



The Effect of Sensory Level Versus Motor Level Electrical Stimulation of Pharyngeal Muscles in Acute Stroke Patients with Dysphagia: A Randomized Trial

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Abstract

Dysphagia is a serious cause of morbidity and mortality in stroke survivors. Electrical stimulation is often included as part of the treatment plan for dysphagia and can be applied at a sensory or motor level intensity. However, evidence to support these different modes of stimulation is lacking. This study compared the effectiveness of sensory and motor level stimulation on post-stroke dysphagia. This is a randomized trial conducted in an inpatient rehabilitation facility. Thirty-one participants who had dysphagia caused by stroke within 6 months prior to enrolment were included. Participants were excluded if they had a contraindication for electrical stimulation, previous stroke, psychiatric disorder, contraindications for modified barium swallow study (MBSS), or pre-morbid dysphagia. Each patient received ten sessions that included 45 min of anterior neck sensory or motor level electrical stimulation in addition to traditional dysphagia therapy. Motor stimulation was administered at an intensity sufficient to produce muscle contractions. Sensory stimulation was defined as the threshold at which the patient feels a tingling sensation on their skin. Swallow functional assessment measure (FAM), dysphagia outcome severity scale (DOSS), national outcome measurement system (NOMS), penetration aspiration scale (PAS), diet change, and the swallowing quality of life questionnaire (SWAL-QOL). Clinical outcomes were analyzed using a Wilcoxon signed-rank test, Mann–Whitney *U* test, RM ANOVA, or chi-square analysis. There was no significant difference in age, length of stay, or initial swallow FAM between groups. Patients in the sensory group showed significant improvement on swallow FAM, DOSS, and NOMS, while those in the motor group did not (Sensory: Swallow FAM ($S=48$, $p=0.01$), DOSS ($S=49.5$, $p=0.001$), NOMS ($S=52.5$, $p=0.006$); Motor: Swallow FAM ($S=20.5$, $p=0.2$), DOSS ($S=21$, $p=0.05$), NOMS ($S=29.5$, $p=0.2$)). When the groups were combined, there was statistically significant improvement on all measures except the PAS (Swallow FAM ($S=138.5$, $p=0.003$), DOSS ($S=134.5$, $p<0.001$), NOMS ($S=164$, $p=0.0004$)). When comparing motor to sensory NMES, there was no significant difference between groups for Swallow FAM ($p=.12$), DOSS ($p=0.52$), or NOMS ($p=0.41$). There was no significant difference in diet change for solid food or liquids among the groups, although 50% more participants in the sensory group saw improvement in diet. This study supports the use of electrical stimulation as part of the treatment plan for post-stroke dysphagia. Sensory-level stimulation was associated with greater improvement on outcome measures compared to motor level stimulation.

Keywords Dysphagia · Neuromuscular electrical stimulation · Swallow · Outcomes · Stroke

Introduction

Dysphagia is a serious cause of morbidity and mortality in stroke survivors [1–3]. Electrical stimulation as a treatment for dysphagia may augment recovery of impaired muscles that are involved in swallowing [4–7]. Electrical stimulation can be delivered peripherally or cortically. Transcutaneous or surface electrical stimulation (SES) is more commonly used than percutaneous due to its noninvasive nature. Whereas SES is applied to the skin surface, the percutaneous method

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provides stimulation to nerve endings through implanted electrodes and is more specific to targeted muscles. Sensory stimulation triggers the cutaneous afferents, while sensory and motor stimulation is activated with higher intensities and stimulates cutaneous afferents and motor nerves. Other stimulation such as transcranial magnetic stimulation and transcranial direct current stimulation focus on neuroplasticity and are used to stimulate the excitability of the motor cortex [8]. A range of stimulus intensities, frequencies, and durations have been implemented attempting to maximize swallowing ability in stroke survivors [9–12]. Despite these efforts, the optimal dysphagia-attenuating protocol has not been determined. It is hypothesized that motor stimulation yields improved outcomes over sensory stimulation and that a typical 10 day treatment course may not be sufficient for significant clinical outcomes with post-stroke dysphagia.

Recent evidence on swallowing supports the notion of reciprocal or heterarchical control among cerebral cortex, forebrain, brainstem and cerebellum [13, 14]. Functional neuroimaging studies demonstrate an elaborate network of cortical areas participating in both reflexive and volitional swallow. Reflexive swallows are localized bilaterally to the lateral primary somatosensory and motor cortex. Volitional swallows show bilateral activation in the insula, prefrontal, anterior cingulate, parieto-occipital and primary somatosensory and motor cortices [15–17].

The stimulus level used for motor stimulation directly leads to contraction of the supra/infrahyoid and pharyngeal constrictor muscles used in swallowing. In contrast, with the sensory approach, the sensory threshold is identified as the lowest current level at which the patient feels a tingling sensation on their skin [18]. The reduced intensity of sensory only stimulation may increase afferent drive and promote cortical plasticity [11, 19]. Although direct muscle contractions may strengthen the innervated muscles and protect the striated muscles from atrophy, it may not confer the same cortical reorganization [20]. Pharyngeal motor cortical representations undergo expansion and suppression, respectively, following brief periods of electrical pharyngeal sensory stimulation in healthy adult participants [15]. While both sensory and motor stimulation have been shown to be beneficial post-stroke [21], some studies propose that sensory stimulation as compared to motor, may have better long term reorganization of the human cortex to improve swallowing function [11, 19]. There is one study that directly compared sensory to motor stimulation following medullary stroke and found that sensory stimulation may result in better outcomes [22], however it included a narrow spectrum of stroke etiology and furthermore the NMES protocol was very extensive and may be difficult to replicate within the medical system in the United States. Therefore, in this study the aim was to compare the effectiveness of sensory and motor level stimulation on post-stroke dysphagia.

Methods

Study Design

This study was completed as a randomized blinded trial with 31 patients in an acute rehabilitation facility. All research was completed in the inpatient rehabilitation unit with ethical approval from the Casa Colina Institutional Review Board (IRB00002372). The study was registered with ClinicalTrials.gov (#NCT05102877). The lead investigators reviewed the medical records for all patients that were admitted with a diagnosis of stroke. The goal for enrolment was 32 patients as determined by a power analysis for two group independent sample t test based on the DOSS (group means = 3 ± 1 and 4, power set at 0.8 and alpha at 0.05 using JMP statistical software).

Study Participants

Study recruitment took place over a nearly 2 year period between December 2018 and October 2020. Patients were included in the study if they met the following criteria: between 50–75 years of age, confirmed stroke diagnosis by CT/MRI and diagnosed dysphagia from a clinical swallow evaluation following a stroke onset within 6 months prior to admission. Patients were excluded by the following criteria: contraindications or precautions for electrical stimulation, previous stroke, psychiatric disorder, contraindications for modified barium swallow study (MBSS), or history of dysphagia. Contraindications for Neuro Muscular Electrical Stimulation (NMES) as stated by the FDA include active neoplasm or active infection; and precautions are indicated as pacemaker, brain stimulation devices, or seizures [23]. Patients that met criteria were then screened by the treating Speech Language Pathologist using a facility generated four question screening tool (Table 1), a score of two or more qualified patients as a research candidate.

Outcome Measures

Once a patient was deemed an appropriate candidate for the study and consent was obtained a number of outcome measures were completed by the lead SLP investigator who was blinded to the neuromuscular stimulation group. 1: The swallow FIM + FAM scores (which were developed as an adjunct for areas less emphasized on the Functional Independent Measures) were obtained for pre and post treatment [24]. 2: The DOSS (primary outcome) is a seven-point functional outcome scale designed to assess dysphagia severity on the MBSS [25] (see Appendix 1 for detailed MBSS protocol). 3: The NOMS Functional Communication Measures, a 7-level classification system of swallow was also used [26].

Table 1 Screening questionnaire

Question (points)	Yes (2)	Sometimes/Partial (1)	No (0)
1. Does patient, caregiver, or family report swallowing difficulty?			
2. Is patient unable to manage secretions?			
3. 3 oz water swallow test- coughing present			
4. Will patient benefit from dysphagia therapy?			

*Score of 2 or greater qualifies participant

4: The PAS evaluates the depth response and clearance of material entering into the airway [27]. After completion of the 10 day NMES treatment protocol a repeat MBSS was completed where additional DOSS and PAS scores were obtained. Pre- and post- therapy diet consistencies were gathered using the International Dysphagia Diet Standardization Initiative (IDDSI) [28]. Finally, we assessed quality of life using the SWAL-QOL at enrolment, following the 10 day NMES treatment and 1 month following completion. The SWAL-QOL was completed by the patient or patient's family member if the patient was unable to complete the metric themselves. The SWAL-QOL, a 93-item outcome tool [29] was used to determine impact on quality-of-life and quality-of-care; this was collected at the time of enrolment, after completion of 10 treatment sessions and one month after completion of the intervention. Upon discharge, patients were given a third SWAL-QOL with a stamped addressed envelope to be completed on an identified date of 30 days after completion of treatment in the study. Some patients required follow up phone calls for completion of the SWAL-QOL. The Swallow FAM, DOSS, and NOMS served as the primary outcomes for the study with the PAS, diet information, and SWAL-QOL serving as the secondary outcomes.

Procedures

Upon qualification and physician clearance for NMES and study participation, informed consent was obtained by the lead investigators from the patient or designated family member. Patients were randomized utilizing a random number generator, and enrolled in either sensory or motor level stimulation groups accordingly. Randomization was performed by a researcher not involved in providing SLP treatment or outcome metric obtainment and thus allowed for allocation concealment. Group assignment was blinded to the researcher collecting outcome metrics and to the participant who had never experienced either treatment and therefore would not be able to differentiate between sensory or motor level stimulation.

All participants received 45 min standardized dysphagia treatment sessions coupled with NMES. As NMES is

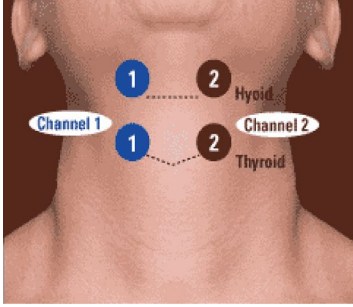
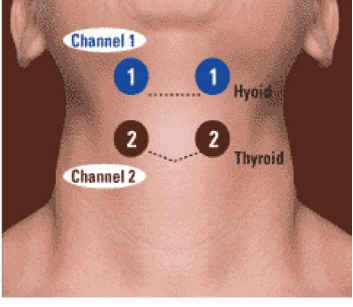
standard of care at our institution for dysphagia treatment, it was determined that a control group not receiving NMES would be unethical. For NMES treatment, placement of electrodes was dependent upon clinical judgment of the MBSS results and (Fig. 1: see diagram below of A and B for Vital Stim) using the Experia Vital Stim machine under the vital stimulation mode. Sessions were completed over a 10-day period with a protocol targeting 10 trials per exercise and included thermal tactile stimulation, oral motor exercises including lingual isometrics, gargle, pitch glide, masako and chin tuck against resistance. Respiratory exercises included ten trials of the incentive spirometer. Finally, per oral (PO) trials of various food or liquid consistencies appropriate for the patient, varying from ice chips to solids. (See Appendix 2 for protocol of exercises completed).

The clinician would initiate each session by stating the following, "I'm going to place the electrodes and start the machine. There will be intermittent pauses in the stimulation given. As we start, I want you to tell me when you feel something. I will continue to increase stimulation until we have reached our optimal level. If it becomes uncomfortable let me know." NMES was performed in each of the ten sessions. For patients in the sensory group, the clinician noted the level of the patient's first reported sensation and stimulated at no greater than 3–4 mA. For patients in the motor group, the clinician increased the level of mA to the patient's maximum tolerated level and sufficient to achieve muscle contraction. After completion of the study protocol, continued dysphagia therapy and NMES were provided per patient need including facial NMES.

Statistics

The statistical analyses were performed using JASP version 14.1. Results were presented as the mean \pm SD or median and interquartile range (IQR) for those outcomes with ordinal scales. Demographic data and clinical outcomes were analyzed using independent *t* tests, 2-tailed Mann–Whitney *U* tests, or chi-square as appropriate. The pre- post- intervention differences within individuals were evaluated using Wilcoxon signed-rank tests, while the differences between groups were assessed by the Mann–Whitney *U* test for

Fig. 1 Vital Stim Therapy Electrode Placement Guide and signs/symptoms for placement. Modified from Vital Stim Therapy Electrode Placement Guide (vitalstimtherapy.com) VitalStim Therapy Training Manual – Electrode Placement Abstract © Copyright Yorick Wijting, PT and Marcy Freed, M.A., CCC-SLP

<p>A</p> 	<p>B</p> 
<p>Possible Signs/Symptoms for Selection of A Placement:</p> <ul style="list-style-type: none"> • Decreased hyolaryngeal excursion • Penetration/Aspiration • Voice abnormalities • Decreased/delayed upper esophageal sphincter (UES) opening • Pooling and residuals <p>Uses:</p> <ul style="list-style-type: none"> • Facilitation of digastric and thyrohyoid muscles • Focus on hyolaryngeal excursion 	<p>Possible Signs/Symptoms for Selection of B Placement:</p> <ul style="list-style-type: none"> • Slow anterior/posterior transit • Premature spillage • Tongue base residue • Delayed swallow initiation • Vallecular pooling • Penetration/Aspiration • Decreased/Delayed upper esophageal sphincter (UES) opening <p>Uses:</p> <ul style="list-style-type: none"> • Thyrohyoid recruitment • Focus on pharyngeal constriction

outcomes with ordinal scales. Since the SWAL-QOL data represents subtotals, a RM ANOVA was used to analyze these results. For all analyses, statistical significance was set at $p < 0.05$.

Results

Thirty-four participants were recruited over 18 months. Thirty-one patients completed the protocol and post-treatment outcome metrics. Three participants were not included because of early discharge from the hospital which prevented study completion. Sixteen patients completed sensory NMES and fifteen completed motor NMES. Due to oral apraxia, cognitive deficits, aphasia, or severe dysarthria,

five patients were unable to complete every exercise of the treatment protocol, however they were able to do 90% of the exercises and therefore included in the study. Each session documented exercises completed, stimulation provided, placement, visit number and duration of NMES treatment. There were no significant differences between the groups for age, length of stay, and initial swallow FAM or electrode placement at enrolment (Table 2). The majority of strokes included in the study were ischemic (90%), with over 50% on the left side, 35% right side. Approximately 13% did have strokes involving the brainstem and all four of these participants were in the sensory group. The average time since injury was 21 days. Table 3 shows the median and interquartile range (IQR) for the clinical outcomes pre and post sensory or motor NMES intervention. The Sensory

Table 2 Demographics of participants

Participant variables	Sensory NMES (n = 16)	Motor NMES (n = 15)	p value
Sex			
Female	5 (31.2%)	7 (46.7%)	
Male	11 (68.8%)	8 (53.3%)	
Age	65.3 ± 12.3	71.1 ± 13.4	0.21
Length of Stay	23.3 ± 5.3	25.4 ± 5.8	0.30
Pre-swallow FAM median (IQR)	4 (2.5)	4 (1)	0.89
Electrode placement			
Position 3A	6 (37.5%)	4 (27%)	
Position 3B	10 (62.5%)	11 (73%)	

Results were presented as the median and interquartile range (IQR). Data were analyzed using independent t tests and a Kruskal–Wallis test

For all analyses, statistical significance was set at $p < .05$

NMES group showed statistically significant improvement on Swallow FAM ($S = 48, p = 0.01$) DOSS ($S = 49.5, p = 0.001$), and NOMS ($S = 52.5, p = 0.006$) after the intervention. The Motor NMES group did not show statistically significant improvement on the outcome measures (Swallow FAM: $S = 20.5, p = 0.2$), (DOSS: $S = 21, p = 0.05$), (NOMS: $S = 29.5, p = 0.2$). The PAS did not show significant changes for either group (Table 2). When the groups were combined, there was statistically significant improvement on all measures except the PAS (Swallow FAM: $S = 138.5, p = 0.003$), (DOSS: $S = 134.5, p < 0.001$), (NOMS: $S = 164, p = 0.0004$). When comparing changes from motor NMES to changes in sensory NMES we used a Mann–Whitney U test but observed no significant difference between groups for Swallow FAM ($U = 0.82, p = 0.12$), DOSS ($U = 104, p = 0.52$), NOMS ($U = 99.5, p = 0.41$) or PAS ($U = 86.5, p = 0.38$). Patients in the sensory group also had an increased propensity to improve their diet versus the motor group as demonstrated in Table 4: (58.3% vs. 25% for solid and 55.6% vs. 27% for liquid diet), though these results were not

Table 3 Effect of NMES on swallow ability

Outcomes	Pre median (IQR)	Post median (IQR)	p value	S Statistic (Wilcoxon signed rank)	Mann–Whitney U between groups
Swallow FAM	4 (1)	4 (1)	$p = 0.003$	$S = 138.5$	$U = 82, p = 0.12$
Sensory NMES	4 (2.5)	4 (1)	$p = 0.01$	$S = 48$	
Motor NMES	4 (1)	4 (1)	$p = 0.20$	$S = 20.5$	
DOSS	3.5 (2)	4 (2)	$p < 0.001$	$S = 134.5$	$U = 104, p = 0.52$
Sensory NMES	4 (2)	5 (1.25)	$p = 0.001$	$S = 49.5$	
Motor NMES	3 (2)	3 (1.5)	$p = 0.05$	$S = 21.0$	
NOMS	4 (1)	4 (1)	$p = 0.0004$	$S = 164$	$U = 99.5, p = 0.41$
Sensory NMES	4 (3.25)	4.5 (1.75)	$p = 0.006$	$S = 52.5$	
Motor NMES	4 (1)	4 (2)	$p = 0.20$	$S = 29.5$	
PAS	1 (4)	1 (0.75)	$p = 0.12$	$S = - 55.5$	$U = 86.5, p = 0.38$
Sensory NMES	1 (3)	1 (0)	$p = 0.44$	$S = - 8.0$	
Motor NMES	1 (4)	1 (1.75)	$p = 0.31$	$S = - 17.5$	

Results were presented as the median and interquartile range (IQR). The pre-intervention, post-intervention, for all patients and by treatment group were evaluated using a Wilcoxon signed-rank test. The Mann–Whitney test was used to compare changes between groups

For all analyses, statistical significance was set at $p < .05$

Table 4 Effect of NMES on diet

Outcome variable	Motor vs. sensory	% Change motor	% Change sensory
Solid diet change	Chisq = 2.8, $p = 0.09$	25%	58.3%
Liquid diet change	Chisq = 1.7, $p = 0.20$	27%	55.6%

Changes in solid and liquid diet were compared between the intervention groups. A chi sq analysis was used as well as percent change

Table 5 Effect of NMES on quality of life

Outcome subtotal	Pre mean (\pm SD)	Post mean (\pm SD)	1 mo post mean (\pm SD)	<i>p</i> value	ANOVA <i>F</i> (df)
Burden	2.8 \pm 1.4	3.1 \pm 1.7	2.2 \pm 2.2	<i>p</i> =0.09	<i>F</i> =2.5 (2, 56)
Sensory NMES	3.0 \pm 1.3	3.3 \pm 1.7	2.3 \pm 2.3	<i>p</i> =0.38	<i>F</i> =0.1 (2, 28)
Motor NMES	3.1 \pm 1.3	3.3 \pm 1.3	2.4 \pm 2.2	<i>p</i> =0.20	<i>F</i> =1.7 (2, 28)
Symptom frequency	3.4 \pm 1.2	3.2 \pm 1.4	2.3 \pm 2.2	<i>p</i> =0.006	<i>F</i> =5.7 (2, 56)
Sensory NMES	3.7 \pm 0.7	3.5 \pm 1.5	2.4 \pm 2.3	<i>p</i> =0.07	<i>F</i> =2.9 (2, 28)
Motor NMES	3.4 \pm 1.1	3.5 \pm 0.7	2.4 \pm 2.1	<i>p</i> =0.07	<i>F</i> =2.9 (2, 28)
Food selection	3.0 \pm 1.5	2.9 \pm 1.6	2.1 \pm 2.2	<i>p</i> =0.05	<i>F</i> =3.2 (2, 56)
Sensory NMES	3.0 \pm 1.3	3.2 \pm 1.5	2.3 \pm 2.3	<i>p</i> =0.48	<i>F</i> =0.8 (2, 28)
Motor NMES	3.3 \pm 1.4	3.2 \pm 1.5	2.1 \pm 2.2	<i>p</i> =0.06	<i>F</i> =3.2 (2, 28)
Communication	2.7 \pm 1.6	2.7 \pm 1.6	2.1 \pm 2.2	<i>p</i> =0.26	<i>F</i> =1.4 (2, 56)
Sensory NMES	3.0 \pm 1.3	2.9 \pm 1.6	2.2 \pm 2.2	<i>p</i> =0.50	<i>F</i> =0.8 (2, 28)
Motor NMES	2.8 \pm 1.6	2.9 \pm 1.5	2.3 \pm 2.2	<i>p</i> =0.55	<i>F</i> =0.6 (2, 28)
Fear	3.4 \pm 1.5	3.2 \pm 1.6	2.3 \pm 2.2	<i>p</i> =0.01	<i>F</i> =4.8 (2, 56)
Sensory NMES	3.7 \pm 1.0	3.4 \pm 1.6	2.4 \pm 2.4	<i>p</i> =0.16	<i>F</i> =1.9 (2, 28)
Motor NMES	3.5 \pm 1.4	3.4 \pm 1.3	2.3 \pm 2.1	<i>p</i> =0.06	<i>F</i> =3.2 (2, 28)
Mental health	3.1 \pm 1.5	3.2 \pm 1.7	2.1 \pm 2.2	<i>p</i> =0.02	<i>F</i> =4.4 (2, 56)
Sensory NMES	3.5 \pm 1.1	3.4 \pm 1.8	2.4 \pm 2.3	<i>p</i> =0.17	<i>F</i> =1.9 (2, 28)
Motor NMES	3.2 \pm 1.5	3.2 \pm 1.5	2.2 \pm 2.0	<i>p</i> =0.08	<i>F</i> =2.7 (2, 28)
Social	3.5 \pm 1.5	3.2 \pm 1.7	2.1 \pm 2.2	<i>p</i> =0.004	<i>F</i> =6.0 (2, 56)
Sensory NMES	4.0 \pm 1.0	3.4 \pm 1.7	2.4 \pm 2.4	<i>p</i> =0.09	<i>F</i> =2.6 (2, 28)
Motor NMES	3.4 \pm 1.5	3.3 \pm 1.3	2.1 \pm 2.1	<i>p</i> =0.03	<i>F</i> =4.2 (2, 28)
Fatigue	3.1 \pm 1.5	3.1 \pm 1.6	1.9 1.9	<i>p</i> =0.003	<i>F</i> =6.4 (2, 56)
Sensory NMES	3.5 \pm 1.2	3.3 \pm 1.7	2.0 2.0	<i>p</i> =0.05	<i>F</i> =3.3 (2, 28)
Motor NMES	3.0 \pm 1.4	3.3 \pm 1.2	2.1 1.9	<i>p</i> =0.05	<i>F</i> =3.3 (2, 28)
Sleep	3.4 \pm 1.6	2.8 \pm 1.4	2.0 \pm 2.0	<i>p</i> =0.004	<i>F</i> =6.2 (2, 56)
Sensory NMES	3.9 \pm 1.1	3.1 \pm 1.6	2.1 \pm 2.1	<i>p</i> =0.02	<i>F</i> =4.7 (2, 28)
Motor NMES	3.2 \pm 1.6	2.9 \pm 0.8	3.1 \pm 1.3	<i>p</i> =0.18	<i>F</i> =1.8 (2, 28)

Results were presented as the mean and SD. The pre-intervention, post-intervention, and 1 month follow up for all patients and by treatment group were evaluated using a repeated measure ANOVA

For all analyses, statistical significance was set at $p < .05$

statistically significant (Chi-square 2.8 $p=0.09$ for solid and chi-square 1.7 $p=0.20$ for liquid).

The SWAL-QOL was used to evaluate patient reported changes in swallow. From this 44-item tool we assessed 10 quality of life concepts following McHorney et al. 2002 [29]. We found a significant change from pre-NMES to 1 month post in six of nine QoL domains. Post hoc analysis with Bonferroni correction show the significant relationship is between the pre or post testing and the 1 month follow up, not between the pre and post NMES intervention (Burden of Dysphagia: $F=2.5$ (2, 56), $p=0.09$, Symptom: $F=5.7$ (2, 56), $p=0.006$, Food Selection: $F=3.2$ (2, 56), $p=0.05$, Communication: $F=1.4$ (2, 56), $p=0.26$, Fear: $F=4.8$ (2, 56), $p=0.01$, Mental Health: $F=4.4$ (2, 56), $p=0.02$, Social: $F=6.0$ (2, 56), $p=0.004$, Fatigue: $F=6.4$ (2, 56),

$p=0.003$, Sleep: $F=6.2$ (2, 56), $p=0.004$) (Table 5). No significant difference was observed between the sensory and motor groups.

Discussion

This study represents one of the first to directly compare the effect of motor and sensory stimulation on swallowing function in patients with various types of stroke. Utilizing a standardized protocol and screening questionnaire, patients were selected based on the clinical history and clinician examination. The groups were randomized and blinded, and had no significant differences in their demographics or level of dysphagia as measured on outcome metrics. The

present study supports the use of electrical stimulation during speech therapy to treat stroke-related dysphagia. The benefit of NMES is evidenced by our combined group (all patients in the study) showing a significant improvement on all of the outcome metrics tested. It is acknowledged that without a control group, the degree of influence from spontaneous recovery can't be fully accounted for. This bolsters the findings of previous research which showed improved outcomes with the use of this modality during dysphagia therapy [30–35]. When analyzed within sensory and motor groups, our study shows significant improvement on all outcome measures in the sensory group and while there were changes in the motor group, they did not reach significance. This study is in alignment with previous studies which have also found improvement from sensory level stimulation [19]. Zhang et al. which compared motor and sensory level stimulation found greater improvements with sensory level stimulation as compared to motor [22]. The present study confirms those findings in a different population (Zhang et al. included medullary stroke only), and over a time course (10 sessions versus 30 days) which is more relevant to inpatient rehabilitation in the US healthcare system. Additionally, their NMES intervention took place twice per day, while ours was provided in once-daily therapy sessions. In our direct comparison, we show the potential for greater improvement in outcome measures for sensory versus motor stimulation. This was seen in FAM, DOSS, and NOMS but did not reach statistical significance. A larger sample size in future studies may help elucidate potential differences between sensory and motor NMES.

The clinical relevance of this study is multifaceted and provides evidence to support the benefits of sensory (lower-level) stimulation. The mechanism for this may be an increased number of swallows, [32] thereby having a positive effect on dysphagia remediation. One of the principles of electrical stimulation is that larger or deeper contractions can be triggered once the motor contraction has been achieved [36]. The tissues affected will be dependent on the intensity of stimulation provided. Therefore, in the case of the sensory stimulation provided at 3–4 ma the area reached by the stimulation would be smaller than that of motoric stimulation at higher intensities. In the study by Costa et al. [37] sensory level stimulation was provided at 2 mA below the motoric level which was 2 mA below the maximum threshold. These sensory levels are much higher than those in this study and could involve some degree of muscle contraction. Nagami et al. [38] used interferential current transcutaneous electrical sensory stimulation which stimulates afferent nerves and activates the superior laryngeal nerve at 3 mA to avoid causing muscle contraction,

which was more similar to our approach. The lack of guidelines on the most effective setting and use of NMES in the stroke dysphagia population leads to treatment that is clinician or facility determined. These findings aid clinicians in determining how to maximize the benefit of NMES. Additionally, some patients have poor tolerance with the higher levels of stimulation needed to induce motor activity during NMES treatment. This leads to a change of the VMS mode on the Vital Stim unit which allows for adjustment of phase duration, frequency and work/rest time. VMS mode was not utilized during this study. Given the current results, sensory level stimulation may be effective and may also improve tolerance in these patients, preventing discontinuation of NMES in patients who otherwise would do so if only motor level stimulation is offered.

Although in the present study PAS scores did not reveal a clinically significant change, it is a valuable tool that should continue to be monitored. Patients with facial droop have oral stage dysphagia that affects intraoral pressure and bolus manipulation and although remediation of lingual strengthening was targeted, labial weakness was not. This initial critical stage of swallow impacts oropharyngeal pressures affecting pharyngeal clearance and glottal protection. Another consideration of the lack of significant change may be related to inconsistencies in swallow function. This was observed across the bolus trials with varied consistencies given during the MBSS. Whereas one trial of a particular consistency was swallowed efficiently and effectively, another may have resulted in penetration or even aspiration; bolus volume is a consideration in this. Additionally, a 10 day course of treatment may not be long enough for impact on the PAS scores.

Several metrics were utilized to better understand the effects of sensory vs. motor NMES paired with dysphagia treatments on quality of life. These included the SWAL-QoL as well as improvements in diet texture. The SWAL-QoL was broken into ten QoL domains and analysis was completed for each domain. A significant effect was observed between the pre-NMES values and those at 1 month post-intervention. There was no significant difference between motor and sensory level stimulation. Since other factors including natural recovery could account for the QoL data at 1 month post completion of the NMES we are not able to conclude that the NMES had a direct effect on QoL. We did notice a potential trend toward increased improvement in QoL within the sensory groups which would be consistent with the diet consistency and tolerance data which has also been found to contribute to QoL [39].

Since the underlying mechanism of NMES is largely unknown, it remains unclear why we see improved swallow

safety with sensory level stimulation. In previous studies, use of sensory versus motor NMES resulted in improved clearance of pharyngeal residue and timeliness in swallow, ultimately resulting in improved scores on the PAS [11]. Improvements in swallow cannot be solely attributed to electrical stimulation as standard of care dysphagia therapy was provided during this time frame [41].

Limitations

Some limitations may have impacted the outcomes of our study results. Although a placebo control group would be ideal for the research study, NMES is the standard of care in our facility and therefore considered to be unethical to withhold a potentially beneficial treatment from our patients during this critical recovery time. We found both the motor stimulation and sensory stimulation to be beneficial but a larger sample size and longer monitoring period would help elucidate the effectiveness of each type of stimulation. The different electrode placement between groups may present a limitation when comparing groups as well. During the COVID-19 Pandemic, our patients who required family assistance for completion of the SWAL-QOL may have had less accurate scoring due to family members having limited contact with patients during hospitalization. Three of the surveys were completed by the treating clinician for the above reason, which may have introduced performance bias. We also did not restrict outpatient or additional therapy following the NMES intervention and thus the 1 month post SWAL-QOL data is not a direct measure of the intervention only. During treatment sessions, it was not always possible to complete the entire 45 min treatment duration as some patients required assistance with toileting or nursing assistance to get out of bed, delaying start times. Additional limitations include patients with severe apraxia or aphasia inhibiting accuracy or ability to follow oral motor exercises in the study regimen. Further, the study did not allow for patients to receive facial stimulation until after the completion of the 10 sessions, which can help patients maintain the bolus in the oral cavity and create necessary intraoral pressure. Spontaneous recovery must be considered as patients were in their early stages of recovery from stroke. Finally, we did have four participants with strokes involving brainstem, which may impact the severity of dysphagia. Although severity was matched pre-intervention the recovery trajectory may be slower for these participants, who were all four in the sensory group and thus could have limited the outcomes for the sensory group. However, potential limitation appears minimized since there was no significant difference in pre-intervention scores between the two groups.

Conclusion

This study aimed to determine the efficacy of sensory (no greater than 3–4 mA) versus motor NMES following acute CVA over a 10 day regimented dysphagia treatment program. Results from the pre-NMES to 1 month post indicated a statistically significant improvement in perception of swallow in SWAL-QOL in the both groups, and a propensity for diet change in the sensory group although not statistically significant. These results contribute to clinical decision making regarding the use of sensory versus motor stimulation for dysphagia remediation. There is limited research on the use of sensory settings for dysphagia management and therefore may limit clinicians' application. Additionally, this evidence shows the benefits of NMES when coupled with traditional dysphagia therapy. There is still much to be researched to determine treatment frequency, duration, and type (motor vs. sensory NMES) for long term effects on dysphagia recovery.

Appendix 1

Procedure Supplement

MBSS Protocol

Patients were seated in an upright position in their wheelchair with both lateral and anterior–posterior views taken at 15pps. A structured protocol of barium administration was followed including: 2 trials of 5 ml Varibar thin liquid barium by spoon, 5 ml thin liquid barium by cup, 30 ml thin liquid barium sequential swallows by cup, 5 ml slightly thick liquid barium by cup using EZ Paque, 5 ml mildly thick Varibar by cup, 30 ml mildly thick barium sequential swallows, 5 ml moderately thick Varibar by cup, 5 ml applesauce (classified as a wet puree) with EZ HD barium powder, 5 ml pudding (classified as a thick puree) with EZ HD barium powder, 5 ml tuna (minced and moist) with EZ HD barium powder by spoon, 5 ml chopped chicken (soft and bite sized) coated with 2 ml moderately thick barium, and a Lorna Doone cookie coated with 3 ml honey thick barium. This protocol was followed and was only deviated from if the patient was deemed unsafe to continue with that particular consistency based on mastication ability, pharyngeal clearance and penetration or aspiration. Behavioral maneuvers such as chin tuck, effortful swallow, head turn were trialed when deemed appropriate based on MBSS findings and patient's ability to comply with instructions given.

Appendix 2

NMES Daily Data Collection Sheet

NMES RESEARCH DAILY DATA COLLECTION SHEET

NMES PLACEMENT (“I’m going to place the electrodes and start the machine. There will be intermittent pauses in the stimulation given. As we start I want you to tell me when you feel something, I will continue to increase the stimulation until we have reached our optimal level. If it becomes uncomfortable let me know.” Reported sensation at _____ mA

SENSORY STIMULATION- THERMAL TACTILE STIMULATION: CENTER OF TONGUE, SIDES OF TONGUE

1	2	3	4	5	6	7	8	9	10
1	2	3	4	5	6	7	8	9	10

ORAL MOTOR EXERCISES (lingual isometrics: pt pull in with therapist holding)

	1	2	3	4	5	6	7	8	9	10
LINGUAL ISOMETRICS										
TONGUE DEPRESSOR FRONT										
TONGUE DEPRESSOR SIDES										
GARGLE										

PHARYNGEAL STRENGTHENING EXERCISES

	1	2	3	4	5	6	7	8	9	10
PITCH GLIDE										
MASAKO										
BALL SQUEEZE										

RESPIRATORY

INCENTIVE SPIROMETER	1	2	3	4	5	6	7	8	9	10
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