26237048

Request # 26237048 **JAN 02, 2009**

Email (PDF) To: library.services@allina.com

ABBOTT NORTHWESTERN HOSPITAL/Allina Health System
LIBRARY ILL - 14001
800 E 28TH ST
MINNEAPOLIS, MN 55407

DOCLINE: Journal Copy EFTS Participant

Title:	Oral oncology
Title Abbrev:	Oral Oncol
Citation:	2008 Dec 16; [Epub ahead of print]
Article:	The effect of electrical stimulation therapy on dy
Author:	Ryu JS;Kang JY;Park JY;Nam SY;Choi SH;Roh JL;Kim SY;Choi KH
NLM Unique ID:	9709118 Verify: PubMed
PubMed UI:	19095492
ISSN:	1368-8375 (Print)
Publisher:	Pergamon,, Oxford ;
Copyright:	Copyright Compliance Guidelines
Authorization:	MGT
Need By:	N/A
Maximum Cost:	**$18.00**
Patron Name:	nancy.hutchison allina
Referral Reason:	Not owned (title)
Library Groups:	FreeShare
Phone:	1.612.863-4312
Fax:	1.612.863-5695
Email:	library.services@allina.com
Ariel:	library.services@allina.com
Alternate Delivery:	Ariel,Email(PDF),Fax,Web(PDF),Web(TIFF)
Routing Reason:	Routed to NYUMSK in Serial Routing - cell 2
Received:	Jan 02, 2009 (11:50 AM EST)
Lender:	Memorial Sloan-Kettering Cancer Center/ New York/ NY USA (NYUMSK)

Bill via EFTS only to: MNUANW

ABBOTT NORTHWESTERN HOSPITAL/Allina Health System
LIBRARY ILL - 14001
800 E 28TH ST
MINNEAPOLIS, MN 55407

Oral Oncology xxx (2008) xxx–xxx

Contents lists available at ScienceDirect

Oral Oncology

journal homepage: www.elsevier.com/locate/oraloncology

The effect of electrical stimulation therapy on dysphagia following treatment for head and neck cancer

Ju Seok Ryu [a], Jin Young Kang [a], Ji Young Park [a], Soon Yuhl Nam [b], Seung Ho Choi [b], Jong Lyel Roh [b], Sang Yoon Kim [b], Kyoung Hyo Choi [a,*]

[a] Department of Physical Medicine and Rehabilitation, University of Ulsan College of Medicine, 388-1 Pungnap-2dong, Songpa-gu, 138-736 Seoul, Republic of Korea
[b] Department of Otolaryngology, University of Ulsan College of Medicine, Seoul, Republic of Korea

ARTICLE INFO

Article history:
Received 29 July 2008
Received in revised form 7 October 2008
Accepted 8 October 2008
Available online xxxx

Keywords:
Deglutition disorder
Electric stimulation
Head and neck neoplasms
Rehabilitation

SUMMARY

The purpose of this study was to evaluate the effect of neuromuscular electrical stimulation (NMES) in patients suffering from dysphagia following treatment for head and neck cancer. In a prospective, double blinded, randomized case control study between January 2006 and December 2007, 14 patients were randomized to 30 min of NMES and 30 min of traditional swallowing training for 5 days per week for 2 weeks (experimental group), and 12 patients were randomized to sham stimulation plus traditional swallowing training (control group). Effects were assessed using the clinical dysphagia scale (CDS), the functional dysphagia scale (FDS), the American speech-language-hearing association national outcome measurement system (ASHA NOMS) and the M.D. Anderson dysphagia inventory (MADI). Pretreatment evaluation showed no significant differences between the two groups for all parameters. Average changes of FDS score were 11.4 ± 8.1 for the experimental group and 3.3 ± 14.0 for the control group ($P = 0.039$). CDS, ASHA NOMS and MADI showed some difference with treatment, but the changes were not significant ($P > 0.05$). NMES combined with traditional swallowing training is superior to traditional swallowing training alone in patients suffering from dysphagia following treatment for head and neck cancer.

Introduction

Dysphagia is a common complication following treatment of head and neck cancer, with aspiration being the most common manifestation. This symptom refers to difficulty in swallowing. Destruction of the normal anatomy by tumor growth, surgery or chemotherapy or by radiation-induced scarring, is potential a mechanism responsible for dysphagia in head and neck cancer patients.[1,2] Dysphagia in these patients is caused mainly by incomplete laryngeal closure, sphincter dysfunction or pharyngeal pooling and reduced or delayed laryngeal elevation which is thought to be the most common cause of dysphagia and aspiration.[3,4] Methods traditionally used to treat neuromuscular dysphagia have generally been unsuccessful in restoring safe swallowing to patients with severe dysphagia.[5–7] Deep pharyngeal neuromuscular electrical stimulation (NMES) is a more specific technique, in which controlled neuromuscular electrical stimulation is used to strengthen the muscles used in swallowing and to improve laryngeal elevation.[8–11] In NMES, electrodes are simultaneously activated over the submental and laryngeal regions on the throat, with the aim of producing a simultaneous contraction of the mylohyoid in the submental region (to elevate the hyoid bone) and the thyrohyoid in the neck (to elevate the larynx to the hyoid bone).[8]

About 90% of therapists who use NMES also use additional techniques,[12] confounding the effects of NMES and raising doubts about its effectiveness.[10,13–16] Although several studies have addressed the diagnosis and evaluation of dysphagia following treatment for head and neck cancer, there have been few studies on patient treatment.

The purpose of this investigation was to evaluate the effect of NMES on dysphagia following treatment for head and neck cancer.

Patients and methods

Study population

Between January 2006 and December 2007, 267 patients (219 men, 48 women; mean age, 61.4 ± 10.6 years) underwent curative surgical and/or radiation treatment for head and neck cancer at Asan Medical Center, Seoul, Korea. Primary tumors were located in the larynx in 141 patients, in the hypopharynx in 11, in the oral cavity in 82, and in the oropharynx in 33. Of these 267 patients, 46 patients were referred to the dysphagia clinic for the evaluation and treatment of dysphagia.

* Corresponding author. Tel.: + 82 2 3010 3800, fax: +82 2 3010 6964.
E-mail address: khchoi@amc.seoul.kr (K.H. Choi).

1368-8375/$ - see front matter © 2008 Elsevier Ltd. All rights reserved.
doi:10.1016/j.oraloncology.2008.10.005

The inclusion criteria for study subjects included patients who had undergone surgical or radiation treatment for head and neck cancer, those suffering from dysphagia as a treatment complication, those confirmed on a ideofluoroscopic swallowing study (VFSS), and patients currently on a restricted diet, with stable vital signs, and who were able to participate in our treatment program. Patients with cognitive impairment, history of cerebrovascular disease, serious psychologic disorder, cardiac pacemaker, aged less than 20 years, or unable to tolerate electrical stimulation were excluded.

Randomization

This study was a prospective, double-blinded, randomized case control study. The trial statistician randomly allocated each patient to either the experimental ($n = 21$) or the control group ($n = 25$). The patients were blinded to their group identification, and the outcome assessor was also blinded to the groups and the results of the treatment sessions. This author was unaware of the swallowing status of each patient on all evaluations and had no information provided regarding patient progress during the treatment period. Seven patients in the experimental group and thirteen in the control group were lost to follow-up. The causes of follow-up loss in the experimental group included orocervical fistula ($n = 1$), early discharge and traffic problems ($n = 3$), and unwillingness to participate in the experimental group during our treatment program ($n = 3$), while the causes in the control group included deep neck infection ($n = 1$), early discharge and traffic problems ($n = 7$), incorrect pathology diagnosed as inflammation ($n = 1$), and unwillingness to participate during our treatment program ($n = 4$). Therefore, the experimental group consisted of 14 patients, and the control group consisted of 12 patients.

Of the 14 patients in the experimental group, 6 had supraglottic carcinoma, four had tonsillar carcinoma, and one each had hypopharyngeal, transglottic, nasopharyngeal and mouth floor cancers. Of the 12 patients in the control group, four had supraglottic cancer, three had tonsillar cancer, two had mouth floor cancer, and one each had hypopharyngeal cancer and neck schwannoma. One patient underwent radiation treatment alone, and the others underwent surgical treatment, with or without radiation treatment.

The study protocol was approved by the Institutional Review Board of the Asan Medical Center. All patients who agreed to participate provided written informed consent.

Interventions

Each patient in the experimental group received NMES for 30 min, followed by conventional rehabilitation treatment for 30 min, for 5 days per week for 2 weeks. Each patient in the control group received sham stimulation, followed by conventional rehabilitation treatment, on the same time schedule. NMES was performed by occupational therapists trained and certified in Vital Stim™. NMES was delivered using a dual-channel, electrotherapy system with a pulsed current at a fixed pulse rate of 80 Hz and fixed pulse duration of 700 ms (Vital Stim™ Model 5900, Chattanooga Group, Hixon, TN). The skin of the anterior neck was prepared with a 70% isopropyl alcohol pad. The method of electrode placement is described in Figure 1. The amplitude of the electrical current was based upon subjects' verbal feedback. As the amplitude was gradually increased, subjects indicated when they experienced tingling, crawling, burning, or grabbing. When a grabbing sensation was reported, the amplitude was kept at that level for the remainder of the 30 min session.[9] Patients in the control group underwent sham stimulation using low intensity transcutaneous electrical nerve stimulation (TENS; AUTO-TENS HL®, Homer Ion, Inc. Japan).

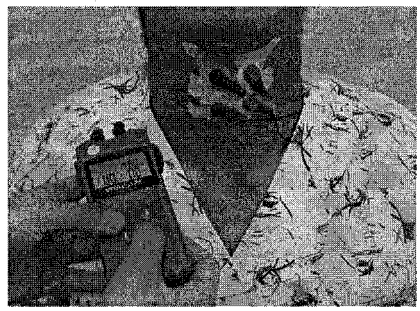

Figure 1 NMES electrode placement.[8] Channel 1 is horizontally immediately above thyroid notch. Channel 2 is parallel, below notch. Alternatively, channels can be connected vertically.

Conventional rehabilitation training consisted of oral motor exercises, pharyngeal swallowing exercises, use of compensatory strategies during meals, thermal/tactile stimulation, Mendelsohn maneuver and diet-texture modifications.

Outcome measures

Functional changes in each patient were evaluated before and after treatment. The evaluation tools included the functional dysphagia scale (FDS)[17] the clinical dysphagia scale (CDS),[18] the American speech-language-hearing association national outcome measurement system swallowing level scale (ASHA NOMS),[19,20] and the M.D. Anderson dysphagia inventory.[21]

VFSS was performed as described previously.[22] FDS and CDS, both of which are numeric scales were used for quantitative evaluation of dysphagia. FDS is directly converted from the physiologic parameters of the VFSS and CDS from the clinical information. The validity of these scales, compared with the ASHA NOMS scale, has been confirmed.[17,18] ASHA is a widely used, highly valid scale that measures clinical status transcendentally.[19,20] The M.D. Anderson dysphagia inventory is validated, reliable, self-administered questionnaire designed specifically to evaluate the impact of dysphagia on quality of life of patients with head and neck cancer.[21]

Statistical analysis

The software program SPSS for Windows, version 12.0 (SPSS, Chicago, IL) was used for statistical analyses. Parameters of the

Table 1
Demographic data of study subjects.

		Experimental Group	Control Group
No.		14	12
Age (yrs)		63.4±7.3	60.8±12.0
Gender (M/F)		14/0	11/1
Tumor stage	I	2	2
	II	4	5
	III	5	2
	IV	3	2
	Unknown	0	1
Radiotherapy (%)		8 (57)	5 (42)
Chemotherapy (%)		6 (43)	6 (50)
Duration 1 (days)		16	16
Duration 2 (days)		28	35
Location	Larynx	6	5
	Hypopharynx	3	1
	Oral cavity	1	2
	Oropharynx	4	4

Duration 1: The median numbers of days from operation to the initial evaluation.
Duration 2: The median number of days from operation to final evaluation.

Please cite this article in press as: Ryu JS et al., The effect of electrical stimulation therapy on dysphagia following treatment ..., *Oral Oncol* (2008), doi:10.1016/j.oraloncology.2008.10.005

Table 2
Differences in parameters pretreatment evaluation and post treatment evaluation.

	Experimental group		Control group		p-value
	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment	
FDS	33.9 ± 13.2	22.4 ± 13.4	38.6 ± 15.9	35.3 ± 17.7	0.04*
CDS	46.1 ± 21.0	44.8 ± 19.6	42.8 ± 16.5	44.3 ± 17.7	0.07
ASHA NOMS	2.57 ± 1.65	3.86 ± 1.80	2.92 ± 1.93	3.67 ± 2.10	0.27
MADI	48.2 ± 9.8	53.4 ± 11.0	53.1 ± 10.2	55.9 ± 11.2	0.35

FDS: Functional dysphagia scale.
CDS: Clinical dysphagia scale.
ASHA NOMS: American speech-language-hearing association national outcome measurement system.
MADI: M.D. Anderson dysphagia inventory.
* Statistically significant.

experimental and control groups were compared using Levene's test, the Mann-Whitney U test, Fisher's exact test and the Chi-square test, as appropriate. Significance was defined as $P < 0.05$.

Results

Ages, gender distribution, days from surgery to initial or final evaluations, and pretreatment measurements of dysphagia were similar in the two groups (Table 1). All data from this study were summarized in Table 2. FDS scores decreased from 33.9 ± 13.2 to 22.4 ± 13.4 in the experimental group and from 38.6 ± 15.9 to 35.3 ± 17.7 in the control group, with average change in FDS score was being significantly greater in the experimental group (11.4 ± 8.1 versus 3.3 ± 14.0, $P = 0.04$; Fig. 2). Although changes in CDS score (1.4 ± 2.9 versus −1.5 ± 5.0, $P = 0.07$; Fig. 2), ASHA grade (1.29 ± 1.2 versus 0.75 ± 1.06, $P = 0.27$), and M.D. Anderson dysphagia inventory (5.2 ± 3.7 versus 2.8 ± 7.5, $P = 0.35$) were greater in the experimental group, the differences were not significant (Fig. 3).

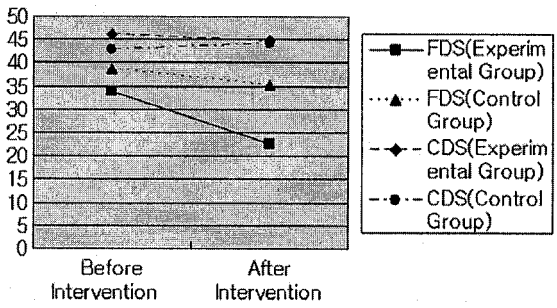

Figure 2 Effects of NMES on the functional dysphagia scale (FDS) and the clinical dysphagia scale (CDS). Improvements of FDS were significantly greater in the experimental group than in the control group. $P < 0.05$.

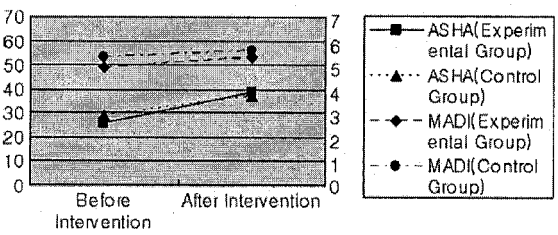

Figure 3 Effects of NMES on the American speech-language-hearing association national outcome measurement system swallowing level scale (ASHA NOMS) and the M.D. Anderson dysphagia inventory (MADI). Improvements were greater in the experimental group than in the control group, but the differences were not significant.

Discussion

The primary objective of NMES in pharynx or larynx is to use an electrical current to activate the pharyngeal/laryngeal musculature through intact peripheral nerves.[9,14,15] For example, NMES has been used to stimulate the thyrohyoid muscle, with the goal of improving laryngeal elevation in patients with dysphagia.[15] Although dysphagia of subjects improved, this study did not include a control group, failed to control for spontaneous recovery, and failed to determine inter- and intra-judge reliability for interpretation of VFSS. In addition, stroke patients receiving NMES for the treatment of dysphagia showed significant functional gains,[9] but that study did not determine the specific effects of treatment on swallowing physiology, failed to randomize subjects to treatment, and failed to determine inter- and intra-judge reliability for interpretation. Two weeks of NMES treatment on the submental muscles was not found to increase myoelectrical activity,[14] but functional improvements were not assessed. In treating dysphagia, NMES may be more beneficial when paired with volitional exercise, such as effortful swallowing.[23]

There have been few studies of therapy for dysphagia following treatment of head and neck cancer. Although surface electromyographic biofeedback applied to a structured behavioral therapy program facilitated increased functional oral intake within a limited time frame,[24] stroke patients showed greater functional gains than head and neck cancer patients. Dysphagia in patients treated for head and neck cancer may have a larger mechanical component owing to structural and mucosal changes caused by cancer treatment.[25] Patients who present with anatomic restrictions contributing to dysphagia may be less likely to have the physiologic capability to change swallowing patterns. Although some improvements of dysphagia were observed in head and neck cancer patients, the study lacked a control group; thus the effectiveness of NMES could not be confirmed.

To overcome the above limitations, we used a prospective, double-blinded, randomized case control design. To control for inter- and intra-judge reliability, patients were randomly assigned to treatment groups, and VFSS was performed by one physician blinded to treatment groups. Dysphagia was evaluated quantitatively using the CDS and FDS. We found that patients with dysphagia caused by treatment for head and neck cancers showed greater FDS improvements following NMES combined with conventional rehabilitation treatment than following conventional rehabilitation treatment alone. Although differences in the CDS, ASHA NOMS, and the M.D. Anderson dysphagia inventory were not significant, these parameters also showed greater improvements in the experimental group.

The mechanism by which NMES may improve swallowing function is not known. Disuse of a striated muscle can lead to atrophy of that muscle, even if the medical condition leading to disuse has no direct effect on the muscle or associated nerves.[26] Electrically stimulated contractions recruit more motor units than volitional contraction.[27] In addition, electrical stimulation selectively activates type II muscle fibers that have a greater ability to develop tension.[28] These benefits may allow for enhanced strength development. In a previous study regarding the immediate physiologic effects of NMES, the patients who had reduced aspiration and penetration during swallowing with NMES had greater hyoid depression during stimulation while at rest.[11] Those patients who felt a greater downward pull on the hyoid, when stimulation was turned on to the maximal level, made a greater effort to elevate the hyolaryngeal complex when swallowing in an attempt to overcome the

Please cite this article in press as: Ryu JS et al., The effect of electrical stimulation therapy on dysphagia following treatment ..., *Oral Oncol* (2008), doi:10.1016/j.oraloncology.2008.10.005