Critical Review: Is Neuromuscular Electrical Stimulation (NMES) a beneficial supplement to existing dysphagia interventions for post-stroke patients?

Lyndsay Desimone and Julia Lovis
M.Cl.Sc (SLP) Candidates
University of Western Ontario: School of Communication Sciences and Disorders

Neuromuscular electrical stimulation (NMES) is well-informed in other rehabilitative practices; however, the use of NMES in the field of speech-language pathology remains controversial. This critical review examined the use of NMES as a beneficial supplement to existing dysphagia interventions for post-stroke patients. Studies analyzed included four randomized clinical trials, one case series and one retrospective case study. Inclusion of NMES alongside traditional dysphagia therapy was observed to increase swallowing safety and oral intake across the majority of studies. However, a lack of both consistency in outcome measures and in the standardization of procedures, limited the generalizability of findings to clinical practice. Overall, NMES, as a supplement to existing dysphagia therapy, does not appear to offer a clear benefit to post-stroke patients.

Introduction

Dysphagia, or the clinical manifestation of a swallowing disorder, following acute stroke has a reported incidence between 37% using bedside screening assessments and 78% using instrumental evaluations (Martino et al., 2005). Those who suffer from dysphagia post-stroke experience varying degrees of severity. Levels of severity can range from mild, requiring diet modifications and/or other compensations, to severe, potentially rendering a patient *nil per os* and requiring clinically assisted nutrition and hydration (Martindale et al., 2019). In working with this population, it is important to understand how best to preserve/rehabilitate swallowing function in order to maintain quality of life and provide better long-term outcomes.

Swallowing requires a series of complex movements involving the coordination of oral, pharyngeal and laryngeal muscles to ensure the safe and efficient passage of a bolus (Perlman et al., 1999). Traditional Dysphagia Therapy (TDT) focuses on enhancing the complex sensory and motor processes of the oropharyngeal musculature through a combination of individualized exercises, compensatory maneuvers, postural adjustments and diet modifications (Meng et al., 2018). Neuromuscular electrical stimulation (NMES) is a relatively new dysphagia intervention, that is often paired with TDT. NMES involves the stimulation of peripheral nerves, via electrical current transmitted from electrodes placed transcutaneous or subcutaneous, to produce muscle activation (Huckabee & Doeltgen, 2007). The use of transcutaneous electrical stimulation (TES) is well-informed and widely accepted in the field of physiotherapy. There is considerable evidence of TES efficacy for the motor rehabilitation of various upper and lower extremity impairments post-stroke, strengthening of muscles post-surgery and combating muscle wasting by those with critical illness (Nussbaum et al., 2017). However, this same unanimity is not apparent in the field of speech-language pathology. TES has been adopted into swallowing rehabilitation but remains a somewhat controversial method as evidence of its efficacy remains unclear (Serel Arslan et al., 2018).

Non-invasive NMES, as a treatment for dysphagia, involves the application of electrodes to the laryngeal region (typically the submental and/or infrahyoid region), during a functional task such as therapeutic swallowing exercises (Suiter et al., 2006). It has been proposed to result in improved hyolaryngeal elevation due to an increased aerobic capacity of the suprahyoid muscle afforded by increased circulation, muscle mass, range of motion and endurance (Suiter et al., 2006). It is suggested that NMES recruits more motor units than volitional contraction would, therefore producing greater gains in muscle strength than exercise alone (Lee et al., 2014). Using this critical analysis to investigate whether or not NMES is an appropriate supplement to traditional dysphagia therapy may allow for greater uptake of this type of intervention in the field of speech-language pathology.

Objectives

The first objective of this critical analysis was to evaluate the efficacy of NMES as a supplement to existing dysphagia therapies in post-stroke patients. The second objective was to provide recommendations for clinical best practice and future research for the treatment of dysphagia in the post-stroke population.

Methods

Search Strategy

Online databases (Google Scholar, Western Libraries, Wiley Online Library) were searched using the following terms:

[(dysphagia therapy) OR (dysphagia treatment) OR (swallowing therapy) OR (swallowing treatment)] AND [(neuromuscular electrical stimulation) OR (NMES) OR (transcutaneous electrical stimulation) OR (TES)] AND [(stroke) OR (post-stroke)]

Of note, many of the articles reviewed, and included in this analysis, used varying terms synonymous with NMES, including transcutaneous electrical stimulation (TES) and transcutaneous electrical neuromuscular stimulation (TENS). For the purpose of this report, neuromuscular electrical stimulation (NMES) will be used to denote these procedures.

Selection Criteria

Studies selected for inclusion were required to implement NMES as part of the outlined intervention procedure as well as report outcomes investigating the efficacy of its use in tandem with existing dysphagia interventions. Studies were excluded if they were published prior to 2014 to ensure current best practice.

Data Collection

Results of the literature search yielded six articles that met the inclusion criteria. The articles included four randomized clinical trials (level 1 research evidence); one case series study (level 3 research evidence); and one case study (level 4 research evidence).

Results

Randomized Clinical Trials

Randomized clinical trials (RCT) consist of an experimental group and a control group to which participants are randomly assigned. Between group comparison allows for changes in outcome measures to be concluded as a result of treatment.

Carnaby et al. (2020) completed a double-blind randomized clinical trial that investigated the use of NMES in addition to an exercise-based swallowing therapy – the McNeil Dysphagia Therapy Program (MDTP). This intervention was provided to post-stroke patients (6-8 days post-stroke). This study included a placebo group who underwent MDTP and imitation NMES (n = 18), a control group that received TDT (n = 17), and a treatment group that received true NMES and MDTP (n = 18). Recruitment information, inclusion criteria and detailed participant demographics were outlined. Participants completed 1 hour of daily intervention for 3 weeks (15 hours total) or until earlier discharge. Clinicians assigned to each group were blind to other arms of the study, and those assigned to the imitation NMES and MDTP group were blind to the falsehood of the imitation NMES. Primary outcome measures included Mann Assessment of Swallowing Ability (MASA) scores and Functional Oral Intake Scale (FOIS) scores. Patients were assessed by a blinded independent evaluator at baseline, end of treatment and 3-months post-treatment. Appropriate between-group statistical analyses were performed. End-of-treatment results revealed significant increases in MASA scores for the MDTP only group, and a significant change in FOIS scores for both groups who underwent MDTP.

The use of a clearly defined MDTP exercise protocol contributed to this study's replicability, and the use of double blinding contributed to its reliability. However, MDTP is not widely used, and evidence for its efficacy alone remains unclear. Another strength of this study was the inclusion of a standardized measure to promote psychometric integrity (MASA). However, the majority of post-treatment results were gathered via telephone, limiting the researchers' ability to reassess this primary outcome measure for the majority of participants. Further, little detail was provided about post-treatment results. Of note, two of the authors of this article (Carnaby and Crary) are the creators of MDTP, and as such, there was potential for bias and financial conflict (not disclosed in the article). Overall, this study provided somewhat suggestive evidence to refute the use of NMES as an adjunct to exercise-based swallowing therapy.

Lee et al. (2014) used a randomized clinical trial to investigate the use of NMES alongside TDT for post-stroke patients. Fifty-seven participants, 10 days post-stroke, were randomly divided into two treatment groups: one experimental group including NMES and TDT and a control group including only TDT. Each group received TDT from the same therapist; however, maneuvers and exercises varied for each individual and included a combination of thermal-tactile stimulation with lingual and laryngeal strengthening exercises. The experimental group used NMES during the first 30 minutes of each TDT session. This treatment involved the placement of two sets of electrodes on the infrahyoid region to target the sternohyoid muscles. The primary outcome measure was FOIS score determined using a

videofluoroscopic swallowing study (VFSS) at baseline (10 days post-stroke) and at 3, 6, and 12-weeks. Appropriate statistical analyses were completed. Only the NMES/TDT group saw a statistically significant increase in FOIS at 3- and 6-weeks post-baseline, however, FOIS score for each group did not differ significantly at 12-weeks. Results of this study suggest that early treatment using NMES combined with TDT provides a greater increase in swallowing function for acute/subacute stroke patients with dysphagia in comparison to TDT alone.

A strength of this study was the use of NMES during the acute stage. However, as such, there was no exclusion of patients who had spontaneous recovery, and no complete assurance that group differences were a direct result of variable treatment (although, groups were not found to be statistically different at baseline). Additionally, functional improvement was only measured for a period of 3 to 12 weeks post-stroke, and recovery may extend beyond this point. Overall, this study provided somewhat suggestive evidence that NMES is a beneficial supplement to traditional dysphagia intervention for post-stroke patients.

Meng et al., (2018) completed a randomized clinical trial to investigate a) the effectiveness of NMES as an adjunct to TDT and b) the functional effect of variable electrode placement with the use of kinematic analysis. This study included 30 patients with post-stroke (~28-30 days) dysphagia, who were randomly divided into three equal groups: treatment group A (TGA; placement of electrodes in supra- and infra-hyoid regions), treatment group B (TGB; placement of electrodes confined to suprahyoid region) and a control group. Recruitment information, inclusion/exclusion criteria and detailed participant demographics were clearly outlined. All groups received TDT, but Group A and Group B both received NMES applied to different sites. TDT included diet changes, compensatory maneuvers, functional practice (i.e., swallowing food) and exercises unique to each individual. Treatment of all groups was completed in 30-minute sessions, 5 times per week for 10 total sessions. Outcomes were measured pre-treatment, and 2-weeks post treatment using the water swallow test (WST), repetitive saliva swallowing test (RSST), VFSS alongside the Dysphagia Outcome and Severity Scale (DOSS) and a kinematic evaluation of hyolaryngeal complex elevation. An appropriate statistical analysis was completed for all data. When compared to the control group, the results of the post-treatment evaluation showed significant improvements between TGA and TGB across all outcome measures. However, between the treatment groups there was no statistically significant difference, suggesting that placement of the stimulation was not found to have a differential effect on swallowing outcome. Kinematic evaluation revealed only a significant difference of anterior hyoid movement for TGB at 2-weeks post-treatment.

The results of this study did not provide definitive evidence for the inclusion of NMES due to multiple limitations of the research including a small sample size of only 30 participants, short duration of treatment and lack of follow-up observation to prove maintenance of results. There was no discussion of potential contributing variables, such as inconsistency in the TDT used for each patient, which limited the replicability of this study. Overall, this study provided suggestive evidence for the inclusion of NMES as a beneficial supplement to dysphagia intervention for post-stroke patients.

Park et al. (2016) completed a single-blind randomized clinical trial to investigate the use of NMES, in addition to effortful swallowing, as an adjunct to conventional dysphagia therapy for the treatment of post-stroke (~36 days) dysphagia. Detailed information about the participants was outlined, and recruitment information was provided. Participants were randomly divided into two groups: experimental (n = 25; electrical stimulation at increasing levels meant to induce motor activation) and placebo (n = 25; minimal electrical stimulation meant to induce sensory activation). All participants received 30 minutes of NMES in conjunction with effortful swallowing exercise over 5 sessions per week for 6 weeks. They followed a set procedure provided by various trained professionals. Primary outcome measures included videofluoroscopy dysphagia scale (VDS) score, penetration-aspiration scale (PAS) score and change in hyoid bone movement as per the Image J Program. Participants were assessed pre- and post-treatment by the same evaluator who was blinded to participants' group allocation. Appropriate between- and within-group statistical analyses were completed. Results revealed a statistically significant improvement in total VDS and oral VDS scores for both groups. However, statistically significant improvement in pharyngeal VDS score and PAS score were only seen in the experimental group. With regards to hyoid movement, only the experimental group showed a statistically significant improvement in both anterior and superior hyoid bone movement. Across all outcome measures, excluding oral VDS score, the

experimental group showed statistically significant improvement over the placebo group.

One strength of this study was the use of a defined exercise protocol which limited the number of potential confounding variables, thus contributing to the study's construct validity and replicability. The authors suggested that NMES combined with effortful swallowing improved pharyngeal swallowing physiology (hyoid elevation), however, their study was limited by a small sample size, and lack of post-treatment data to demonstrate maintenance. Overall, this study provided suggestive evidence to support the use of NMES in conjunction with conventional dysphagia therapy, although specifically when combined with effortful swallowing.

Case Series

A case series is an account of multiple participants who have received the same intervention. It is an observational study that allows for within-group comparison.

Martindale et al. (2019) used a single-arm clinical trial to determine the outcome of an intensive therapy program which included NMES with exercise resistance on select stroke and non-stroke patients with dysphagia. This study included 31 patients (17 stroke and 14 non-stroke) who were experiencing chronic dysphagia, characterized by reduced hyolaryngeal elevation and confirmed by VFSS. Participant outcomes were assessed using the FOIS, PAS and Swallow-Related Quality of Life questionnaire (SWAL-Qol). Measures were completed pre-treatment and post-treatment (within two weeks of completion of the program). Twenty 45-minute treatment sessions were offered to each participant, in which they received NMES stimulation and individualized swallowing exercises. These sessions were completed in 4-7.5 weeks' time. Appropriate within-group data analysis was conducted following amalgamation of the new data collected with the data of the previously published pilot study of the same design. Results revealed statistically significant positive change across all outcome measures. The researchers suggested that adjunctive NMES results in greater improvement in swallowing safety, oral intake and quality of life for both stroke and non-stroke patients.

One strength of this study was the clarity of inclusion criteria for participants, and a detailed description of the NMES treatment procedures making this method easily replicable. Limitations of this study included the lack of a standardized exercise program used across participants as well as a lack of a standardized rating scale to score the patients' dysphagia severity. Another limitation was the small sample size and absence of a control group limiting the ability to draw a conclusive link between the intervention program and beneficial outcomes. Overall, this study provided equivocal evidence for the benefit of NMES as a supplement to TDT for post-stroke patients.

Case Study

A case study provides an in-depth account of a specific case with the aim of generalizing the findings to other individuals with similar characteristics. It is a naturalistic study design.

Banik and Hattiangadi (2019) reported the results of retrospective case studies of two individuals with dysphagia as a result of posterior stroke. Participants were assessed pre-treatment using the Nair hospital bedside swallowing assessment (NHBSA), Nair hospital swallowing ability scale (NHSAS) and Dysphagia Handicap Index (DHI). Each individual completed initial sessions (4 and 7) of solely NMES stimulation followed by trial feeds until hyolaryngeal excursion was appreciated. Then, each individual completed 1-hour daily sessions (total of 9 and 19) of TDT, including various maneuvers, postural adjustments, thermal stimulation, and rehabilitative and proprioception exercises. TDT was performed at intervals of 10 minutes supplemented with 5-minute intervals of NMES. Session notes included qualitative observations of duration of swallow based on the Four Finger Test, and swallowing ability/duration of swallow for various consistencies. Post-treatment results indicated improvements in NHSAS score, NHBSA score and DHI for both participants. However, no statistical analysis was conducted to prove the significance of these improvements.

A limitation of this study included the fact that the researchers failed to disclose how cases were selected for inclusion. This raised the question of potential selection bias. The authors offered no information regarding who collected session notes and information bias was highly probably. Also, given the lack of a control, this article offered no distinction between the effects of TDT in comparison to adjunctive NMES. Overall, this study provided equivocal evidence for the use of NMES as an adjunct to existing dysphagia interventions for post-stroke individuals.

Discussion

Across all studies, the value of NMES as a supplement to existing dysphagia interventions for post-stroke patients was investigated. Taken together, the results of the six articles reviewed provided somewhat suggestive evidence that NMES, in conjunction with existing dysphagia interventions, may contribute to improvement in some aspect of post-stroke dysphagia recovery. Equivocal evidence to support adjunctive NMES was a result of low-level study designs with lack of control group, small sample size (Banik & Hattiangadi, 2019; Martindale et al., 2019), and potential selection and information bias (Banik & Hattiangadi, 2019). Lee et al. (2014) provided somewhat suggestive evidence, to support the use of NMES, while Carnaby et al. (2020) provided somewhat suggestive evidence to refute the use of NMES. Concluded strengths of these articles were a result of clearly outlined experimental procedures and control/placebo groups allowing for direct between-group comparisons supported by appropriate statistical analyses. Carnaby et al.'s inclusion of a standardized measure further contributed to its psychometric integrity (MASA score). However, both studies were still limited by small sample sizes and lack of sufficient reassessment and follow-up data post-treatment. Studies conducted by Meng et al. (2018) and Park et al. (2016) provided the most compelling evidence (suggestive) due to their use of sound experimental methods (RCT) alongside appropriate statistical analyses, and objective measures of dysphagia severity contributing to increased reliability. Further, Park et al.'s (2016) use of a clearly-defined exercise protocol increased construct validity and contributed to the study's replicability. However, both studies were limited in power by sample size and lack of follow-up data post-treatment.

Each study used differing outcome measures to estimate dysphagia recovery, however, some commonalities were noted between articles. All articles included measures that considered the occurrence of penetration/aspiration and level of oral intake. Park et al. (2016) and Martindale et al. (2019) report significant changes to PAS score following treatment including NMES. Similarly, Carnaby et al. (2020), Lee et al. (2014) and Martindale et al. (2019) all included the FOIS as a primary outcome measure, and all reported statistically significant improvements to FOIS score following treatment. Carnaby et al. (2019) cited this result following 3 weeks of intervention, Martindale et al. (2019) following 4-7.5 weeks, and Lee et al. (2014) following 3 and 6 weeks. Trends noted between articles may suggest a link between inclusion of NMES and time to recovery. However, this conclusion is difficult to ascertain across studies given a number of inconsistent variables. Primarily, studies varied in time to treatment, with the inclusion of post-stroke individuals in the acute stage (Carnaby et al., 2020; Lee et al., 2014; Banik & Hattiangadi, 2019), subacute stage (Meng et al., 2018; Park et al., 2016) and those with chronic dysphagia (Martindale et al., 2019). Dysphagia rehabilitation during the acute and subacute stages takes advantage of spontaneous recovery, which cannot be ethically measured or fully accounted for. Also, across all studies, participants varied with respect to type of stroke and affected lesion, making it unclear as to which subset of clients may benefit most from the use of adjunctive NMES.

Throughout the articles analyzed there was a lack of homogeneity in the prescribed intervention procedures. While Carnaby et al. (2020) and Park et al. (2016) used defined and uniform intervention protocols, the remainder of the research studies implemented nonuniform and individualized TDT in addition to NMES (Lee et al., 2014; Meng et al., 2018; Banik & Hattiangadi, 2019; Martindale et al., 2019). The use of a defined swallowing protocol increased validity, while limiting the number of contributing variables. Also, the use of a replicable procedure contributed to unity across research, while expanding the evidence base for NMES use. Not only did the studies report variable intervention procedures, but they also lacked consistency in the intensity of these outlined procedures. Intervention intensity ranged from 30- (Meng et al., 2018 and Park et al., 2016) to 60-minutes a day (Carnaby et al., 2020; Lee et al., 2014; Banik & Hattiangadi, 2019) and across 2- (Meng et al., 2018) to 7.5- weeks of treatment (Martindale et al., 2019). The lack of a consistent timeframe for which intervention was completed perpetuates the issues related to spontaneous recovery previously discussed.

The lack of objectivity across studies was not only a limitation concerning intervention protocols but also concerning physiologic measures of dysphagia recovery. The proposed goal of NMES is to improve hyolaryngeal elevation and range of motion; therefore, studies measuring its efficacy should include objective physiologic measures (Suiter et al., 2006). Park et al. (2016) and Meng et al. (2018) were the only researchers to include physiologic measures. This lack of inclusion resulted in limited data demonstrating any immediate or long-term physiological changes in swallowing as a result of NMES.

Conclusion

Overall, the studies reviewed provided somewhat suggestive evidence for the inclusion of NMES as a beneficial supplement to existing dysphagia interventions for post-stroke patients. Limitations of the currently available research include a heterogenous target population, small sample sizes, variability in treatment protocols, and a lack of control groups, follow-up data and objective/standardized measures.

In future studies investigating the effectiveness of NMES as an adjunct to existing dysphagia interventions, the following recommendations should be considered:

1. Use of large scale randomized controlled trials.
2. Use of distinct treatment protocols to increase construct validity and unity among research studies.
3. Inclusion of post-treatment data measures to ensure maintenance of statistically significant results.
4. Inclusion of objective and standardized measures of swallowing ability to promote psychometric integrity.
5. Inclusion of physiologic measures of swallowing function to investigate impact on the system.

Clinical Implications

Based off of the critical analysis of six articles evaluating the inclusion of NMES as an adjunct to existing dysphagia therapies, it was concluded that there is a lack of sufficient evidence to support the use of NMES. Although five of the six studies included in this critical review provided overall positive results for the implementation of NMES, caution must be used when applying these findings clinically. Functionally, NMES applied to the infrahyoid region results in a descent of the hyolaryngeal complex (Meng et al., 2018). Although this resistance has been shown to result in greater anterior and superior movement of the hyolaryngeal complex physiologically (Park et al., 2016; Meng et al., 2018), this descent may pose a risk of aspiration while wearing the device for those unable to overcome this descent. Dysphagia intervention post-stroke is widely accepted as best practice, with the inclusion of early intervention showing even stronger positive outcomes (Bakhtiyari et al., 2015). However, the post-stroke population is an extremely heterogenous population, and the lack of unity among research makes it difficult to confirm what demographic is best suited for the use of NMES. Therefore, continued research on the potential value of NMES as an adjunct to existing dysphagia therapies is warranted.

References

Bakhtiyari, J., Sarraf, P., Nakhostin-Ansari, N., Tafakhori, A., Logemann, J., Faghihzadeh, S., & Harirchian, M. H. (2015). Effects of early intervention of swallowing therapy on recovery from dysphagia following stroke. *Iranian Journal of Neurology*, *14*(3), 119.

Banik, A. A., & Hattiangadi, G. A. (2019). Transcutaneous electrical neuromuscular stimulation (TENS) along with traditional dysphagia therapy in patients with posterior stroke: a case study. *Indian Journal of Otolaryngology and Head & Neck Surgery*, *72*(3), 279-283.

Carnaby, G. D., LaGorio, L., Silliman, S., & Crary, M. (2020). Exercise-based swallowing intervention (McNeill Dysphagia Therapy) with adjunctive NMES to treat dysphagia post-stroke: a double-blind placebo-controlled trial. *Journal of Oral Rehabilitation*, *47*(4), 501-510.

Huckabee, M. L., & Doeltgen, S. (2007). Emerging modalities in dysphagia rehabilitation: neuromuscular electrical stimulation. *New Zealand Medical Journal*, *120*(1263), U2744.

Lee, K. W., Kim, S. B., Lee, J. H., Lee, S. J., Ri, J. W., & Park, J. G. (2014). The effect of early neuromuscular electrical stimulation therapy in acute/subacute ischemic stroke patients with dysphagia. *Annals of Rehabilitation Medicine*, *38*(2), 153.

Martindale, N., Stephenson, J., & Pownall, S. (2019). Neuromuscular electrical stimulation plus rehabilitative exercise as a treatment for dysphagia in stroke and non-stroke patients in an NHS Setting: feasibility and outcomes. *Geriatrics*, *4*(4), 53.

Martino, R., Martin, R. E., & Black, S. (2012). Dysphagia after stroke and its management. *Canadian Medical Association Journal*, *184*(10), 1127-1128.

Meng, P., Zhang, S., Wang, Q., Wang, P., Han, C., Gao, J., & Yue, S. (2018). The effect of surface neuromuscular electrical stimulation on patients with post-stroke dysphagia. *Journal of Back and Musculoskeletal Rehabilitation*, *31*(2), 363-370.

Nussbaum, E. L., Houghton, P., Anthony, J., Rennie, S., Shay, B. L., & Hoens, A. M. (2017).

Neuromuscular electrical stimulation for treatment of muscle impairment: critical review and recommendations for clinical practice. *Physiotherapy Canada*, *69*(5), 1-76.

Park, J. S., Oh, D. H., Hwang, N. K., & Lee, J. H. (2016). Effects of neuromuscular electrical stimulation combined with effortful swallowing on post-stroke oropharyngeal dysphagia: a randomised controlled trial. *Journal of Oral Rehabilitation*, *43*(6), 426-434.

Perlman, A. L., Palmer, P. M., McCulloch, T. M., & Vandaele, D. J. (1999). Electromyographic activity from human laryngeal, pharyngeal, and submental muscles during swallowing. *Journal of Applied Physiology*, 86(5), 1663-1669.

Serel Arslan, S., Azola, A., Sunday, K., Vose, A., Plowman, E., Tabor, L., Singer, M., Robison, R., & Humbert, I. A. (2018). Effects of submental surface electrical stimulation on swallowing kinematics in healthy adults: an error-based learning paradigm. *American Journal of Speech-Language Pathology*, *27*(4), 1375-1384.

Suiter, D. M., Leder, S. B., & Ruark, J. L. (2006). Effects of neuromuscular electrical stimulation on submental muscle activity. *Dysphagia*, *21*(1), 56-60.