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Clinical trial

The effect of transcutaneous electrical nerve stimulation on pain, muscle strength, balance, and gait in individuals with dementia: A double blind, pilot randomized controlled trial

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ABSTRACT

Introduction: The effect of transcutaneous electrical nerve stimulation (TENS) for functional management in patients with dementia has not been reported yet. Thus, the aim of present study was to investigate the effect of TENS on pain, muscle strength, balance, and gait ability in patients with dementia who have difficulty exercising independently.

Methods: Thirty-two subjects with dementia were randomly allocated into either a TENS group (n = 16) or a placebo-TENS group (n = 16). TENS (4 Hz), above motor threshold intensity, was applied to both calf muscles for 20 min, 2 times per day. Placebo-TENS was applied for 30 s and then ramped down to zero for 15 s at the same location. The intervention was performed 5 days per week for 2 weeks. Pain was quantified with pain pressure threshold (PPT). Strength of the calf muscles was assessed using a hand-held dynamometer. To assess balance and gait, functional reach test (FRT), 10-m walk test (10MWT), and timed-up and go test (TUG) were used.

Results: There were significant differences in PPT ($p = 0.001$) after TENS application, and the PPT was significantly increased in TENS group compared with placebo-TENS group ($p = 0.0495$). TENS group showed significant improvements of plantarflexor strength ($p = 0.008$). Balance and gait were also significantly affected in TENS group, as assessed by 10MWT ($p = 0.018$) and TUG ($p = 0.007$). The placebo-TENS group did not show significant improvements for any outcome measures.

Conclusions: These results suggest that TENS application can be used for functional maintenance of patients with dementia. Further research is needed to underpin these preliminary results.

1. Introduction

Dementia is characterized by cognitive dysfunction, and it leads to limitations in motor function, such as balance disturbances and slow gait velocity, which may result in high fall risk [1–3]. Patients with dementia who experience falls demonstrate decreased self-confidence in movement and balance during gait performance, which may lead to loss of quality of life [4]. Thus, it is important to manage functional problems in patients with dementia.

Transcutaneous electrical nerve stimulation (TENS) is well known as an application of electrical stimulation through surface electrodes for pain control [5]. Many health professionals have used TENS to treat patients with acute or chronic pain. TENS is rarely used in the clinical treatment of cognitive impairments, but some studies have identified that TENS application improves neuropsychological aspects, such as memory and behavior in individuals with dementia in Alzheimer's disease [6,7]. Interestingly, recent animal and clinical research has also reported that TENS improves spasticity, muscle strength, balance, and gait ability in a variety of neurologic disorders [8–12]. Repetitive muscles stimulation by electrical stimulation may be an alternative intervention to manage functional problems in patients with dementia.

Considering difficulties of performing physical training by cognitive dysfunction of dementia patients, TENS may be useful as an alternative intervention for their functional management. However, the effect of

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TENS for functional management in patients with dementia has not yet been investigated.

In this respect, the purpose of the present study was to demonstrate the effect of TENS on pain, muscle strength, balance, and gait in individuals with dementia. The hypothesis was that repetitive TENS applications are effective for improving pain, muscle strength, balance, and gait ability in individuals with dementia.

2. Methods

2.1. Design and sample size

This study was designed as a double-blinded, randomized controlled trial. This experiment was approved by the Gachon University Institutional Review Board (1044396-201511-HR-053-003). The sample size was calculated using the timed up and go test (TUG), which expresses dynamic balance and gait ability [13]. In the present study, the effect size was set to 1.037 based on previous study. Using computer software G-power 3.1.9.2, it was determined that 16 subjects per group were needed to achieve 90% power for determining significance in between-group differences at a level of 0.05 of p-value.

2.2. Participants

Participants were included if they had cognitive impairment (mild to moderate stages of dementia, Mini-Mental State Examination (MMSE) score of 17–26) [14,15], could follow introductions, and could walk independently for 10 m without an aid. Participants were excluded if they had orthopedic disorders, apraxia, cardiovascular disease, or skin problems, and if they had previous experience of TENS treatment.

Fifty-nine patients were recruited from a day-care center and a dementia-care center. After applying the inclusion and exclusion criteria, 26 participants were excluded from this study. All patients gave their written informed consent.

2.3. Experimental procedure

Thirty-two subjects were randomly assigned to either the TENS group (n = 16) or the placebo-TENS group (n = 16) using the stratified randomization method. The treatment allocation was concealed from the data collector and the data analyst by blinding group allocation. For blinding of participants, those who did not have previous experience of TENS treatment recruited and the appropriate application of placebo-TENS was used in the placebo-TENS group [16]. TENS or placebo-TENS was applied for 20 min 2 times per day. The intervention was performed 5 days per week for 2 weeks. Pain, muscle strength, balance, and gait were measured before and after intervention by a skilled examiner, who had extensive experience in the assessment tools. The pain threshold and muscle strength was measured by using an algometer and a hand-held dynamometer, respectively. Balance and gait were measured by using the functional reach test (FRT), the 10-m walk test (10MWT), and the timed up and go test (TUG). All measurements were performed a day before and after intervention.

2.4. Intervention

Low-frequency TENS (intensity, above the motor threshold; frequency, 4 Hz; pulse width, 200 μs; application type, burst mode) was applied to both calf muscles for 20 min using a 2-channel TENS unit (TENS-7000, Koalaty Products Inc., USA). Calf muscles were selected as the site of TENS application because pain or weakness of calf muscle is associated with decreased balance and gait ability [17–19].

In the placebo-TENS group, electrodes were attached on the same location, and then TENS delivered a transient current (intensity, sensory threshold; frequency, 4 Hz; pulse width, 200 μs; application type, burst mode) for 30 s and then ramped down to zero over 15 s [16].

2.5. Outcome measurements

This study consisted of two primary (pain pressure threshold and muscle strength) and two secondary (balance and gait ability) outcome measures.

2.5.1. Pain

To investigate changes of deep tissue nociception of the calf region by TENS, pain pressure threshold (PPT) was measured by using a distal algometer (Somedic AB, Farsta, Sweden) with a 1-cm probe. The pressure head of the algometer contacted the muscle belly, and the pressure intensity was increased progressively in 10 kPa/s increments until subjects expressed a pain response, such as withdrawal and a gesture related to pain (hand grasp or eye blink).

2.5.2. Strength

Strength was assessed using a hand-held dynamometer. Previous research has reported that hand-held dynamometers have high reliability (ICC = 0.840–0.990) for muscle strength of lower limbs with neurological disorders [20]. The dorsiflexion and plantarflexion of the ankle joint were measured with the patient sitting in a chair with 90° hip flexion and full extension of the knee. Before the test, the examiner tried to pre-test for adaptation in patients. The test was performed twice and the mean was used as the representative value. The participants rested for 2 min between trials to minimize the development of muscle fatigue.

2.5.3. Balance and gait ability

The FRT was used to measure dynamic postural balance (r = 0.71–0.81) [21]. The FRT was conducted by instructing the patient to stand close to a wall, without touching the wall, with 90° of shoulder flexion and a closed fist. The third metacarpal head was measured at the beginning and ending positions, and the difference between them was recorded as the reach difference [22]. The test was performed two times and the mean was used as a representative value.

To assess the gait speed, the 10MWT was performed [23]. Subjects started approximately 3 ft behind a tape line and were instructed to walk with a comfortable pace until they passed the tape line as fast as possible. The test was performed two times and the mean was used as a representative value.

The TUG was performed to test dynamic balance and gait ability. In this study, the TUG was used as the primary outcome measure. This test requires the performance of sequential motor tasks (r = 0.95): standing up, walking straight for 3 m, turning, walking back to the chair, and sitting down [24]. The score for this test was the time required to complete the test, which was measured using a stopwatch. The test was performed two times and the mean was used as a representative value.

2.6. Data analysis

Statistical analysis was performed using SPSS version 21.0 (SPSS Inc., Chicago, USA). The statistician was blinded to group allocation for all analyses. Mann-Whitney U Test and Chi-squared test were performed to analyze the general characteristics between the two groups. Wilcoxon signed-ranks test was used to compare the changes before and after intervention. Mann-Whitney U test was used to compare the changes between the two groups. A p-value of less than 0.05 was considered statistically significant.

3. Results

3.1. Demographic characteristics of participants

A total of 32 patients completed the study. Fig. 1 shows the selection

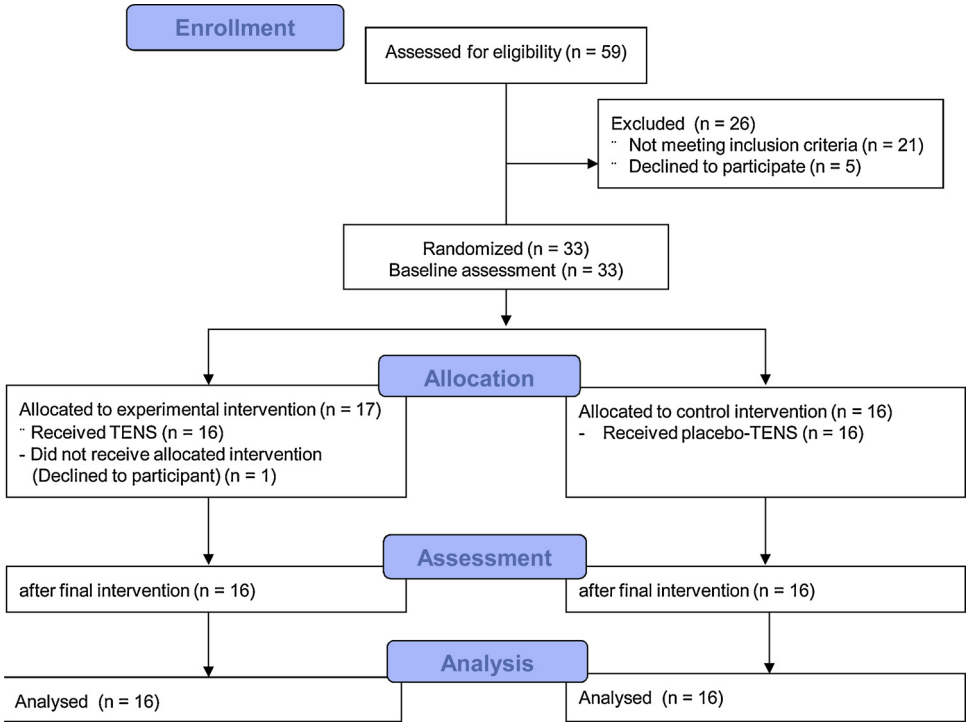

Fig. 1. CONSORT flow-diagram showing the details of randomized controlled trial.

Table 1
General characteristics of participants.

	TENS (n = 16)	Placebo (n = 16)	p
Age (y)	77.1 ± 7.1	77.8 ± 8.0	0.791
Sex (male/female)†	8/8	7/9	0.723
Height (cm)	160.7 ± 9.7	160.8 ± 9.3	0.880
Weight (kg)	66.5 ± 9.7	66.6 ± 10.2	0.985
MMSE	19.5 ± 2.1	20.4 ± 2.1	0.168

Values are expressed as mean ± SD or †number of participants.
MMSE, Mini-Mental State Examination.

of participants in this study. There were no significant differences between the TENS group and the placebo-TENS group in terms of the general characteristics of patients with dementia (age, sex, height, weight, and MMSE) (Table 1). Further, there were no significant differences in the pre-values of the outcome variables assessed between the two groups.

3.2. Changes in pain

As shown in Table 2, PPT was significantly increased in the TENS group after intervention ($p = 0.001$), while there were no significant differences of PPT in the placebo-TENS group. The TENS group showed significantly increased PPT compared with the placebo-TENS group ($p = 0.0495$).

3.3. Changes in strength

In the TENS group, there were significant differences in plantarflexor ($p = 0.013$) and dorsiflexor ($p < 0.001$) muscle strength after the intervention. Placebo-TENS changed muscle strength compared with pre-values in each group. There were significant differences in platarflexor muscle strength ($p = 0.008$) between the two groups (Table 3).

3.4. Changes in balance and gait ability

As shown in Table 4, the TENS group showed significant increase in FRT ($p = 0.009$), 10MWT ($p = 0.002$), and TUG ($p = 0.003$), while there were no significant differences for balance and gait ability in the placebo-TENS group. The TENS group did not show significant increase for FRT, but showed significant improvements for 10MWT ($p = 0.018$) and TUG ($p = 0.007$) compared with the placebo-TENS group (Table 4).

4. Discussion

This study is the first trial investigating the effect of TENS on pain, muscle strength, balance, and gait ability in patients with dementia who find it difficult to perform exercise independently. The TENS group reported significantly reduced pain evoked by pressure and improved muscle strength. In addition, TENS significantly improved balance and gait ability. These results support that TENS can be a part of alternative

Table 2
Changes in pain pressure threshold.

	TENS (n = 16)			Placebo (n = 16)			Group difference		
	pre	post	p	pre	post	p	TENS post-pre	Placebo post-pre	p
Algometer (Kg)	5.3 ± 1.8	5.9 ± 1.8	0.0 01*	5.8 ± 2.3	6.1 ± 2.2	0.548	0.6 ± 0.7	0.3 ± 0.9	0.0495*

Values are expressed as mean ± SD.
* $p < 0.05$.

Table 3
Changes in dorsiflexor and plantarflexor muscle strength.

	TENS (n = 16)			Placebo (n = 16)			Group difference		
	pre	post	P	pre	post	p	TENS post-pre	Placebo post-pre	p
Dorsiflexor (Nm)	8.5 ± 2.4	10.0 ± 2.6	0.013*	8.5 ± 3.0	9.1 ± 3.0	0.438	1.5 ± 2.6	0.5 ± 1.5	0.065
Plantarflexor (Nm)	11.5 ± 2.3	13.2 ± 2.7	< 0.001*	11.2 ± 4.2	11.6 ± 4.8	0.438	1.8 ± 1.1	0.3 ± 1.3	0.008*

Values are expressed as mean ± SD.
* $p < 0.05$.

intervention for functional improvement in dementia patients. Our results also may support further studies about TENS combined with conventional medicine for management of patients with dementia.

Dementia patients suffer from communication problems due to cognitive deficits. A previous study reported that the PPT of patients with dementia is decreased compared with that of healthy control subjects [25]. Considering the challenges with communication and decreased pain thresholds in dementia patients, it is important to prevent or manage pain for rehabilitation of dementia patients. This study also used PPT to assess pain intensity because using pain threshold by an incremental increase in pressure may be more suitable than using self-response pain assessment tool, such as visual analogue scale, in patients with cognitive problem. Our results showed a significant decrease in the evoked pain response in soft tissue as shown by an increase in PPT in patients with dementia. Similarly, Gemmell et al. reported that the PPT of a trigger point in the upper trapezius is increased when using low-frequency TENS compared with placebo-TENS [26]. Some animal researchers have also demonstrated the analgesic effect of low-frequency TENS on pain by activating opioid receptors or changing neurotransmitter release, which decreased the excitability of spinal neurons [27,28]. These studies support our results. In addition, in this study, the TENS group showed significant improvements in balance and gait ability. Previous studies have reported that decreased motor control ability by musculoskeletal pain affects gait ability and calf muscle pain is associated with balance and gait function [17,29]. Thus, improved balance and gait function of dementia patients may result from increased PPT of calf muscles by TENS.

In our study, the effect of repeated TENS over 2 weeks on muscle strength in patients with dementia was investigated. We found that this induce a significant increase in strength in plantarflexor muscle compared with placebo-TENS. Change in plantarflexor muscle was observed in the TENS group compared with the placebo-TENS group (1.8 ± 1.1 vs 0.3 ± 1.3). A previous report that repeated TENS applications have a positive effect on muscle strength [6] also supports our results. Considering that patients with dementia frequently have a high risk of falls due to poor balance and reduced movement and postural control [3] and weak lower extremities lead to decreased gait velocity and step length, and toe drag [30], muscle strength increase by using repetitive TENS may be helpful for management of dementia patients.

Cognitive deficiency caused by dementia leads to decreased locomotor function, such as decreased gait velocity and increased stride time, which is correlated with loss of executive function [1]. In this study, TENS significantly improved balance as assessed by the FRT, the TUG and gait ability assessed by the 10MWT and the TUG. Previous studies have also shown that TENS application in stroke patients improved abnormal gait function and balance [9,31]. Considering these findings, we assumed that improvements in balance and gait after using TENS may reduce fall risk and improve independent activity and activities of daily living in patients with dementia.

5. Limitations

Although we demonstrated the effect of low-frequency TENS on pain, muscle strength, balance, and gait in patients with dementia, this study has some limitations. According to the result of sample size calculations, this study was deemed to hold adequate methodological quality. Although the number of participants in this study was in line with the previous study, a further study with a larger sample size is still needed to support the findings of this study. In addition, further studies are required to conclusively determine the functional improvements that TENS could provide for patients with dementia. Specifically, future research should focus on determining optimal intensity and frequency of TENS treatment.

6. Conclusion

The findings of the study demonstrated the feasibility and effectiveness of TENS as an alternative therapeutic-intervention on pain, muscle strength, balance, and gait ability in patients with dementia. These results may recommend the use of TENS for functional management of dementia patients in the clinic. To reach a consensus of clinical TENS uses for functional management and support TENS as an evidence-based alternative intervention in patients with dementia, further studies with a larger sample size and a diversity of application conditions are needed.

Ethics approval and informed consent

This study has been approved by the Institutional Review Board of the Gachon University (Approval number: 1044396-201511-HR-053-003). Experimental procedures performed in the study involving subjects were in accordance with the Helsinki declaration and later amendments. All individuals participated in the study signed informed consent following receiving study explanation.

Table 4
Changes in dynamic balance and gait ability.

	TENS (n = 16)			Placebo (n = 16)			Group difference		
	pre	post	p	pre	post	p	TENS post-pre	Placebo post-pre	p
FRT (cm)	18.7 ± 6.0	20.4 ± 6.4	0.009*	19.5 ± 5.8	19.3 ± 5.5	0.706	1.7 ± 2.2	−0.2 ± 2.8	0.059
10-m walk test (s)	10.7 ± 3.3	9.4 ± 2.5	0.002*	10.4 ± 3.5	10.4 ± 3.3	0.733	1.4 ± 1.3	−0.0 ± 1.6	0.018*
TUG (s)	12.5 ± 4.3	11.0 ± 3.4	0.003*	12.3 ± 3.9	12.2 ± 3.6	0.887	1.5 ± 1.8	0.1 ± 1.1	0.007*

Values are expressed as mean ± SD.
FRT, functional reach test; TUG, timed up and go test.
* $p < 0.05$.

Declaration of Competing Interest

The authors in this study declare that there are no conflicts of interest.

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