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The role of transcranial direct current stimulation in diminishing the risk of pneumonia in patients with dysphagia: A double-blinded randomized clinical trial

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Keywords
Deglutition; Stroke; Electrical Stimulation; Transcranial Direct Current Stimulation; Randomized Clinical Trial; Dysphagia; Pneumonia

Abstract

Background: Dysphagia can be a life-threatening issue for post-stroke patients, with aspiration pneumonia (AP) being a common risk. However, there is hope through the potential combination of transcranial direct current stimulation (tDCS) and classical behavior therapy. Our study aims to investigate the effectiveness of this combination in diminishing the risk of AP in patients with dysphagia who suffered from stroke.

Methods: In this randomized, parallel-group, blinded clinical trial, 48 patients were allocated into the sham group (speech therapy + 30 seconds of tDCS) and the real group (speech therapy + 20 minutes of tDCS). We used the Mann Assessment of Swallowing Ability (MASA) as an assessment tool. We assessed patients at baseline, one day after treatment, and at a one-month follow-up.

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Results: Groups showed no significant difference at baseline. After treatment, the real group showed a significant difference in the severity risk of AP (P = 0.02); the same was for the follow-up (P = 0.04). The number of patients showing severe risk of AP was higher in the sham group after treatment (n = 13, 54.20%) and at follow-up (n = 4, 18.20%) than the real group (n = 4, 16.70%; n = 1, 4.50%, respectively). None of the patients reported the history of AP at any stage of assessment.
Conclusion: Although the results were more promising in the real group than the sham group in reducing the risk of AP, both techniques can prevent AP. Therefore, we recommend early dysphagia management to prevent AP regardless of the treatment protocol.

Introduction

Long-term disability is a common consequence of stroke, with both hereditary and environmental risk factors.[1,2] Studies showed that pneumonia such as aspiration pneumonia (AP) was a leading cause of approximately 35% of death in patients with acute stroke.[3,4] AP has been found in 20% of stroke patients in their first days after stroke and it is the first cause of death during the first year after stroke.[5] Besides the life-threatening aspects of AP in stroke patients, studies showed that the total medical cost and hospitalization cost were significantly higher in stroke patients with AP compared with the stroke patients without it.[6]

Dysphagia is an important cause of AP after stroke. Stroke patients with dysphagia demonstrated 3 to 11 fold increased chance of developing AP compared with the stroke patients without dysphagia.[7,8] To mitigate this risk, experts suggest managing dysphagia[9,10] with behavioral therapies, such as speech therapy techniques.[9] Although these techniques have promising results, they have some limitations such as a large number of treatment sessions to achieve the desired outcome and the reduction of patient's adherence to finish their therapy sessions.[11,12] Therefore, scientists recommend that these techniques be complemented with other neurorehabilitation techniques such as transcranial direct current stimulation (tDCS) to gain the best results.[11,13]

According to multifactorial nature of AP,[14] we do not know whether implementing speech therapy with tDCS has the same effect on AP prevention, like improving dysphagia, or not. According to our knowledge, there is no study to compare the effectiveness of speech therapy alone with speech therapy complemented with tDCS in decreasing the risk of AP in patients with dysphagia who suffered from stroke. Therefore, the aim of this study was to compare the effectiveness of two protocols of dysphagia therapies in reducing the risk of AP in these patients.

Materials and Methods

This study was conducted in the hospitals affiliated to Shiraz University of Medical Sciences, Shiraz, south of Iran. We designed a randomized, parallel-group, blinded clinical trial and recruited forty-eight patients with ischemic stroke in the acute/subacute phase at 18 years old or more for the study according to inclusion/exclusion criteria. This study derived from a larger one, and the detailed methodology is reported in our published article, Farpour et al.[15] All patients with ischemic stroke were recruited according to the guidelines for the early management of patients with acute ischemic stroke.[16] The patients with dysphagia were screened based on the Northwestern Dysphagia Patient Check Sheet Screening (NDPCS) and were recruited for the study.[17] Patients under 18 years old, with other neurological disorders than ischemic stroke and neurodegenerative diseases as well as those who reported a previous history of dysphagia, with a tracheal cannula, altered level of consciousness, severe uncontrollable medical condition, and auditory or visual conditions interfering in the intervention process were excluded. Moreover, we excluded the patients who had the risk of interference with tDCS.[15]

All the included patients or their caregivers/families signed the informed consent form. The Ethics Committee of Kerman University of Medical Sciences, Kerman, Iran (IR.KMU.REC.1399.366) approved the study. This study was registered in the Iranian Registry of Clinical Trials (IRCT20200520047521N1). We randomly allocated patients to the real group or the sham group. The allocation was done by a secretary according to the table prepared by random allocation software before starting the study. Using this method, each patient had a 1:1 chance of being included in each group. The secretary wrote the names of groups on an envelope and gave it to the trained nurse who set up the tDCS montage.

All the patients received 20 minutes of speech therapy online with the tDCS for five sessions (once a day). The difference between groups was the duration of tDCS stimulation, 20 minutes of stimulation in the real group versus

30 seconds in the sham group.[15] Applying this procedure, patients/families/caregivers and the speech therapist were kept blinded to the groups of patients.[15] At the end of treatment, the speech therapist provided the patients/families/caregivers with consultations regarding the compensation strategies, and the behavioral techniques delivered for 10 minutes.[15]

Electric stimulation was given via a stimulation device (NeuroStim 2, Medina Teb Gostar Company, Iran). We used two carbon pad electrodes covered by saline-soaked sponges. We placed 4*4 cm anode electrode on the supramarginal gyrus (CP5 or CP6),[18] and 4*6 cm reference electrode on the contralateral supraorbital region. The current intensity was 2 mA. We placed the anode electrode on the right hemisphere in the brainstem stroke patients.[10,15,19] The neurologist of the team determined the placement of the anode electrode.

In this study, one day after finishing the treatment, we reassessed all the patients. We also reassessed the patients after a month. The assessor, speech therapist, patients, families, or caregivers were blinded to the grouping of the patients. We recorded the history of AP during the treatment phase and after one month, that was confirmed by the physician. We also recorded the history of nasogastric (NG) tube feeding or percutaneous endoscopic gastrostomy (PEG) feeding. We determined the severity of the ischemic stroke and the severity of dysphagia and aspiration by the National Institutes of Health Stroke Scale (NIHSS) score and the Mann Assessment of Swallowing Ability (MASA) scale, respectively.

We used SPSS statistics software (version 20, IBM Corporation, Armonk, NY) to analyze the data. Descriptive statistics were reported by mean and standard deviation (SD) or number (percentage). After testing the normality of data by Kolmogorov-Smirnov test, we used Mann-Whitney U and Friedman tests in both between groups and within groups with scale data. For categorical data, we used chi-square test or Fisher's exact test to compare the groups. The significance level was ≤ 0.05.

Results

According to our inclusion/exclusion criteria, 48 patients enrolled in the study. All 48 patients finished the treatment phase, and the assessor reassessed them one day post-treatment. In the follow-up reassessment phase, four patients were not assessed because of cardiac arrest (3 patients) and not answering the phone to organize the follow-up assessment (1 patient).

The mean age of the included participants was 67.96 (SD: 15.98, minimum: 24.00, maximum: 94.00). Most of the patients were elderly people who were ≥ 65 years old (64.60%). Twenty-six patients (54.20%) were men. Few patients (18.80%) reported a previous history of coronavirus disease 2019 (COVID-19), and most of the patients (n = 33) were NG tube-fed (68.80%).

No patient reported unintended weight loss before stroke at baseline. Twenty-six patients (54.20%) had all their teeth, 19 (36.90%) wore complete dentures, 2 (4.20%) had some teeth (≥ 10), and 1 (2.10%) patient had no teeth. Only 7 patients (14.60%) did not use a toothbrush every day, while most of the patients brushed their teeth at least once a day (85.40%). Most of the patients (n = 32) did not use dental floss every day (66.70%) and only a few of them (33.30%) used dental floss at least once a day before their stroke.

According to the demographic and primary outcome measures at baseline, no significant difference was found between the groups (Table 1).

According to within-group statistics of the MASA score, both groups improved significantly (P < 0.001) after treatment (the sham group mean score: 137.87 ± 35.75; the real group mean score: 170.46 ± 27.29) and after a one-month follow-up (the sham group mean score: 154.00 ± 39.28; the real group mean score: 186.91 ± 16.31).

According to between-group statistics, the severity of dysphagia and aspiration differed significantly in the sham group with the real group at one day after finishing the treatment. The result was the same for a one-month follow-up as well (Table 2).

After treatment, an improvement was found regarding the decrease in the number of the patients who were fed by NG tube [the sham group: n = 13 (54.20%); the real group: n = 7 (29.20%)]. These data were significantly lower compared to data from baseline (P < 0.001). Regarding the between-group statistics in this domain, no significant difference was found between groups at this stage (P = 0.08). After a one-month follow-up, the number of patients who were fed by NG tube in the real group (n = 1, 4.20%) was significantly lower (P = 0.046) than the number of patients in the sham group (n = 7, 31.80%).

History of AP which was confirmed by the physician was not reported in the hospital files of the patients nor by the patients/families or their care givers and nurses after 5 days of treatment.

Table 1. The comparison between groups regarding demographic data and primary outcome measures at baseline

Data	Characteristics	Sham group (n = 24)	Real group (n = 24)	P
Demographic characteristics	Age (year) (mean ± SD)	69.92 ± 17.97	66.00 ± 16.08	0.35
	Sex (male) [n (%)]	11 (45.8)	15 (62.5)	0.25
	COVID-19 history [n (%)]	5 (20.8)	4 (16.7)	NS
	Right-handedness [n (%)]	22 (91.7)	24 (100)	0.49
	Dental status [n (%)]			0.75
	Having all the teeth	12 (50.0)	14 (58.3)	
	Having some teeth	1 (4.2)	1 (4.2)	
	No teeth	1 (4.2)	0 (0)	
	Wearing complete denture	10 (41.7)	9 (37.5)	
	Tooth brushing [n (%)]			0.06
	3 times a day	3 (12.5)	11 (45.8)	
	2 times a day	7 (29.2)	6 (25.0)	
	Once a day	10 (41.7)	4 (16.7)	
	Not every day	4 (16.7)	3 (12.5)	
	Using dental floss [n (%)]			0.23
	3 times a day	1 (4.2)	5 (20.8)	
	2 times a day	4 (16.7)	2 (8.3)	
	Once a day	3 (12.5)	1 (4.2)	
	Not every day	16 (66.7)	16 (66.7)	
	Previous history of stroke [n (%)]	6 (25.0)	5 (20.8)	0.73
	Region of stroke [n (%)]			0.20
	Cortical	24 (100)	21 (87.5)	
	Brainstem	0 (0)	2 (8.3)	
	Multiple	0 (0)	1 (4.2)	
	Cortical side of stroke [n (%)]			0.60
	Right	11 (45.8)	9 (37.5)	
	Left	12 (50.0)	12 (50.0)	
	Both	1 (4.2)	0 (0)	
	Severity of stroke [n (%)]			0.91
	Moderate	12 (50.0)	12 (50.0)	
	Moderate to severe	8 (33.3)	7 (29.2)	
	Severe	4 (16.7)	5 (20.8)	
	NIHSS score (mean ± SD)	16.00 ± 5.12	14.37 ± 5.17	0.62
	Days after stroke to be included in the study (mean ± SD)	4.33 ± 3.83	4.42 ± 4.00	0.90
Primary outcome measures	MASA score (mean ± SD)	118.87 ± 36.20	123.62 ± 38.48	0.62
	Dysphagia severity [n (%)]			NS
	Mild	3 (11.5)	3 (11.5)	
	Moderate	9 (37.5)	9 (37.5)	
	Severe	12 (50.0)	12 (50.0)	
	Aspiration severity [n (%)]			0.16
	Nil abnormality	3 (12.5)	2 (8.3)	
	Mild	2 (8.3)	8 (33.3)	
	Moderate	3 (12.5)	1 (4.2)	
	Severe	16 (66.7)	13 (54.2)	

NS: Not significant; NIHSS: National Institutes of Health Stroke Scale; MASA: Mann Assessment of Swallowing Ability; SD: Standard deviation; COVID-19: Coronavirus disease 2019

In addition, none of the patients reported the history of AP at one-month follow-up.

Discussion

Studies show that dysphagia can increase the future risk of AP.[7,20] In this study, our aim was to compare two protocols of dysphagia therapy in reducing the risk of AP. According to our results, both speech therapy and speech therapy combined with tDCS showed promising results in reducing the risk of AP. Dysphagia is a major health problem which has the potential to increase the risk of malnutrition, dehydration, and poor oral health.[21]

Table 2. Comparison of severity of dysphagia and aspiration between groups after treatment and at one-month follow-up

Reassessment time	Variables	Sham [n (%)]	Real [n (%)]	P
One day (after treatment) (n = 48)	Dysphagia severity:			0.01
	Nil abnormality	4 (16.7)	12 (50.0)	
	Mild	4 (16.7)	2 (8.3)	
	Moderate	3 (12.5)	6 (25.0)	
	Severe	13 (54.2)	4 (16.7)	
	Aspiration severity:			0.02
	Nil abnormality	7 (29.2)	14 (58.3)	
	Mild	4 (16.7)	3 (12.5)	
	Moderate	0 (0)	3 (12.5)	
	Severe	13 (54.2)	4 (16.7)	
One-month (follow-up) (n = 44)	Dysphagia severity:			0.02
	Nil abnormality	6 (27.3)	15 (68.2)	
	Mild	4 (18.2)	4 (18.2)	
	Moderate	8 (36.4)	3 (13.6)	
	Severe	4 (18.2)	0 (0)	
	Aspiration severity:			0.04
	Nil abnormality	10 (45.5)	18 (81.8)	
	Mild	4 (18.2)	3 (13.5)	
	Moderate	4 (18.2)	0 (0)	
	Severe	4 (18.2)	1 (4.5)	

On the other hand, the combination of dysphagia, malnutrition/dehydration as well as poor oral health may increase the risk of developing AP; therefore, a multidisciplinary team consisting of physicians, speech therapists, nutritionists, and dentists/dental nurses is needed to prevent and manage AP in the patients.[22] In this view, early diagnosis and early intervention by trained personnel seem to play a crucial role in preventing AP.[23,24]

Our data showed that speech therapy combined with tDCS decreased the severity of AP more than speech therapy alone. TDCS is a new neuro-rehabilitative technique which is used online with speech therapy, showing promising results in improving dysphagia.[15,25] Although the results were promising, more investigations are needed to individualize this technique for the patients. On the other hand, guidelines and courses for speech therapists should be developed, so that they can use them in their settings in an evidence-based manner to avoid malpractice.

More than half of our patients at baseline were fed by NG tubes. There are controversies about usefulness of NG tube feeding in reducing AP in patients with dysphagia who suffer from stroke. Some studies showed that the incidence of pneumonia was higher in the patients who were fed orally compared with those fed by NG tubes.[26] On the contrary, some studies found that NG tube feeding showed no significant better outcome regarding AP than the patients fed orally.[27] Some scientists believe that NG tube feeding reduces the salivary flow, so that it has the potential to alter oropharyngeal colonization, and colonization of gram-negative bacteria may increase the AP risk. Furthermore, tube feeding will increase the risk of gastroesophageal reflux disease and will predispose the patients to pneumonia.[28] Therefore, it is believed that patients who are prescribed to be fed by tubes should be informed that the purpose of recommendation is not to reduce the risk of AP, but it is geared more towards nutritional sustenance.[29] On the other hand, unnecessary prescription of "Nil by Mouth" at hospital admission due to prevention of AP resulted in unintended effects such as decline in the ability of swallowing and increase in hospital stay.[30] Therefore, dysphagia management including early diagnosis and early intervention would be a wise way to reduce the side effects of NG tube feeding. According to our results, both speech therapy and speech therapy combined with tDCS reduce the number of patients fed by NG tube after therapy. Albeit, complementing tDCS with speech therapy has the potential to reduce this rate significantly and more effectively than that of speech therapy alone after one month.

This study has some limitations: First of all, none of the patients were suspected of developing

AP; therefore, instrumental assessments such as chest X-ray was not performed for any patient. On the other hand, silent aspiration is a very important issue which can be undiagnosed during clinical assessments. Silent aspiration can be detected via video fluoroscopic swallowing (VFS) assessment. Therefore, we recommend conducting such studies with more objective ways to detect AP and silent aspiration in the future.

None of the patients in this study developed AP at any stages of assessment. It seems that regardless of the type of treatment, dysphagia therapy of any kind has the potential to prevent AP; however, speech therapy combined with tDCS would be an ideal. This result is in the same line with previous results which showed swallowing therapy would reduce AP rate in patients with post-stroke dysphagia.[9,10] Despite these advances, we should remember that these studies, as well as ours, investigated the risk of AP in the acute onset phase, which may develop within the first month after a stroke.[31] However, we should also consider the chronic phase, which develops one-month after stroke. Therefore, we recommend that such studies be conducted in the chronic phase of stroke in the future.

On the other hand, dysphagia is not the only risk factor of AP, and there are other factors which have the potential to develop this disease, such as dependency on eating/drinking, oral health, enteral feeding, polypharmacy, malnutrition, and smoking.[32,33] Therefore, it is recommended that the patients should be managed from a holistic point of view. Using pharmacological treatments alongside rehabilitation techniques including physical and pulmonary rehabilitation as well as dysphagia rehabilitation combined with appropriate nutritional management are recommended to manage AP effectively.[30,31]

However, we should consider that even VFS is unable to detect aspiration of small amounts of oropharyngeal secretions such as saliva aspiration during sleep or after finishing the assessment process. These micro-aspirations have the potential to develop AP. Therefore, alongside the approaches which we mentioned before, we should consider a comprehensive approach to prevent aspiration at home.[34]

Some of these techniques are regarding preparing the meals such as: changing the physical properties of the meals under the supervision of swallowing experts which can be done by using thickeners to modify the texture of the diet,[34,35] changing the temperature of, and spices in the meals which can stimulate the transient receptor potential (TRP) receptors that have the potential to sharpen the swallowing and cough reflexes. Hot temperatures above 60 ˚C have the potential to stimulate TRP vanilloid 1 (TRPV1) receptors and cold temperatures below 17 ^{0}C have the potential to stimulate TRP melastatin 8 (TRPM8) receptors. On the other hand, spices such as chili peppers and mint have the potential to stimulate TRPV1 and TRPM8 receptors, respectively. The other techniques are sitting and holding position after meals and oral care. It is recommended that people who are at risk of developing aspiration such as elderly people and patients with dysphagia are placed with a head-of-bed elevated to 30˚ or higher known as a "semi-recumbent position" after taking meals for two hours. Studies show that oral care which can reduce gram-negative bacteria has the potential to prevent the onset of pneumonia.[34]

Conclusion

Swallowing management of any type may decrease the risk and the severity of AP. However, holistically viewing AP and complementing classical speech therapy techniques with the new neuro-rehabilitation ones would be ideal. There is a need for further studies in implementing these new neuro-rehabilitation techniques to individualize these techniques for all types of patients. Besides, to draw a better picture of developing AP, we recommend conducting studies on the stroke population in chronic phase. Moreover, there is a need to develop guidelines to avoid malpractice.

Conflict of Interests

The authors declare no conflict of interest in this study.

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