

Evidence Table

Clinical Area: Neuromuscular electrical stimulation (NMES) for the treatment of dysphagia

Reference: Carnaby-Mann GD, Crary MA. Examining the evidence on neuromuscular electric stimulation for swallowing. A meta-analysis. *Arch Otolaryngol Head Neck Surg.*2007;133:564-571

Study Type: Meta-analysis of non-randomized controlled studies and case series.

Study Aim: To evaluate the effect of transcutaneous neuromuscular electrical stimulation (NMES) on swallowing rehabilitation.

Outcomes

Primary: Change in swallowing score.

Design

- *Focused on a discrete clinical question:* Yes.
- *Explicit description of literature search:* Yes.
- *State inclusion and exclusion criteria for studies:* Inclusion: Randomized and quasi-experimental trials including a measurable independent variable, and including: men or women 18 years of age or older with a secondary diagnosis of oropharyngeal dysphagia, and who received NMES for swallowing and rehabilitation. Exclusion: animal studies, studies without a clinical prognostic population, experiment reporting results on muscles other than the throat or neck, and studies on intramuscular applications of electrical stimulation.
- *Description of study populations:* No.
- *State criteria used to evaluate quality of studies:* Yes, the authors used the Physiotherapy Evidence Database (PEDro) scale.
- *Method used to synthesize data (fixed-effects model, random-effects model, both):* Both the fixed-effects and the random effects models were used.

Validity:

- *Is the study type of the included studies appropriate for the question(s) being asked?* No.
- *Did two or more independent reviewers select studies and extract data?* Yes.
- *Data tested for homogeneity?* Yes.
- *If data were heterogeneous, was the analysis method appropriate? (E.g. stratified analysis or random effects model)?* Yes.
- *Did the authors do sensitivity analysis to examine robustness of findings (e.g. by quality of studies)?* No.
- *How did the authors address possible publication bias?* Publication bias was assessed using funnel plots and the Egger test.
- *Industry funding:* The meta-analysis was supported by a grant from the Chattanooga group, the manufacturer of VitalStim.

Conclusions regarding validity of methods:

The meta-analysis included only one small nonrandomized controlled study, a retrospective study with a comparison group, and very small case series on the NMES for the management of dysphagia. The methodology of the meta-analysis was generally valid, however its quality and strength is dependent on the methodological quality of the studies it includes.

Results

- The analysis included 7 studies with 255 participants treated with NMES for dysphagia of multiple etiologies.
- Two of the studies (N=179) were controlled (one was prospective, and the other retrospective), and five studies (N=76) used the before and after comparison.
- All studies used transcutaneous electrical stimulation to the throat, and one used it simultaneously with surface electromyography.
- All studies included a mix of gender, age, and etiology of dysphagia including stroke, cancer, head trauma, and respiratory failure.
- Outcomes in the studies included swallowing scale, weight gain, functional eating, residue on a swallowing x-ray study or laryngeal elevation.
- Duration of treatment of NMES varied between studies from 1 month to 24 weeks.
- The number of total treatment sessions varied across studies.
- The methodological score using the Pedro scale ranged from 3 to 6 points with a mean of 3.71. Three studies had a high quality rating, and 4 had a mean score of 3 which is considered to be low quality
- There were signs of heterogeneity between the studies.

Change in swallowing score*

	Effect size (95% CI)	p
For all seven studies combined	0.66 (0.47-0.85)	<0.001
For 5 studies using similar outcomes**	0.62 (0.40-0.83)	<0.001

*Mean improvement in swallowing performance was 20% after electrical stimulation therapy across all 7 studies

**Same clinical outcome measure of clinical swallowing score. This was a subjective outcome that could be influenced by the clinicians' assessment of the swallowing ability of the patient.

Authors' Conclusions:

The authors concluded that the results of the meta-analysis show a small but significant improvement in swallowing with transcutaneous electrical stimulation therapy. They however recommended that the results of the analysis be treated with caution due to the absence of randomized controlled trials and the limitations of the studies included in the meta-analysis.

Reviewer's Conclusions:

The results of the meta-analysis do not provide sufficient evidence to determine the effectiveness of NMES in the treatment of dysphagia. It did not include any randomized controlled trials, only small non-randomized controlled and case series which provide a low grade of evidence. These studies included selected groups of patients, had mainly subjective outcomes, were not blinded, and had a poor overall rating by the authors of the meta-analysis. Moreover, the meta-analysis was supported by a grant from the Chattanooga group, the manufacturer of VitalStim.

Evidence Table

Clinical Area: Neuromuscular electrical stimulation (NMES) for the treatment of dysphagia

Reference: Bulow M, Speyer R, Baijens L, et al. Neuromuscular electrical stimulation (NMES) in stroke patients with oral and pharyngeal dysfunction. *Dysphagia* April 2008

Study Type: Randomized controlled trial.

Study Aim: To evaluate and compare the outcome of NMES to the traditional swallowing therapy in stroke patients.

Outcomes

- *Primary:* Clinical and videographic evaluation of swallowing, nutritional status, and oral motor function.

Design

- *Number of subjects:* N=25 (N=12 in the NMES group, and 13 the traditional swallowing therapy group [TT]).
- *Description of study population:* The study was conducted in the Netherlands, and included 16 (64%) men, and 9 (36%) women, with a mean age of 70 years.
- *Inclusion criteria:* 1. Age 50-80 years of age, 2. History of a stroke more than 3 months prior to randomization, 3. Hemispheric stroke and no signs of brainstem involvement, 4. Ability to elicit some pharyngeal swallow as revealed by videographic swallowing evaluation, 5. With no nasogastric tube, and ability to communicate.
- *Exclusion criteria:* 1. Progressive cerebrovascular disease, 2. Other neurologic diseases, 3. Tumors in the swallowing apparatus and undergoing radiotherapy of the neck, 4. history of surgery for the swallowing apparatus, 5. Inability to elicit pharyngeal swallow, and 6. Nasogastric tube.
- *Intervention:* The patients were randomly assigned to receive either the NMES or TT therapy both administered by a speech-language pathologist trained in dysphagia management. NMES (VitalStim) group had two sets of electrodes placed on each side of the midline of the throat, and two sets placed just at or above the level of the thyroid notch over the thyroid muscle. The mean level of ES was 13mA with a range of 40.5 to 25 mA. They received 15 treatments (one 60-min session every day for 5 days a week over 3 weeks). Patients were allowed to have a modified diet if they had it modified before enrollment in the trial, and were only allowed spontaneous maneuvers. TT group underwent diet modification, other treatment techniques or maneuvers as determined by their physician, they received 15 treatment sessions (60 minutes a day, 5 days a week for three weeks), and were given exercise sheets for the specific exercises they had to perform.
- *Source of outcome data:* Clinical evaluation, qualitative assessment of swallowing using a visual analog scale, assessment of nutritional status, oral motor function test, videographic swallowing evaluation, and radiographic evaluation by video fluoroscopy.

- *Length of follow-up*: Not discussed but the patients received therapy for 3 weeks.

Validity:

- *Blinding?* The authors indicate that the radiologist who examined the videographic results was blinded to whether the examination was performed before of after the treatment. They did not discuss blinding of the physician examining the patients, and obviously the patients were not blinded to the therapy received.
- *Appropriate randomization procedures?* Yes.
- *Appropriate comparison intervention (placebo or adequate dose of accepted intervention)?* Yes.
- *Treatment/control groups comparable at baseline?* No, there were differences between the two groups in the VAC nutritional status, and some of the variables in the oral motor function, and video fluoroscopy.
- *Other than intervention, was care/follow-up similar in each group?* Yes.
- *Adequate compliance with intervention?* Not discussed.
- *Sufficient statistical power?* Not discussed.
- *Intention to treat analysis?* Not discussed.
- *Completeness of follow-up*: Apparently all patients completed the study.
- *Industry funding*: Yes.

Conclusions regarding validity of methods:

The trial is randomized and controlled, however it is very small, with no power calculations, apparently unblinded, and the authors did not discuss compliance, whether they performed ITT analysis or adjusted for the baseline differences between the study groups.

Results

Visual Analog Scale (VAS) pre and post treatment*

	Pretreatment (Median)	Post minus pretreatment (Median)
NMES (N=12)	7.4	-2.9
TT (N=13)	5.7	-2.5
P (NMES vs. TT)		0.40

*Maximum score of the scale is 10 (0 points = no difficulties at all, 10 points =maximum/unable to swallow

The difference between pre and post treatment was significant for each of the two treatment groups.

Actual nutritional status using Actual nutrition Scale (ANS)

	Pretreatment (Median)	Post minus pretreatment (Median)
NMES (N=12)	2.5	-1.0
TT (N=13)	3.0	0.0
P (NMES vs. TT)		0.189

*Maximum score of the scale is 6

The difference between pre and post-treatment was significant for each of the two treatment groups.

Oral Motor Function test (OMFT)*

Total *	Pretreatment (Median)	Post minus pretreatment (Median)
NMES	6.5	-2.0
TT	8.0	-2.0
P (NMES vs. TT)		0.506

*This consisted of 7 items with a maximum score of 4 for each (0= normal, and 4 =impossible to perform the exercise), and a maximum total score of 28. The difference between pre and post-treatment was significant for each of the two treatment groups.

*Videographic evaluation of swallowing (VFS) **

Total *	Pretreatment (Median)	Post minus pretreatment (Median)
NMES	25	0
TT	6	0
P (NMES vs. TT)		NS

*This consisted of 5 items (dissociation, misdirected swallow, retention, and pharyngoesophageal segment (PES) width

No difference was found between pre and post-treatment in each of the treatment groups.

Authors' Conclusions

The authors concluded that the results of the trial show no statistically significant differences in the effects of therapy between the NMES and the traditional swallowing therapy. They however, indicated that more studies are needed before recommending NMES as a treatment option for dysphagia persons.

Reviewer's Conclusions

The study was a small, randomized, controlled trial with several limitations. Its results show significant difference among post and pre-treatment comparisons for each of the treatment groups. No statistically significant differences were observed when NMES was compared head to head with the traditional swallowing therapy. The trial was too small and was likely not powered to detect significant differences between the two treatment groups.