

ORIGINAL RESEARCH

Transcutaneous electrical stimulation versus traditional dysphagia therapy: A nonconcurrent cohort study

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OBJECTIVE: The purpose of this investigation was to critically evaluate the efficacy of electrical stimulation (ES) in treating persons with dysphagia and aspiration.

STUDY DESIGN: Nonconcurrent cohort study.

METHODOLOGY: The charts of 40 consecutive individuals undergoing ES and 40 consecutive persons undergoing traditional dysphagia therapy (TDT) were reviewed. Pre- and post-therapy treatment success was compared utilizing a previously described swallow severity scale. A linear regression analysis was employed to adjust for potential confounding variables.

RESULTS: The swallow severity scale improved from 0.50 to 1.48 in the TDT group ($P < 0.05$) and from 0.28 to 3.23 in the ES group ($P < 0.001$). After adjusting for potential confounding factors, persons receiving ES did significantly better in regard to improvement in their swallowing function than persons receiving TDT ($P = 0.003$).

CONCLUSIONS: The results of this nonconcurrent cohort study suggest that dysphagia therapy with transcutaneous electrical stimulation is superior to traditional dysphagia therapy alone in individuals in a long-term acute care facility.

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Swallowing difficulties (dysphagia) affect nearly 15 million adults in the United States.¹ Dysphagia can be extremely morbid. Complications include aspiration pneumonia, malnutrition, dehydration, pulmonary fibrosis, and

death. There have been very few innovations in the treatment of swallowing disorders in recent years. The mainstay of nonsurgical therapy continues to be dietary restriction, swallowing maneuvers, and swallowing exercise. The treatment efficacy of these modalities is generally poor.²

Electrical stimulation has been used in rehabilitative medicine to retard disuse atrophy, exercise striated muscle, and accelerate wound healing. The idea of utilizing electrical stimulation (ES) to rehabilitate the swallowing mechanism is relatively new. Park et al administered electrical stimulation via an oral prosthesis placed on the soft palate.³ Aiming to re-educate neural pathways associated with the swallowing reflex with electrical stimulation, they achieved a 50 percent success rate in improving the swallow of patients already capable of oral feeding. Freed et al reported the efficacy of transcutaneous ES in 63 persons with dysphagia.⁴ In this study, they compared dysphagia in patients treated with electrical stimulation to those treated with thermal stimulation. Leelamanit et al reported their experience with synchronized ES in 23 persons with dysphagia and concluded that dysphagia was improved in these patients.⁵ A control group was not utilized. Although these investigations concluded that ES appeared to be beneficial, the efficacy of ES for treating dysphagia remains uncertain. The purpose of this investigation was to critically evaluate the efficacy of ES by comparing this treatment modality to

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traditional dysphagia therapy in treating persons with dysphagia and aspiration in a long-term acute care facility.

METHODOLOGY

Two groups of 40 consecutive patients admitted to a long-term acute care hospital (Kindred Hospital, San Diego, CA) were retrospectively evaluated. Approval was attained by the Institutional Review Board per protocol. Patients receiving traditional dysphagia therapy were recruited from January 1, 2003 to December 31, 2003. Patients receiving electrical stimulation dysphagia therapy were recruited from January 1, 2004 to December 31, 2004. All patients underwent diagnostic swallowing assessment upon admission and prior to discharge. Assessments were completed by an interdisciplinary team consisting of a speech language pathologist, otolaryngologist, and technician utilizing both video-fluoroscopy (GE Medical Systems, Salt Lake City, UT) and fiberoptic endoscopic evaluation of swallowing (Pentax Medical Company, Montvale, NJ). Swallowing function was gauged by a previously described swallow severity scale (Table 1).⁴ The system is based on the safest tolerable ingestible material and ranges from 0 (profound swallowing impairment) to 6 (no swallow impairment). Treatment success was determined by comparing admission and discharge swallow scores. To evaluate potential confounding variables, data regarding the patient admit diagnosis, initial disease severity (APACHE II score⁶), number of dysphagia treatments administered, patient demographics, presence of a tracheotomy tube at admit and discharge, and patients' overall length of hospital stay (LOS) was also abstracted.

Patients in the traditional dysphagia therapy (TDT) cohort received interventions that focused on a combination of therapeutic exercise, compensatory maneuvers, and diet-texture modifications. The goal of therapeutic exercise was to improve the overall integrity of the swallow mechanism by increasing strength, endurance, range of motion, and mobility of orofacial, lingual, and laryngeal musculature. Specific exercises employed included any combination of laryngeal adduction and elevation exercises, Shaker exercises, and oral motor exercises. Compensatory maneuvers

and diet texture modifications were selected based upon specific deficits noted during diagnostic testing. All TDT sessions were administered by a speech language pathologist. Exercises were performed continuously for 30 minutes.

Patients in the electrical stimulation (ES) cohort were treated solely with the electrical stimulation modality. All sessions were performed by speech pathologists trained and certified in the use of VitalStim therapy (Chattanooga, TN). The primary objective was to use the electrical current to activate pharyngeal/laryngeal musculature through intact peripheral nerves. Technical specifications of the VitalStim unit include fixed pulse rate of 80 hz and fixed pulse duration of 700 usec. Electrodes were placed in a horizontal montage just above the thyroid notch. Dysphagia treatment sessions were comprised of placement of electrodes with gradual increase in intensity (mA) in concert with administration of food/liquid trials. Specific textures were provided based upon the severity of swallowing dysfunction. Optimal ES intensity was determined when a motor response was identified either visually or verbally. ES was administered continuously for 30 minutes. The number of TDT and ES treatment sessions was based on progress toward a stated goal in the patient plan of care. A target consistency was established prior to the initiation of treatment. This consistency was usually a regular or soft mechanical diet depending on the patient's baseline performance level. Once this goal was achieved or the patient demonstrated a plateau in therapy, treatment was discontinued.

All data were coded and recorded into SPSS 11.0 for the Macintosh (Chicago, IL). The independent samples *t* test was utilized to compare the differences between nonpaired means in the ES and TDT groups. Pretreatment and post-treatment swallow scores were compared using the matched-pairs *t* test. The χ^2 test was used to ascertain statistical significance between categorical variables. A multiple stepwise linear regression model was used to evaluate the association between swallowing improvement and treatment modality while adjusting for potentially confounding variables (age, gender, diagnosis, presence of a tracheotomy tube, and initial disease severity—APACHE II score).

RESULTS

The charts of 40 consecutive individuals undergoing ES and 40 consecutive persons undergoing TDT were reviewed. The mean age of the entire cohort was 72 (± 11) years. There was no significant difference in age between the two treatment groups ($P > 0.05$). The etiology of dysphagia was respiratory failure (60/80 or 75%), stroke (4/80 or 5%), sepsis (3/80 or 4%), and other chronic conditions. There was no significant difference between the two groups in regard to age, gender, diagnosis, presence of a tracheotomy tube, initial disease severity score, or initial swallow severity scale ($P > 0.05$). The treatment was tolerated by all patients and there were no known complications related to TDT or ES therapy.

Table 1
Swallow function scoring system

Swallow score	Safe food consistency	Level of impairment
0	Nothing safe/aspirates saliva	Profound
1	Saliva	Profound
2	Pudding/paste/slush	Substantial
3	Honey consistency	Moderate
4	Nectar consistency	Mild
5	Solid food dysphagia	Minimal
6	All consistencies tolerated	Normal

Table 2
Improvement in swallow severity scale

	Traditional dysphagia therapy	Electrical stimulation dysphagia therapy
Swallow severity scale at admission	0.50 (\pm 1.34)	0.28 (\pm 0.91)
Swallow severity scale at discharge	1.48 (\pm 1.70)	3.23 (\pm 2.23)

The initial swallow severity scale scores were 0.50 (\pm 1.3) and 0.28 (\pm 0.91) for the TDT and ES groups respectively ($P = 0.382$.) Both groups showed significant improvement in swallow severity score after treatments (Table 2). The electrical stimulation group, however, displayed significantly more improvement with treatment than did the TDT group. The mean improvement in swallow severity score for the TDT group was 0.98 (\pm 1.70) in comparison to 2.95 (\pm 2.23) for the ES group ($P = 0.002$). The mean number of treatments was 13 (\pm 7) in the TDT group and 10 (\pm 5) in the ES group ($P = 0.014$). The mean length of stay was 87 (\pm 156) days for the TDT group and 51 (\pm 33) days for the ES group ($P = 0.154$). After adjusting for age, gender, diagnosis, and initial disease severity in a multivariate linear regression analysis, treatment with ES was significantly associated with swallow scale improvement.

DISCUSSION

Electrical stimulation is currently being used by numerous disciplines to control pain, to enhance muscle performance, to stimulate wound healing, and to enhance sensorimotor recovery after stroke. Peurala et al compared cutaneous ES to placebo in 59 patients with paretic limbs after stroke. Significant improvements were realized only in the ES group.⁷ de Kroon et al conducted a meta-analysis on the effect of ES on upper extremity disability after stroke. Four of 6 (67%) of the studies identified in the meta-analysis reported a positive effect on motor control.⁸ It is known that disuse of a striated muscle leads to atrophy of that muscle, even if the medical condition leading to disuse has no direct effect on the muscle or associated nerves.⁹ Contraction of the affected muscle group is critical to regaining function. ES may enhance tone so that exercise may strengthen or activate the muscle.

The mechanism of improvement for the reported efficacy of ES is uncertain. The stimulation is thought to increase local blood flow and diminish extracellular fluid, thus reducing edema.¹⁰ Electrically stimulated contractions recruit more motor units than volitional contractions.¹¹ ES also selectively activates type II muscle fibers that have a greater ability to develop tension. These benefits may allow for enhanced strength development.¹² ES to the lower extremity has been associated with brain activation in both sensory and motor regions.¹³ Kimberley et al demonstrated that intensive ES to the upper extremity improved hand function

and was associated with an increase in cortical intensity in the sensory cortex on functional MRI after stroke.¹⁴ The stimulation in cortical sensory areas may be responsible for the improved swallowing coordination in some patients undergoing ES dysphagia therapy.

This study retrospectively compared traditional dysphagia therapy to electrical stimulation therapy in a cohort of patients with chronic dysphagia in a long-term acute care facility. Patients receiving ES displayed a significant improvement in swallowing function, required fewer treatment sessions, and showed a trend toward a shorter length of hospitalization than did persons receiving traditional dysphagia therapy. There were no complications related to ES therapy in this study and all patients tolerated the treatments without event.

Several limitations of this study must be recognized. This investigation is a retrospective review and is subject to all of the inherent limitations of a nonconcurrent (historical) cohort design. The clinicians administering the swallowing therapy were also the individuals performing the swallow evaluations. They were not blind to the treatment received. This may result in a potential ascertainment bias due to diagnostic discrepancies in the clinicians' interpretation of the swallow studies. Perhaps clinicians were more favorable in their interpretation of swallow studies for individuals receiving the novel ES therapy. In addition, there may also be a participation bias due to some unidentified factor associated with the type of therapy (TDT vs ES) that the patients received. Perhaps clinicians were less likely to perform ES therapy on individuals with a poorer prognosis. This would tend to bias the results away from the null hypothesis in favor of a positive treatment effect for ES therapy. This study was also limited to individuals in a long-term acute care facility. This population is, in general, fairly homogenous in regard to its disease acuity and rehabilitation potential. The results of this study must not be generalized to other individuals in greater or poorer health. In order to adequately eliminate the potential for bias the results of this study must be confirmed with a prospective, randomized, placebo-controlled, clinical trial in individuals of varying disease severity and rehabilitation potential. Such efforts are currently underway at our swallow center.

CONCLUSIONS

The results of this retrospective case control study suggest that dysphagia therapy with transcutaneous electrical stim-

ulation is superior to traditional dysphagia therapy alone in individuals in a long-term acute care facility. Individuals receiving ES therapy required fewer treatment sessions and displayed a trend toward a shorter length of hospitalization than persons receiving traditional dysphagia therapy. Confirmation of these findings with a prospective, placebo-controlled, randomized clinical trial is necessary before a definitive determination regarding the efficacy of ES dysphagia therapy can be made.

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