Original Article

Efficacy of Transcranial Direct Current Stimulation in the Treatment of Post-Stroke Aphasia: A Randomized Controlled Trial

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ABSTRACT

Objectives: To evaluate the efficacy of anodal transcranial direct current stimulation (tDCS) on improving language ability in patients with post-stroke aphasia

Study design: Double-blind randomized controlled trial

Setting: Department of Rehabilitation Medicine, Maharat Nakhon Ratchasima Hospital

Subjects: Post-stroke aphasia patients aged 18 years and over, with at least three months from stroke onset

Methods: Forty patients were randomly assigned to intervention and control groups. The intervention group received 2 mA of anodal tDCS over Broca's area (F5) combined with speech therapy for 20 minutes per session per day on five consecutive days. The control group received sham-tDCS combined with speech therapy in the same protocol as the intervention group. Language skills were evaluated using the Thai Western Aphasia Battery at pre-treatment, post-treatment (after the session on the fifth day of treatment), and 1-month follow-up. The accessor was blinded.

Results: Thirty-two patients completed the assigned sessions. The mean age of the patients was 52.7 (SD=11.4) years. Most of them had an ischemic stroke (71.9%). The mean difference in Thai WAB-AQ scores between the intervention and control groups at post-treatment and 1-month follow-up were -0.05 (95% CI: -4.4, 4.3) and -2.38 (95% CI: -11.7, 6.9), respectively. However, the difference between the two groups did not reach statistical significance at either time point. No serious complication was found.

Conclusions: This study did not show sufficient evidence to support anodal tDCS concurrent speech therapy with additional improvement in language ability beyond those observed in patients undergoing speech therapy alone, among those with post-stroke aphasia.

Keywords: transcranial direct current stimulation, aphasia, stroke, speech therapy, stroke rehabilitation

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Introduction

Aphasia is an impairment of language, affecting the production or comprehension of speech and the ability to read and write. The most common cause of aphasia is cerebrovascular disease. Approximately 30% of stroke patients will be diagnosed with aphasia.[1] Currently, there is no known effective treatment. The most popular treatment used today is the practice of communication with a speech-language pathologist (SLP).[2] A SLP assists the patient in recovering linguistic abilities and training the patient and family members in exercising alternative strategies for communication.

However, current speech therapy strategies have limited and variable effectiveness in improving aphasia.[2,3] Transcranial Direct Current Stimulation (tDCS) is a non-invasive brain stimulation that has been used in adjunctive therapy with rehabilitation in stroke patients for various disabilities including muscle weakness,[4] cognitive impairment,[4] dysphagia,[5] and aphasia.[6-10] Also, tDCS is a neuromodulatory technique that affects the resting membrane potentials of neurons through modulation of sodium-channel, calcium-channels, and NMDA (N-methyl-D-aspartate) receptor activity, resulting in long-term potentiation, long-term depression, and synaptic plasticity.[6,7]

Anodal tDCS over the left frontal or temporal regions effectively performs linguistic tasks. For instance, Baker et al. and Fiori et al. reported significant improvements in naming accuracy following tDCS interventions.[8,9] Campana et al. demonstrated enhanced picture description abilities among patients who received tDCS stimulation.[10] Furthermore, Vilanowa et al. indicated enhancements in articulatory accuracy following anodal tDCS application.[11] However, Fridriksson et al. and Spielmann et al. did not find a significant difference improvement in naming accuracy between the anodal tDCS group and the control group.[12,13] Polanowska et al. likewise concluded that naming accuracy and naming time had no significant difference improvement after applying anodal tDCS.[14]

Elser et al. conducted a systematic review and metaanalysis and found that tDCS was not superior to the conventional

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treatment in improving functional communication, language impairment, and cognition in patients with chronic post-stroke aphasia.[15] Biou et al. performed a systematic review of 5 meta-analyses and 48 studies and concluded that tDCS is effective for post-stroke aphasia rehabilitation.[16]

Even though there were systematic reviews, those studies had heterogenicity in the phase of stroke, polarity, and area of brain stimulation. The effectiveness of tDCS for improving aphasia is controversial. Therefore, this study aimed to investigate the efficacy of anodal tDCS combined with speech therapy in patients with post-stroke aphasia.

Methods

Study design

This study was a double-blind, randomized control trial conducted at the Department of Rehabilitation Medicine of Maharat Nakhon Ratchasima Hospital (tertiary care hospital) in Nakhon Ratchasima, Thailand, from March 2019 to September 2022. Ethical approval was obtained from the Maharat Nakhon Ratchasima Hospital Institution Review Board (approval ethical number 041/2019) and was registered in the Thai Clinical Trials Registry (TCTR 20200204007).

Participants

The participants of this study were patients with post-stroke aphasia who were diagnosed at least three months. They received treatment at the Department of Rehabilitation Medicine at Maharat Nakhon Ratchasima Hospital. The inclusion criteria included the following requirements: age 18 years or over, the first diagnosis of stroke, communication impairment that affects communication in daily life or Thai WAB-AQ score less than 93.8, the cut-off for aphasia diagnosis,[17] and willingness to provide consent to participate in the study. The exclusion criteria included the following specifications: unstable vital signs or neurological symptoms, communication impairment prior to the stroke, receiving neuromodulation therapy, including tDCS, transcranial magnetic stimulation (TMS), and acupuncture during the previous three months, and having contraindications for tDCS including a history of craniectomy or craniotomy, a history of seizure within twelve months, cochlear implants, intra-cardiac devices implanted, and metallic material implanted.[7]

The sample size calculation was based on a study by Shah-Basak et al.[18] The primary outcome variable selected was WAB-AQ score. The power of the study was set at 80%, and the significance level was 0.05. There were 18 patients required in each study group and a control group. Taking into account a 10% dropout, the number of patients was increased to 20 subjects in each group, and 40 participants were recruited in total.

Randomization

The patients were randomized to either an intervention or a control group by a research coordinator from a computer-generated random number system (http://randomization.com) for a block of four randomizations. After baseline testing, the patients received notification of their group allocation in a sealed envelope. Patients and SLPs were blinded to the intervention assignment.

Intervention

Patients in the intervention and control groups received speech therapy for 20 minutes per session per day, five sessions on consecutive days. During the speech therapy session, tDCS was applied with an anode over the left Broca's area (F5) according to the 10-20 EEG system, and the cathode on the right supraorbital area. Patients in the intervention group received an electrical current of 2 mA for all 20 minutes during the speech training session. In contrast, those in the control group received an electrical current for only 30 seconds to simulate being treated with the electricity. The tDCS method was chosen based on the previous studies[9,10,19] that assessed the effectiveness and safety of tDCS.

Outcome measurements

The clinical outcome measure was the Thai Western Aphasia Battery-Aphasia Quotient (Thai WAB-AQ) score after the session on the fifth day of the treatment (post-treatment) and one month after the last treatment session. The Thai WAB-AQ was modified from the Western Aphasia Battery Aphasia Quotient.[17] The Thai WAB-AQ score has a reliability of 0.99.[20] The scale was zero to a hundred. The one hundred scores meant normal. It consisted of 4 tasks: spontaneous speech, comprehension, repetition, and naming. The accessor was the SLP, who was blinded to the intervention assignment. The flow chart of the study is shown in Figure 1.

Statistical methods

The baseline characteristics of both groups were analyzed with descriptive statistics, shown as a number, percentage, mean, and standard deviation. The researchers used mixed-effect restricted maximum likelihood regression to compare the mean difference of Thai WAB-AQ between the two groups on the fifth day after treatment and one month after the last session. The 95-percent confidence interval, which did not overlap with 0, was statistically significant.

Result

Forty patients with post-stroke aphasia participated in the study and were randomly assigned to one of two groups: the intervention (anodal-tDCS) or the control (sham-tDCS) group. Three patients from the intervention group and four from the control group dropped out between treatments due to transportation issues. Also, one patient from the intervention group dropped out on the first day of treatment due to stress from the speech training. One month after treatment, two patients from the intervention group failed follow-up due to transportation challenges. The last observation carried

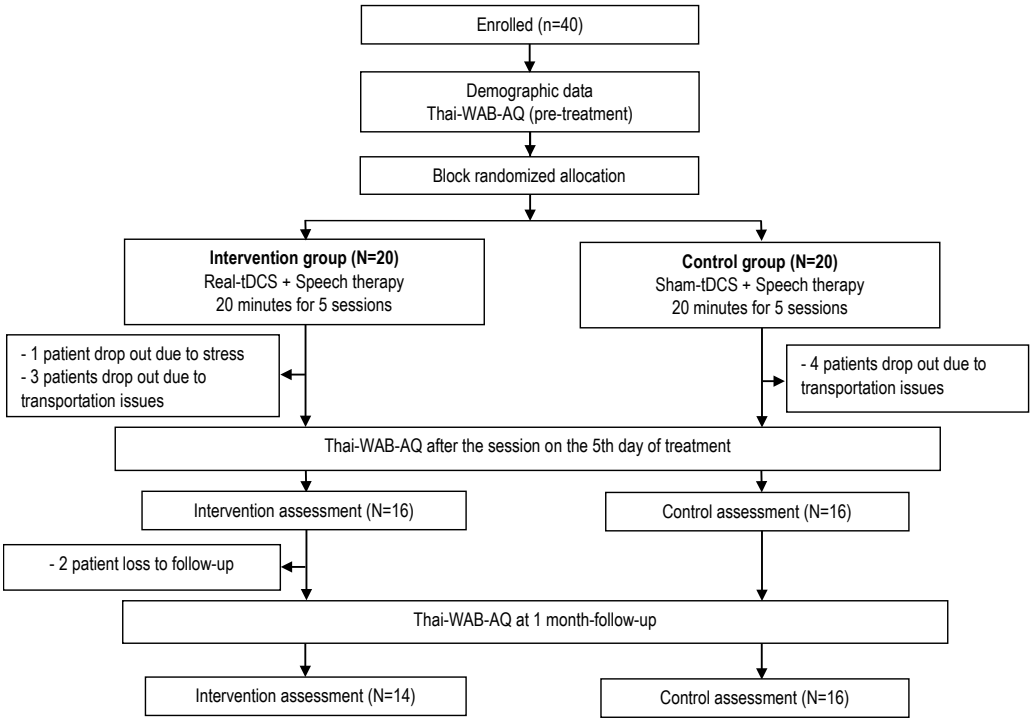

Figure1. Flow diagram of the patients through the trial

Table 1. Demographic data of the patients

Characteristics	Intervention group (n = 16)	Control group (n = 16)
Male gender[1]	9 (56.25)	12 (75)
Age (year)[2]	53.1 (10.97)	52.5 (12.26)
Education level[1]		
• Primary school	10 (62.5)	6 (37.5)
• Secondary school	5 (31.25)	10 (62.5)
• Bachelor's degree	1 (6.25)	0 (0)
Underlying disease[1]	14 (87.5)	13 (81.25)
• Hypertension	7 (43.75)	8 (50)
• Diabetes mellitus	5 (31.25)	2 (12.5)
• Dyslipidemia	1 (6.25)	1 (6.25)
• Heart disease	5 (31.25)	7 (43.75)
• Other	3 (18.75)	6 (18.75)
Duration from the onset of stroke to intervention (month)[2]	9.2 (56.25)	4.9 (2.41)
Right hand dominant[1]	15 (93.75)	15 (93.75)
Ischemic stroke[1]	11 (68.75)	12 (75)
Location[1]		
• Left MCA infarction	7 (43.75)	8 (50)
• Left frontoparietal	2 (12.5)	2 (12.5)
• Left basal ganglion	5 (31.25)	3 (18.75)
• Right MCA infarction	0 (0)	1 (6.25)
• Other	2 (12.5)	2 (12.5)
Type of aphasia[1]		
• Non-fluent	9 (56.25)	7 (43.75)
• Fluent	7 (43.75)	9 (56.25)
Speech therapy before Intervention[1]	14 (87.5)	10 (62.5)

[1]Number (%); [2]Mean (SD)

forward analytic technique was used to impute the Thai WAB-AQ scores at one month for data from patients who did not complete the 1-month follow-up. Data from patients who dropped out between the 5-day treatment sessions were excluded.

The baseline demographic data of patients are shown in Table 1. Gender, age, education level, underlying disease, dominant hand, type of lesions, location of lesions, and type of aphasia were similar between the two groups. However, the intervention group had a longer mean duration from the

onset of stroke to the treatment than the control group. Specifically, the mean time duration from the onset of stroke was 9.2 months for the intervention group, whereas it was 4.9 months for the control group.

Thai WAB-AQ Score

The intervention groups had slightly higher mean scores of Thai WAB-AQ at baseline than the control group, with 45.44 (SD=28.24) in the intervention group and 43.76 (SD=24.61) in the control group. Post-treatment and one month after treatment, the mean scores of the intervention groups were 51.61 (SD=27.54), 52.12 (SD=27.35), and the mean scores of the control group were 49.97 (SD=28.04), and 52.81 (SD=29.38) (Figure 2) as shown in Table 2. The mean score of Thai WAB-AQ at post-treatment and one month after treatment in both intervention and control groups was statistically significantly higher than the baseline.

After adjusting the baseline of the Thai WAB-AQ score, the adjusted mean difference score between the intervention group and control group were -0.05 (95% CI, -4.37, 4.26) at post-treatment and -2.38 (95% CI, -11.71, 6.95) at one month after treatment (Table 2). However, the difference between the two groups did not reach statistical significance at either time point (Figure 2b).

Spontaneous speech, comprehension, repetition, and naming scores improved post-treatment and one month after treatment compared to baseline. However, there was no statistically significant difference between the groups at both times (Table 2). The side effects of tDCS treatment observed in this study were skin redness in 2 patients, which resolved within 15 minutes. No serious complication was found.

Table 2. Mean score and mean score difference of Thai WAB-AQ score at pre-treatment, post-treatment, and 1-month follow-up between intervention and control groups

Group	The mean score (SD)			Adjusted mean difference changed score, Intervention group-control group (95% CI) at post-treatment	Adjusted mean difference changed score, Intervention group-control group (95% CI) at 1 month
	Pre-treatment	Post-treatment	1 month-follow up		
Thai WAB – AQ					
Intervention	45.44 (28.42)	51.61 (27.54)	52.12 (27.35)	-0.05 (-4.37, 4.26)	-2.38 (-11.71, 6.95)
Control	43.76 (24.61)	49.97 (28.04)	52.81 (29.38)		
Spontaneous speech					
Intervention	8.25 (5.79)	10.13 (5.30)	10.00 (4.47)	0.38 (-1.18, 1.94)	-1.31 (-4.38, 1.76)
Control	8.13 (5.24)	9.63 (5.90)	11.19 (6.60)		
Comprehension					
Intervention	6.45 (2.64)	6.81 (2.66)	6.76 (2.89)	0.00 (-0.50, 0.49)	-0.05 (-0.85, 0.75)
Control	6.03 (2.81)	6.41 (2.58)	6.42 (2.76)		
Repetition					
Intervention	4.91 (3.74)	5.21 (3.69)	5.04 (3.54)	-0.30 (-0.66, 0.07)	0.40 (-1.30, 0.50)
Control	4.38 (3.61)	4.99 (3.79)	4.92 (3.85)		
Naming					
Intervention	3.11 (3.44)	3.65 (3.48)	3.83 (3.48)	-0.07 (-0.61, 0.46)	0.05 (-1.11, 1.22)
Control	3.35 (2.99)	3.96 (3.48)	4.02 (3.39)		

Mean difference changed score = changed score from baseline in the intervention group – changed score from baseline in the control group.

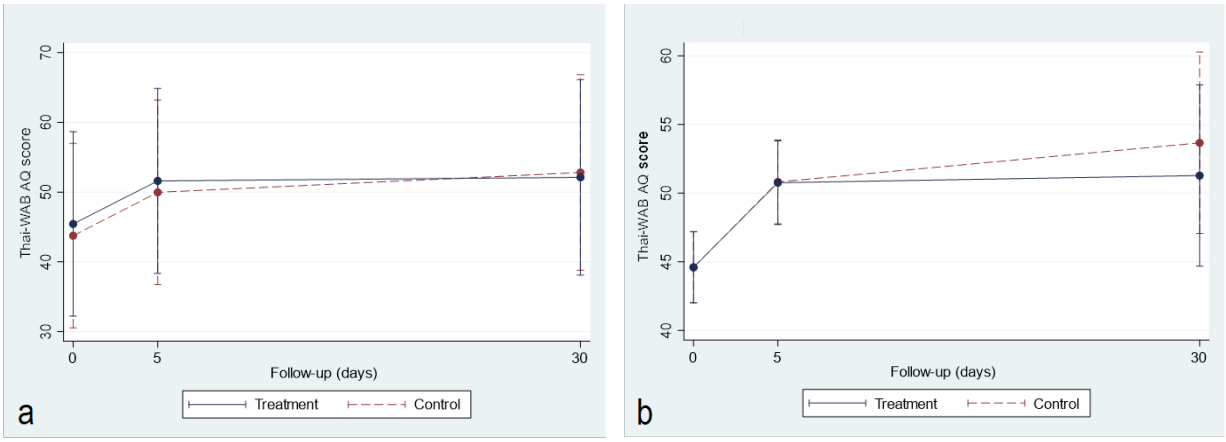

Figure 2. The chart shows the mean score of Thai-WAB AQ at pre-treatment, post-treatment (5 days), and 1-month follow-up (30 days) of intervention and control groups. (a) unadjusted (b) after adjusting the baseline of the Thai WAB score.

Discussion

According to the findings of this study, patients with post-stroke aphasia who received a dosage of 2 mA of anodal tDCS over Broca's area (F5) combined with speech therapy for 20 minutes per session per day for five consecutive days improved in Thai WAB-AQ score at post-treatment and one month after treatment. However, there was no statistically significant difference when compared to the sham-tDCS group. The findings agreed with some previous studies, Polanowska et al.[14] Otal et al.[21] and Fridriksson et al.[12] that showed no significant improvement in language ability between the tDCS group and the control group. However, Fiori et al.[9] Silva et al.[22] Shah-Basak et al.[18] and Baker et al.[8] demonstrated the effectiveness of tDCS in improving the language abilities of patients with post-stroke aphasia. The different results are caused by numerous factors, including the time from onset of the stroke to treatment,[23] the severity of aphasia,[23,24] the dose, and the protocol of tDCS that may influence the effectiveness of tDCS in treating aphasia.

In this study, the mean stroke duration was 9.2 months in the intervention group, whereas it was only 4.9 months in the control group. Both groups showed improvement in language ability after the intervention. However, there was no significant difference between the groups. The improvement in the control group may be associated with spontaneous recovery, which happened in the first six months.[23] Maas MB et al. found that 74% of patients with stroke had the complete resolve of aphasia in six months.[25]

Aphasia severity is a strong predictor of response to the therapy.[24] In this study, the severity of aphasia was assessed using the Thai WAB-AQ. The mean baseline Thai WAB-AQ score of the intervention groups was 45.4, which was classified as a severe degree.[17] This study did not show the superiority of tDCS over the sham group in terms of effectiveness. On the other hand, Shah-Basak et al. conducted a cross-over randomized control trial in patients with a moderate degree of aphasia, with a mean baseline WAB score of 53.3. They reported that tDCS can improve the WAB score significantly compared to the sham group.[18] This difference in results can be attributed to the fact that the patients in the study by Shah-Basak et al. had less severe aphasia, which has a high recovery rate after therapy.[26] Therefore, the severity of aphasia is a crucial factor to consider when evaluating the effectiveness of therapeutic interventions.

This study utilized a dosage of 2 mA of tDCS over Broca's area (F5) combined with speech therapy, with 20 minutes per session, for five days. The dosage was adapted from the study by Fiori et al., who used 1 mA of anodal tDCS at the left Broca's area, 20 minutes per session per day, for five days. Their finding showed that this dose can enhance the naming accuracy in patients with aphasia.[9] However, our study found no significant difference in the improvement of language ability between the tDCS group and the sham group. There existed a wide range of doses of tDCS which showed the effective improvement of language ability, including 2 mA, 30 min, 10 days,[27] 2 mA, 20 min, 10 days,[18] 1 mA, 20 min, 5 days,[8, 9] or 1 mA, 20 min 1 day.[28] Nevertheless, some previous studies showed no effect of tDCS despite selecting the high dose of tDCS. For example, Fridriksson et al. administered 1 mA, 45 minutes 15 days of anodal tDCS,[12] and Polanowska et al. used 1 mA, 10 min 15 days of tDCS.[14] Even though the intensity of tDCS can be precisely determined, the amount of current that reaches the affected site may vary among individuals due to various factors such as the size and shape of the skull, scalp characteristics, and hair length. The amount of current at the target site may differ in each patient and not achieve the therapeutic effect in some cases.[29]

The selection of polarity of tDCS has been a controversial issue. Anodal stimulation at the affected site was selected in this study because it is understood to be effective and safe. Inhibiting the unaffected hemisphere by the cathode might be harmful when it is compensatory.[30] Furthermore, Rosso et al. conducted a meta-analysis. They found that the improvement of naming accuracy among individuals with post-stroke aphasia following anodal stimulation was more remarkable compared to cathodal stimulation.[31] Meinzer et al. also found that functional communication significantly improved more in the anodal tDCS group immediately after treatment and six months after treatment than in patients treated with sham tDCS.[32] However, Silva et al. applied the cathodal tDCS over the right Broca's area (F8) with a dose of 2 mA, 20 minutes per session on five consecutive days: the same dose but different polarity as our study. The improvement in correct naming was found to be significant in the tDCS group.[22] Fregni et al. reported that enhancing excitability at the affected site is more difficult than diminishing excitability at the unaffected site.[33] Thus, this may be why this study showed no significant difference between the tDCS and the sham groups.

In this study, patients with various brain lesions were enrolled, and Broca's area (F5) was selected as the stimulation site for all patients using tDCS. This decision was based on the effective nature of tDCS in a wide area. Fiori et al. also chose the left Broca's area and found a significantly different improvement in verb naming in the tDCS group compared to the sham group.[9] However, direct electrode placement on the lesion site would result in a favorable therapeutic outcome. Baker et al. selected areas for anodal tDCS based on functional magnetic resonance imaging (fMRI) activity during language tasks. Research demonstrated a significant improvement in the naming accuracy of treated items with tDCS compared to sham tDCS.[8] Nevertheless, Fridriksson et al. also placed the anodal electrode at the target area based on fMRI. However, significantly different improvements in correct naming were not found between the tDCS and sham groups.[12] The target area applying the electrode is still considered controversial. Therefore, future studies should be investigated.

Thai-WAB-AQ was selected to be the assessment tool in this study due to the reliability used in the Thai context with its focused questions, scoring system, and questionnaires based on the patient's daily life. In addition, previous studies[8,18] using this assessment tool detected the effectiveness of tDCS in improving language ability. Unfortunately, this assessment tool did not detect highly sensitive indicators such as response time. Polanowska et al. found that the anodal tDCS group obtained larger effect sizes in naming time than the sham tDCS group.[14] Silva et al. discovered a significant difference in the meantime for correct responses with strategy between the tDCS group and the sham group.[22] Also, Thai-WAB-AQ had a lengthy evaluation process, which lasted approximately 30 minutes. Some patients reported fatigue, and their decreased cooperation during the final assessment sessions could have compromised the results' accuracy.

Several limitations occurred during this study. First, many patients dropped out of this study. Therefore, more than the number of samples included in this study would be required to demonstrate the superiority of anodal-tDCS over sham-tDCS. Second, the patients in this study showed heterogeneous clinical features in terms of time from the stroke onset, type and severity of aphasia, and brain lesion site. This characteristic was seen in the actual situation in clinical practice. However, it made the result restricted in applied generalizability. Third, the assessment tool needed to be more sensitive to detect the differences between the two groups. The tool should have a response time to language tasks, particularly in naming. Finally, the one-month duration may have been inadequate to detect the therapeutic effect of tDCS. A longer-term follow-up study may reveal a greater degree of improvement.

Conclusions

This study did not show sufficient evidence to support anodal tDCS concurrent speech therapy with additional improvement in language ability beyond those observed in patients undergoing speech therapy alone, among those with post-stroke aphasia.

Disclosure

The authors declare no conflicts of interest.

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