

Impact of transcutaneous neuromuscular electrical stimulation on dysphagia in patients with head and neck cancer treated with definitive chemoradiation

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ABSTRACT: *Background.* The purpose of this study was to investigate the role of transcutaneous neuromuscular electrical stimulation (TNMES) therapy in maintaining swallowing function during chemoradiation for locally advanced head and neck cancer.

Methods. We retrospectively compared 43 consecutive patients with locally advanced head and neck cancer treated with TNMES (treatment group) to 55 control patients. Validated swallowing scale scores were assigned.

Results. All patients' swallowing scores declined post-chemoradiotherapy. A difference in mean decline in scores for the control group versus the treatment group using the Functional Oral Intake Scale (FOIS) was seen, favoring TNMES intervention (23% vs 7%; $p =$

.015). Age, race, >10 pack-years smoking, diabetes, stage, nodal disease, accelerated fractionation, weight loss, dietary modification, no TNMES, and radiotherapy dose were all significant for poorer scores on the swallowing scales.

Conclusion. TNMES should be considered an adjunct to dysphagia reduction and possible prevention in patients with locally advanced head and neck cancer. Further studies should be conducted to define the benefit of TNMES intervention. © 2015 Wiley Periodicals, Inc. *Head Neck* 37: 1051–1056, 2015

KEY WORDS: Vital Stim, laryngectomy, dysphagia, radiation, chemotherapy

INTRODUCTION

Dysphagia or dysfunctional swallowing is one of the most detrimental side effects of radiation therapy for head and neck cancer. Concurrent chemoradiotherapy confers a survival advantage over radiotherapy alone for locoregionally advanced disease and is the standard of care.^{1,2} However, the addition of chemotherapy is known to exacerbate radiotherapy toxicity, further worsening swallowing function.³ Severe dysfunction of the structures involved in swallowing, including the base of tongue, larynx, and various muscles, has been observed on swallowing studies after chemoradiotherapy.^{4,5} The rates of chronic dysphagia range from 30% to 50% with prolonged (>2 years) need for feeding tubes.⁶ Dysphagia has been associated with a compromised quality of life, anxiety, depression, aspiration leading to pneumonias, dehydration, failure to

thrive, longer hospital stays, and ultimately even death.^{7–9} In addition to being a side-effect of therapy, dysphagia is a common presenting symptom in patients with head and neck cancer.¹⁰ Management of dysphagia poses a very complex and challenging problem.

Transcutaneous neuromuscular electrical stimulation (TNMES) is a relatively new therapy that involves the transmission of low-voltage current via skin surface electrodes triggering muscles to induce contraction. It is felt to improve the contractile properties of the muscles and their strength after damage.¹¹ There have been several studies showing TNMES to have benefit over traditional dysphagia therapy alone in patients with varying etiologies including stroke, neuromuscular disorders, and head trauma,^{12–14} whereas some question the benefit.¹⁵ A meta-analysis examining the effect of TNMES on swallowing concluded that, although there appeared to be a benefit, more data were needed to draw definitive conclusions.¹³ TNMES is now commonly used in the physical and occupational therapy rehabilitation settings, however, its role in patients with head and neck cancer is not well established but has been explored with encouraging results.¹⁶ The main purpose of our study was to analyze how TNMES intervention affects dysphagia outcome measures in patients with locally advanced head and neck cancer undergoing chemoradiotherapy.

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TABLE 1. Swallowing Scoring Scales.

Score	FOIS (1–7)	Swallowing Performance Status Scale (1–7)*	8-point PAS (1–8)
1	No oral intake	Normal swallowing	Material does not enter airway
2	Tube dependent with minimal/inconsistent oral intake	Within functional limits	Material enters the airway, remains above the vocal folds, and is ejected from the airway
3	Tube supplements with consistent oral intake	Mild impairment	Material enters the airway, remains above the vocal folds, and is not ejected from the airway
4	Total oral intake of a single consistency	Mild-moderate impairment	Material enters the airway, contacts the vocal folds, and is ejected from the airway
5	Total oral intake of multiple consistencies requiring special preparation	Moderate impairment	Material enters the airway, contacts the vocal folds, and is not ejected from the airway
6	Total oral intake with no special preparation, but must avoid specific foods or liquid items	Moderate-severe impairment	Material enters the airway, passes below the vocal folds, and is ejected into the larynx or out of the airway
7	Total oral intake with no restrictions	Severe impairment	Material enters the airway, passes below the vocal folds, and is not ejected from the trachea despite effort
8	–	–	Material enters the airway, passes below the vocal folds, and no effort is made to eject

Abbreviations: FOIS, Functional Oral Intake Scale; PAS, Penetration-Aspiration Scale.

* Descriptive of individual impairments not been listed here.

Bold descriptions represent aspirator- and tube-dependent patients.

MATERIALS AND METHODS

Under an institutionally approved institutional review board protocol, we conducted a retrospective review of a prospectively maintained database of 1141 patients with head and neck cancer treated at our institution from January 2006 to March 2011. Inclusion criteria included the use of definitive chemoradiotherapy, availability of a pre-modified barium swallow (MBS) and post-MBS and/or fiber-optic endoscopic evaluation of swallowing, and TNM stages III and IV. The post-MBS study was typically done at or shortly after completing chemoradiotherapy, usually within a 2-week period. Patients were excluded if they received radiotherapy alone, definitive surgery alone, TNM stages I and II, had recurrent disease, and if they had only 1 or no MBS done. We also excluded patients who had undergone prior neck surgery, including a tracheostomy.

TNMES is a noninvasive external electrical stimulation therapy (electrotherapy) performed by a qualified speech language pathologist. Four electrodes with leads are attached to various locations on the anterior neck as determined by the speech language pathologist based on the site of primary and cause of dysphagia. The leads are controlled via a Food and Drug Administration approved hand-held device (Vital Stim; DJO, Vista, CA). The most common electrode placement was neck nodal level (3a/3b). These placements are intended to target the anterior belly of the digastrics, mylohyoid, geniohyoid, and thyrohyoid to improve hyolaryngeal excursion with muscle contraction. The intent is to combat disuse atrophy and weakness. Ther-

apy involves administration of at least 5 mA current, 80 Hz frequency with phase duration of 300 microseconds given 3 times a week beginning at the first week of chemoradiotherapy. Each session lasted about 45 to 60 minutes.

All patients were offered therapeutic exercises, compensatory strategies, and diet modification, as deemed necessary by the speech language pathologist, in addition to the TNMES. TNMES was routinely offered to patients who exhibited some degree of dysphagia during the initial pretreatment evaluation by a speech language pathologist. We used 3 established scoring scales (see Table 1) to assign swallowing scores based on an MBS before and after completion of chemoradiotherapy. All interpretations were performed by a qualified speech language pathologist (N.G.). Assigned scores consisted of a raw score from 1 to 7 (Functional Oral Intake Scale [FOIS]¹⁷ and Swallowing Performance Status Scale¹⁸) and 1 to 8 (8-point Penetration-Aspiration Scale [PAS]¹⁹), and a functional score of aspiration (tube dependence) or no-aspiration (non-tube dependence) (Table 1). A paired sample analysis was performed between the treatment group and control group using an independent samples *t* test. Data obtained from these 3 scales were then compared between the 2 groups of patients. Correlation was also made to several baseline patient and treatment-related characteristics for the 2 groups and statistics, including univariable and multivariable analyses, were performed to evaluate for any potential predictive factors of swallowing outcomes.

TABLE 2. Patient demographic data.

	Control group (N = 54)			Treatment group (N = 41)			p value*
	Mean, SD	Frequency	%	Mean, SD	Frequency	%	
Age	58.74, 7.93			62.15, 10.34			.072
Male sex		40	83.3		35	85.4	.173
Pack-years							.282
Never smoked		9	16.7		9	22.0	
<10		4	7.4		1	2.4	
10–50		23	42.6		16	39.0	
>50		18	33.3		15	36.6	
Site							.128
Oral		2	3.7		2	4.9	
Pharynx		39	72.2		28	68.3	
Larynx		12	22.2		10	24.4	
Unknown primary		1	1.9		1	2.4	
Stage							.323
III		13	24.1		13	31.7	
IVa		33	61.1		24	58.5	
IVb		8	14.8		4	9.8	
Node positive status		44	81.5		34	82.9	.857
Radiation therapy dose	70.14, 6.42			71.13, 1.12			.273
Treatment technique							.316
3D-CRT		32	59.3		20	48.8	
IMRT		22	40.7		21	51.2	
Chemotherapy type							.668
CDDP		34	63.0		26	63.4	
Eribitux		5	9.2		2	4.9	
CDDP + Eribitux		6	11.1		3	7.3	
Carbo/taxol		9	16.7		10	24.4	

Abbreviations: 3D-CRT, 3D conformal radiotherapy; IMRT, intensity-modulated radiation therapy; CDDP, cis-diamminedichloroplatinum; Carbo/taxol, carboplatin/taxol combination.

* Differences between treatment and control groups were assessed using chi-square or independent sample *t* tests. Resultant *p* values are reported.

RESULTS

A total of 95 patients met the inclusion criteria and were the subject of our evaluation (Table 2). Number of TNMES applications was initially evaluated to determine how the number of TNMES applications affected outcome measures. Because the Vital Stim protocol recommends at least 10 treatment sessions, a breakpoint was established at ≥ 10 applications. The reason for receiving fewer than 10 treatments included: lack of significant dysphagia on initial evaluation ($n = 20$), patient refusal ($n = 15$), hospitalization during treatment resulting in premature discontinuation ($n = 7$), severe skin toxicity or additional toxicity resulting in patient discontinuation ($n = 8$), insurance denial ($n = 2$), and unknown reason ($n = 2$). Patients receiving 1 to 9 applications had statistically similar mean scores on baseline measures of swallowing function to those receiving zero applications ($p > .05$). Patients were then divided into 2 groups. A treatment group that received ≥ 10 TNMES applications ($n = 41$) and a control group (control group) that received ≤ 9 (or 0) applications ($n = 54$). The 2 groups were well balanced with regard to baseline patient characteristics, and this was confirmed by nonsignificance in independent samples *t* tests comparing group differences (all $p > .05$). The median number of TNMES treatments were 14 (range, 10–38) in the treatment group and 0 (range, 0–9) in the control group. Average time between completion of external radiation therapy and follow-up data collection, including formal swallow evaluation, was 4.5 months.

Both groups showed worsening swallowing function post-chemoradiotherapy when compared to pretreatment with a decline seen in all 3 swallowing scores (Table 3 and Figure 1). Repeated measures analysis of covariance models controlling for relevant confounds (eg, age, nodal status) demonstrated a lower decline in swallowing dysfunction based on FOIS raw score between control group versus the treatment group (23% vs 7%; $p = .015$). Similar trends were demonstrated in a lower decline in swallowing function between the control group and treatment group based on the 8-point PAS raw score (41% vs 5%; $p = .121$) and Swallowing Performance Status Scale raw score (45% vs 18%; $p = .393$), although results were not significant for these scales.

Logistic regression analysis of predictive factors for outcome was performed (Tables 4, 5, and 6). Using FOIS functional scores, we identified older age, African American race, >10 pack-years smoking, diabetes, American Joint Committee on Cancer (AJCC) stage IVA, bilateral node involvement, accelerated fractionation, >10 pound weight loss, those requiring dietary modification, no TNMES intervention, and increased radiotherapy dose as significant for a poor posttreatment scores. Similar findings were seen using the Swallowing Performance Status Scale scale functional score. Fewer factors were identified as significant when using the 8-point PAS functional score, including older age, >10 pack-years smoking, diabetes, AJCC stage IVA, bilateral lymph node involvement, and increasing radiotherapy dose.

TABLE 3. Outcome data based on transcutaneous neuromuscular electrical stimulation intervention.

	Control group (N = 54)				Treatment group (N = 41)				Results	
	Baseline		Follow-up		Baseline		Follow-up		F	p value
	Mean	SD	Mean	SD	Mean	SD	Mean	SD		
FOIS	5.981	1.380	4.593	2.311	6.195	1.382	5.732	1.566	6.122*	.015
8-point PAS	3.056	2.543	4.315	2.590	2.927	2.494	3.073	2.514	2.445	.121
Swallowing Performance Status Scale	2.815	1.738	4.074	2.222	2.902	1.530	3.415	1.658	.736 [†]	.393

Abbreviations: FOIS, Functional Oral Intake Scale; PAS, Penetration-Aspiration Scale.

* Analysis adjusted for race.

[†] Analysis adjusted for nodal status.

DISCUSSION

Traditionally, patients are evaluated and treated for dysphagia months after completion of chemoradiotherapy, at which time many are feeding tube dependent. They are offered dysphagia exercises and certain techniques and physical maneuvers, which, although helpful, rarely restore full function. TNMES has been used in the rehabilitation of stroke patients and in several neuromuscular disorders (like Parkinson Disease, Muscular Dystrophies, Amyotrophic Lateral Sclerosis, and Multiple Sclerosis) and is felt to be superior to traditional dysphagia therapy.^{12,13} It has effects of increasing muscle size, endurance, improving the range of motion, and improving circulation. TNMES has also been shown to improve muscle performance and exercise capacity in patients with chronic obstructive pulmonary disease.²⁰ Our study suggests that early intervention with TNMES may also successfully reduce swallowing morbidity after chemoradiotherapy for locally advanced head and neck cancers.

Although our data suggest a benefit in reducing dysphagia with TNMES in patients with locally advanced head and neck cancer, significant benefits were only demonstrated using the FIOS assessment. FOIS was originally designed and validated for stroke patients.¹⁷ This test is appropriate for estimating and documenting functional eating abilities because it makes a clear distinction between feeding tube dependency and the ability to take food by mouth. Swallowing Performance Status Scale

does not specifically address functional limitations. This scale is highly sensitive for aspiration, but does not clearly separate ability to take in food orally versus feeding tube dependence. Similarly, the 8-point PAS is limited. This scale gives a rating to the level of penetration or aspiration of any bolus with concomitant behaviors and bases the rating on the bolus that performs the worst. Aspiration with thin liquids gives a poor score but does not necessarily mean the patient has severe dysphagia.¹⁸

The act of swallowing is a complex neurophysiological process. Patients with head and neck cancer have a higher rate of swallowing impairment at presentation because of a variety of possible causes, including mechanical obstruction, nerve or muscle involvement, reduced base of tongue retraction, or inadequate laryngeal vestibule closure. Aspiration rates before treatment range from 30% to 80%, depending on the site of primary involvement.¹⁰ Swallowing dysfunction after curative chemoradiotherapy can worsen the already existing dysphagia at presentation or can present as a new sequelae of the treatments. Swallowing difficulty because of acute toxicity could be due to mucositis, odynophagia, trismus, loss of taste, and saliva alterations. Some of these issues resolve, however, postradiation edema and radiation-induced fibrosis of the pharyngeal musculature lead to noncompliance of tissue and immobility of underlying muscles.²¹ This results in significant difficulty moving a food bolus through the pharynx and closing off of the airway, leaving residue

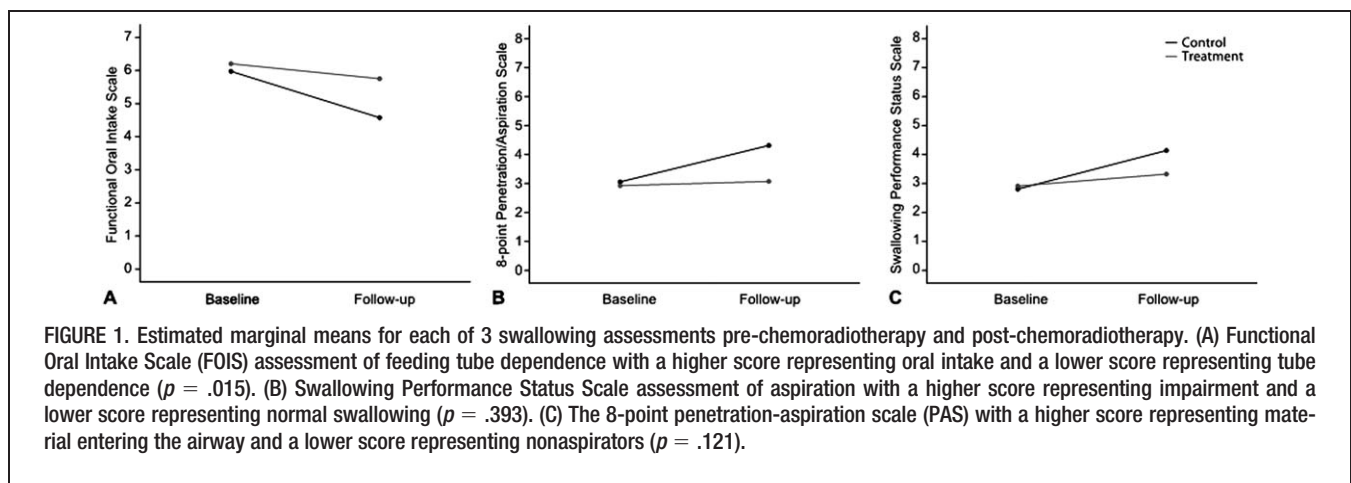


TABLE 4. Logistic regression model for probability of Functional Oral Intake Scale.

Predictor	<i>p</i> value	OR	95% CI
Age	.010	5.733	1.513–21.711
Race	.011	6.488	1.533–27.467
Sex	.007	6.160	1.627–23.319
Smoking	.012	5.434	1.443–20.456
Medical comorbidities	.011	5.480	1.468–20.463
Stage	.012	5.365	1.438–20.012
Node laterality	.011	5.615	1.473–21.413
RT fractionation	.019	4.841	1.287–18.209
Chemotherapy type	.098	5.110	0.602–19.234
Weight loss	.022	4.891	1.252–19.115
Dietary modification	.023	4.891	1.240–19.282
No TNMES	.036	5.895	1.126–30.859
RT dose	.012	5.368	1.441–20.001

Abbreviations: OR, odds ratio; CI, confidence interval; RT, radiotherapy; TNMES, transcutaneous neuromuscular electrical stimulation.

within the pharynx and increasing the risk of aspiration.²² These late effects of therapy may persist for months or years, leaving a chronic severe dysphagia. It is well known that dysphagia and quality of life are worsened with the addition of chemotherapy.²³

Our data demonstrate that certain factors, such as advanced age, >10 pack years smoking, diabetes, AJCC stage IVA, bilateral node involvement, accelerated fractionation, >10 pound weight loss, those requiring dietary modification, no TNMES intervention, and increased radiotherapy dose as significant for predicting a poor posttreatment swallowing outcome. Some of these issues resolve, but postradiotherapy edema and radiotherapy-induced fibrosis of the muscles lead to noncompliance. Late chemoradiotherapy-related toxicity has been significantly associated with advancing age, T3 or T4 stage, laryngeal or hypopharyngeal primaries, and with neck dissection.⁶ Many of these factors are unavoidable, therefore, aggressive early intervention to prevent dysphagia and aspiration is important to maintain a patient's quality of life.

Treatment modification may also play a role in conjunction with aggressive intervention in the prevention of dysphagia posttreatment. Studies have identified the swallowing organs at risk and have evaluated the emerging role of intensity-modulated radiation therapy (IMRT) in dysphagia prevention by placing appropriate dose constraints on these organs at risk.^{7,24,25} Chemotherapy-based anatomic guidelines for delineating the potential organs at risk for swallowing have also been proposed.⁶ Investigators have proposed dysphagia-optimized IMRT and swallowing sparing IMRT.^{26,27} Predictive models for swallowing dysfunction show potential reductions in physician-rated and patient-rated swallowing dysfunction with IMRT that was specifically optimized to spare swallowing organs at risk.²⁷

Although our study suggests that early intervention with TNMES during chemoradiotherapy may reduce posttreatment sequelae relating to swallowing dysfunction, limitations exist. The use of TNMES was not administered in a randomized fashion. This study represents a paired-sample analysis, in which TNMES was only

TABLE 5. Logistic regression model for probability of Swallowing Performance Status Scale.

Predictor	<i>p</i> value	OR	95% CI
Age	.007	0.162	0.043–0.609
Race	.008	0.143	0.034–0.595
Sex	.005	0.146	0.039–0.641
Smoking	.009	0.171	0.046–0.641
Medical comorbidities	.007	0.165	0.044–0.617
Stage	.009	0.172	0.046–0.638
Node laterality	.214	3.069	0.839–11.095
RT fractionation	.014	0.191	0.051–0.715
Chemotherapy type	.078	0.973	0.864–4.175
Weight loss	.019	0.179	0.046–0.763
Dietary modification	.019	0.195	0.499–0.763
No TNMES	.036	0.169	0.032–0.881
RT dose	.008	0.169	0.046–0.629

Abbreviations: OR, odds ratio; CI, confidence interval; RT, radiotherapy; TNMES, transcutaneous neuromuscular electrical stimulation.

offered to people with dysphagia before initiation of chemoradiotherapy. TNMES was also not administered independent of other traditional dysphagia therapy. TNMES therapy is intended as an adjunct modality to facilitate the other therapeutic interventions by the speech-language pathologist instead of a standalone therapy, which complicates the evaluation of the effectiveness of TNMES outside a randomized setting. Additionally, the role of TNMES as a prophylactic modality versus therapeutic is not well defined. Despite these uncertainties, TNMES is well tolerated and our data suggest that TNMES should be initiated early during radiotherapy, especially if dysphagia is reported at presentation.

CONCLUSIONS

Dysphagia is a major problem with chemoradiotherapy resulting in worsening swallowing function in most patients. Our study found a significant benefit using FOIS swallowing scoring scales with trends using Swallowing Performance Status Scale and the 8-point PAS. TNMES can be an effective adjunctive therapy in addition to

TABLE 6. Logistic regression model for probability of 8-point scale.

Predictor	<i>p</i> value	OR	95% CI
Age	.046	0.381	0.148–0.982
Race	.054	0.393	0.152–1.019
Sex	.445	1.507	0.526–4.319
Smoking	.039	0.366	0.141–0.952
Medical comorbidities	.043	0.374	0.144–0.969
Stage	.045	0.378	0.146–0.977
Node laterality	.041	0.354	0.131–0.958
RT fractionation	.059	0.398	0.153–1.038
Chemotherapy type	.068	0.400	0.149–1.071
Weight loss	.067	0.379	0.133–1.073
Dietary modification	.096	0.423	0.154–1.167
No TNMES	.590	0.723	0.222–2.358
RT dose	.044	0.377	0.146–0.974

Abbreviations: OR, odds ratio; CI, confidence interval; RT, radiotherapy; TNMES, transcutaneous neuromuscular electrical stimulation.

traditional swallowing exercises and could be considered in both reduction and prevention of dysphagia in patients with locally advanced head and neck cancer.

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