ORIGINAL ARTICLE

Examining the Evidence on Neuromuscular Electrical Stimulation for Swallowing

A Meta-analysis

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

Data Sources: MEDLINE, PubMed, CINAHL, NML, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, doc online, Google, and EMBASE were searched for studies using NMES to treat dysphagia between January 1966 and August 2006.

Study Selection: Included were published or unpublished, English-language, clinical trials with a quantifiable dependent variable.

Data Extraction: Two researchers independently performed data extraction. A random-effects model was used to pool study results. The Cochran Q test was used to evaluate heterogeneity, and a funnel plot and Egger test were used to evaluate publication bias. A best-research synthesis using a methodological quality analysis was conducted.

Data Synthesis: A total of 81 studies were reviewed. Seven were accepted for analysis. A significant summary effect size was identified for the application of NMES for swallowing (Hedges *g*, 0.66; $P<.001$). Heterogeneity was significant for the combined trials ($P<.10$). When 2 outlier trials were removed, heterogeneity was no longer significant ($P<.08$). Publication bias was not identified on the funnel plot or Egger test ($P=.25$). Best-evidence synthesis showed indicative findings in favor of NMES for swallowing.

Conclusions: This preliminary meta-analysis revealed a small but significant summary effect size for transcutaneous NMES for swallowing. Because of the small number of studies and low methodological grading for these studies, caution should be taken in interpreting this finding. These results support the need for more rigorous research in this area.

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TRANSCUTANEOUS ELECTRICAL stimulation involves the application of electrical current across the skin to excite nerve or muscle tissue during a functional task. It is a commonly applied treatment modality in physical and occupational therapy and is believed to support muscle performance and strength development. It has been used to increase muscle size, and improve range of motion, circulation, and muscle endurance by increasing aerobic capacity of the muscle.[1-5]

It is important to differentiate the many variants of electrotherapeutic intervention. Transcutaneous electrical nerve stimulation supports circulation to the muscle and is primarily used to control pain. It can be used on atrophied or denervated muscle. However, it does not cause a muscle contraction. Neuromuscular electrical stimulation (NMES) is used on innervated muscle and is used to recruit motor units and increase muscle strength. Neuromuscular electrical stimulation facilitates a muscle contraction and works on a "Fittest Fibers Fire First" paradigm. Neuromuscular electrical stimulation selectively targets healthy innervated muscle fibers but does not always stimulate atrophied or denervated muscle. Functional electrical stimulation or, in some cases, functional NMES facilitates muscle contraction during functional activities. Neuromuscular electrical stimulation may be considered similar to functional electrical stimulation in situations in which a muscle contraction is facilitated during a functional task. A large amount of research from animal[6,7] and human[8-12] models suggests a positive effect of NMES on muscle recovery following injury or disease.

Recently, NMES has been proposed for the treatment of swallowing disorders (dysphagia). To date, more than 9000 speech-language pathologists in the United States have been trained to use this technique, and it continues to gain popularity as a

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treatment modality. However, only a few published studies[13-19] report investigations of this treatment technique. Although most studies have reported positive results, many have been criticized for design flaws and threats to external validity. These design limitations reduce the application, and clinical utility, of the technique. In addition, a recent national survey[18] reported that speech-language pathologists not using this technique believe that more research data would help them make decisions about the acceptability of NMES for swallowing.

Reviews of research are valuable to many health fields; however, not all scientific information is of equal quality. When details are presented and described only qualitatively, the results of conflicting studies can be confusing. One method to address discrepancies across research studies is to combine the results of individual studies into a meta-analysis. A meta-analysis is essentially a survey in which all of the included studies are similar enough statistically that the results are combined and analyzed as if they were 1 study. Meta-analysis serves to increase the sample size estimate effect on a larger population sample and, thus, improve the generalizability of previously conducted studies.[20] This technique has several advantages over the traditional method of systematic narrative review. Traditional reviews are often unable to cover large numbers of studies; instead, reviewers tend to focus on smaller selected subsets of studies, without describing how the subset was chosen. Similarly, reviewers often cite conclusions from previous reviews without critically examining those reviews. Finally, narrative reviews can be highly impressionistic. Reviewers are often active in the field in which the review is undertaken and, therefore, may not give full weight to evidence that is contrary to their own positions.

In contrast, meta-analysis involves the collection of research studies that are selected following an a priori set of criteria, coded, and interpreted using statistical methods similar to those used in primary data analysis. The result is an integrated review of findings that is more objective and exact than a narrative review. Meta-analytic techniques permit researchers to arrive at conclusions regarding treatment that are more accurate and credible than can be presented in any 1 primary study or in a nonquantitative narrative review.[21]

The objective of this present meta-analysis, therefore, was to examine the evidence on the effect of NMES in improving clinical swallowing ability. Given the rapid emergence of evidence in this area, objectively illustrating the effect (either positive or negative) of NMES for swallowing therapy may help clinicians evaluate this rehabilitation tool and its potential as an adjunctive treatment method for patients with dysphagia.

METHODS

A systematic search was conducted to identify all articles published between January 1966 and August 2006. The search was conducted in MEDLINE, PubMed, CINAHL, NML, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, doc online, EMBASE, and Google.

Two researchers independently searched these electronic databases for relevant articles. The search strategy was built on participants, study type, intervention type, and outcome measures. The types of studies considered were quantifiable trials, including randomized and quasi-experimental trials, in which a measurable dependent variable was included. Excluded were studies that included animals, studies without a clinical diagnostic population, experiments reporting results on muscles other than the throat and neck, and studies of intramuscular applications of electrical stimulation. The criterion for participants to be considered was a secondary diagnosis of oropharyngeal dysphagia. The age limit included participants 18 years and older. No gender limit was considered. No limit was applied to the timing of intervention after the onset of dysphagia. The intervention criteria included the application of transcutaneous NMES to the throat for swallowing rehabilitation. The criteria for outcome measures required that the dependent variable be measurable. The following Medical Subject Headings and keywords were used for the electronic database search: *swallowing electrical stimulation*, *NMES*, *rehabilitation*, and *swallowing therapy*. Bibliographies of review articles, narrative reviews, and abstracts published in conference proceedings were also evaluated for relevant publications. In addition, citation tracking of all article references was conducted. Only sources written in English were accepted. A paired consensus between the authors ensured that the articles met the criteria for inclusion.

1. Eligibility criteria were specified	No ❑	Yes ❑	Where:
2. Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	No ❑	Yes ❑	Where:
3. Allocation was concealed	No ❑	Yes ❑	Where:
4. The groups were similar at baseline regarding the most important prognostic indicators	No ❑	Yes ❑	Where:
5. There was blinding of all subjects	No ❑	Yes ❑	Where:
6. There was blinding of all therapists who administered the therapy	No ❑	Yes ❑	Where:
7. There was blinding of all assessors who measured at least one key outcome	No ❑	Yes ❑	Where:
8. Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	No ❑	Yes ❑	Where:
9. All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome were analyzed by "intention to treat"	No ❑	Yes ❑	Where:
10. The results of between-group statistical comparisons are reported for at least one key outcome	No ❑	Yes ❑	Where:
11. The study provides both point measures and measures of variability for at least one key outcome	No ❑	Yes ❑	Where:

Figure 1. The Physiotherapy Evidence Database scale was developed to facilitate analysis of research trial design and evidence-based clinical practice guidelines.

METHODOLOGICAL QUALITY

In reviewing the research literature on transcutaneous electrical stimulation for swallowing, several methodological limitations are noted. One of the major concerns is the lack of controlled trials performed to study the efficacy of swallowing rehabilitation. A second limitation is the subjective measurement of swallowing improvement. Although swallowing improvement has been quantified in a number of studies as an outcome measure, the use of consistent validated scales across studies is restricted. As a result of the procedural variability across studies, the methodological quality of the identified articles was critically appraised using the Physiotherapy Evidence Database (PEDro) scale[22,23] (**Figure 1**).

Table 1. Best Evidence Synthesis

Strong evidence – Provided by statistically significant findings in outcome measures in
- At least 2 high-quality RCTs with PEDro scores of at least 4 points

Moderate evidence – Provided by statistically significant findings in outcome measures in
- At least 1 high-quality RCT and
- At least 1 low-quality RCT (PEDro score <3) or 1 high-quality CCT

Limited evidence – Provided by statistically significant findings in outcome measures in
- At least 1 high-quality RCT or
- At least 2 high-quality CCTs (in the absence of high-quality RCTs)

Indicative findings – Provided by statistically significant findings in outcome measures in
- 1 high-quality CCT or low-quality RCTs (in the absence of high-quality RCTs) or
- 2 studies of a single group nonexperimental or experimental nature with sufficient quality (in the absence of RCTs or CCTs)

Insufficient (no) evidence
- Results of eligible studies do not meet the criteria above or
- In the case of conflicting results (statistically positive and statistically negative) among RCTs and CCTs or
- In the case of no eligible studies

Abbreviations: CCT, controlled clinical trial; PEDro, Physiotherapy Evidence Database scale; RCT, randomized controlled trial.

This scale was developed for a similar allied health therapy field and has shown adequate reliability across multiple raters (intraclass correlation coefficient mean, 0.56; range, 0.47-0.65) and via consensus rating (intraclass correlation coefficient mean, 0.68; range, 0.57-0.76). Interrater reliability between evaluators has been calculated for the individual items of the PEDro scale using the Cohen κ, and demonstrates moderate to high agreement (κ=0.40-0.73). In cases of disagreement, consensus is sought. A PEDro scale score of 4 points or higher is considered high quality, whereas studies with a score of 3 points or lower are considered lower quality. In this study, PEDro scale scores were used for best-evidence synthesis rather than inclusion/exclusion criteria and to evaluate strengths and weaknesses of each study.

BEST-EVIDENCE SYNTHESIS

Statistical pooling of studies is not always valid because of differences in outcomes, intervention application, patient characteristics, lack of point estimates (means or medians), and/or measures of variability (standard deviations and confidence intervals [CIs]). In these situations, a best-research synthesis strategy can be applied. This strategy involves using the criteria provided by van Tulder et al[24] based on the total methodological score from the PEDro scale. An overall quality rating is then compiled for each study. Subsequently, studies are categorized into (1) strong, (2) moderate, (3) limited, (4) indicative, or (5) insufficient evidence (**Table 1**).

QUANTITATIVE ANALYSIS

Data from each study meeting the inclusion criteria were analyzed using meta-analytic techniques. Two reviewers independently performed data extraction from the studies using standardized forms to ensure accurate copying of the data. All results from the data extraction were checked for consistency between the 2 raters. Any discrepancy was discussed until the 2 reviewers reached consensus. The data extracted included type of analysis conducted; group means, medians, and standard deviations; number of patients treated; number analyzed; and statistical values.

Study Diversity

Systematic reviews bring together studies that are variable in subjects, study type, methods, and measured outcome. As a result, not all studies can or should be combined. For this analysis, we established an a priori comparison of all clinical treatment trials using at least 1 measurable dependent variable of swallowing performance. In addition, a prespecified analysis of studies using similar outcome measures (clinical swallowing score) was conducted. These procedures were used to facilitate comparison of study diversity.

Effect Size

Effect sizes were calculated to compare results across studies. The effect sizes for the studies were calculated using the following equation:

$$d=(m_t-m_c)/s,$$

where d is the effect size index; m_t, the mean change in swallowing score in the treatment group (NMES) in the controlled trials or the posttreatment measure in the before-after (1-group) trials; m_c, the mean change in swallowing score in the control group in controlled trials or the pretreatment measure in the before-after trials; and s, the pooled standard deviation between the m_t and m_c measures. For before-after trials, s is equal to the average standard deviation of the m_t and m_c groups. For controlled trials, S is equal to the following:

$$S^2=[(n_t-1)(s^t)]^2+[(n_c-1)(s^c)]^2/(n_t+n_c)-2,$$

where n_t and n_c are the sample sizes of the treatment and control groups, respectively; and s^t and s^c are the standard deviations of the treatment and control groups, respectively.

One effect size only was calculated for each study because in most of the studies only a single outcome measure was provided with enough data for computation. In the 1 study in which more than 1 outcome was reported, the authors chose only to include the most comparable measure (clinical swallowing score) for analysis. Review of the effect size from each study was based on the Cohen[25] classification of effect sizes, where 0.2 or less was considered small; 0.2 to 0.5, medium; and greater than 0.5, large.

Heterogeneity

Heterogeneity is a statistical measure of the variability of the treatment difference between the studies. Individual estimates of treatment effect may vary because of chance, so some variation is expected. However, it is important to know whether there is more variation than would be expected by chance alone. Plotting standard deviations and examining outliers initially reviewed variability of effect sizes across studies. To confirm that the chosen studies were sufficiently similar to be confident of a combined estimate of effect, a statistical check for heterogeneity was performed by visual inspection of the CIs on all the studies and by using the Cochran Q test. The recommended level of significance for this test is $P \leq .10$.

Because all the studies were not comparable in terms of interventions and outcomes, and between-study variation existed (statistical heterogeneity), a random-effects model was applied to determine the statistical differences of the combined results.[26] A random-effects model is a statistical method that assists in reviewing studies that have some level of heterogeneity. It is based on the assumption that individual studies are estimating different treatment effects.

Table 2. Effect Size for Studies Included in the Meta-analysis

Source	Type of Intervention	No. of Participants	Type of Participant	Intensity of Intervention	Outcome	Methodological Quality (PEDro)	Effect Size (g)	Raw Weight
Belafsky et al,[16] 2004	NMES plus therapy	22	Mixed	1 h/d, mean of 10 sessions	Swallow score change preoperative/ postoperative	Prospective case series	0.78	21.69
Blumfeld et al,[15] 2005	NMES plus therapy	80 (40 experimental and 40 controls)	Mixed	1 h/d, variable sessions	Swallow score change preoperative/ postoperative	Retrospective case-control	0.45	24.23
Freed et al,[13] 2001	NMES plus therapy	110 (63 experimental and 36 controls)	Stroke	1 h/d, variable sessions	Swallow score change preoperative/ postoperative	Nonrandomized clinical trial	0.53	27.46
Carnaby-Mann and Crary,[17] 2005	NMES plus therapy	6	Mixed	1 h/d for 3 wk (13 sessions each)	MASA, FOIS, weight, patient perception	Prospective case series	0.93	6.39
Langemore et al,[19] 2006	NMES plus therapy	7	Head and neck cancer	20 min 3 times per day for 3 mo	Asp/pen-MBS, diet, patient perception	Prospective case series	0.51	8.74
Leelamanit et al,[14] 2002	NMES plus sEMG plus therapy	23	Mixed	4 h/d, variable sessions	Laryngeal elevation (in centimeters)* and weight gain	Prospective case series	0.95	20.23
Shaw et al,[28] 2006	NMES plus therapy	18	Mixed	1 h/d, 12 sessions	Swallow score, diet, residue, and larynx elevation	Retrospective case series	0.63	15.80

Abbreviations: Asp/pen, aspiration and penetration counts; FOIS, Functional Oral Intake Scale; MASA, Mann Assessment of Swallowing; MBS, modified barium swallow; NMES, neuromuscular electrical stimulation; PEDro, Physiotherapy Evidence Database; sEMG, surface electromyography.
*Discrete outcome measure.

In addition to the study effect size, the standardized mean difference, g^u (Hedges g), was also determined for each study by calculating the difference between mean changes in experimental and control groups and dividing by the average population standard deviation. A 95% CI was also used to determine whether the population effect size estimated from the sample studies would fall within the interval, rejecting the hypothesis that transcutaneous electrical stimulation for swallowing is not effective.

The impact of sample size was addressed by estimating a weighting factor for each study (W_i). Larger effect weights were assigned to studies with larger sample sizes. The W was calculated for each study using the following formula:

$$W = 2[(n_1 + n_2)(n_1)(n_2)]/2[[(n_1 + n_2)^2] + [(n_1)(n_2)(d_2)]]$$

where n_1 and n_2, are the sample size for the treated and control groups, respectively, and d is the effect size.

Subsequently, the g^u values of the individual studies were averaged, resulting in a weighted summary effect size. Analyses were conducted using SAS statistical software, version 12.0 (SAS Institute Inc, Cary, NC) and Comprehensive Meta Analysis.[27]

Publication Bias

Publication bias is the tendency for positive trials to be published and the tendency for negative or null trials not to be published. Because the treatment effect estimated from a biased collection of studies would tend to overestimate the true treatment effect, it is important to assess the likely extent of the bias and its potential impact on the conclusions. In the case of publication bias, large studies tend to be included in an analysis regardless of their treatment effect, whereas small studies are more likely to be included when they show a relatively large treatment effect. Under these circumstances, there will be an inverse correlation between study size and effect size. Consequently, this correlation can serve as a test for publication bias. To test for publication bias, we used a funnel plot (graphical display) and Egger test. The Egger test assesses this bias by using precision (the inverse of the standard error) to predict the standardized effect (effect size divided by the standard error).

RESULTS

The literature search strategy applied in this study yielded 81 citations. After applying the selection criteria, only 7 studies remained. Seventy-four studies were excluded from the analysis for the following reasons: animal studies (n=29), intramuscular applications (n=5), not transcutaneous stimulation (n=20), not clinical treatment trials (n=13), and review articles (n=7). The 7 studies focusing on the clinical application of transcutaneous NMES for swallowing were considered eligible for further analysis.

CHARACTERISTICS OF INCLUDED STUDIES

The 7 studies meeting the inclusion criteria investigated the effects of NMES for swallowing in a total of 255 patients with dysphagia due to multiple etiologies. Two of the trials were controlled studies, with 103 subjects in the treatment group and 76 subjects in the control group. The 5 other trials used a before-after design, with 76 subjects receiving treatment. The number of patients, characteristics of the interventions, measures of outcome, and observed effects are provided in **Table 2**. Only 1 study[13]

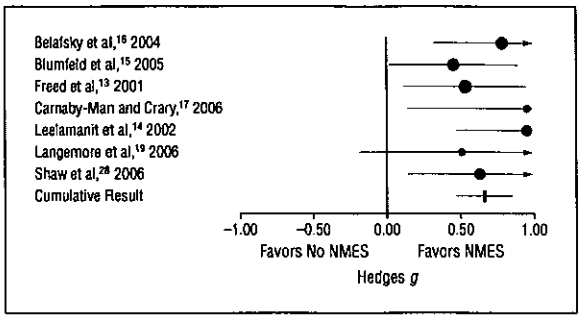

Figure 2. The neuromuscular electrical stimulation (NMES) effect size display, using the random model, provides a graphical representation of the results of the meta-analysis of the 7 clinical trials. Each line represents a separate trial (point estimate and 95% confidence interval). The cumulative result represents data synthesis from all included trials.

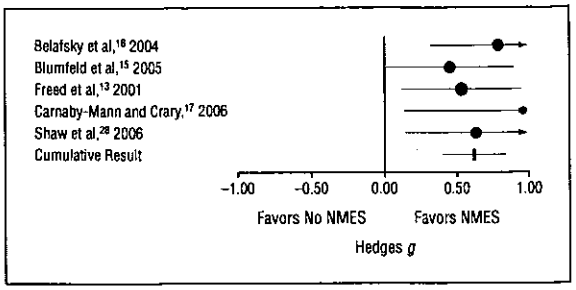

Figure 3. The neuromuscular electrical stimulation (NMES) effect size display, using the random model, provides a graphical representation of the results of the meta-analysis of the 5 clinical trials with similar outcome measures. Each line represents a separate trial (point estimate and 95% confidence interval). The cumulative result represents data synthesis from all included trials.

Table 3. Neuromuscular Electrical Stimulation Data for the 7 Included Studies Using the Random Model

Source	Hedges *g* (Lower-Upper Limit)	SE	Variance	Relative Weight	*z* Value	*P* Value
Belafsky et al,[16] 2004	0.78 (0.32 to 1.25)	0.24	0.06	16.68	3.31	.001
Blumfeld et al,[15] 2005	0.45 (0.02 to 0.89)	0.22	0.05	18.64	2.02	.04
Freed et al,[13] 2001	0.54 (0.12 to 0.95)	0.21	0.04	21.12	2.54	.01
Carnaby-Mann and Crary,[17] 2005	0.96 (0.14 to 1.77)	0.42	0.17	5.41	2.30	.02
Leelamanit et al,[14] 2002	0.95 (0.47 to 1.44)	0.25	0.06	15.56	3.88	<.001
Langemore et al,[19] 2006	0.51 (−0.19 to 1.21)	0.36	0.13	7.41	1.43	.15
Shaw et al,[28] 2006	0.63 (0.14 to 1.12)	0.25	0.06	15.18	2.54	.01
Cumulative result*	0.66 (0.47 to 0.85)	0.10	0.009	NA	6.84	<.001

Abbreviation: NA, data not applicable.
*The result of data synthesis from all included trials.

Table 4. Qualitative Analysis of Studies Based on the PEDro Scale*

	Item on PEDro Scale										
Source	Eligibility Criteria	Random Allocation	Concealed Allocation	Similar Baseline	Blinding Patients	Blinding Therapist	Blinding Assessors	Outcome >85%	Intent to Treat	Between Group Comparison	PM and MV
Belafsky et al,[16] 2004								X		X	X
Blumfeld et al,[15] 2005				X				X		X	X
Freed et al,[13] 2001				X				X		X	X
Langemore et al,[19] 2006	X							X		X	
Leelamanit et al,[14] 2002	X							X	X		X
Carnaby-Mann and Crary,[17] 2005	X						X	X	X	X	X
Shaw et al,[28] 2006								X		X	X

Abbreviations: PEDro, Physiotherapy Evidence Database; PM and MV, point measures and measures of variability provided.
*The letter "X" indicates the presence of an item in a specific study, and an empty cell indicates the absence of an item in a specific study.

used a CCT design. However, all studies used transcutaneous electrical stimulation to the throat; 1 study[14] used simultaneous electrical stimulation and surface electromyography. All studies included a mix of patient etiologies, including stroke, cancer, head trauma, and respiratory failure. All studies included a mix of gender and age. Therapeutic outcome was evaluated using a swallowing scale,[13,15-17,28] weight gain,[14,17] functional eating,[17] residue on a swallowing x-ray study,[28] or laryngeal elevation.[14,28] All but 2 studies[14,19] followed a similar treatment schedule of NMES for 1 hour per day. Treatment was provided over a variable period of 1 to 24 weeks, with the number of total treatment sessions varying across the studies. In addition, NMES electrode placement was not detailed in 2 of the 7 studies.

In the forest plot of the individual effect sizes (**Figure 2** and **Table 3**), only 1 trial had a 95% CI that included an effect size of 0, consistent with no effect. However, 1

Table 5. Neuromuscular Electrical Stimulation Data for the 5 Studies With Similar Outcome Measures Using the Random Model

Source	Hedges *g* (Lower-Upper Limit)	SE	Variance	Relative Weight	*z* Value	*P* Value
Belafsky et al,[16] 2004	0.78 (0.32-1.25)	0.24	0.06	21.66	3.31	.001
Blumfeld et al,[15] 2005	0.45 (0.02-0.89)	0.22	0.05	24.20	2.02	.04
Freed et al,[13] 2001	0.54 (0.12-0.95)	0.21	0.04	27.42	2.54	.01
Carnaby-Mann and Crary,[17] 2005	0.96 (0.14-1.77)	0.42	0.17	7.03	2.30	.02
Shaw et al,[28] 2006	0.63 (0.14-1.12)	0.25	0.06	19.70	2.54	.01
Cumulative result*	0.62 (0.40-0.84)	0.11	0.01	NA	5.60	<.001

Abbreviation: NA, data not applicable.
*The result of data synthesis from all included trials.

other study[15] also showed an interval close to the null effect. All other trials had effect sizes in excess of 0.4, suggesting a modest effect.

HETEROGENEITY

A review of the individual CIs for each study on the forest plot (Figure 2 and Table 3) demonstrated significant overlap between studies, indicating only minor variation. The Cochran Q test revealed heterogeneity among study results ($P<.098$), suggesting something more than a random difference among the trials may have contributed to the variation of study effect sizes. When the 2 studies[14,19] with the greatest variance in methods were removed, heterogeneity among the remaining studies was no longer significant ($P=.76$).

METHODOLOGICAL QUALITY ANALYSIS

The mean methodological score using the PEDro scale was 3.71 points (SD, 1.10 points). Methodological quality ratings for the included studies ranged from 3[16,19,28] to 6[17] PEDro scale points (**Table 4**). The mean score of the controlled trials was 4, and the mean score of the before-after trials was 3. The Cohen κ, as an estimate of the agreement between the 2 raters for methodological quality of the 7 trials, was 0.82 (95% CI, 0.66-0.97) ($P<.001$). The best-evidence synthesis of the included studies also revealed indicative findings in favor of NMES for swallowing therapy.

QUANTITATIVE ANALYSIS

Outcome measures and effect sizes for the studies are shown in Table 2. Given the variability of the studies, meta-analytic pooling was conducted in 2 ways: (1) to combine all studies meeting the inclusion criteria and (2) to include only the 5 studies using a similar clinical outcome measure (clinical swallowing score).

Pooling via a random-effects model for all acceptable studies (n = 7) revealed a significant summary effect size for the application of NMES for swallowing therapy (Hedges *g*, 0.66; 95% CI, 0.47-0.85; $P<.001$). Pooling for the subgroup analysis of the 5 studies using similar outcome measures also revealed a significant summary effect size (Hedges *g*, 0.62; 95% CI, 0.40-0.83; $P<.001$) (**Figure 3** and **Table 5**). Furthermore, a comparison of fixed-effects to random-effects models revealed no difference in the summary effect size statistic, suggesting that statistical heterogeneity among the 5 studies was unlikely. Analysis of change in swallowing score over all the included studies demonstrated a mean improvement of 20% in swallowing performance following treatment.

PUBLICATION BIAS

A review of the funnel plot revealed the absence of publication bias in this sample. Furthermore, the Egger test also supported the absence of publication bias in this sample ($P=.25$ [1-tailed] and $P=.49$ [2-tailed]).

COMMENT

This preliminary meta-analysis showed a statistically significant summary effect size supporting the use of NMES in the rehabilitation of swallowing disorders. In addition, we found no evidence of publication bias in this sample of studies, supporting a modest estimate of efficacy from best available evidence.

A total of 2 controlled trials and 5 before-after trials examining the effectiveness of NMES for swallowing were included in this analysis. The CCTs and the before-after trials demonstrated positive overall effects. Furthermore, this result represents a mean improvement of 20% in swallowing performance following treatment across all the studies. The exact clinical meaning of this reported improvement in swallowing performance from NMES is difficult to interpret. The only comparable "measured" outcome between the studies was clinical swallowing score, an outcome influenced by clinician's subjective assessment of a patient's swallowing ability. Despite this subjectivity, the present findings do lend support to the use of NMES to improve clinical swallowing performance in adult patients with dysphagia. This meta-analysis also suggests that therapy using NMES can produce sustained improvements in swallowing even after the stimulator is turned off (therapeutic effect).

The qualitative "best-evidence" synthesis provided indicative findings to support this form of treatment for swallowing rehabilitation, with 3 of the 7 included studies recording "high" quality ratings on this scale. Similarly, a significant association between PEDro scale score and

year of publication indicated an increased awareness of researchers to strive for better quality and unbiased assessment of effectiveness in this area.

The present meta-analysis has a number of shortcomings. We recognize that a meta-analysis cannot address the problem of design flaws in the original studies. Most of the studies included in the review exhibited significant methodological flaws, such as lack of randomization, failure to include a control group, lack of details regarding the interventions, and the use of unblinded observers of outcome. Similarly, the studies included used low numbers of subjects, increasing the possibility of low statistical power to reveal significant effects. Because of these issues, the role of bias in the observed outcomes is problematic. The previously mentioned methodological problems combined with disregard for systematic dropouts tend to overestimate observed effects. We attempted to adjust for these issues by using strict inclusion criteria, limiting analysis to a single discrete measurable outcome variable, and running several meta-analytic comparisons.

Clinical swallowing score was the only variable used as an outcome measure across all studies. It is among the most commonly used measures in studies examining the effectiveness of behavioral swallowing interventions and NMES for swallowing. Despite being influenced by a clinician's perception, these scores do provide a widely accepted measure of a patient's swallowing performance over time.

To our knowledge, no randomized controlled studies of NMES for swallowing exist. Consequently, before-after trials were included in this analysis to provide a comprehensive review of the topic. Although it is difficult to show the cause-and-effect relation of an intervention with this single-group design, this design does permit subjects who have a history of swallowing difficulties to act as their own controls. This is a benefit when studying a patient population with such varied levels of weakness as a result of underlying disease or when examining studies with variability in swallowing therapy protocol.

Despite identifying a modest effect size from meta-analysis, and a qualitative grading of indicative from the best-evidence synthesis, the shortcomings in the current evidence on NMES for swallowing underscore the need for further clinical research into this area of swallowing intervention.

In conclusion, this preliminary meta-analysis examining the effectiveness of NMES has shown a small statistically significant improvement in clinical swallowing performance for adult dysphagic patients receiving this form of treatment. Although limited by the rigor of the studies available for analysis, these results provide some evidence that NMES for swallowing therapy may be an effective tool in the rehabilitation of dysphagic patients. Recommendations for the use of this technique should be reevaluated as more data become available. Further independent trials with rigorously controlled designs and intent-to-treat analyses are needed to establish whether NMES for swallowing has greater efficacy than traditional swallowing treatments alone. Similarly, such trials will help to identify a subgroup of patients who have a greater response to this treatment, if such a subgroup exists.

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