

# Effect of transcranial direct current stimulation on dysphagia in patients with post thermal inhalation injury: A randomized controlled trial

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## ABSTRACT

**Background:** The most dangerous complications of post-thermal inhalation injury dysphagia are aspiration risks and the inability to efficiently manage solid food textures, which almost persist for weeks and even for months. **Objectives:** To investigate the effect of transcranial direct current stimulation (tDCS) to conventional therapy for treating post thermal inhalation injury dysphagia. **Participants and Methodology:** Sixty patients aged from 13 to 35, suffering from post-thermal inhalation injury dysphagia were randomly allocated into two equal groups. The experimental group(A) received 2-mA tDCS through 2 surface electrodes, three times/week for 3 weeks plus conventional physical therapy. While the control group (B) received sham tDCS as a placebo plus the same conventional physical therapy. The Mann Assessment of Swallowing Ability (MASA) as well as Video fluoroscopy Swallow Study (VFSS) were used to assess the swallowing ability in both groups before and after 3 weeks of intervention. Outcome measures included oral transportation time, hyoid elevation, laryngeal elevation, the oesophageal sphincter opens, and aspiration measured by VFSS as well as swallowing ability measured by the MASA. **Results:** Post-treatment results showed a significant decrease in the oral transportation time, hyoid elevation, laryngeal elevation, the oesophageal sphincter opens, and aspiration, as well as outcomes of the MASA in both groups in favour of the tDCS group( $p < .05$ ). **Conclusion:** Application of tDCS has a significant effect as an adjuvant strategy during swallowing training in patients with post thermal inhalation injury dysphagia.

**Keywords:** Post thermal inhalation dysphagia; Therapeutic exercises; Transcranial direct current stimulation.

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## INTRODUCTION

Dysphagia is defined as the inability to effectively transfer food and liquid from the mouth to the stomach (Macht, Wimbish & Clark, 2011). It occurs across all age groups and as a result of many factors like congenital, neurological, medical, and/or structural damage (Clayton, Kennedy & Maitz, 2010). One of the most problematic complications in patients with thermal inhalation injury is dysphagia due to upper airway irritation (Rumbach, Ward & Cornwell, 2012). The consequences of dysphagia in patients with thermal inhalation injury are prolonged patient recovery by limiting their capacity to safely meet high nutrition and hydration requirements via oral intake. As a result, it places these patients at risk of aspiration and subsequent respiratory complications and increases the length of time for a feeding tube (Rumbach, Ward & Cornwell, 2012).

Thermal inhalation injury occurs due to inhalation of hot air, smoke, and possibly chemical irritants as a result of fire when patients are in an enclosed environment at the time of exposure (Rumbach, Ward, & Cornwell, 2011; DuBose, Groher, & Mann, 2005). Edema with inadequate vocal fold closure which results from Inhalation injury leads to misdirection of food or fluids into the airway (Woodson, 2009; Valdez, Desai, & Ruhl, 2006). The vocal folds local irritation from endotracheal intubation may result in a lack of airway protection during swallowing and true vocal fold paresis (Casper, Clark, & Kelley, 2002).

Critical care medical interventions as endotracheal intubation, re-intubation, tracheostomy, and nasogastric tube feeding are frequently required in patients with thermal inhalation injury (Aggarwal, Smailes, & Dziejulski, 2009). Increase the risk of developing laryngopharyngeal pathology and/or dysphagia could occur as consequences of using these critical care medical interventions (Carnaby, Clayton & Dubose, 2007; Ikonomidis, Lang, & Radu, 2012). Currently, there are no clear consensus guidelines for the diagnosis and grading of inhalation injury (Woodson, Talon, & Traber, 2012; Ekberg, 2012). Clinical diagnosis of inhalation injury however is challenging and is often based on subjective assessments of history and physical examination, that may be confirmed with bronchoscopy (Valdez, Desai, & Ruhl, 2006). Reviewing the literature, few studies were found on the nature of swallowing impairment in post thermal burn injury. In the majority of the cohort studies, swallowing impairment resulted from generalized oro-motor weakness upon Clinical Swallowing Examination (CSE), with functional deficits of the oral phase reserved for the few patients with dysphagia and oro-facial contractures (Casper, Clark, & Kelley, 2002).

The main causative factor and a potential aim for treatment of swallowing dysfunction may be sensorial impairment (Rofes, Arreola, & Lopez, 2013) Compensatory and rehabilitation techniques are the two main approaches of intervention. Compensatory techniques include positioning of the patient head to close the epiglottis (e.g., chin tuck and head-turning techniques), and dietary modification (Vilardell, Rofes, & Ortega, 2016). While rehabilitation techniques include exercises that aim to increase muscle strength (e.g., tongue resistance training, effortful swallow, and Mendelsohn manoeuvre) (Doeltgen, & Huckabee, 2012). Also, the Thermo tactile stimulation (TTS) may be used to sensitize the area of the oral cavity to trigger the swallowing (Teismann, Suntrup, & Warnecke, 2011).

The direct current application has been used for over 100 years to stimulate the body (Simons, & Hamdy, 2017). Opposite to transcranial magnetic stimulation, the transcranial direct current stimulation (tDCS) delivers a small electric current with intensity below 2 mA through 2 surface conductive rubber electrodes over the external surface of the brain through the scalp and cranium (Doeltgen, Bradnam, & Young, 2015). Using electrodes of a large surface area (around 20–35 cm<sup>2</sup>) is necessary to keep the current density low and makes it difficult to focus the stimulation, thus only a tingling or itching sensation on the scalp under the

electrodes perceived by the subjects (Paulus, 2003). It was shown that cathodal stimulation reduces the excitability of the motor cortex by hyperpolarizing the neurons, whereas anodal tDCS enhances its excitability by increasing the spontaneous firing rate (Nitsche, Seeber, & Frommann 2005; Nitsche, & Paulus, 2000). Electrical stimulation may help the recovery of dysphagia by early initiating the swallow response and protecting the respiratory airway (Aziz, Rothwell, & Barlow, 1995). Due to the lack of adequate research that investigate the use of the tDCS in patients with post thermal inhalation dysphagia, this study aimed to investigate the additive effect of tDCS to conventional physical therapy program on post thermal inhalation dysphagia. So, it was hypothesized that there was a significant value of adding tDCS to conventional physical therapy programs on post-thermal inhalation dysphagia.

## METHODOLOGY

### **Study design & participants**

A randomized clinical trial has been conducted on sixty patients, dysphagia was enrolled in this study after assessment for eligibility, were from both sexes( 20 subjects were under 18 years old and the rest from 18 to 35 y with 15 females and 45 males), with post thermal inhalation dysphagia, aged from thirteen to thirty-five, had sufficient cognitive abilities according to The Mini-Mental State Examination (MMSE). The clinical application of both tDCS and exercise therapy as well as the physical assessment of patients were conducted in the physiotherapy department, Kasr El-Aini, Cairo University. All patients were cooperative with no previous complains of dysphagia before the thermal inhalation injury. The study was conducted between April 2020 and July 2020. The study was registered at the Pan African Clinical Trials Registry (PACTR 202006869392862). At the beginning of this study, each patient/parent signed informed written consent according to the principles of the Declaration of Helsinki of 1975. Patients with dysphagia due to another health condition, such as a stroke, head injury, multiple sclerosis dementia cancer, or gastro-oesophageal reflux disease are exclusion.

### **Randomization**

Seventy patients with post-thermal inhalation injury dysphagia were randomly assigned into 2 equal groups, according to the type of therapy received using random allocation software to minimize selection bias (Saghaei, 2004). Three patients did not meet the inclusion criteria, three patients refused to enrol to study. Four cases were lost from post-assessment. The experimental group(A) received treatment with 2-mA tDCS delivered for only 30 min through 2 surface electrodes, plus conventional physical therapy for 30 min. While the control group (B) received the same conventional physical therapy for 30 min, in addition to sham tDCS (not turned on) for 30 min. Different treatment protocols were conducted for 3 days /weeks for 3 successive weeks. All patients were assessed by FOIS, MASA, and Video fluoroscopy Swallow Study (VFSS) at the baseline and post 3 weeks of treatment. All patients were blinded to the study hypothesis. A randomization diagram of participants is shown in Figure 1.

### **Outcome measures**

- The Mann Assessment of Swallowing Ability (MASA) is a screening tool used to identify eating and swallowing disorders, also quantify the aspiration risk via a bedside test. It has high sensitivity and specificity for a prediction of dysphagia (Antonios, Carnaby, Crary, Miller, Hubbard, & Hood 2010). It consists of 24 items, each measured score is converted into a weighted 5 or 10 points (Mann, 2002) which are then summed to a 200-point maximum score. The total scores are then used to define four categories of aspiration risk, as follows: 170-200, no abnormality; 149-169, mild; 141-148, moderate; ≤140, sever.

- Video fluoroscopy Swallow Study (VFSS) is a radiographic, videotaped X-rays procedure that provides a direct, dynamic view of oral, pharyngeal, and upper oesophageal function during the process of swallowing. It is a commonly recommended and accepted way to assess the unseen swallowing process of pharyngeal and oesophageal stages and the presence of aspiration or penetration. (Shin, & Umezaki, 1995)
  - The participants were positioned in a standing or sitting position to place the patient in a physiological position for the swallowing act. Lateral images were monitored and recorded by a DVD recorder at 30 frames/s. The examination generally begins with the latero-lateral view, which allows identification of the reference points, namely, the cervical rachis, the prevertebral soft tissues, the tongue base, the hyoid bone, and the larynx. These structures can be studied either at rest or whilst performing a dry swallow.
  - Each patient was asked to swallow 10 mL thin liquid boluses was a 50/50 mixture of barium sulphate powder for suspension with carefully controlled the viscosity of the boluses through maintaining constant temperature and rechecks with a Brookfield viscometer periodically. The outcome measures were oral transportation time, hyoid elevation, laryngeal elevation, the oesophageal sphincter opens, and aspiration. All these outcome measures were assessed pre and after 3weeks of intervention programs.

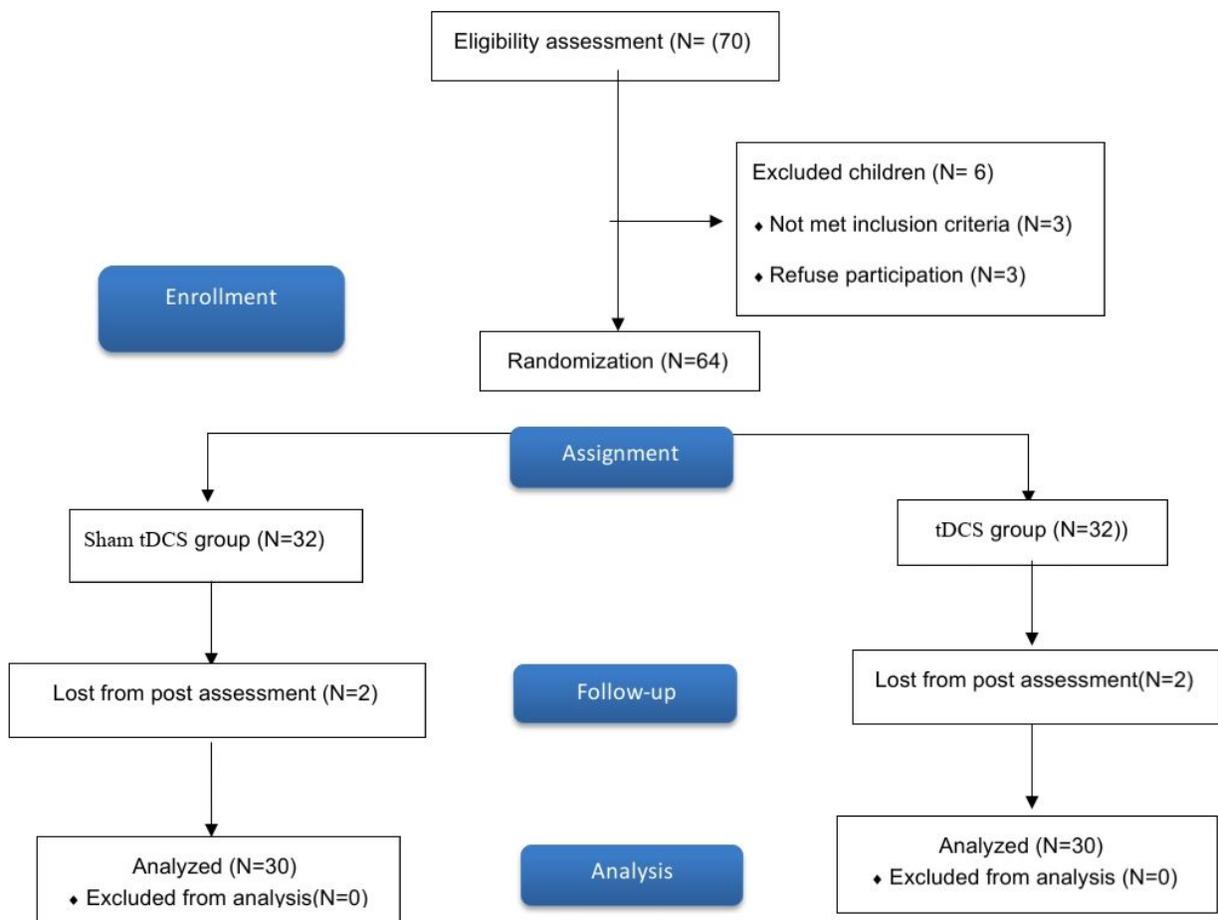


Figure 1. Flowchart.

### **Intervention**

Group (A): Received tDCS combined with the conventional treatment in the form of thermo tactile stimulation, strengthening exercise and range of motion, effortful swallowing of the tongue, Mendelsohn manoeuvre, supraglottic swallow, and head and neck positioning, it for 30 min. in addition to tDCS in the form of 2 mA of anodal tDCS as it delivered for only 30s for 3 pulses. The total time of application of tDCS was 30 min.

TDCS therapy; Patient sat well supported in a chair. Before the application of the electrodes, cleaning of the treated area after shaving it and detecting any wounds was performed.

The therapist stood facing the patient to place the electrodes as follows: The targeted cortical area was the pharyngeal motor cortex. The 25-cm<sup>2</sup> rectangular surface electrodes, in saline-soaked synthetic sponges, were applied between C3/T3 on the left and C4/T4 on the right, according to the international 10-20 EEG electrode system (Valeria, et al., 2018).

Group (B): Received the same conventional therapy for 30 min. and Placebo tDCS (not turned on) for 30 min. Both groups receive the treatment protocols 3 days per week, for 3 successive weeks.

### **Power analysis**

To avoid a type II error, a preliminary power analysis [power (1 – error p) = 0.95, effect size = 0.34] determined a sample size of 30 for each group in the study. Calculation of effect size was in accordance with a pilot study involving 10 cases (5 in the tDCS group and 5 in the Sham tDCS group), with the consideration of swallowing ability as a primary outcome.

### **Statistical analysis**

Statistical analysis was done via SPSS software for Windows, version 25.0 (Armonk, NY, USA). Descriptive statistics were calculated for both groups at baseline and after 4 weeks. A 2X2 mixed-design multivariate analyses of variance (MANOVA), with treatment groups as the between-subjects variable and time (baseline, 3 weeks) as the within-subjects variable, were used to determine any differences between the mean change scores of groups regarding oral transportation and the Mann Assessment of Swallowing Ability. The F value used was based on Wilks' lambda and when the MANOVA demonstrated a significant effect ( $p < .05$ ), a follow-up univariate ANOVAs were performed with Bonferroni adjusted p-values to avoid type I error. Mann-Whitney U tests were performed to determine any differences between the groups' medians regarding the Functional Oral Intake Scale. Chi-square was used to describe data of hyoid elevation, Laryngeal elevation, Oesophageal opening, and aspiration.

## **RESULTS**

The results showed no statistically significant differences between groups on baseline demographic and clinical characteristics of subjects regarding age, weight, height, body mass index, and gender, ( $p > .05$ ) as shown in Table 1.

Two-way mixed MANOVA was conducted to assess the difference between participants in the study and control groups in the amount of change in their scores on the outcome measures. Statistically Significant multivariate effects were found for the main effects of groups, Wilk's A = 0.81,  $F_{(2,57)} = 6.74$ ,  $p = .002$ ,  $\eta^2 = 0.19$ , for time, Wilk's A = 0.32,  $F_{(2,57)} = 61.02$ ,  $p < .001$ ,  $\eta^2 = 0.68$ , as well as for the interaction between groups and time, Wilk's A = 0.77,  $F_{(2,57)} = 8.33$ ,  $p < .001$ ,  $\eta^2 = 0.23$ . Follow-up univariate ANOVAs reveal that

significant change for oral transportation outcome variable,  $F_{(1,58)} = 15.2$ ,  $p < .001$ ,  $\eta^2 = 0.21$ , for MASA outcome variable,  $F_{(1,58)} = 18.63$ ,  $p < .001$ ,  $\eta^2 = 0.24$ .

Table1. Baseline clinical characteristics of subjects (N = 60)\*

Characteristics	tDCS Group (n = 30)	tDCS Group (n = 30)	MD(95% CI)	p-Value
Age(years)	23.53 ± 7.03	25.50 ± 7.39	-1.97 (-4.86, 1.59)	.3
Weight(kg)	71.48 ± 11.57	71.17 ± 9.61	0.31 (-2.75, 2.18)	.91
Height(cm)	160.97 ± 8.54	161.87 ± 5.42	1.16 (-1.57, 4.85)	.36
Sex(n)				
Male (%)	24 (33.3%)	21(43.3%)	$\chi^2 = 0.802$	.38
Female (%)	6(66.7%)	9(56.7%)		

Table 2. The design MANOVA for all dependent measuring variables within and between groups.

Test	Variables		Groups (Mean ±SD)		MD (95%CI)	p-value
			tDCS Group (n=30)	Sham tDCS Group (n=30)		
VFSS	Oral trans. (sec)	Baseline	32.4 ± 11.68	36.4 ± 13.12	-3.6 (-10.02,2.82)	
		Post-treatment	18.3 ± 6.84	27.93 ± 11.68	-9.63 (-14.58,4.69)	
	Hyoid elev. (-ve)	Baseline	22(73.3%)	18(60%)	$\chi^2 = 1.2$	.27
		Post-treatment	4(13.3%)	15(50%)	$\chi^2 = 9.32$	.002
	Hyoid elev. (+ve)	Baseline	8(26.7%)	12(40%)	$\chi^2 = 1.2$	.27
		Post-treatment	26(86.7%)	15(50%)	$\chi^2 = 9.32$	.002
	Laryngeal elev. (-ve)	Baseline	23(76.7%)	20(66.7%)	$\chi^2 = 0.74$	.39
		Post-treatment	4(13.3%)	15(50%)	$\chi^2 = 9.32$	.002
	Laryngeal elev. (+ve)	Baseline	7(23.3%)	10(33.3%)	$\chi^2 = 0.74$	.39
		Post-treatment	26(86.7%)	15(50%)	$\chi^2 = 9.32$	.002
	Oesophageal Op. less	Baseline	8(26.7%)	7(23.3%)	$\chi^2 = 0.27$	.87
		Post-treatment	5(16.7%)	6(20%)	$\chi^2 = 11.26$	.004
	Oesophageal Op. open	Baseline	7(23.3%)	6(20%)	$\chi^2 = 0.27$	.87
		Post-treatment	21(70%)	9(30%)	$\chi^2 = 11.26$	.004
	Oesophageal Op. spasm	Baseline	15(50%)	17(56.7%)	$\chi^2 = 0.27$	.87
		Post-treatment	4(13.3%)	15(50%)	$\chi^2 = 11.26$	.004
Aspiration (-ve)	Baseline	11(36.7)	10(33.3%)	$\chi^2 = 0.73$	.79	
	Post-treatment	26(86.7)	14(46.7%)	$\chi^2 = 10.8$	.001	
Aspiration (+ve)	Baseline	18(63.3%)	20(66.7%)	$\chi^2 = 0.73$	.79	
	Post-treatment	4(13.3%)	16(53.3%)	$\chi^2 = 10.8$	.001	
Swallowing ability	MASA	Baseline	123.2 ± 22.01	127.3 ± 20.37	-4.48 (-15.13,6.79)	.45
		Post-treatment	164.1 ± 21.65	143.7 ± 14.04	20.33 (10.9,29.76)	.0001

tDCS, transcranial direct current stimulation; MD, Mean Difference; CI, Confidence Interval; P-value, Probability value;  $\chi^2$ , chi-square; Oral trans, oral transportation; sec, seconds; MASA, Mann Assessment of Swallowing Ability; Hyoid elev., Hyoid elevation; Lary elev., Laryngeal elevation; Op., Opening; -ve, negative; +ve, positive. \* Data are mean ± SD for oral and MASA and counts and percentages for other outcomes, p-Value < .05 indicate statistical significance.

Pre-treatment results showed no significant difference in all measured variables of VFSS (oral transportation time, hyoid elevation, laryngeal elevation, the oesophageal sphincter opens, and aspiration), as well as outcomes of the MASA in both groups ( $p > .05$ ), on the other hand, post-treatment results showed a significant decrease in the oral transportation time, hyoid elevation, laryngeal elevation, the oesophageal sphincter opens, and aspiration, as well as outcomes of the MASA in both groups in favour of the tDCS group ( $p < .05$ ), as shown in Table 2.

## DISCUSSION

There has been an encouraging result in the possible therapeutic effect of neuromodulation in swallowing disorders due to the involvement of the neural repair mechanisms in the recovery process of dysphagia. Recently, non-invasive techniques for brain stimulation attract attention and are used to assess both the swallowing physiology and effects on dysphagia. Additionally, the swallowing musculature is represented in both the cerebral hemisphere, thus theoretically, stimulation of either hemisphere could have an improving effect on dysphagia (Ghandehari, Erfani, & Kiadarbandsari, 2016).

Sixty participants with post-thermal inhalation injury dysphagia aged from thirteen to thirty-five with mean age  $23.53 \pm 7.03$ , mean weight was  $71.48 \pm 11.57$ , mean height was  $160.97 \pm 8.54$  in the study group, whereas  $25.50 \pm 7.39$ ,  $71.17 \pm 9.61$ , and  $161.87 \pm 5.42$  respectively in control group. This wide range of age due to the small number of cases that suffer from post-thermal inhalation injury dysphagia. Also, oral transit time, vertical displacement of the hyoid bone and larynx elevation are not influenced by age (Rumbach, Ward & Cornwell, 2011).

This study examined mainly if tDCS could have or not any effect or a considerable value for enhancing the swallowing function after its affection inpatient with post thermal inhalation dysphagia and whether we can use it as well as the conventional therapy treatment for these cases. Within the limitation of this study, as shown in the literature section, few literatures demonstrate the nature of swallowing dysfunction follows thermal burn injury, many studies showed a generalized weakness of oro-motor on (CSE) in most of the cases, whether the rest fewer cases showed dysphagia with functional deficits of the oral phase and orofacial contractures (Casper, Clark, & Kelley, 2002; Rumbach, Ward, & Cornwell, 2011).

Severe burns could have a long-term disabling factor for returning to normal oral intake (Rumbach, Ward, & Cornwell, 2012), and as it can cause orofacial scarring and contractures. Oral deficits may be presented in different swallowing preparations and phases poor as affection inability of containing and manipulation of cohesive bolus and its forming with suitable texture and size for swallowing (Casper, Clark, & Kelley, 2002; Carnaby, Clayton, & Dubose, 2007). The choice of tDCS was due to sub sensory level of electrical stimulation that avoid any painful, shocking or annoying sensation. In addition, tDCS done not interfere with normal mechanism of swallowing as its application done not lead to an effective muscle contraction. Also, it improves cortical functions in motor organization (Doeltgen, Bradnam, & Young, 2015).

By using the MASA scale as well as oral transportation, hyoid elevation, laryngeal elevation, oesophageal opening, and aspiration. In pre-treatment evaluation and statistical analysis of all examined variables in both groups showed no significant difference between the pre-treatment data of the two groups regarding the baseline, the outcome measure of MASA scale, oral transportation, hyoid elevation, laryngeal elevation, oesophageal opening, and aspiration (as described in results). While there was a significant difference between the means values of these outcome measures in post-treatment evaluation and statistical analysis of data in both groups compared to its pre-treatment means values in favour of the tDCS group. The

significant improvement of the tDCS group may be due to the effect of tDCS inactivation and promotion of cortical functions that cause improving the swallowing functions in these patients with post thermal inhalation dysphagia as Nitsche, Seeber, & Frommann, 2005; Mann, Hankey, & Cameron, 2000 concluded that there was a delayed response of evocation of the cortical functions in patients with post inhalation thermal dysphasia to electrical stimulation of pharynx when compared to healthy volunteers.

Regarding pathophysiology sensory impairment plays a critical role in swallowing dysfunction so its treatment a beneficial and a powerful effect on alleviating This swallowing dysfunction (Rumbach, Ward, & Cornwell, 2012; Ward, Uriarte, & Spath, 2001). In patients with affected sensation due to post thermal inhalation dysphagia, They are in a bad need of stimulation; thus, electrical stimulation has a potent effect on the swallow dynamic system as its impact on both thresholds needed to begin a swallow response decreasing it and also decrease the time of swallowing enhancement (Paulus, 2003). Increasing the sensory input to the swallowing centre in the brain stem could be obtained via electrical or pharmacological oropharyngeal stimuli which in its role initiates the swallowing response earlier protecting the respiratory airway, also sensory stimulation may improve brain plasticity, promoting recovery of a patient with post inhalation injury dysphagia (Carnaby, Clayton, & Dubose, 2007).

This technique was expected to generate the maximum current density over the motor and premotor areas, which, as shown by previous studies, (Doeltgen, Bradnam, & Young, 2015) play a prominent role in the reorganization of the swallowing motor cortex the stimulation was applied during the swallowing rehabilitation therapy. The patients were encouraged to repeatedly swallow hard using endogenous saliva.

This study may help in the clinical use of tDCS which still does not unfold and participates in demonstrating its beneficial effects in cases of post inhalation burn dysphagia (Ghandehari, Erfani, & Kiadarbandsari, 2016). The result of our study was in agreement with a study in 2016 tDCS may be a new promising remedy for post-stroke dysphagia, also a recent study that recognized a significantly higher improvement in post-stroke dysphagic patients without nasogastric tube received tDCS therapy as compared with placebo (Valeria, Alberto, & Alberto, 2018).

Some limitations of this study should be considered. First, the study investigated the additive effect of tDCS to conventional physical therapy on post inhalation thermal injury dysphagic patients with treatment duration three weeks only. Therefore, the findings of the current study need to be examined with longer duration of treatment. Second, this study measured the short term effect of tDCS with conventional physical therapy. Further studies are therefore needed to determine the long-term effect of adding the tDCS to conventional physical therapy on post inhalation thermal injury dysphagic patients. Moreover, further investigations are needed to optimize this promising beneficial effect of tDCS therapy by recognizing the needed parameters in form of preferred time, intensity, frequencies and criteria of patient selection.

## CONCLUSION

Neuromodulation therapy using tDCS is a minimally invasive procedure that might enhance the swallowing ability in patients suffering from post-thermal inhalation dysphagia. It should be considered as an adjunctive treatment option to conventional physical therapy for such patients.

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The authors declare that there are no financial or non-financial competing interests to declare to this manuscript.

## CONFLICTS OF INTEREST

There are no conflicts of interest.

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