Cutaneous electrical stimulation to improve balance performance in patients with sub-acute stroke: a randomised controlled trial

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KEY MESSAGES

1. In subjects with sub-acute stroke, rehabilitation that combined transcutaneous electrical nerve stimulation (TENS) with task-oriented balance training (TOBT) was superior to placebo stimulation with TOBT in improving balance performance and motor functions.
2. In subjects with sub-acute stroke, TENS is particularly useful as a complementary therapy to TOBT.

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Introduction

Falls and fall-related injuries after stroke are common and include fractures, fear of falling, and the consequent restriction of activity. Physical rehabilitation can restore balance control, promote functional recovery, and prevent secondary complications, disability, and handicap.

In chronic stroke patients, electric somatosensory stimulation can augment the effects of task-related training in improving lower limb strength and walking capacity.[1,2] The anatomic connections between the somatosensory cortex and motor cortex have been shown to provide the anatomic substrate through which electrical stimulation-induced somatosensory inputs can enhance motor cortical reorganisation following stroke.[3] The greatest improvement in motor function occurs between 3 and 6 weeks post-stroke, and plateaus at 90 days.[4] The first 8 weeks after stroke are the best time to enhance motor recovery.

The null hypothesis was that transcutaneous electrical nerve stimulation (TENS) plus task-oriented balance training (TOBT) did not differ significantly to placebo-stimulation (P-STIM) plus TOBT in recovery of balance and motor function after the first sub-acute stroke.

Methods

This single-blinded, randomised, placebo-controlled study was conducted from February 2011 to March 2013. It was approved by the local ethics committee. Informed consent was obtained from each subject. According to two clinical studies of sub-acute stroke patients using Berg Balance Scale (BBS) scores and distance covered in 6-minute walk test (6MWT), the weighted effect size was 0.75. Therefore, a sample of 68 subjects was necessary to achieve 80% chance (beta level=0.2) of detecting 20% difference (alpha level=0.05) in changes among the two treatment groups. Anticipating a possible dropout, the sample size was increased from 68 to 76.

Subjects were included if they had a single stroke within 3 to 11 weeks of the first onset of stroke, were able to stand upright unsupported for 1 minute, and had moderate gait deficit (Functional Ambulatory Category >II). Those with medical comorbidity, receptive dysphasia, or cognitive impairment denoted by scoring <7 of 10 on the Abbreviated Mental Test were excluded.

Subjects were randomised to receive TENS+TOBT or P-STIM+TOBT. They were required to attend twice per week for 8 weeks (16 sessions). The TENS+TOBT group received 60 minutes of TENS from a TENS stimulator. Electrodes were placed over the common peroneal nerve and sural nerve of the paretic leg. The P-STIM+TOBT group received 60 minutes of placebo stimulation from an identical-looking TENS device with the electrical circuit disconnected inside. Concurrently, all subjects had 60 minutes of TOBT that included six exercises: (1) stepping up and down exercise, (2) heel-raising exercise, (3) gait re-education, (4) walking exercise across obstacles, (5) standing exercise on balance board, (6) kicking exercise with alternate legs, (7) partial squatting exercise, and (8) transitional training between sit-to-stand and walking tasks. Standardised progression was made by the physiotherapist.

All subjects received 2.5 hours of conventional rehabilitation that involved 60 minutes each of standardised physiotherapy and occupational

therapy, followed by 30 minutes of speech therapy and/or health talks arranged by the geriatric day hospitals as usual practice.

Subjects were assessed at four time points by an assessor blinded to treatment allocation: before treatment (baseline), after eight sessions, after 16 sessions, and 3 months after treatment. Primary outcomes included BBS and 6MWT. Secondary outcomes included modified Rivermead Mobility Index (MRMI), timed up and go test (TUG), incidence of falls, and Short Form General Health Questionnaire (SF-36).

Multiple analysis of covariance incorporating all outcome measures at all time points was used to test the time-by-group effect of the intervention. The post-hoc analysis was conducted using univariate two-way analysis of covariance to indicate at which time point significant difference between two groups occurred, with the significance level set at 5%. Intention-to-treat analysis was performed, and missing values for any drop-outs were imputed using the last observation carried forward method.

Results

A total of 76 subjects (age, 70.1±9.9 years) were included at 6.2±2.8 weeks after stroke. Seven (9.2%) subjects dropped out during the 8-week intervention period, and 17 (22.4%) subjects dropped out 3 months after treatment. The TENS+TOBT and P-STIM+TOBT groups were comparable in terms of demographics and baseline outcomes (Table 1).

Both groups generally showed improvement in all outcomes at all time points, compared with baseline values. Compared with P-STIM+TOBT group, the TENS+TOBT group achieved significantly greater improvement in BBS and MRMI scores after eight sessions, as well as in BBS and TUG scores, and physical function subscale in SF-36 after 16 sessions (Tables 2 and 3). The effect on BBS and SF-36 was maintained 3 months after treatment. The two groups did not differ significantly in 6MWT distance, and did not report any fall 3 months after treatment.

Discussion

The effects of spontaneous recovery on outcome observed mostly in acute and sub-acute stroke must be considered when evaluating clinical trials of exercises, as the spontaneous gain makes between-group effects more difficult to detect because controls are also improving.

Both groups' training involved repetitive strengthening exercises of muscles relating to balance control and functional tasks that challenged

TABLE 1. Subject characteristics and baseline outcome between the transcutaneous electrical nerve stimulation (TENS) plus task-oriented balance training (TOBT) group and placebo-stimulation (P-STIM) plus TOBT group

Variable	Mean±SD or No. (%) of subjects		P value
	TENS+TOBT (n=37)	P-STIM +TOBT (n=39)	
Age (years)	72.6±97	69.3±100	0.145
Gender			
Male	24 (64.9)	24 (61.5)	
Female	13 (35.1)	15 (38.5)	
Hemiparetic side			
Left	18 (48.6)	20 (51.3)	
Right	19 (51.9)	19 (48.7)	
Time post-stroke (weeks)	6.1±2.7	6.3±2.9	0.783
Type of stroke			
Ischaemic	31 (83.8)	34 (87.2)	
Haemorrhagic	6 (16.2)	5 (12.8)	
Height (cm)	160.1±8.6	159.1±8.4	0.627
Weight (kg)	59.5±10.3	57.7±10.1	0.455
Body mass index (kg/m^2)	23.1±3.0	22.7±3.1	0.570
No. of stroke	1.0±0.00	1.05±0.223	0.167
No. of subjects having falls in previous 4 weeks	5	7	
No. of falls in previous 4 weeks	0.3±0.9	0.2±0.5	0.704
Abbreviated Mental Test	9.1±1.1	9.0±1.1	0.829
Modified Functional Ambulatory Category	5.6±0.6	5.4±0.8	0.218

TABLE 2. Comparison of outcome measures between the transcutaneous electrical nerve stimulation (TENS) plus task-oriented balance training (TOBT) group and placebo-stimulation (P-STIM) plus TOBT group

Outcome measure	Mean±SD			
	Baseline	After 8 sessions	After 16 sessions	3 months after treatment
Berg Balance Scale				
TENS+TOBT	37.78±7.59	44.7±6.63*	47.68±5.69†	49.05±6.78*
P-STIM+TOBT	35.41±10.95	40.62±9.38	44.23±7.40	46.08±5.79
Distance covered in 6-minute walk test (m)				
TENS+TOBT	127.27±73.10	174.78±79.98	197.16±82.88	210.59±92.04
P-STIM+TOBT	107.56±59.20	148.56±76.84	171.56±95.36	199.51±99.64
Modified Rivermead Mobility Index				
TENS+TOBT	31.51±2.93	34.73±3.06*	36.27±2.99	36.84±3.98
P-STIM+TOBT	30.31±4.72	32.74±4.08	34.97±3.83	36.56±3.15
Timed up and go test (s)				
TENS+TOBT	42.89±27.06	30.38±17.75	22.82±10.75†	21.33±10.75
P-STIM+TOBT	45.60±23.67	34.27±18.52	31.68±22.08	19.41±21.18

* P<0.05 compared with P-STIM+TOBT group
† P<0.01 compared with P-STIM+TOBT group

TABLE 3. Comparison of sub-scores of SF-36 between the transcutaneous electrical nerve stimulation (TENS) plus task-oriented balance training (TOBT) group and placebo-stimulation (P-STIM) plus TOBT group

SF-36 Subscales	Mean±SD		
	Baseline	After 16 sessions	3 months after treatment
Physical function			
TENS+TOBT	39.86±19.38	62.84±22.56*	68.92±17.60*
P-STIM+TOBT	38.46±20.59	50.38±22.98	57.05±23.53
Role physical			
TENS+TOBT	46.35±20.09	63.2 0± 25.50	66.22±25.04
P-STIM+TOBT	45.19±31.75	66.92±25.82	67.82±21.20
Bodily pain			
TENS+TOBT	71.96±26.37	75.20±24.26	77.43±23.37
P-STIM+TOBT	71.73±31.75	75.19±26.57	75.19±27.83
General health			
TENS+TOBT	52.70±20.97	54.73±18.41	62.57±21.90
P-STIM+TOBT	52.31±21.91	56.41±19.73	61.92±21.63
Vitality			
TENS+TOBT	58.92±17.68	68.63±17.86	68.57±14.95
P-STIM+TOBT	56.92±13.61	64.87±16.68	66.28±19.73
Social functioning			
TENS+TOBT	56.58±22.85	67.51±19.64	67.74±16.15
P-STIM+TOBT	58.79±20.65	64.17±16.69	64.65±20.77
Role functioning-emotion			
TENS+TOBT	77.16±22.13	80.86±18.92	77.61±17.85
P-STIM+TOBT	73.47±22.59	80.51±18.40	76.75±19.51
Mental health			
TENS+TOBT	68.49±22.35	70.93±15.75	68.92±17.23
P-STIM+TOBT	68.62±22.35	69.97±20.76	70.89±19.35

* P<0.05 compared with P-STIM+TOBT group

dynamic balance. Both groups demonstrated improvement in MRMI, BBS, and TUG scores after 8 sessions of intervention compared with baseline. The mechanism underlying improvement in motor functions following TOBT appears multi-factorial, and could be attributed to enhancement of descending voluntary commands to the paretic muscles, reduced agonist-antagonist co-contraction, improved gross motor efficiency induced by exercise-mediated neuromuscular adaptations, and reorganisation of synapses and cortical representation following repetitive practice of functional tasks.[1,2]

The TENS+TOBT group was superior to P-STIM+TOBT group in improving balance performance and motor functions. This finding is consistent with that in studies in which TENS applied to areas supplied by the common peroneal nerves improved walking functions in patients with chronic stroke.[1,2] TENS can be a useful complementary therapy to TOBT. Possible mechanisms underlying the motor improvements following TENS could be disinhibition of descending voluntary commands to the motoneurons of paretic muscles and decreased co-contraction of the spastic antagonist.[1,2] In addition, TENS sent afferent input to the sensorimotor cortex that in turn enhanced output from the primary motor cortex, thereby improving motor function. The anatomic connections between somatosensory cortex and motor cortex have been shown to provide the anatomic substrate through which electrical stimulation can enhance motor cortical reorganisation after stroke.[3]

A BBS score <45 has been reported as a threshold of fall risk.[5] All our subjects had attained a BBS score >45 after 16 sessions of treatment and 3 months after treatment.

The TUG test includes a series of motor tasks that demand balance control in addition to muscle strength and movement coordination.[6] Older adults who were able to complete the TUG task in <20 seconds were more likely to be independent in the transfer tasks needed for the activities of daily living, whereas those who required ≥30 seconds tended to be more dependent in their activities of daily living and require assistive devices for ambulation. In the TENS+TOBT group, the TUG time was 42.89±27.1 seconds at baseline and improved to 21.3±10.8 seconds after 16 sessions of treatment.

Task-related exercise played a main role in increasing the 6MWT distance in both groups. Physical exercise might modify any physical deconditioning, and might improve gross motor efficiency by inducing exercise-mediated neuromuscular adaptations, thus improving walking endurance in subjects with sub-acute stroke.

One limitation of the study was the absence of an independent task-orientated balance training group to delineate the effects of exercise. Due to time and resource constraints, treatment effectiveness was assessed only up to 3 months after treatment. Whether greater improvement in motor functions can be attained with longer treatment remains unknown.

Conclusion

In patients with sub-acute stroke, TENS+TOBT was generally more effective than P-STIM+TOBT in improving balance and motor functions. Improvement in balance was maintained even 3 months after treatment. Future studies should examine the optimal combined training programme in terms of frequency, duration, and intensity.

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