.646
	4 week follow-up	2.4	0.789	0.078	3.168
	8 week follow-up	2.1	0.891	0.495	4.172
	12 week follow-up	2.2	0.803	0.568	3.833
	16 week follow-up	2.1	0.8976	0.119	3.619
TENS	Initial	6.2	0.855	1.484	6.503
	4 week follow-up	3.6	0.878	1.697	5.493
	8 week follow-up	3.1	0.869	1.026	5.402
	12 week follow-up	3.8	0.832	2.134	6.312
	16 week follow-up	3.7	0.878	1.431	5.427

SCENAR: Self-Controlled Energo-Neuro-Adaptive-Regulator; TENS: transcutaneous electrical nerve stimulation.

Table 3. The mean neck disability index scores

Intervention	Assessment	Mean	Standard error	95% confidence interval	
				Lower bound	Upper bound
SCENAR	Initial	23.75	3.001	14.49	27.01
	4 week follow-up	11.13	3.448	7.29	13.305
	8 week follow-up	9.25	4.303	6.275	11.225
	12 week follow-up	9.53	3.857	5.955	13.045
	16 week follow-up	9.5	4.511	6.84	12.66
TENS	Initial	24.28	3.208	13.594	26.978
	4 week follow-up	15.5	3.686	11.025	16.454
	8 week follow-up	14.14	4.6	11.548	17.138
	12 week follow-up	16.46	4.123	14.97	19.173
	16 week follow-up	14.3	4.823	12.797	18.916

SCENAR: Self-Controlled Energo-Neuro-Adaptive-Regulator; TENS: transcutaneous electrical nerve stimulation.

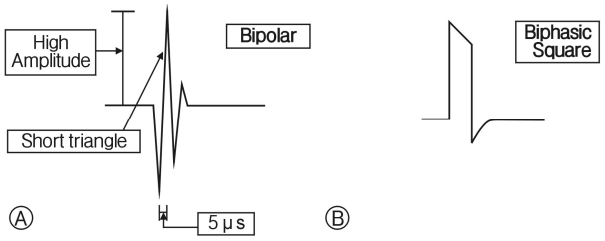

Fig. 2. Comparison between the impulse of Self-Controlled Energo-Neuro-Adaptive Regulator (SCENAR) and the impulse of transcutaneous electric nerve stimulation (TENS). SCENAR impulse (A) shows high amplitude, bipolar and spike shape and the impulse of TENS (B) reveals asymmetrical biphasic square wave.

pulses similar to neural impulses of human body through the skin and measures the response. In respond to a SCENAR impulse, reflex biofeedback, which means the communication between the brain and the affected part, proceeds at real time and biological speed. It is able to instruct the brain and body to generate specific neuropeptides by our body to heal itself. By continuously using biofeedback, the SCENAR modifies each successive input signal to either amplify or dampen the form of the pathological signals that exist in the body.

The SCENAR is very different from other electrotherapy such as TENS. The feature of TENS impulse is asymmetrical biphasic square wave. TENS only stimulates A and B fibers and lack biofeedback capability. However, SCENAR device has a fixed and constant distance between cathode and anode (Fig. 1). The SCENAR impulse (Fig. 2) is high amplitude so it stimulates C-fibers, which make up about 85% of all nerves in the body. This explains the speed and effectiveness of SCENAR therapy. Moreover, SCENAR impulses contain numerous random features to prevent the body from adapting to the stimulation, compared to TENS[1,4,7,10]. The C-fibers react most readily to the electrical stimulation and are responsible for the production of neuropeptides and other regulatory peptides. The SCENAR catalyzes the process to produce regulatory peptides by stimulation of C-fibers in the body for it to use where necessary. It is these neuropeptides that are responsible for the healing process. As these peptides last up to several hr the healing process will continue even after treatment is over[3]. Pain is the most common complaint to be dealt with in the SCENAR therapy by block of transmission of the pain impulses in the nerve endings of the peripheral nerve fibers, pain focus suppression of brain cortex, and reduction of the edema around the nerve fibers leading to reduction of pressure effect. To summarize, the SCENAR impulse is similar to our own endogenous nerve impulses and the electrical impulse has a unique wave form that is almost identical to the body's own nervous system.

There are several limitations to this study. (1) The study was conducted in small population. Thus, present findings need to be validated in lager populations. (2) We could not conclusively rule out some other potential confounders such as exposure to different environmental factors (such as smoking, vocational education, and occupation).

CONCLUSION

The present study demonstrates that SCENAR therapy is a more effective and safe method of treating patients with neck pain following whiplash compared with TENS. However, we should perform further research aimed at establishing the long-term effect of SCENAR therapy in the treatment of neck pain following whiplash.

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