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Effect of transcutaneous electrical nerve stimulation and conventional therapy in post-stroke dysphagic patients: a randomized controlled trial

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Post stroke dysphagia (PSD) can decrease the quality of life, increase the risk of medical complications and mortality. So it is a great concern for patients and a tough problem for clinicians. Purpose: The current study was conducted to investigate the effect of adding TENS to the conventional therapy of treating PSD. Thirty patients complaint from post stroke dysphagia were participated in this study, their ages ranged from 45 to 85 years old. They were randomly divided into two equal groups. Group (A): Received 3 weeks of treatment with Transcutaneous Electrical Nerve Stimulation (TENS), frequency 80 HZ, pulse duration of 300 µsec, intensity according to the patient's tolerance ranging from 2.5 to 25 mA, duration of treatment 30 min three times/week in addition to the conventional therapy. While Group (B): Received 3 weeks of treatment with conventional therapy and placebo TENS, duration of treatment 30 min three times/week. Both treatment protocols are effective, minimally invasive options for treatment of patients complaining of post stroke dysphagia, both groups produced subjective improvement and there was a significant increase in both The Functional Oral Intake Scale (FOIS) and The Mann Assessment of Swallowing Ability (MASA) of group A and B post treatment if compared with pre-treatment scores. In addition, There was a significant increase in the MASA of group A compared with that of group B post treatment. Moreover, there was a significant increase in the median values of FOIS of group A post treatment compared with that of group B.

•Conventional treatment with placebo TENS improves swallowing function 10 % on the MASA scale
•Adding TENS to the conventional treatment of PSD improves the swallowing function 37 % on the MASA scale.
•Regular TENS units like the ET-3000 can be used and no need for specialized machines.

Keywords: Post stroke dysphagia, Transcutaneous Electrical Nerve Stimulation, Conventional therapy, Mann Assessment of Swallowing Ability (MASA), Functional oral intake scale (FOIS).

INTRODUCTION

Dysphagia is a common impairment after stroke; It is a disruption of bolus flow through the mouth and pharynx (Wirth et al.,2016) with incidence around 45.1% upon admission (Vilardell et al.,2016) Early management of it has reduced the rate of aspiration pneumonia (AP) and improved survival rates (Ickenstein et al.,2010) and (Muriana et al.,2016).However, the current standard of care for the majority of patients with PSD is very poor (Ickenstein et al.,2011).Sensorial impairment may be the main causative factor and a potential aim for treatment of swallowing dysfunction (Rofes et al.,2013).Two approaches of intervention exist compensatory techniques that include positioning of the patient head to close the

epiglottis like the chin tuck and head turning techniques (Young, et al.,2015).and dietary modification (Vilardell et al.,2016).While the other approach is the rehabilitation techniques that include exercises (e.g. tongue resistance training, effortful swallow and Mendelsohn maneuver) that aim to increase muscle strength Doeltgen and Huckabee.(2012.) .In addition to the thermo tactile stimulation (TTS) to sensitize the area of the oral cavity where the swallow is triggered (Teismann et al.,2011).Sensory stimulation electrically is another approach that may initiate the swallow response earlier and protecting the respiratory airway as well as promoting brain plasticity helping in the recovery of post stroke dysphagia (Rofes, et al.,2014)

In this study, valid, reliable and objective scales have been used to determine the efficacy of the different interventions, which include The Functional Oral Intake Scale (FOIS) (Crary et al.,2005)

and The Mann Assessment of Swallowing Ability (MASA) (Ohira et al.,2017),(Mann et al.,2000) 30 patients with mean age around 67.5 years old, from both sexes were randomly assigned into 2 equal groups. Group A: 15 patients received TENS combined with the conventional treatment in the form of thermotactile stimulation, tongue strengthening exercise, tongue range of motion (ROM), effortful swallowing, mendelsohn maneuver, supraglottic swallow, head and neck positioning and diet modification. The frequency of sessions was 3 times a week for 3 weeks. TENS were then delivered continuously at 80 Hz for pulse duration of 300 μs and intensity ranging from 2.5 to 25 mA depending on the patient's tolerance. The therapy was given for 30 min 3 days per week for 3 weeks. (Mathela et al.,2013).Group B: 15 patients received the same conventional therapy in addition to Placebo TENS 3 times a week for 3 weeks. The study protocol was registered at Pan African Clinical Trial Registry (Registry ID PACTR201710002724163). Inclusion criteria: all patients diagnosed as PSD after ischemic stroke from 1 to 3 months. Their age ranged from 45 to 85 years from both sexes. All of them have sufficient cognitive abilities, assessed by The Mini Mental State Examination (MMSE). Exclusion criteria: All patients were free from pacemakers, metal implants, orthotics and skin breakdown around neck, and free from seizure disorders, pregnancy, head and neck cancer.

MATERIALS AND METHODS

Procedures:

A-Evaluation procedure:

Begin with taking the patients' vital signs and fill evaluation sheet including their age, sex, chronic diseases and weight. Then dysphagia assessment was performed for both groups before and after treatment using 2 swallowing scales, The Mann Assessment of Swallowing Ability (MASA) (Ohira et al.,2017) and Functional oral intake scale (FOIS) (Crary et al.,2005)

B- Treatment procedure:

Group A:

Received 2 concurrent interventions (TENS+ Conventional therapy) :

TENS therapy; The first 2 electrodes was placed in the submental region, 3ed and 4th electrodes was placed at equal distances from first two electrodes on both sides of the larynx traditional TENS were then delivered continuously at 80 Hz for pulse duration of 300 μs and intensity ranging from 2.5 to 25 mA depending on the patient's tolerance. The patients were encouraged to repeatedly swallow hard using endogenous saliva. With progress, the patients were upgraded to swallow solid foods during the protocol. The therapy was given for 30 min 3 days per week for 3 weeks (Mathela et al.,2013).Thermotactile stimulation (TTS) was the next thing. Therapist stood facing the patient holding the dental mirror and the iced water within his reach. Five trials with stimulation were performed by stroking the patient's anterior faucial pillar with the back of the cold mirror. Stroke direction was from top (medial) to bottom (lateral). This was done 5 times within 2 minutes 3 days per week for 3 weeks. The exercise program is the last thing to do which was performed for 20 min 3 days per week for 3 weeks (Lazarus et al., 1993).that will include tongue training for strengthening and enhancing ROM, effortful swallowing, mendelsohn maneuver, supraglottic swallow head and neck positioning as well as diet modification. Each exercise was repeated about ten times according to the patients' ability in every session.

Effortful swallow:

The patient is instructed to swallow and push hard with the tongue against the hard palate ten times every session.

Mendelsohn maneuver:

The patient instructed to swallow his/her saliva ten times every session and simultaneously hold the larynx in an elevated position at the peak of hyolaryngeal elevation. Patient can use his hand to palpate the larynx and to get feedback.

Supraglottic swallow:

This exercise is designed to close the vocal folds by voluntarily holding one's breathe before and during swallow in order to protect the airway. The patient is instructed to hold his or her breath just before swallowing to close the vocal folds. The swallow is followed immediately by a volitional cough. The exercise to be repeated ten times every session.

Tongue strengthening and range of motion exercise

Therapist stood facing the patient and holding a teaspoon in front of the patient's mouth as a guidance tool. The patient was asked to touch the spoon with the tip of their tongue. The therapist would move the spoon in both sides of the mouth and ask the patient to touch it again.

Group B:

It will receive the same thermotactile stimulation and exercise program (conventional therapy) in addition to Placebo TENS.

Statistical Design:

In this study, the descriptive statistics (the mean and the standard deviation) were calculated for all patients (Group 1 and Group 2). The mean and standard deviation was used as a kind of central tendency to describe a group of individuals with single measurement (descriptive statistics). Data of the MASA pre and post was manipulated by descriptive analysis and inferential statistics Mixed ANOVA. Mann–Whitney U test was carried out for comparison of FOIS between groups. Finally, Wilcoxon Signed Ranks Test was carried out for comparison of pre and post treatment median values of FOIS in each group with level of significance of (0.05).

RESULTS

Effect of treatment on Mann assessment of swallowing ability (MASA):

Group A In group A the mean ± SD MASA pre- treatment was 122.4 ± 34.1 while post treatment was 167.66 ± 25.19. The percent of improvement was 36.97%. There was a significant increase in the mean value of MASA post treatment compared with pre -treatment ($p = 0.0001$). (Table 1).Group B In group B the mean ± SD MASA pre -treatment was 129.06 ± 31.68 while post treatment was 142.93 ± 35.95. The percent of improvement was 10.74%. There was a significant increase in the mean value of MASA post treatment compared with pre- treatment ($p = 0.001$). (Table 1).Effect of treatment There was no significant effect of treatment on MASA ($p = 0.08$). Effect of time There was a significant effect of time on MASA ($p = 0.0001$). Interaction effect There was a significant interaction effect of treatment and time on MASA ($p = 0.0001$). (Table 1, figure 1).

Comparison between groups

Multiple pair wise comparison showed that there was no significant difference in the mean values of MASA pre- treatment between both groups ($p = 0.58$). However, there was a significant increase in the mean values of the MASA post treatment in the group A compared with that of group B ($p = 0.03$). (Table 1).

Pre and post treatment median values of FOIS of group A:

The median value of FOIS pre- treatment of group A was 3 and that post treatment was 6. Wilcoxon signed ranks test for comparison between pre and post treatment median values of FOIS of group A have been performed and revealed that there was a significant increase in the median values of FOIS post treatment compared with pre- treatment ($p = 0.001$).

Pre and post treatment median values of FOIS of group B:

The median value of FOIS pre- treatment of group B was 2 and that post treatment was 4. Wilcoxon signed ranks test for comparison between pre and post treatment median values of FOIS of group B have been performed and revealed that there was a significant increase in the median values of FOIS post treatment compared with pre- treatment ($p = 0.001$).

Post treatment median values of FOIS of group A and B:

The median value of FOIS post treatment of group A was 6 and that of group B was 4. Mann–Whitney U test for comparison between post treatment median values of FOIS of group A and B have been performed and revealed that there was a significant increase in the median values of

FOIS of group A post treatment compared with that of group B (p = 0.02).

Table 1. Mean values of MASA pre and post treatment of group A and B:

MASA					
Group A		**Group B**			
Pre	**Post**	**Pre**	**Post**		
$\overline{X}$ ±SD	$\overline{X}$ ±SD	$\overline{X}$ ±SD	$\overline{X}$ ±SD		
122.4 ± 34.1	167.66 ± 25.19	129.06 ± 31.68	142.93 ± 35.95		
Mixed ANOVA					
Effect of treatment					
$F_{(1,28)}$ = 0.62		p = 0.43			
Effect of time					
$F_{(1,28)}$= 149.65		p = 0.0001			
Interaction effect (treatment*time)					
$F_{(1,28)}$ = 42.19		p = 0.0001			
Multiple pairwise comparison (Bonferroni correction)					
			MD	**p-value**	**Sig**
Within group comparison	**Pre vs post**	**Group A**	-45.26	0.0001	S
		Group B	-13.87	0.0001	S
Between group comparison	**Group A vs B**	**Pre treatment**	-6.67	0.58	NS
		Post treatment	24.73	0.03	S

$\overline{X}$: Mean SD: Standard deviation MD: Mean difference
p value: Probability value S: Significant NS: Non significant

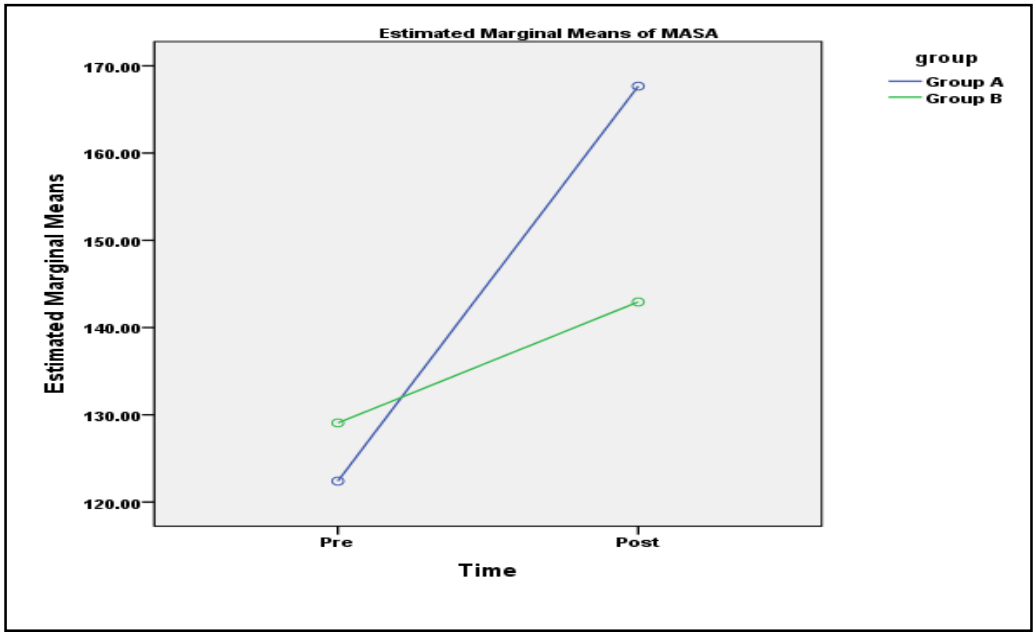

Figure (1). Interaction effect of treatment and time on MASA.

The study main purpose is to determine whether or not there is considerable value of adding Transcutaneous Electrical Nerve Stimulation (TENS) to the conventional therapy on the treatment of PSD (post stroke dysphagic) patients.

The electric stimulation was in the sensory level to avoid any discomfort or shocking sensation. The sensory stimulation is beneficial too in avoiding possible muscle contraction that may disrupt the normal mechanism of swallowing. In addition, TENS was used to promote cortical motor organization (Gallas et al.,2010).By using the MASA (Mann Assessment of Swallowing ability) and FOIS (Functional Oral Intake Scale) Scales, Post treatment comparison of all different variables in the two groups (GA & GB) indicates that there is significant difference between the pre and post treatment data for both groups. Moreover, there is significant difference between the two groups with rates of improvement up to 37% and 10% in GA and GB respectively.

This can be attributed to improving the cortical activation of stroke patients with post stroke dysphagia (PSD) (Rofes et al.,2013) It was suggested that the cortical activation of stroke patients with PSD in response to pharyngeal electrical stimulus is delayed in comparison to healthy volunteers. This sensorial impairment may be a critical pathophysiological element and a potential aim for treatment of swallowing dysfunction (Rofes et al.,2013)

The need for sensory stimulation may be critical for those with reduced sensation as a result of the stroke; thus, sensory stimulation may force the swallow system to reduce the threshold needed to begin a swallow response and enhance the timeliness of the swallow. Improving the sensorial stimuli by electrical or pharmacological oropharyngeal stimuli may increase the sensorial input to the swallowing center of the brain stem, therefore, initiating the swallow response earlier and protecting the respiratory airway, in addition, there is mounting evidence that sensorial stimuli may promote brain plasticity, helping in the recovery of post stroke dysphagia (Rofes, et al.,2014)

CONCLUSION

There was a significant increase in the MASA of group A compared with that of group B post treatment. Moreover, there was a significant increase in the median values of FOIS of group A post treatment compared with that of group B.

CONFLICT OF INTEREST

The authors declared that present study was performed in absence of any conflict of interest.

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AUTHOR CONTRIBUTIONS

RMH recruited patients, performed the experiments and wrote the manuscript. AEA and THE designed experiments, performed data analysis and reviewed the manuscript. All authors read and approved the final version.

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