# RESEARCH



# The effect of transcranial direct current stimulation paired with neuromuscular electrical stimulation on swallowing function in post stroke dysphagia

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# Abstract

**Background** Transcranial direct current stimulation (tDCS) and neuromuscular electrical stimulation (NMES) are noninvasive neuromodulation techniques that have shown positive effects in a variety of neurological disorders. Most protocols apply one modality at a time. Here we tested the effect of tDCS applied together with NMES on patients with dysphagia after acute stroke. To assess the efficacy of combined tDCS and NMES on improvement of dysphagia after acute stroke, guided by Fiber-optic endoscopic evaluation of swallowing (FEES). This study is a double-blinded randomized case-controlled study conducted in a University hospital. This study enrolled 48 patients diagnosed by FEES and assigned to 3 groups of 16 patients each. The first group received both tDCS and NMES, the second group received NMES only and the third group received sham NMES. Gugging Swallowing Screen (GUSS) test was done before and after intervention.

**Results** Significant improvement was seen in all tested materials on GUSS test in tDCS/NMES group. While in the other two groups, there was only improvement for safety of liquid swallowing.

**Conclusion** This study shows that the combined application of tDCS and NMES has an advantage in improvement of PSD over active NMES and sham NMES groups in all materials tested by GUSS.

Keywords PSD, FEES, GUSS test, tDCS, NMES

## Background

Dysphagia is a symptom of swallowing dysfunction defined as difficulty to form or move the alimentary bolus safely from mouth to stomach [4].

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It is a commonly documented morbidity after stroke, with a frequency that can reach up to 50% [18]. Additionally, patients with dysphagia have a fourfold risk of developing pneumonia, longer hospital stay, discharge to nursing homes and even increased mortality rate [11, 14, 19].

There is evidence that early detection of dysphagia in patients with acute stroke not only reduces complications, and hospital stay, but also reduces the overall healthcare expenditures [18].

Currently, the clinical guidelines for management of dysphagic patients depend mainly on compensatory



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strategies or postural changes to try to prevent complications [5].

However, there is a recently growing interest in including non-invasive stimulation in dysphagia management. The commonly used techniques are repetitive transcranial magnetic stimulation (rTMS), transcranial directcurrent stimulation (tDCS), neuromuscular electric stimulation (NMES), as well as paired associative stimulation (PAS), that was applied experimentally in the treatment of PSD [21].

tDCS uses a weak direct current to modulate the activation of sodium- and calcium-dependent channels and NMDA receptor activity and enhance or depress excitability depending on the duration and polarity of stimulation [28]. While NMES is a non-invasive technique, where an electrical current is applied to the targeted muscle groups via electrodes placed on the surface of the skin [2]. NMES is thought to improve dysphagia by strengthening muscles of deglutition via depolarization of nerve endings within muscles leading to muscle contraction. Additionally, NMES can stimulate the ascending sensory tracts to enhance reorganization of cortical motor areas for deglutition [3].

In the current study we aimed to assess the efficacy of tDCS combined with NMES in management of PSD. The primary end point was to shift from severe/moderate to mild/normal category on total GUSS in patients with dysphagia. The secondary end point is to achieve a significant improvement on total GUSS.

### Methods

#### Study design

This is a double-blind randomized case controlled study conducted in the Ain Shams university hospital (stroke unit) and in phoniatric department clinic at Ain Shams University hospital.

#### Subjects

The required sample size was calculated using G\*Power software version 3.1.0. The primary objective of the current study was to compare the mean (FEES) and the mean functional assessment scales of dysphagia between the three study groups. Assuming a type I error of 0.05, and 80% power, a sample size of 20 participants, in each study group will be needed to detect an effect size (f) of 0.42 in the primary outcome of interest.

Patients included were above 18 years of age, had PSD within 2 weeks of stroke onset, presenting with right middle cerebral artery territory or brainstem stroke, and both ischemic and hemorrhagic strokes were included. Patients were excluded if they had disturbance of consciousness, any contraindications for NIBS as brain surgeries or skull defects, seizures, medical implantation,

scalp or skin disease and pregnancy. Also, those with preexisting dysphagia due to any neurological or non-neurological causes were excluded.

A total of 48 patients were recruited. All patients were diagnosed as acute stroke by clinical history and examination then confirmed by CT scan on admission and MRI brain after 2 to 3 days, as per stroke unit protocol.

Assessment of swallowing was done initially by GUSS test and FEES, and follow up by GUSS. The examining physicians were blinded for the type of intervention. GUSS test was previously reported as a valid and reliable screening test for swallowing in patients with dysphagia [1].

It is composed of two parts: a non-swallow clinical screening test followed by a direct bolus-swallowing screening test. The first part consists of the ability to maintain vigilance for 15 min, produce a voluntary cough and successfully swallow saliva without voice change or drooling.

Those who passed the first part of the GUSS entered the second part, which evaluates swallowing performance with three different consistencies starting with the non-liquid, liquid (water) and then solid (dry bread).

The second part was prematurely terminated if one of the four aspiration signs was observed (delayed or absent deglutition, coughing, drooling and voice change). The GUSS scores yield 4 categories of severity. Zero to 9 points are rated severe, 10 to 14 points moderate, 15 to 19 points mild, and 20 points no dysphagia.

According to GUSS scores for aspiration risk, the patients in each group were categorized to unsafe swallowing (0-14) and safe swallowing (15-20) [1].

#### **Ethical approval**

The study was approved by the IRB of the hospital and all patients gave an informed consent for participation in the study. The ethical approval number FWA 0000 17585.

Fibro-optic endoscopy evaluation of swallowing (FEES): Laryngoscope (OLYMPUS MEDICAL SYSTEMS CORP, Model UL 60601-1, manufactured by MAF-GM, flexible endoscope, Tokyo, Japan)attached to a CCD camera and a color monitor was used. Any pooling or aspiration was noted for saliva, graded volumes of water, semisolids and solids.

Penetration is defined as any material entering the laryngeal vestibule but remaining at or above the level of the vocal cords and aspiration is defined as penetration of material below the level of the vocal cords [8].

For intervention, patients were assigned to 3 groups of 16 patients each by randomly generated treatment allocations with sealed opaque envelopes. The first group received active tDCS concomitantly with NMES (tDCS/NMES) with both devices applied and started simultaneously for a preset duration of 20 min. The second group received active NMES only and the third group received sham NMES.

tDCS was delivered by a direct current stimulator (ActivaDoseII) model P/N 001-48 Rev A, manufactured by ActivaTek Inc. in Taiwan. The device has two rubber electrodes (5 cm \* 3 cm) covered in saline-soaked sponge were placed on the scalp. The anode was placed over the left pharyngeal motor area 7 cm lateral and 4 cm anterior to Cz and the cathode over the right shoulder. Placing the cathode on an extracephalic site was to exclude the effect of the reference electrode on cortical modulation [17].

The 2 electrodes were secured using rubber bands. Stimulation intensity was set at 1.5 mA for 20 min per session, to be repeated for six daily sessions [7].

NMES was given by 4 of self-adhesive electrodes (50\*50 mm); 1pair placed bilaterally sub-mentally and the other pair on either side of the thyroid cartilage, aiming at simultaneous stimulation of suprahyoid and infrahyoid muscles [6]. Electric current delivered was biphasic, fixed at 80 Hz, of pulse duration 700 us with adjustable intensity up to 25 mA. Intensity was set to the maximum tolerable by the patient. Session duration was 20 min, daily for six sessions.

Sham NMES was delivered by applying the same procedure as active NMES except for using non-conductive electrodes. The patients were informed that they might or might not perceive tingling sensation and all patients were naïve for NMES.

Statistical analysis was done using SPSS version 19th version Statistics (SPSS Inc., Chicago, 2011). The Shapiro-Wilks test was performed to test the normality of continuous data distribution. Median and interquartile range (IQR) were used for skewed data, whereas categorical data were presented as frequencies. Kruskal–Wallis test used to compare not normally distributed continuous variable with nominal independent variables. The chi-square test was used for comparison of nominal data. For comparison of groups effect size, since the three groups are of equal numbers, we used Cohen's d and Glass' Delta according to differences in standard deviations among groups.

#### Results

Demographic data of both groups are shown in Table 1.

Comparison of GUSS results at baseline among the three groups showed non-significant differences for swallowing of different consistencies, total GUSS score and severity of dysphagia (Table 2).

Comparing each group for the number of patients who shifted from categories moderate/severe to normal/mild showed significant shift only in DCS/NMES group, p: 0.004 (Table 3).

Table 1	Demograph	ic data and	risk factors
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	DCS/NMES	Active NMES	Sham NMES
	No: 16	No: 16	No: 16
Age (years) mean±SD Range	63.67±13.70 (43-95)	66.07±12.70 (42-88)	59.44±13.93 (17-77)
Sex (females)	10 (62.5%)	5 (31.3%)	9 (56.3%)
Smoking	5 (31.3%)	7 (43.8%)	7 (43.8%)
Diabetes	8 (50.0%)	10 (62.5%)	3 (18.8%)
Heart disease	3 (18.8%)	9 (56.3%)	6 (37.5%)
Hypertension	14 (87.5%)	14 (87.5%)	7 (43.8%)
Previous stroke	7 (43.8%)	3 (18.8%)	3 (18.8%)

Also, comparison of total GUSS score before and after intervention among the 3 groups showed that only DCS/ NMES group showed significant improvement,  $P \le 0.001$  with 95% CI 2.6–7.1 (Table 4).

Effect size for one-way ANOVA using group mean information showed that for intergroup effect size, the overall effect size was f=0.792.

Group DCS/NMES versus sham NMES showed the highest inter-group effect size: f = -2.1, 95% CI -2.1, -0.04. The effect size for DCS/NMES vs active NMES is f = -0.63, 95% CI -1.637, 0.371. The effect size for active NMES vs sham NMES is f = -0.57, 95% CI -1.5, 0.42.

We also tested if there was a correlation between FEES and GUSS test at baseline. Table 5 and Fig. 1 show a significant correlation between results of FEES and GUSS test in evaluation of dysphagia for semisolid and solid material (p=0.001). While there was an insignificant correlation for liquid material (P=0.18).

#### Discussion

Early treatment of dysphagia aims to reduce complications and enhance spontaneous recovery of swallowing function [25].

Several physiological and neuroimaging studies have demonstrated the involvement of cortical areas in the function of swallowing. Accordingly, cortical reorganization for recovery of dysphagia has been studied and adopted as a basis for management. Central and peripheral neurostimulation techniques were explored [5], and either tDCS or NMES were used in isolation for management of post-stroke dysphagia.

In the current study we explored the advantage of applying tDCS with NMES; thus combining both central and peripheral stimulation for the treatment of dysphagia. We compared this technique with active NMES and sham NMES.

As tDCS was studied before showed significant results as adjuvant to other modalities so we choose to study it's combination with peripheral stimulation, and wanted to

GUSS before		DCS/NMES	Active NMES	Sham NMES	Test value	P-value
		No. = 16	No. = 16	No. = 16		
Preliminary	Median (IQR)	4 (3–4.5)	4 (2–4)	3.5 (2.5–4.5)	1.048 <sup>c</sup>	0.306
	Range	2–5	1-5	2–5		
Liquid	Median (IQR)	1.5 (1–2)	1.5 (1–3)	2.5 (2-3)	0.201 <sup>c</sup>	0.654
	Range	1–3	1–4	0-4		
Semisolid	Median (IQR)	3 (2.5–4.5)	4 (3–5)	4 (3.5–5)	0.638 <sup>c</sup>	0.425
	Range	1–5	1–5	0–5		
Solid	Median (IQR)	3.5 (3–4.5)	4 (3–5)	4.5 (3.5–5)	682 <sup>c</sup>	0.409
	Range	2–5	1–5	0–5		
Total	Mean ± SD	$12.0 \pm 3.50$	$13.06 \pm 4.22$	13.68±4.77	0.661 <sup>b</sup>	0.521
	Range	5–17	4–19	2-18		
GUSS categories	Severe	3 (18.8%)	3 (18.8%)	2 (12.5%)	2.476 <sup>a</sup>	0.649
	Moderate	9 (56.3%)	6 (37.5%)	6 (37.5%)		
	Mild	4 (25.0%)	7 (43.8%)	8 (50.0%)		
	No	0 (0.0%)	0 (0.0%)	0 (0.0%)		

#### Table 2 Comparison of GUSS results at baseline among the three groups

Severe (0–9), moderate (10–14), mild (15–19), no dysphagia (20) P-value > 0.05: non significant; P-value < 0.05: significant; P-value < 0.01: highly significant

<sup>a</sup> Chi-square test

<sup>b</sup> Paired t-test

<sup>c</sup> Wilcoxon test

NMES : Neuromuscular Electrical Stimulation, DCS : Direct-current stimulation

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	DCS/NMES		Active NMES		Sham NMES					
	Before	After	Before	After	Before	After				
Moderate/severe	12	4	9	5	8	3				
Normal/mild	4	12	7	11	8	13				
P value	0.004		0.15		0.13					

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Total GUSS	Before	After	Difference	95% CI	t	Р
DCS/NMES	12 (3.5)	16.9 (2.8)	4.9 (3.6)	2.6, 7.1	4.3	0.0001
ActiveNMES	13.06 (4.2)	16.1 (4.78)	3 (2.25)	-0.2, 6.2	1.9	0.06
ShamNMES	13.68 (4.77)	15.6 (5.18)	1.92 (1.4)	- 1.6, 5.4	1	0.2

apply different techniques in management of post-stroke dysphagia.

Our results showed that only patients in tDCS/NMES group reached the primary and secondary endpoints. They showed shift from severer to milder categories of dysphagia, as well as significant improvement on total score of GUSS. As for evaluation of the effect size between groups, there was a perceivable effect in favor of DCS/NMES compared with sham NMES alone. However, although not very large, still there was an effect size for DCS/NMES compared to active NMES, and even a modest effect was found for active NMES versus sham NMES. This implies that although pairing central and peripheral stimulation is superior, yet still peripheral stimulation alone is better than sham stimulation.

Several previous studies have reported on the effect of NIBS. Jefferson et al. [9] found that anodal stimulation increased cortical excitability while cathodal stimulation induced inhibition of pharyngeal cortical area. They concluded that anodal stimulation might beneficially

#### Liquid by GUSS before Liquid by FEES before T-value P-value No Yes % % n n Unsafe 4 80.0% 41 95.3% 1.801 0.180 Safe 1 20.0% 2 4.7% Semisolid by GUSS before Semisolid by FEES before T-value P-value No Yes n % n % Unsafe 2 7.7% 18 81.8% 26.939 0.001 Safe 24 92.3% 4 18.2% Solid by GUSS before Solid by FEES before T-value P-value No Yes n % n % Unsafe 6 16.7% 12 100.0% 26.667 0.001 Safe 30 83.3% 0 0.0%

#### Table 5 Correlation between FEES and GUSS test in evaluation of dysphagia before intervention

Chi-square test



Fig. 1 Correlation between FEES and GUSS test in evaluation of dysphagia

enhance recovery of dysphagia patients through stimulating pharyngeal cortex.

In line with this, it has been reported that ipsilesional anodal tDCS together with conventional swallowing therapy resulted in significant improvement of patients [23, 26]. Moreover, bilateral stimulation was found to be even more effective than unilateral stimulation [27]. Also, in the context of NIBS, rTMS has been combined with NMES and proved to be superior to NMES alone in functional recovery of dysphagia [29], and despite improvement of the group of NMES with sham rTMS, yet still NMES with real rTMS was significantly better, and this nicely agrees with our findings regarding tDCS and NMES. Similarly, Michou et al. [20] showed that the excitability of pharyngeal cortex was modulated mostly by pharyngeal electrical stimulation, paired associative stimulation but to a lesser extent by TMS alone.

To our knowledge, the current study is the first to combine tDCS with peripheral stimulation. The differential improvement combining central with peripheral sensorimotor stimulation can consolidate relearning to a level unachievable by either of these modalities alone [13] of the tDCS/NMES group reported here, can be explained in view of evidence indicating that.

It has also been reported that various protocols of either inhibition of intact hemisphere or stimulation of lesioned hemisphere showed favorable results [10, 12, 22, 24].

In contradistinction, Kumar et al. [13] delivered anodal tDCS to the intact hemisphere with favorable results. The pharyngeal motor area was found to be bilaterally represented [15, 16], thus recovery of deglutition might occur from either the lesioned or intact hemisphere. Consequently, we found it more plausible to stimulate the intact hemisphere (left side in our cases) since inhibition of the intact pharyngeal motor area might possibly deter recovery if plasticity was intended to arise from the healthy side. In addition, it is safer to stimulate the intact hemisphere in cases of cortical strokes to avoid any epileptogenesis.

It is worth mentioning that most past studies have combined NIBS or NMES with swallowing therapies. Thus, it is not clear whether improvement stemmed from stimulation or from behavioral therapy. Moreover, in everyday clinical practice we are commonly unable to introduce any form of oral intake for some patients to avoid aspiration.

So, in the current study we intentionally investigated the sole effect of stimulation without any behavioral training. Consequently, we could conclude that combining central and peripheral stimulation can safely improve dysphagia without pairing it with any form of swallowing exercise.

In the second part of the study we tried to explore if the yield of the initial assessment by GUSS was consistent with the assessment by FEES. Both of them showed correlation for detection of dysphagia for semisolid and solid material, but not for liquids. This denotes that GUSS is a bedside screening test, yet it cannot identify silent aspiration and still clinicians need a more objective test as FEES.

Some limitations was applied to this study: First, the number of patients is relatively small and might result in low statistical power for detecting significant differences between subgroups. Second, in this study, FEES was not repeated after intervention thus outcome could not be precisely evaluated. However, in the context of a stroke center, it was not feasible to keep patients hospitalized till performing a second FEES.

#### Conclusion

This study showed that using both tDCS/NMES had an advantage over NMES and Sham NMES in management of PSD. Thus, tDCS is an effective adjuvant strategy to improve swallowing function in PSD.

#### Abbreviations

CCD Charge coupled device

- Cz Cranial vertex
- FEES Flexible endoscopic evaluation of swallowing
- GUSS Gugging Swallowing Screen
- MRI Magnetic resonance image
- NIBS Noninvasive brain stimulation
- NMES Neuromuscular electrical stimulation
- PSD Post-stroke dysphagia
- rTMS Repetitive transcranial magnetic stimulation
- SD Standard deviation
- SPSS Statistical package for social science
- tDCS Transcranial direct-current stimulation
- TENS Transcutaneous electrical neuromuscular stimulation

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#### Author contributions

SH: data collection and research project execution. MF: contribution to the concept and design, drafting the manuscript. AA: conception of the work, manuscript revision. ED: acquisition of data and analysis of data. EH: analysis and interpretation of data. HA: conception of the work, approved the version to be published. NE: conception and design, revised the manuscript critically for important intellectual content. All authors have agreed to conditions noted on the Authorship Agreement Form and have read and approved the final version submitted. The content of the manuscript has not been published, or submitted for publication elsewhere.

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#### Availability of data and materials

All raw data will be available on the editor request through communication with the corresponding author.

#### Declarations

#### Ethics approval and consent to participate

All procedures performed in the study were in accordance with the ethical standards of the faculty of medicine, Ain Shams university research and ethical committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. We obtained approval from research ethics committee no. FWA 0000 17585. On 22/3/2021. Written informed consent was obtained from participants for participation. We obtained approval from research ethics on 2/3/2021.

#### **Consent for publication**

Not applicable.

#### **Competing interests**

All authors declare that they have no conflict interest.

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