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Is Electrical Muscle Stimulation Effective in the Progression of Oral Feeding, for Patients with Dysphagia, Caused by a Stroke?

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Is Electrical Muscle Stimulation Effective in the Progression of Oral Feeding, for Patients with Dysphagia, Caused by a Stroke?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

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ABSTRACT

OBJECTIVE: The objective of this selective EBM review is to determine whether or not electrical muscle stimulation is effective in the progression of oral feeding, for patients with dysphagia, caused by a stroke.

STUDY DESIGN: Review of 3 randomized controlled trials, published between 2008-2009.

DATA SOURCES: All 3 randomized controlled trials were found using the Cochrane database.

OUTCOMES MEASURED: All 3 studies measured subjective swallowing function pre- and post-treatment, however, each trial differed in the way they measured this. Permsirivanich et al used a functional oral intake scale (FOIS), or a 7-point scale reflecting the patient's report of foods safely ingested by mouth, on a consistent basis. Bulow et al determined swallowing function using an alternate 7-point scale, called the actual nutrition scale (ANS). Lim et al measured swallowing function using a third, unnamed, 7-point scale. The percentage of patients progressing from tube feeding to oral feeding was also measured in Lim et al.

RESULTS: Bulow et al concluded that no statistically significant difference was found in the therapy effects between neuromuscular electrical stimulation (NMES) and traditional therapy (TT) groups, however, when looking at both groups as a whole, there were significant improvements noted. In Permsirivanich et al, both rehabilitation swallowing therapy (RST) and NMES therapy (combined with diet modification and oral motor exercises) showed positive effects in the treatment of persistent dysphagia in stroke patients, but NMES therapy was significantly superior. Finally, in Lim et al, NMES combined with thermal tactile stimulation (TTS) had a significantly higher score change in swallowing measures (indicating a progression of oral feeding) than those receiving TTS alone.

CONCLUSION: As indicated by the 3 studies, NMES therapy, as an adjunct treatment to standard dysphagia treatment, is an effective intervention in the progression of oral feeding, in patients with dysphagia, caused by a stroke. Further studies should be performed to determine if NMES is a valuable therapy alone, or only advantageous when paired with a traditional therapy.

KEY WORDS: "dysphagia", "stroke", "electrical muscle stimulation"

INTRODUCTION:

The seemingly simple act of swallowing is actually a very complex process that is initiated by the cerebral cortex and followed through by the brain stem. When these specific areas of the brain are injured, such as in a stroke, the act of swallowing is disrupted (known as dysphagia) and the airway becomes vulnerable.[1] In fact, 45-65% of all acute stroke patients, which accounts for approximately 3.3 million healthcare visits annually[2], will develop dysphagia. Dysphagia leaves patients at risk for aspiration, because the muscles and nerves surrounding the oropharynx are not able to aid in safely transporting food from the mouth into the stomach. Aspiration can then lead to aspiration pneumonia, which accounts for approximately 34% of stroke related deaths, as well as causing complications such as choking, bronchospasm, increased infection rate, dehydration and nutritional compromise.[1] Dysphagia can also have a negative social impact and thus affect one's quality of life.

While the majority of stroke survivors have a return to normal swallowing function fairly rapidly after a cerebral vascular accident, this is not always the case, and thus healthcare providers must recognize the high healthcare costs of stroke survivors suffering from dysphagia. While it is not known what the exact healthcare costs may be, it has been proven that dysphagia after stroke lengthens hospital stays, thus carrying substantial economic burdens. In fact, Altman et al[3] found that in patients with hemorrhagic stroke, hospital stays increased from 4.74 days, in those without dysphagia, to 10.55 days, in those suffering from dysphagia. Obviously, the longer the hospital stay, the greater the cost.

Fortunately, the majority of healthcare workers are aware of dysphagia and its negative impact on one's health, as well as its economic burden, thus, making it a topic of study in the medical community. Presently, there are a few successful methods used to treat dysphagia post-

CVA. Diet modification and specific exercises designed to strengthen the muscles surrounding the swallowing apparatus are two simple methods currently used.[4] Thermal-tactile stimulation (TTS), which involves stroking a patient's anterior faucial pillars with a cold probe prior to swallowing, is an alternate technique used.[1] Yet another approach is rehabilitation swallowing therapy (RST), which includes supraglottic swallowing, effortful swallowing and the Mandelsohn maneuver, or purposeful prolongation, mid-swallow, of anterosuperior laryngeal traction.[5] Current research is proposing electrical muscle stimulation, or neuromuscular electrical stimulation (NMES), which uses electrodes to deliver electrical stimulation to muscles, in turn causing muscle contraction by the depolarization of nerve fibers, and an increase in muscle strength, to aid in the treatment of dysphagia.[1] A few studies have shown favorable effects of NMES on the symptoms of dysphagia, including reorganization of the human motor cortex, but studies are still being preformed on how pharyngeal function is truly affected by NMES.[4] This review analyzes three randomized controlled trials which address NMES therapy versus control therapy, in the progression of oral feeding, in stroke patients suffering from dysphagia.

OBJECTIVE:

The objective of this selective EBM review is to determine whether or not electrical muscle stimulation is effective in the progression of oral feeding, for patients with dysphagia, caused by a stroke.

METHODS:

The studies included in this review were found within the Cochrane database, after preforming an advanced search with the following parameters: only articles published in English, studies published after 2006 and the exclusion of previously published meta-analysis or systematic reviews. The key words "dysphagia", "stroke" and "electrical muscle stimulation"

were used to search for relevant studies. Published articles were then selected based on relevance to the topic and how the outcomes were measured: disease oriented evidence (DOE) was excluded, while patient oriented evidence that matters (POEM) was included. Inclusion criteria comprised of stroke survivors who were medically stable and able to elicit some pharyngeal swallowing. Exclusion criteria included patients with neurologic disease other than a stroke, as well as patients unable to receive treatment for a minimum of 1 hour in duration. Furthermore, the studies needed to be randomized and controlled and could not involve patients under 18 years old, or involve patients with dysphagia not caused by a stroke.

The 3 articles chosen for this review are all randomized controlled trails, each of which compare the efficacy of NMES alone or with diet modification and/ or oral motor exercises, versus a traditional therapy. The intervention in each study is electrical muscle stimulation, while the comparisons are traditional therapies (including TTS, RST, diet modification, clinician determined appropriate maneuvers or other treatment techniques). The outcomes measured include either subjective swallowing function or tube to oral feeding progression, post- therapy. The population studied across all three articles is adults over 18 years of age with mild to severe dysphagia caused by a stroke. A summary of the statistics reported or used includes: p-values, RBI, ABI and NNT. The demographics of included studies can be found in **Table 1**.

Table 1*: Characteristics and Demographics of Included Studies.*

Study	Type	# of pts	Age	Inclusion criteria	Exclusion criteria	W/D	Interventions
Bulow[4] (2008)	RCT	25	50-80 (mean age 70 for NMES and 71 for TT group)	-Patients 50-80 y/o with CVD >3 months prior to the study -Patients with hemispheric stroke and without neurologic signs	-Patients with progressive CVD, other neurologic diseases or neoplastic disease of the swallowing apparatus and radiotherapy to the neck	N/A	Neuro-muscular electrical stimulation (NMES), using a hand-held electrical stimulator

				typical for brainstem involvement -Patients had to be able to elicit some pharyngeal swallowing -Patients had to be able to communicate	-Patients who had undergone surgery to the swallowing apparatus -Patients who were not able to elicit pharyngeal swallow -Patient with an NG tube		(VitalStim®), for one-hour sessions, 5 days a week for 3 weeks, compared to TT.
Permsirivanich[5] (2009)	Single blind RCT	23	>18 (64.73 ± 9.39 for RST; 64.50± 8.80 for NMES)	-Hospitalized stroke survivors with persistent dysphagia for > 2 weeks between November 2007 and September 2008. -Video-fluoroscopic study (VFSS) finding that indicated pharyngeal dysphagia with safe swallowing	N/A	5	NMES, via VitalStim®, combined with diet modification and oral motor exercise, done for 1 hour sessions, for 5 consecutive days with 2 days off for 4 week, compared to RST.
Lim[1] (2009)	RCT	28	>18 (mean SD: 67.8 (8.1) for exp; 60.8 (12.3) for control)	-Primary diagnosis of stroke with MRI or CT scans -Confirmation of a swallowing disorder by videofluoroscopy -Score of 21 or greater on the MMSE -Medically stable at the time of the study	-Inability to receive the treatment for 1 hour -A neurologic disease other than a stroke or behavioral disorder that interfered with administration of therapy -Current illness or upper GI disease -Inability to give informed consent	8	NMES, via VitalStim®, and TTS for 1 hour, 5 days a week, compared to TTS alone.

OUTCOMES MEASURED:

As previously mentioned, the primary outcomes measured in each article included either subjective swallowing function or tube to oral feeding progression. In Bulow et al[4], nutritional status via a 7-point scale, called the actual nutrition scale (ANS), was used to assess outcomes. The 7-point scale is as follows: 0= full oral, no limitations; 1= full oral, with compensation; 2= full oral, with consistency restriction; 3= full oral, with compensation and consistency restriction;

4= partial oral; 5= partial oral, with compensation; 6= tube feeding. In Permsirivanich et al[5], outcomes were assessed based on changes in functional oral intake via the Functional Oral Intake Scale (FOIS), a 7-point scale reflecting the patient's report of food/ liquids safely ingested by mouth on a consistent basis. The FOIS scale is as follows: 1= nothing my mouth; 2= tube dependent with minimal attempts of food or liquid; 3= tube dependent with consistent oral intake of food or liquid; 4= total oral diet of a single consistency; 5= total oral diet with multiple consistencies but requiring special preparation; 6= total oral diet with multiple consistencies without special preparation, but with specific food limitations; 7= total oral diet with no restriction. Finally, Lim et al[1] looked at both tube feeding to oral progression and swallowing function, via an alternate 7 point scale, which is as follows: 0= nothing safe (aspirated saliva); 1= saliva; 2= pudding, paste, ice slush; 3= honey consistency; 4= nectar consistency; 5= thin liquids; 6= water.

RESULTS:

The results obtained in all three studies were presented as continuous data. In Permsirivanich et al[5] and Lim et al[1], some of the data could be successfully converted to dichotomous form. However, this was not a possibility in Bulow et al[4].

The study conducted by Bulow et al[4] used the ANS mentioned above to compare traditional swallowing therapy (TT), conducted for 60 minutes, 5 days a week for 3 weeks versus NMES done for 60 minutes, 5 days a week for 3 weeks. Twenty-five patients over the age of 18 were included, with 12 randomized to the NMES group and 13 to TT. All subjects received 15 therapy sessions, regardless of the group they were randomized to. There was not a significant loss to follow-up in this study, which indicates a loss of < 20%. **Table 2,** taken directly from Bulow et al[4], summarizes the results, which compares median (as well as 25th and 75th percentile)

pre- and post-treatment ANS scores. The data is continuous and could not be converted to dichotomous data. The median post-treatment minus pre-treatment ANS score was 0 for NMES plus TT therapy, as well as TT therapy alone, and -1 for NMES therapy alone. Using the Wilcoxon signed rank test to examine this data, Bulow et al[4] found the data to be statistically significant, with a p-value of .002 (a p-value < 0.05 indicates statistical significance). However, when the therapy effects between the NMES group and the TT group were compared using the Mann-Whitney test, there were no statistically significant differences found between the groups, as indicated by a p-value of 0.189. [4]

Table 2: *Actual nutrition scale (ANS), comparisons pre- and post-treatment*[4]

ANS	Pretreatment			Post minus pre-treatment			p[a]
	Median	25th; 75th	N	Median	25th; 75th	N	
NMES	2.5	0.5; 5.8	12	-1.0	-2.0: 0	12	0.189 (ns)
TT	3.0	0; 5.0	13	0	-1.0; 0	13	
NMES + TT	3.0	0: 5.0	25	0	-1.0: 0	25	0.002

**ns= not significant*

In Permsirivanich et al[5], change in functional oral intake was measured using the functional oral intake scale (FOIS), mentioned above, in order to compare treatment outcomes between RST and NMES intervention in stroke patients. Twenty-three patients enrolled in the study were randomly split into a RST group of 11 and a NMES group of 12. While there were originally 28 patients enrolled in the study, the losses (18%) did not constitute a significant loss. All subjects received 60 minutes of either RST or NMES for 5 consecutive days, followed by 2 days off, then 5 additional consecutive days for a four-week period, until they reached a FOIS level of 7. The summary of results can be found in **Table 3** & **Table 4. Table 3** illustrates continuous data that was converted to dichotomous data. The data in **Table 3,** which uses the percent of patients who managed total oral intake after therapy, in the RST (75%) versus the NMES (90%) group, to determine relative benefit increase (RBI), absolute benefit increase

(ABI) and number needed to treat (NNT) does indicate that treating 7 patients with dysphagia post-stroke with NMES therapy, compared with RST, will have 1 additional patient achieve total oral intake (as noted by the NNT of 7).

Permsirivanich et al[5] also included mean FOIS score changes, post-treatment, for the RST and NMES groups, which was presented as continuous data, as seen in **Table 4**. Using a t-test, the mean FOIS changes, for both the RST and NMES groups, were determined to be statistically significant ($p < .001$), with the NMES therapy group attaining a greater mean FOIS score change of 3.17 ± 1.27 versus 2.46 ± 1.04 in the RST group.

Table 3: *Percentage of patients who managed total oral intake (FOIS levels 4-7) after therapy.*

Total oral intake (FOIS levels 4-7) after therapy.		Relative Benefit Increase (RBI)	Absolute Benefit Increase (ABI)	Numbers Needed to Treat (NNT)
RST	NMES			
75%	90%	20%	15%	7

Table 4*: Mean FOIS score change post-treatment.*[5]

Total oral intake (FOIS levels 4-7)	RST	NMES therapy	p-value
Mean FOIS change	2.46 ± 1.04	3.17 ± 1.27	<0.001

Finally, in Lim et al[1], swallow function scores, based on the swallowing function scoring system mentioned above, were calculated 4 weeks prior to treatment and 4 weeks post-treatment for both the experimental group (NMES & TTS simultaneously) and the control group (TTS only). The therapy sessions in both groups lasted for 1 hour on 5 of 7 days each week. Thirty-six subjects entered the study, while 28 patients (16 in the experimental group and 12 in the control group) with dysphagia completed the study, making the losses to follow-up > 20%, and thus a significant loss. Lim et al[1] stated that the main reason for patients not completing the study was "early transfer to other hospital". **Table 5,** taken directly from Lim et al[1]**,** includes a summary of the initial, final and difference in the median swallow function scores, for the experimental and

control group. While the table indicates a difference in the median initial swallow scores for the control and experimental group (2 in the experimental versus 3 in the control), Lim et al[1] states "there was no difference between the 2 groups at initial evaluation". However, it is evident in **Table 5**, that the median value of swallow function scores in the experimental group changed from 2 to 4, with a p-value <0.05 (as indicated by the Wilcoxon test), signifying a statistically significant difference, while the control group changed from 3 to 4, with a p-value that was not reported but stated to be "not significant". As the study explains, "regarding the difference between the initial and final swallow function score, patients in the experimental group had significantly higher score changes than those in the control group".

Tube feeding to oral-feeding progression was another parameter studied by Lim et al[1]. Before the experiment, 7 out of 12 patients in the control group, and 12 out of 16 patients in the experimental group, were receiving tube feeds. Following the respective interventions, only 1 of the 7 patients in the control group progressed to oral feeds, while 6 out of the 12 patients in the NMES & TTS group progressed. While this data was reported as continuous numbers in the study, it was switched to dichotomous data for this review, as noted in **Table 6.** NNT was calculated at 3, indicating that treating 3 patients with dysphagia post-stroke with NMES & TTS combined compared with TTS alone will have 1 additional patient achieve progression from tube to oral feeding, at 4 weeks after treatment.

Table 5*: Median swallow function scores, using the swallowing function scoring system.*[1]

Swallow Scores	Experimental Group	Control Group
Initial swallow scores	2	3
Final swallow scores	4*	4
Difference in scores after the treatment	2**	1

**p<0.05 by Wilcoxon test between initial and final scores in the same group.*
***p<0.05 by Mann-Whitney U test between experimental and control groups.*

Table 6: *Tube to oral feeding.*

Tube to oral feeding.		RBI	ABI	NNT
TTS alone	NMES & TTS			
14%	50%	25.7%	36%	3

It is important to note that NMES therapy is a relatively safe intervention, with few significant adverse reactions (more information regarding this can be found in the discussion section below). Thus, the studies reviewed for this analysis did not mention much regarding tolerability, or adverse events of therapy, and therefore will not be discussed here.

DISCUSSION:

The goal of this review was to investigate whether or not NMES therapy is effective in the progression of oral feeding, in patients with dysphagia, caused by a stroke. Traditional NMES therapy is perhaps most widely known for its role in muscle rehabilitation, post-injury, because it helps to produce muscle contractions by exciting targeted motor nerves. Some of the common conditions NMES is used for include sprains, strains, muscle weakness and atrophy. The presence of healthy muscle tissue and peripheral nerve excitability are necessary in order to produce therapeutic effects for these individuals.[6] This same thought process is applied when considering NMES for dysphagia. In dysphagia treatment, small, electrical impulses are administered to the musculature overlaying the throat, while the patients exercises the swallowing muscles, for up to 1 hour. It is postulated that this stimulation accelerates cortical reorganization and increases muscle strength. However, traditional NMES electrodes are contraindicated for use on the pharyngeal muscles due to the concern of causing laryngospasms with stimulation of the laryngeal afferents, and the threat of sinus bradycardia if the electrodes are too close to the carotid arteries.[7] Therefore, electrodes, such as those found in the VitalStim® Therapy System, have been developed for use specifically in the treatment of dysphagia. These

electrodes should not be used over an active infection or neoplasm, and should be used cautiously in individuals with seizure disorders or implanted electrical devices like pacemakers, defibrillators, deep brain stimulators, etc. Furthermore, patients with lower motor neuron damage or severely impaired cognition may not benefit as well as other patients from NMES treatment.[7] It is also important to note that NMES therapy for dysphagia is FDA approved, and Medicare provides reimbursement for treatment that is deemed medically necessary.[7]

Despite a lack of evidence, studies are currently being preformed, such as the 3 mentioned in this article, to better understand the role of NMES in the treatment of dysphagia, caused by a stroke. NMES appears to play a significant role in the progression of oral feeding in stroke patients suffering from dysphagia, yet its efficacy when used alone in treatment remains unclear. Bulow et al[4] concluded that no statistically significant difference was found in the therapy effects between NMES and TT groups, however, when looking at both groups as a whole, there were significant improvements noted. In Permsirivanich et al[5], RST (including diet modification, oral motor exercises, thermal stimulation and head and neck positioning) and NMES therapy (combined with diet modification and oral motor exercises) showed a positive effect in the treatment of persistent dysphagia in stroke patients, but NMES was significantly superior. Finally, in Lim et al[1], NMES combined with TTS (vs. TTS alone) had a significantly higher score change in swallowing measures, than those in the control group.

In all 3 studies reviewed, there were several limiting factors, however. All articles[1,4,5] included a relatively small number of subjects, with each comprising of less than 30 participants by the conclusion of the studies. Furthermore, the length of follow up time was limited in all studies[1,4,5], with a 4 week or less follow-up period. More specific limitations were also found in each individual study. In Bulow et al[4], the authors indicated that patients were not stratified by

hemispheric lesion, severity of CVA or time post-onset, which could have an effect on the results. It can also be noted that although randomized, the baseline data for the NMES group was more severe than those in the TT group. In Permsirivanich et al[5], the number of total treatment sessions, as well as the location of the NMES electrode placement, were not controlled for. In Lim et al[1], the participants loss to follow up was greater than 20%, undermining the validity of the study. Also, the effects of swallowing physiology of changing variables of electrical stimulation, like frequency and amplification, were not taken into account.

CONCLUSIONS:

In conclusion, electrical muscle stimulation is subjectively effective in the progression of oral feeding, in stroke patients suffering from dysphagia, according to the three studies explored in this paper. However, there is inconclusive evidence as the whether or not NMES therapy is effective alone, or only in combination with TT, as demonstrated by Bulow et al[4], or combined with TTS, as seen in Lim et al[1]. Further studies should consider controlling for these variables by having the experimental group receive only NMES therapy, versus NMES in combination with another traditional therapy.

Furthermore, the validity of the results could be increased with a greater number of subjects, as well as with long-term follow-up periods. Future studies might also consider exploring the optimal duration time of each session, as well as total number of sessions for NMES therapy, that would lead to optimal progression of oral feeding. Furthermore, it might be interesting for future studies to evaluate the effect of variable frequencies and amplitudes of NMES on swallowing physiology, just as Permsirivanich et al[5] mentions.

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