Critical Review:
Is neuromuscular electrical stimulation more effective than traditional swallowing therapy for treating pharyngeal dysphagia?

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This critical review evaluates whether neuromuscular electrical stimulation (NMES) is superior to traditional rehabilitative swallowing therapy (TT) for treating pharyngeal dysphagia. Randomized, controlled, clinical trials, non-concurrent cohort studies, and a case study were included in a critical review of the literature. Overall, research results were equivocal. There is some suggestion that NMES may provide better outcomes than TT. Further evidence through methodically rigorous research studies is needed.

Introduction

Dysphagia is a defined by Logemann (1997) as "difficulty swallowing for moving food from the mouth to the stomach" (p. 1). As per the College of Audiology and Speech-Language Pathology of Ontario's (CASLPO) best practice guidelines for dysphagia approximately 200,000 individuals in Canada have dysphagia (CASLPO, 2007). The presence of dysphagia may lead to social (CASLPO, 2007) and medical complications such as isolation during mealtimes, pneumonia, malnutrition, and increased risk of death. The current gold standard in dysphagia management is traditional rehabilitative swallowing therapy. Traditional swallowing treatments include diet modification, head and neck positioning, compensatory maneuvers muscle strengthening exercises, and sensory stimulation. These techniques have shown poor efficacy (Blumfield, Hahn, LePage, Leonard & Belafsky, 2006) and are not ideally suited to all patient profiles. NMES is a relatively new technology which has the potential to improve swallowing therapy efficiency and efficacy. It may also facilitate the treatment of clients who are not able to benefit from the full range of rehabilitative swallowing techniques due to motor, behavior, or cognitive difficulties. Theories supporting the use of high amplitude NMES state that it either a) improves elevation of the hyoid bone and the larynx by strengthening muscles involved in swallowing by recruiting a larger number of motor units, by stimulating larger motor units (Clark, Lazarus, Arvedson, Schooling, & Frymark, 2009) b) induces effortful swallowing by having patients swallow against stimulation generated hyo-laryngeal lowering (Ludlow, 2010) and/or c) facilitates "reorganization of the human adult motor cortex" (Bülow, Speyer, Baijens, Woisard & Ekberg, 2008). Most current research has demonstrated that NMES is beneficial in the treatment of dysphagia (Carnaby-Mann & Crary, 2007; Ludlow, 2010) but further investigation is needed to determine whether it proves to be a better, worse, or equivalent option to current dysphagia management techniques.

Objective

The objective of this paper is to critically evaluate existing literature to determine if pharyngeal dysphagia is better rehabilitated through neuromuscular electrical stimulation therapy than traditional rehabilitative swallowing therapy methods.

Methods

Search Strategy

PubMed, Medline-Ovid, CINAHL, and Cochrane Library electronic databases were used to find articles for this critical review using the following key words: ((dysphagia) OR (swallowing therapy) or (deglutition disorders)) AND ((neuromuscular electrical stimulation) OR (VitalStim®) OR (E-Stim) OR (NMES) OR (transcutaneous electrical stimulation)). The search was limited to articles written in English.

Selection Criteria

For the purposes of this review, only studies that included face-to-face contact with a clinician throughout therapy for both experimental conditions were accepted. Studies of traditional rehabilitative swallowing therapy that included fewer than three of the following methods (diet modification, head and neck positioning, compensatory maneuvers, muscles strengthening exercises and/or sensory stimulation therapy) were excluded. All studies that contrasted TT with NMES against traditional rehabilitative swallowing were also excluded.

No exclusions were made based on cause of the swallowing disorder, patient age, or dysphagia severity.

Data Collection

Two randomized, controlled clinical trials, two non-concurrent cohort studies and one case study fit the aforementioned selection criteria for inclusion in this critical literature review.

Results

Evidence was evaluated using a scale adapted from Oxford Centre for Evidence-based Medicine and National Health and Research Council of the Australian government for the course CSD9639/9649 at Western University (Archibald, 2013). The scale progresses from the highest level of evidence (level I) to the lowest level of evidence (level V).

Level	*Research Design*
I	Randomized control trial
IIa	A pseudo-randomized clinical trial
IIb	A comparative study with concurrent controls
IIc	A comparative study without concurrent controls
III	Single group studies without controls and only one variable
IV	Non-experimental designs
V	Expert opinion without explicit critical appraisal

Randomized Clinical Trials (Level I Evidence)

Randomized, controlled studies, historical cohort studies and a case study were systematically evaluated for the quality of their evidence. The two RCTs included were completed by Bülow et al. (2008) and Permsirivanchich et al. (2009). As per Johnson (2006) "the randomized controlled trial (RCT) is a research design used to demonstrate treatment efficacy, that is, a causal relationship between a treatment and an outcome". This study design model is preferred as it provides the highest level of evidence for individual studies and is best suited to answer the clinical question asked in this review.

The Bülow et al. (2008) multi-center study included 25 patients with a prior diagnosis of hemispheric stroke without brain stem involvement. Inclusion and exclusion criterion were clearly outlined and the radiologist was blinded as to whether Videofluroscopic Swallowing Study (VFSS) results were pre or post treatment evaluations. Three outcome measures: subjective rating of complaints related to swallowing, actual nutritional status, and oral motor status were examined. Subjective impressions of swallowing complaints were evaluated using a visual analogue scale. Actual nutritional status was measured using a 7 point scale (0= full oral, no limitations, 6= tube feeding). VFSS was scored for 4 parameters: dissociation, misdirected swallow, retention (fluid level) and pharyngo-esophageal segment (PES) width. All patients were treated by a speech-language pathologist (S-LP) trained in dysphagia management for 60 minute sessions five days a week over three weeks. The TT group participants were provided with applicable case-specific diet modification, swallowing manoeuvers, and other traditional therapy techniques not otherwise specified as per S-LP recommendations. If the patients in the TT group were not able to participate in full 60 min therapy sessions, they were told to complete a training session at home as well. Little information was provided on how many participants were asked to do this or how often. If it was common, the TT group may have an advantage (additional practice) over the NMES group.

The authors found no significant therapy effects between groups for subjective judgments of difficulties related to swallowing (independent samples *t* test, p=0.40). Baseline data in the NMES group was more impaired that TT group participants; however, which may have influenced the fidelity of the results. Therapy effect differences between the groups were non-significant for actual nutritional status (Mann-Whitney test, p=0.189) and videoradiographic evaluation of swallowing (Mann-Whitney test, p=0.506). The authors concluded that further research is needed to determine the value of NMES as a treatment modality for dysphagia. Overall, the validity and importance of this study are suggestive.

Permsirivanch et al.'s (2009) article also describes a study of stroke patients with pharyngeal dysphagia. Twenty-three patients participated in this study (TT 11; NMES 12). No statistical differences between the NMES and TT group was found for age, post-stroke duration, mental score, or Barthel index score as determined using t-tests or gender, side of weakness or type of stroke as per Fisher's exact test results. The patients received twenty 60 minute sessions over a period of four weeks or until they reached a total oral diet with no restrictions (Functional Oral Intake Score (FOIS) of 7). The NMES condition was administered as per VitalStim® protocol by a physiatrist. TT involved any combination of diet modification, oral motor exercise, thermal stimulation, head and neck positioning, and compensatory swallowing techniques deemed appropriate for the client and was administered by an occupational therapist. Facial weakness was treated with oral motor exercise in both groups. This is not believed to have an appreciable impact on changes to the pharyngeal swallow and thus this study was included in this review. Outcome measures included complications related to treatment, FOIS score, and the number of therapy sessions provided.

A t-test determined that a significant difference between the groups for the FOIS change scores ($p<0.001$). No significant difference in the number of therapy sessions was found using a t-test (p=0.57). Neither group had reported complications during the study. The authors of the study concluded that NMES was "significantly superior" to traditional rehabilitative swallowing therapy. The potential for swallowing rehabilitation in individuals with severe dysphagia may

be different from that of the population as a whole. The mean FOIS score of the patients enrolled in the study was 2.40 (SD 1.20), indicating severe dysphagia. Individuals with dysphagia of mild or moderate severity may not respond to treatment in the same degree. Additionally, having treatments provided by different professionals is a potential source of bias. The level of expertise between the professions differs, and patients may respond differently to treatment provided by a doctor than to one provided by an occupational therapist. This methodological limitation is further exacerbated as study outcome measures (FOIS scores, complications related to treatment, and number of sessions provided) were based on patient reports. The validity and importance of this study are equivocal due to result bias, and the minimal advantage in therapeutic effect demonstrated in the NMES group over the TT group.

Cohort Studies (Level IIc Evidence)

Kiger, Brown and Watkins (2006) and Blumfield et al. (2006) presented the results of their non-concurrent cohort studies. This study design provides level IIc evidence as the use of historical data increases the possibility of missing information or the presence of confounding variable(s) (Ho, Peterson, & Masoudi, 2008).

Kiger et al.'s (2006) study evaluated the outcomes of VitalStim® and TT on a group of individuals with dysphagia originating from multiple neurological and non-neurological based etiologies. Twenty-two individuals were included in the study, 11 in each group. The authors selected changes in pharyngeal phase dysphagia severity based on VFSS or FEES examination, need for diet modification, and improvement from NPO status to oral nutrition as outcome measures. Chi-square tests for independent samples were used to evaluate the evidence. There was no statistically significant difference in the pharyngeal swallow between groups on the swallowing severity scale ($p \geq 2.307$), diet consistency changes ($p \geq 1.0526$) or improvement from non-oral nutrition to oral intake ($p \geq 0.0314$).

Important differences in group demographics and treatment protocol were noted in the study. All patients were provided therapy by an S-LP. The person administering the treatments was not consistent from patient to patient in both groups, allowing for some patients to receive different levels of care than others in the study. TT patients were treated in an acute hospital and were provided with strategies appropriate to their needs: strengthening exercises, compensatory swallowing maneuvers and thermal stimulation. The NMES group received VitalStim® services in a variety of settings including skilled nursing facilities, inpatient and outpatient rehab, and home health. The number of treatments received and length of the treatments were also inconsistent both between and within the groups. The TT subjects were provided with an average of 3.36 sessions (range 1-6) and the NMES group had an average of 8.72 sessions with a range of 2-13 treatments. Sessions were reported to be between 15-45 minutes in length for the traditional swallowing rehabilitation group and 45-60 minutes in length in the NMES group depending on the patient's tolerance for the procedure. Overall, the TT group showed greater improvement.

The health care setting, number of sessions and the length of treatment provided are potential confounding factors due to range of overall support provided at the various centers, the differences in each participant's overall health status, and the amount of resources allocated to each person for their swallowing rehabilitation. The NMES group's average age (63.4) and age range (18-81) was also substantially different from that of the TT group (71.5 and 45-91), which could affect rehabilitation potential. Similarly, onset of assessment and treatment occurred eight days from the onset of the dysphagia in the TT group and 31 days in the NMES group. This is an important factor as spontaneous recovery and changes in medical status could impact an individual's progress. The authors acknowledged the limitations related to the study design and implementation, and concluded further research was needed to determine best practice guidelines for when and with which populations NMES should be used in swallowing rehabilitation over traditional methods. Thus, the results of this study are considered equivocal.

Blumfield et al.'s (2006) study involved retrospective evaluation of treatment effects through chart review of 40 patients at a long-term acute care hospital. Seventy-five percent of study participants had dysphagia due to respiratory failure; the remaining 25% were of a variety of neurological and non-neurological origins. Groups were appropriately matched for factors such as age, diagnosis, gender, and initial disease and/or swallow severity score as per the authors but the statistics were not provided. TT patients were provided with an individually-tailored selection of strengthening exercises, compensatory maneuvers and diet text modifications. NMES group participants were provided with VitalStim® therapy. All sessions were 30 minutes in duration and were administered by an S-LP. The number of sessions provided depended on the patient's progress towards a specific diet consistency goal.
Therapy was discontinued when a participant met their target or progress plateaued.

A comparison of admission and discharge swallow scores was used as an outcome measure. A multivariate linear regression analysis revealed that patients in the NMES group demonstrated significantly more improvement than those patients in the other group ($p=0.003$). The NMES participants took significantly fewer treatment sessions to reach the target consistencies or plateau ($p=0.014$) as determined through an independent samples t-test. The authors conclude that NMES was a superior treatment for dysphagia for individuals residing in long-term acute care facilities.

Limitations of the study include a possible selection bias where NMES was the preferred treatment option for patients with less severe profiles, and an evaluator bias related to having the same clinicians administering both the treatment intervention and the post-treatment evaluations. Overall, the evidence from this study suggests that NMES may have an advantage over TT.

Case Studies (Level IV Evidence)

A case study by Barikoo and Lam (2011) was also evaluated. This research design provides valuable preliminary information upon which further investigation can be based. Given the limited sample size, and lack of randomization of treatment protocols, results cannot be easily generalized to the larger population.

An individual with encephalitis was provided with two phases of treatment. Phase one consisted of TT including diet modification, thermal stimulation, positioning, and the chin-tuck maneuver. Phase two involved NMES over the submental and throat region. The patient was seen weekly in both phase one (3 months) and phase two (3 months).

The 3-oz water swallow test, FOIS, and Swallowing Quality of Life questionnaire (SWAL-QOL) were used as outcome measures. The participant was reported to be able to complete the 3-oz water swallow test successfully after phase two only. The SWAL-QOL and FOIS were administered after phase two only. Post measures indicated that the patient progressed from a total oral diet of multiple consistencies requiring special preparation (FOIS=5) to a complete oral diet without restrictions (FOIS=7). The SWAL-QOL post-measure revealed an increase in 12 points, indicating an improvement in the patient's quality of life. This article provides evidence that the NMES treatment warrants further study to explore how it compares to established treatments in this area.

Given the study design, possible bias of the results is of considerable concern. Factors such as an evaluator bias, spontaneous recovery and improvements in overall health were potential confounding variables which could have led to improvements in the pharyngeal swallow. Due to these limitations, the evidence provided in this study is equivocal.

Discussion

The role of NMES in dysphagia management has yet to be clearly established. There is a general consensus in the field that NMES does have some benefit on treating the effects of pharyngeal dysphagia (Clark, 2009; Ludlow et al., 2010). There is also evidence that suggests that NMES may be more effective for the rehabilitation of swallowing difficulties than traditional methods (Barikroo et al., 2010; Blumfield et al., 2006; Permsirivanich et al., 2009) but the mechanisms by which it improves swallowing function are not largely understood. Further research is needed to determine how NMES affects the swallowing mechanism so the frequency and amount of therapy required, and clear indications and contra-indications for its use can be determined.

The research reviewed was limited methodologically due to small sample sizes, and limited use of blinding and randomization. Additionally, many of the studies outcome measures were subjective, which reduces the impartiality of the results. Inclusion of patients with varying degrees of dysphagia severity, different potential for rehabilitation, and varying etiologies also rendered it problematic to generalize specific study results to the population of individuals with dysphagia as a whole.

The evidence collected for this critical review was limited as many published articles used NMES as an adjunct to techniques used in traditional therapy. Further research on the efficacy of NMES in comparison to TT must strive to maintain clear distinctions between the techniques to reduce possible confounding effects and improve the reliability of the evidence acquired.

Additionally no articles on the efficacy of NMES in comparison to TT on individuals with congenital dysphagia met the inclusion criteria for this critical review. It is posited that individuals who had never swallowed normally may respond differently to treatment than individuals who have acquired dysphagia (Christiaanse et al., 2011). Consequently, it is important to include individuals with congenital dysphagia in studies of NMES' efficacy as well as individuals with acquired dysphagia.

Although no complications were reported in any of the treatment groups during the studies, Bülow et al.

(2008) reported that two study participants from the NMES group acquired aspiration pneumonia a couple of months after the study. They cautioned that a "false-positive experience" could lead patients to feel that their dysphagia was less serious and therefore neglect to follow recommendations for continuing dysphagia management. It is important that patients be counseled about potential mismatches between subjective impressions and objective findings of dysphagia severity with either treatment modality.

Overall, the research on efficacy of NMES in comparison to TT is equivocal as it is questionable if the advantage demonstrated for NMES in some of the studies (Barikroo et al., 2010; Blumfield et al., 2006; Permsirivanich et al., 2009) is clinically significant. The quality of the evidence could also be called into question insomuch that experts could come to different conclusions about its validity.

Clinical Implications

Pending further research into this clinical question, it is recommended that NMES be used as an adjunct to rehabilitative swallowing therapy or not at all. Current research does not support the use of neuromuscular electrical stimulation exclusively for the treatment of pharyngeal dysphagia over traditional rehabilitative swallowing methods in clinical practice.

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