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ORIGINAL REPORT

EFFECT OF BIHEMISPHERIC ANODAL TRANSCRANIAL DIRECT CURRENT STIMULATION FOR DYSPHAGIA IN CHRONIC STROKE PATIENTS: A RANDOMIZED CLINICAL TRIAL

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Objective: **To investigate whether bihemispheric anodal transcranial direct current stimulation (tDCS) with conventional dysphagia therapy could improve swallowing function in chronic stroke patients with dysphagia.**

Design: **Randomized controlled trial.**

Subjects: **Twenty-six patients with dysphagia for at least 6 months post-stroke were randomly assigned into: (*i*) bihemispheric anodal tDCS group; or (*ii*) sham group.**

Methods: **All patients underwent 10 tDCS sessions with simultaneous conventional swallowing therapy for 2 weeks. Both anodal electrodes were attached bilaterally to the pharyngeal motor cortices, and cathodal electrodes were attached to both supraorbital regions. Swallowing function was evaluated with the Dysphagia Outcome and Severity Scale (DOSS) before and immediately after the last intervention session.**

Results: **The bihemispheric anodal tDCS group showed a mean significant improvement 0.62 points; standard deviation (SD) 0.77, in the DOSS immediately after all sessions ($p = 0.02$). However, there was no mean significant improvement in the sham group (0.38 points; SD 0.65($p = 0.06$)). There was no significant difference between the 2 groups ($p = 0.48$).**

Conclusion: **The bihemispheric anodal tDCS with conventional dysphagia therapy had additional helpful effects on the improvement in swallowing function in chronic stroke patients.**

Key words: dysphagia; stroke; transcranial direct current stimulation; randomized controlled trial; Dysphagia Outcome and Severity Scale.

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Dysphagia affects over 50% of stroke survivors and leads to serious complications, such as dehydration, malnutrition, and aspiration pneumonia, in these patients (1, 2). Most patients with post-stroke dysphagia recover swallowing function; however, 11–13% still have dysphagia 6 months after stroke (3). Furthermore, dysphagia can predominantly affect the quality of life of stroke patients (4). Therefore, various therapeutic approaches have been developed for improving swallowing dysfunction after stroke. Most of these approaches have focused on peripheral sensorimotor stimulation techniques, including oromotor stimulation, thermal tactile stimulation, and compensatory methods, such as position adjustment and diet modification (5–10). However, it is unclear whether treatment options that stimulate only the peripheral sensorimotor system would significantly improve swallowing dysfunction (11).

Recently, non-invasive brain stimulation methods modulating cortical excitability, such as repetitive transcranial magnetic stimulation (rTMS) and transcranial direct current stimulation (tDCS), had been introduced and applied to various problems after stroke. Previous researchers have shown that non-invasive brain stimulation is useful for improving motor weakness of paretic limbs, aphasia, and neglect after stroke (12–17). Central stimulation combined with peripheral sensorimotor stimulation can be a more effective treatment option for improving dysphagia in stroke patients, and some researchers have reported unihemispheric tDCS to be effective for acute and subacute post-stroke dysphagia (18–20). Therefore, concurrent stimulation of the central nervous system, using tDCS with peripheral sensorimotor activities, could theoretically be effective in improving chronic post-stroke dysphagia.

It is known that the pharyngeal musculature involved in the swallowing function is usually innervated bilaterally (21). Thus, we hypothesized that the bihemispheric anodal tDCS mode, which increases bilateral pharyngeal motor cortical excitability through 2 separate anode stimulation circuits, could be an effective treatment option for post-stroke dysphagia. However, no study has evaluated the effect of bihemispheric anodal tDCS on post-stroke dysphagia.

The aim of this study was therefore to investigate the effect of bihemispheric anodal tDCS with conventional dysphagia therapy on chronic post-stroke dysphagia.

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METHODS

Study design

This study was a prospective, multicentre, double-blinded trial approved by the institutional review board of Pusan National University Yangsan Hospital (PNUYH IRB 03-2015-004). A total of 26 subjects was enrolled, all of whom submitted a written informed consent form. This study was conducted in Medwill Hospital and Pusan National University Yangsan Hospital.

Study subjects

Inclusion criteria were:

- age 18–80 years
- first-ever stroke, confirmed with brain imaging and clinical observation by a doctor
- at least 6 months since stroke onset
- dysphagia due to stroke, with a Dysphagia Outcome and Severity Scale (DOSS) score at enrollment of ≤5 (mild-to-severe dysphagia)
- unilateral cortical or subcortical hemispheric lesion confirmed with brain imaging analysis
- inpatients or outpatients who could receive therapy for dysphagia 5 times per week
- no history of abnormal response to brain or electrical stimulation
- patients who were informed of the purpose of the current study and submitted a written informed consent
- Exclusion criteria were:
- pre-existing and active major neurological disease
- pre-existing and active major psychiatric disease, such as major depression, schizophrenia, bipolar disease, or dementia
- brain lesion in areas other than the cortical and subcortical regions
- presence of a potential tDCS risk factor (intracerebral metal due to previous brain surgery, hypersensitivity to pain, history of seizure, etc.)

Outcome measure

Post-stroke dysphagia was clinically assessed by a physiatrist and an occupational therapist specializing in dysphagia, who were blinded to the study allocation. All patients were rated for swallowing dysfunction with a validated dysphagia scale, the DOSS, on the basis of a video-fluoroscopic swallowing study and interview with the patient or the caregiver. The DOSS score ranges from 1 to 7, with 1 representing severe dysphagia and 7 representing normal swallowing function (22). The DOSS rates the functional severity of dysphagia and recommends a dietary level, independence level, and type of nutrition according to the level of impairment, thus conveying information about the dysphagia severity and related disability. One physiatrist and 1 occupational therapist analysed the video recordings, and the final DOSS was determined according to consensus. We compared DOSS scores before the first stimulation session and immediately after the last session in the bihemispheric anodal tDCS group and the sham group.

tDCS protocol

The tDCS was delivered using a battery-driven constant-current direct current stimulator (Neuroconn GmbH, Ilmenau, Germany) through 2 pairs of saline-soaked electrodes (25 cm^2 rectangular surface electrodes; current density, 0.04 mA/cm^2 at 1 mA). Four electrodes were used for bihemispheric tDCS.

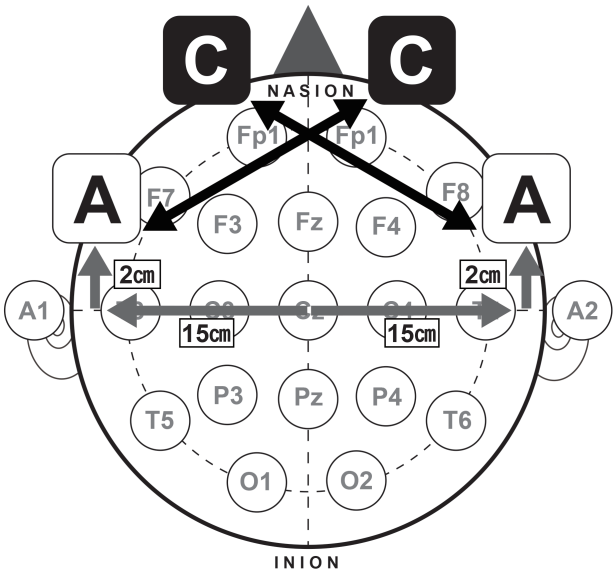

Fig. 1. Experimental design. A: anode electrode; C: cathode electrode.

The 2 anodal electrodes were attached bilaterally to the pharyngeal motor cortices, which were 15 cm from Cz to A1 and 2 cm in the front direction on the right, and from Cz to A2 in the front direction on the left, according to the international 10–20 electroencephalography electrode system (19). The 2 cathodal reference electrodes were attached to both supraorbital regions of the contralateral hemisphere (19) (Fig. 1). The anodal electrode on right hemisphere is coupling to cathodal reference electrode to left supraorbital region. The bihemispheric anodal tDCS group received a total of 10 sessions of 20 min and 1mA stimulation (5 times per week for 2 weeks). In the sham group, the same protocol was applied, except that the 1 mA current was delivered for only 30 s through 2 anodal electrodes, producing an initial tingling sensation but no significant changes in cortical excitability (23).

Conventional dysphagia therapy

In this study, bihemispheric anodal tDCS or sham intervention was simultaneously combined with dysphagia therapy, which consisted of direct and indirect methods, to provide sensorimotor activation of the swallowing cortex (24). The direct approach included compensatory methods, such as diet modification, appropriate positioning, and behavioural manoeuvres, including Mendelsohn manoeuvre, and supraglottic and effortful swallowing (25, 26). The indirect approach included oromotor exercise and thermal tactile stimulation (6, 27). The dysphagia therapy was carried out with the same protocol in both hospitals, and was performed by 2 occupational therapists in each hospital. Furthermore, the therapists were blinded to the experimental protocol and did not participate in the outcome measurement or data analysis.

Statistical analysis

All data were expressed as mean and standard deviation (SD) or numbers with proportions. The improvements in each group were compared by using the Wilcoxon signed-rank test, and improvement in the 2 groups was compared by using the Mann-Whitney *U* test. A p-value of <0.05 was considered statistically

Table I. Basic characteristics of the subjects

	Bihemispheric anodal tDCS group ($n=13$)	Sham group ($n=13$)
Age, years, mean (SD)	61.62 (10.28)	66.38 (10.67)
Sex, *n*		
Male	9	6
Female	4	7
Onset duration, months, mean (SD)	12.27 (4.92)	11.62 (4.56)
Stroke type, *n*		
Infarction	5	11
Haemorrhage	8	2
Lesion, *n*		
Right hemisphere	6	6
Left hemisphere	7	7
Location, *n*		
Cortical	6	10
Subcortical	7	3

tDCS: transcranial direct current stimulation; SD: standard deviation.

significant. Statistical analysis was performed with SPSS version 21.0 (SPSS Inc., Chicago, IL, USA).

RESULTS

Baseline characteristics

Twenty-six subjects were enrolled to the study (15 men, 11 women; mean age 64.0 years (SD 10.5)), and randomized to 2 groups using a random number table: 13 subjects in the bihemispheric anodal tDCS group and 13 to the sham group. The mean duration from onset to intervention was 11.9 months (SD 4.66). Sixteen patients had cerebral infarction and 10 had cerebral haemorrhage. Twelve patients had a right hemispheric lesion and 14 patients had a left hemispheric lesion. Table I lists the basic demographic and clinical characteristics of the patients. All patients underwent 10 intervention sessions with no adverse response, such as seizure, headache, visual disturbance, or skin irritation, as have been previously reported (28).

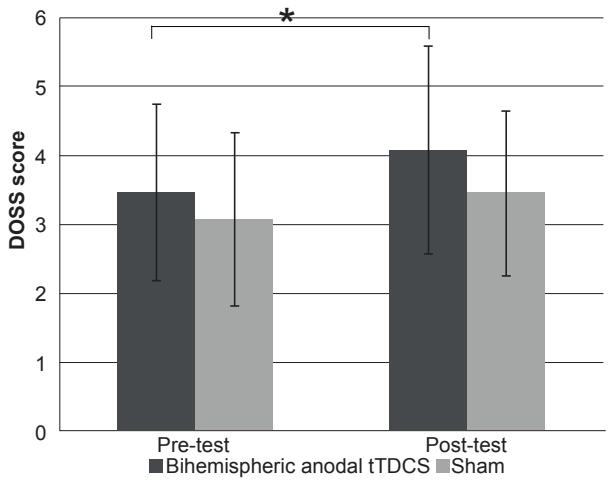

Fig. 2. Changes in the Dysphagia Outcome and Severity Scale (DOSS) in the bihemispheric anodal transcranial direct current stimulation (tDCS) group and the sham group. The bihemispheric anodal tDCS group showed significant improvement after all sessions ($p=0.023$); however, the sham group was not significantly improved ($p=0.06$). *$p<0.05$.

Change in DOSS scores at the endpoint from baseline in each group

A mean significant improvement of 0.62 points (SD 0.77) was observed in the DOSS scores of the bihemispheric anodal tDCS group, from 3.46 (SD 1.27) (pre-DOSS) to 4.08 (SD 1.50) (post-DOSS) (Z=–2.27, $p=0.02$). However, there was a non-significant improvement of 0.38 points (SD 0.65) in the DOSS scores of the sham group, from 3.08 (SD 1.26) (pre-DOSS) to 3.46 (SD1.20) (post-DOSS) (Z=–1.89, $p=0.06$) (Fig. 2).

Comparison between the bihemispheric anodal tDCS group and the sham group of delta change in the pre-DOSS and post-DOSS scores revealed no statistically significant difference (U=70.50, Z=–0.83, $p=0.48$).

DISCUSSION

This study is the first sham-controlled randomized trial to investigate the effect of bihemispheric anodal tDCS with simultaneous dysphagia therapy for chronic stroke patients with dysphagia. A significant improvement in swallowing function was observed in the group treated with bihemispheric anodal tDCS in combination with concurrent conventional dysphagia therapy, and a non-significant improvement was measured in the sham group during a period of 2 weeks. The bihemispheric anodal tDCS group did not show statistical superiority over the sham group.

tDCS is a non-invasive brain stimulation method based on the principle of neuroplasticity, including synaptogenesis, reorganization and brain network strengthening, and depression (29). It provides a steady electrical current of low intensity between the anode and cathode applied to the scalp area, associated with targeting the cerebral cortex. In general, cathodal tDCS decreases cortical excitability and anodal tDCS increases cortical excitability (30).

We tried bihemispheric electrical stimulation, consisting of bilateral anodal tDCS on the ipsilesional and contralesional hemispheres, to increase the bihemispheric cortical excitability, because the swallowing central pattern generator in the brainstem is regulated by the pharyngeal motor cortices (31, 32). In other words, the pharyngeal or laryngeal musculature involved in the swallowing process is governed by bilateral corticobulbar projections, distinct from limb musculature, which is mainly supplied by unilateral innervations. According to the difference in compensatory reorganization between hemispheres during the

recovery of swallowing and limb function, the recovery of swallowing is represented in both hemispheres, although one hemisphere has a larger (or more dominant) swallowing control than the other (33). Furthermore, some studies have proved that recovery of dysphagia after stroke occurs through an increased representation of the contralesional hemisphere, which can also be a useful treatment target (14, 34). Therefore, we expected that concurrent bihemispheric anodal tDCS would provide both increased facilitation of the intact portion in the affected swallowing-dominant hemisphere and more cortical representation of the unaffected hemisphere.

Previous studies have reported the effect of tDCS on dysphagia in acute and subacute stroke; however, there was no agreement on the stimulated hemisphere. Yang et al. demonstrated that unilateral tDCS applied to the affected hemisphere with conventional swallowing training for 10 days improved the functional dysphagia scale in patients with subacute stroke. The authors tried ipsilesional pharyngeal motor cortex stimulation with a unilateral anode, suggesting that stimulation of the affected hemisphere would increase the chances of stimulating over the infarct volume (18). Shigematsu et al. (19) also demonstrated that stimulation of the ipsilesional pharyngeal motor cortex with a single anode combined with simultaneous conventional swallowing therapies improved swallowing function measured with DOSS in patients with subacute stroke, and the effect of tDCS persisted for one month after the last intervention. Kumar et al. (20) showed that single anodal tDCS applied to the unaffected hemisphere with concurrent standard swallowing manoeuvres for 5 days improved swallowing function measured with DOSS during early stroke convalescence. The authors stimulated the contralesional, lateral sensorimotor cortex with unilateral anode because recovery of swallowing functions occurs through expansion of the pharyngeal representation in the uninvolved hemisphere of acute and subacute stroke patients.This is similar to rTMS studies. One study showed that rTMS of the affected motor cortex led to a significantly greater improvement than sham treatment in dysphagia (35), and another study reported that rTMS over the unaffected pharyngeal motor cortex might be beneficial for post-stroke dysphagic patients (36). There were no studies on bihemispheric tDCS for dysphagia; however, there were a few rTMS studies that revealed the effectiveness of bihemispheric stimulation in chronic stroke patients with dysphagia. Momosaki et al (37). showed that intensive swallowing rehabilitation after rTMS to bilateral pharyngeal motor cortices by using a frequency of at 3 Hz for 6 days improved the laryngeal elevation delay time in patients with chronic stroke dysphagia. Cheng et al. (38) tried 5-Hz rTMS to the tongue region of the motor cortex in post-stroke patients with chronic dysphagia, and revealed that this method improved swallowing function and swallowing-related quality of life. These recent rTMS studies could support our results with bihemispheric anodal stimulation.

In previous studies, the researchers tried concurrent central stimulation with tDCS and peripheral stimulation with conventional swallowing therapy. The rationale behind this trial was that the combination of central and peripheral stimulation has been successfully used to enhance motor recovery in an animal model of stroke (39). Moreover, in a study in chronic stroke patients, the combination of tDCS and peripheral stimulation improved motor functions (40). We also intended to increase cortical excitability with simultaneous central and peripheral stimulation in patients with chronic dysphagia after stroke. We aimed to recruit chronic stroke patients as experimental subjects. Previous studies showed the effect of tDCS mainly on acute or subacute stroke patients and during the chronic stroke phase, when the possibility of spontaneous recovery of dysphagia is lower and useful therapeutic options are more limited than during the acute or subacute stroke phases. Therefore, we thought that bihemispheric anodal tDCS with conventional dysphagia therapy would have a synergic effect for improving swallowing function in chronic post-stroke patients, to provide a more effective recovery even in the chronic state, with some potential for restoration.

Study limitations

The current study has some limitations. First, it did not include an ipsilesional or contralesional single anodal tDCS group of chronic stroke patients because pre-existing studies have revealed the effect of ipsilesional or contralesional single anodal tDCS on post-stroke dysphagia in the acute or subacute stage. Secondly, our research had small sample size with differences in stroke type and location between the bihemispheric anodal and sham groups, and showed a short-term effect. Studies with large sample numbers and longer follow-up are needed to generalize the result. Thirdly, the DOSS, the single outcome measure tool in this study, might not have sensitivity to capture detailed variations for a 2-week period in chronic stroke patients. Although the result of this study showed that the bihemispheric anodal tDCS group did not have a statistically superior improvement than the sham group, the detailed outcome scale of dysphagia, using video fluoroscopy swallowing study, patient's report of symptoms, or satisfaction of patient and caregiver can reflect the clinical improvement of dysphagia in the subjects.

Conclusion

Bihemispheric anodal tDCS with conventional dysphagia therapy had additional helpful effects on the improvement of swallowing function in chronic stroke patients. Further research into various tDCS methods, including our protocol, will be needed to determine the optimal stimulation protocol for post-stroke dysphagia.

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The authors declare no conflicts of interest.

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