

Carnaby-Mann GD, Crary MA. Examining the Evidence on Neuromuscular Electrical Stimulation for Swallowing. Arch Otorhyngarol Head Neck Surg 2007;133:564-571.

Design: Meta-analysis of nonrandomized studies

PICOS:

- **Patient population:** Adults with secondary dysphagia from stroke, cancer, TBI, and respiratory failure
- **Intervention:** neuromuscular electrical stimulation to the throat for swallowing stimulation
- **Comparison:** not specified; most studies did not include a control group for comparison
- **Outcomes:** Any measurable variable for swallowing; including aspiration counts, oral intake scales, barium swallow, Mann Assessment of Swallowing, laryngeal elevation, weight gain, and patient perception
- **Study types:** any study in which a measurable dependent variable was used, excluding animal studies, studies without a clinical diagnostic population, studies of intramuscular electrical stimulation, and reports on muscles other than the throat or neck

Study selection:

- Databases included PubMed, MEDLINE, CINAHL, National Library of Medicine, Cochrane Register of Controlled Trials, EMBASE, and Google
- Search terms were: swallowing electrical stimulation, NMES, rehabilitation, and swallowing therapy
- Citation tracking, bibliographies of articles, and abstracts in conference proceedings were also searched
- Authors agreed by consensus on whether articles met inclusion criteria
- Methodological quality was appraised using the Physiotherapy Evidence Database (PEDro) score, an 11 point scale with points awarded for randomization, allocation concealment, baseline similarity between groups, blinding of patients, therapists, and outcome assessors, low attrition, and statistical reporting; a score of 4 or greater was classified as good quality

Results:

- 81 articles were screened, and 7 were selected for final analysis
- 255 patients with dysphagia were reported on in the 7 studies
- Only 2 of the studies were controlled studies; one used alternating assignment, and one compared patients treated during 2003 (conventional treatment) with patients treated during 2004 (NMES)
- Then other 5 studies had no comparison groups, but were case series, involving 76 patients with before-after measurements of swallowing
- The PEDro scores varied from 3 to 6 points; the mean PEDro score was 4
- All but 2 studies applied NMES for 1 hour per day; the treatment period varied from 1 to 24 weeks

- Only 1 study did not report a statistically significant effect (where the 95% confidence interval excluded the null value)
- All other trials reported an effect size of 0.4 standard deviations in the swallowing test score in favor of NMES; this is considered a moderate positive effect size
- Pooling of data in a random-effects meta-analysis model revealed a significant summary effect size for NMES with no heterogeneity between studies
 - o Hedges' g, an estimate of effect size in terms of standard deviations of the outcome variable, was 0.6 in favor of NMES; this is also a moderate effect size (0.8 or greater is a large effect size)
- No evidence of publication bias was seen in the funnel plot or in the statistical test for publication bias

Authors' conclusions:

- Despite their subjectivity, the present findings support the use of NMES to produce sustained improvements in swallowing in adult patients with dysphagia
- The shortcomings in the research underscore the need for more high quality research in this area
- However, 3 of the 7 articles had a high PEDro quality score (4 or more)

Comments:

- It appears that all 7 articles were at a high risk of bias, regardless of the "high quality" rating awarded by the authors
- While non-randomized studies can, under optimal circumstances, yield results similar to those in randomized clinical trials, these circumstances require large enough sample sizes to adjust for all likely confounders, as well as blinded assessment of subjective outcomes, which was done in only one study (a case series)
- The PEDro score of 4 or more on a scale of 0 to 11 is not likely to identify a study with a low threat to internal validity
- Publication bias cannot be tested reliably with either a funnel plot nor a statistical test when only 7 studies are involved
- It appears that in the case series, the "control" group was the "before" score and the "experimental" score was the "after" swallowing score
 - o These are then combined with the between-group change scores for the 2 studies with comparison groups
 - o Because the latter 2 effect sizes are based on the before-after scores for the control groups and for the experimental groups, the nature of the comparison is different for the 5 case series and the 2 controlled studies
- While the effect sizes are large enough to be interesting, they do have a high enough risk of bias that higher quality data is required (from randomized trials)

Assessment: Inadequate as evidence of effectiveness of NMES (all included studies have high risk of bias)