Comparing the Effects of Rehabilitation Swallowing Therapy vs. Neuromuscular Electrical Stimulation Therapy among Stroke Patients with Persistent Pharyngeal Dysphagia: A Randomized Controlled Study

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Background: *Dysphagia after stroke is associated with increased mortality, higher dependence, and longer hospitalization. Different therapeutic strategies have been introduced to improve swallowing impairment. There are no current studies that compare rehabilitation swallowing therapy (RST) and neuromuscular electrical stimulation therapy (NMES).*
Objective: *To compare treatment outcomes between RST and NMES intervention in stroke patients with pharyngeal dysphagia.*
Study design: *A randomized controlled study.*
Material and Method: *Twenty-three stroke patients with persistent pharyngeal dysphagia (RST 11, NMES 12) were enrolled in the present study. The subjects received 60 minutes of either RST or NMES treatment for five consecutive days, had two days off, and then five more consecutive days of treatment for a four-week period or until they reached functional oral intake scale (FOIS) level 7. The outcome measures assessed were change in FOIS, complications related to the treatment and number of therapy sessions.*
Results: *There were no significant differences in the stroke characteristics and the VFSS results between the two groups. At the end of treatment, the average numbers of therapy sessions per subject in the RST and NMES groups were 18.36 $\pm$ 3.23 and 17.25 $\pm$ 5.64, respectively, a non-significant difference. Average changes in FOIS scores were 2.46 $\pm$ 1.04 for the RST group and 3.17 $\pm$ 1.27 for the NMES group, statistically significant at $p < 0.001$. No complications were observed in either group.*
Conclusion: *While both RST and NMES therapy showed a positive effect in the treatment of persistent dysphagia in stroke patients, NMES was significantly superior.*

Keywords: *Deglutition disorders, Electric stimulation therapy, Neuromuscular junction, Stroke, Therapy*

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Dysphagia occurs in up to 50% of acute stroke patients but is resolved in the majority within 2 weeks. Persistent dysphagia beyond this period is associated with increased mortality, higher dependence, and longer hospitalization. The development of the videofluoroscopic study (VFSS) has enabled detailed analysis of different phases of deglutition, including accurate measurement of transit times for the bolus to complete the pharyngeal swallowing and detection of aspiration even in the absence of clinical signs[1,2]. Different therapeutic strategies have been introduced to treat swallowing impairment. Rehabilitation swallowing treatments (RST) are compensatory techniques including postural adjustment, supraglottic swallowing, the Mendelsohn maneuver, and effortful swallowing have been reported as the standard treatment for stroke survivors with dysphagia[3]. New treatments for pharyngeal dysphagia undergoing investigation include neuromuscular electrical stimulation (NMES) has been advocated as an adjunct to swallowing therapy with prior reports of rapid progress in patients treated with this approach[4,5]. At this time, there is a paucity of up-to-date evidence for dysphagia therapy, which has been highlighted in a Cochrane review as well as an American Gastroenterology Association technical review[6,7]. The aim of the present study was to compare treatment outcomes between RST and NMES therapy in stroke patients with pharyngeal dysphagia.

Material and Method

A single blind-controlled, interventional study was undertaken on hospitalized stroke survivors with persistent dysphagia more than two weeks between Nov 2007 and Sep 2008. All patients underwent medical, dental status, neurological, and VFSS examinations. The authors selected subjects with a VFSS finding that indicated pharyngeal dysphagia with safe swallowing to random. A random numbers table was generated using Microsoft Excel 2003 (Microsoft Corp., Redmond, WA) and was used to assign one of two treatment orders, a rehabilitation swallowing therapy (Condition A = RST) or neuromuscular electrical stimulation (Condition B = NMES). Subjects received 60 minutes of either A or B treatment, in a pattern of alternating five consecutive days of therapy with two days off for a four-week period. Stroke patients typically began the protocol with 5 ml of a thickened liquid as this material afforded the best airway protection. If patients had no signs of choking or cough, the therapist would change rheological properties of food which followed gradually according to standard guideline. In both groups, any patient with weakness of facial muscles was treated with facial exercise.

Rehabilitation swallowing therapy

The therapy for each patient followed a similar format. Individual variations within certain limits were allowed at the discretion of the treating clinician, but the format was maintained across all patients. This format was based on a set of swallowing instructions that focused on bolus control and airway protection. The various therapeutic strategies, listed in Table 1, were explained and administered by a well-trained occupational therapist. The selection of treatment based on the VFSS and clinical examination to facilitate a safe and more efficient oral intake. Strategies commonly used were changed in body and head posture or techniques designed to change specific aspects of swallow physiology, oral motor exercises included different lip and tongue exercises if the patient had oral dysfunction, supraglottic swallowing or chin tuck was chosen for a more effective airway protection when VFSS showed retention of contrast medium after swallowing. When residue in the valleculae after swallowing was obvious, effortful swallowing could increase tongue-base retraction. Thermal stimulation was given if there was a delay between oral and pharyngeal swallowing (dissociation) to increase sensory awareness in the oral cavity and thereby decrease the degree of dissociation[8,9].

Neuromuscular electrical stimulation

Electrical stimulation was delivered using a dual-channel electrotherapy system with a pulsed current at a fixed pulse rate of 80 Hz and fixed pulse

Table 1. Treatment strategies between rehabilitation swallowing therapy and neuromuscular electrical stimulation (60 minutes sessions)

Rehabilitation swallowing therapy (RST)	Neuromuscular electrical stimulation therapy (NMES therapy)
Diet modification	Diet modification
Oral motor exercise	Oral motor exercise
Thermal stimulation	NMES therapy
Head and neck positioning	
Supraglottic swallowing	
Effortful swallowing	
Mendelsohn maneuver	

duration of 700 ms (VitalStim Model 5900, Chattanooga Group, Hixson, TN). Treatment was provided by one physiatrist trained in the use of NMES. Pre-treatment, the most frequent experimental sensations to NMES, *i.e.*, tingling, crawling, burning, and grabbing, were demonstrated and the subjects were taught successfully to identify them. These sensations represent a hierarchy of responses to stimulation, with tingling experienced at lower and grabbing experienced at higher amplitudes of stimulation. The thyroid notch was then palpated and the first electrode placed midline 1 mm above the thyroid notch, the second electrode immediately superior to the first, the third electrode 1 mm below the thyroid notch, and the fourth electrode immediately inferior to the third. The amplitude of the electrical current was based upon the subjects' verbal feedback. As the examiner increased the amplitude gradually, the subjects indicated when they experienced tingling, crawling, burning, or grabbing sensations. When a grabbing sensation was reported, the amplitude was left at that level for the remainder of the 60-minute therapy session[10].

Outcome measures

The outcome measures were assessed as changes in functional oral intake, complications related to treatment and number of therapy sessions. The functional swallowing ability of each individual was estimated using the Functional Oral Intake Scale (FOIS), a 7-point ordinal scale reflecting the patient's report of food/liquids safely ingested by mouth on a consistent basis (Table 2). The scale has strong reliability and validity specific to stroke populations[11]. Patient recordings of the daily diet level and method of intake (oral, nonoral, use of compensations) were determined and compared to the FOIS scale results. Each patient's report recorded the typical diet level along with any food modifications and/or behavioral compensations used during eating. Each patient's diet level was documented at the onset of therapy and again at the conclusion of therapy and compared to this scale. The number of total therapy sessions was calculated for each patient. Any complications related to the swallowing treatment were recorded, *i.e.*, pneumonia, choking from food in the trachea, etc.

Statistical analyses

All statistical analyses were completed using SPSS for Windows (version 11.0; SPSS, Chicago, IL). Demographic variables were evaluated between the two subgroups of patients using the t-test (age, poststroke duration, mental score, and the Barthel index score) and Fisher's exact test (gender, side of weakness, and type of stroke). The total number of therapy sessions, pre-therapy FOIS scores, post-therapy FOIS scores and mean changes in FOIS scores in RST, NMES and between both groups were evaluated with the t-test. A statistical significant difference was considered at a p-value test less than 0.05.

Results

Twenty-eigth patients with swallowing problems were randomized between active management with rehabilitation swallowing treatment (RST, n = 13) or neuromuscular electrical stimulation (NMES, n = 15). Twenty-three patients (RST 11, NMES 12) completed the present study. Two subjects in the rehabilitation swallowing therapy group (recurrent stroke 1, inconvenient to travel 1) and three subjects in the NMES group (recurrent stroke 1, uncontrolled hypertension 1, inconvenient to travel 1) had to be withdrawn. There were no significant differences in the patient and stroke characteristics between the two groups (Table 3). The VFSS assessments prior to randomization showed no differences in the initial assessments in the pharyngeal phase of swallowing, number of delayed triggering of swallowing, delayed laryngeal elevation, or pooling in the valleculae or pyriform sinuses. Impairment of the oral phase with dribbling, poor

Table 2. Functional Oral Intake Scale (FOIS)

Level 1	Nothing by mouth
Level 2	Tube dependent with minimal attempts of food or liquid
Level 3	Tube dependent with consistent oral intake of food or liquid
Level 4	Total oral diet of a single consistency
Level 5	Total oral diet with multiple consistencies but requiring special preparation or compensations
Level 6	Total oral diet with multiple consistencies without special preparation, but with specific food limitations
Level 7	Total oral diet with no restrictions

tongue control, or inability to move the bolus was seen in all 23 patients.

Number of therapy sessions

At the end of treatment, the average number of therapy sessions per subject in the RST group was 18.36 ± 3.23 and 17.25 ± 5.64 in the NMES group, a non-significant difference (Table 4).

Change in functional oral swallowing

Overall, 91.30% of patients increased their FOIS functional oral intake by at least one unit compared to the prior-to-therapy score (Table 4), 90.91% in the RST group and 91.67% in the NMES group. The average changes in FOIS scores were 2.46 ± 1.04 for the RST group and 3.17 ± 1.27 for the NMES group, which was statistically significant ($p < 0.001$).

Table 3. Demographic and stroke characteristics of patients with swallowing problems included in the study

	RST	NMES therapy	p-value
Number of patients	11	12	
Age[1]	64.73 ± 9.39	64.50 ± 8.80	0.95
Gender			1
Male (%)	4 (36.36)	5 (41.67)	
Female (%)	7 (63.64)	7 (58.33)	
Poststroke duration(days)[1]	23.18 ± 6.68	24.09 ± 6.61	0.75
Side of weakness (%)			1
Right	63.64	66.66	
Left	27.27	16.67	
Bilateral	9.09	16.67	
Type of stroke (%)			1
Infarction	81.82	75.00	
Hemorrhage	18.18	25.00	
Mini-mental state examination[1]	18.36 ± 5.48	19.67 ± 5.00	0.56
Admission Barthel activities of daily living index[1]	38.64 ± 16.75	40.83 ± 16.35	0.75
Swallowing disorder (%)			1
Oral phase	100.00	100.00	
Pharyngeal phase	100.00	100.00	
Esophageal phase	0.00	0.00	

[1] Reported as mean ± standard deviation

Table 4. Number of therapy sessions, functional oral intake scale (FOIS) scores and complications

	RST	NMES therapy	p-value
Number of therapy[1]	18.36 ± 3.23	17.25 ± 5.64	0.57
Pre-therapy FOIS score[1]	2.40 ± 1.20	2.20 ± 1.10	0.81
Post-therapy FOIS score[1]	4.80 ± 1.50	5.40 ± 1.10	0.28
Mean FOIS change[1]	2.46 ± 1.04	3.17 ± 1.27	<0.001
FOIS change (%)			0.06
0	9.09	8.33	
1	0.00	0.00	
2	36.36	16.67	
3	45.46	16.67	
4	9.09	58.33	
FOIS = 7 (%)	18.18	16.67	0.73
Number of complications	0	0	1

[1] Reported as mean ± standard deviation

The majority (58.33%) of patients in the NMES group improved four levels on the functional oral intake scale, and 33.34% improved two or three levels. In the RST group, most patients (45.46%) improved three levels, and 36.36% improved two levels. No patient in either group improved five levels or more. Before therapy, 78.26% (72.73% of the RST group and 83.33% of NMES group) were reliant on non-oral sources of nutrition (FOIS levels 1- 3), while subsequent to therapy, 83.33% (75.00% of the RST group and 90.00% of NMES group) could manage total oral intake (FOIS levels 4- 7), with 18.18% of the RST group and 16.67% of the NMES group functioning at FOIS level 7.

Discussion

Dysphagia is a common complication following a stroke. Gordon et al. reported that 37% of their subjects had dysphagia for less than eight days following a stroke while about 86% of patients could swallow normally within 14 days[12]. Within 6 months after the stroke, 79% to 92% of these patients had returned to their pre-stroke diet[13]. In the present study, the authors used rehabilitative strategies for swallowing training, the specific strategy chosen depending on the VFSS results. The presented data showed a high percentage of patients with severe dysphagia (FOIS levle1-3). After therapy, 75% of these patients progressed to functional swallowing (FOIS levels 4-7). The good progress of the presented patients was probably because they received intensive rehabilitation in swallowing training (60 min per session) and a longer number of therapy sessions (20 sessions or until the FOIS score reaches level 7). Expert consensus supports the use of maneuvers such as a chin tuck when swallowing, head turn or the Mendelsohn maneuver. The common chin tuck entails asking patients to lower their chin towards their chest before swallowing[14], which brings the epiglottis and the aryepiglottic folds closer to together, allowing the apposition of these structures to close the airway during swallowing. The head turn is a simple rotation of the head to the paretic side in an attempt to increase bolus flow[15]. The Mendelsohn maneuver requires a little more training and entails the sustained contraction of the suprahyoid muscles in an effort to maintain laryngeal elevation and thus upper esophageal sphincter opening and airway closure[16]. Swallowing assessments are thus viewed as individual treatment trials and any of these techniques can be advocated if an individual patient is noted to swallow safely when exercising any particular method.

Transcutaneous neuromuscular electrical stimulation (NMES) is used on innervated muscle to recruit motor units, improve muscle contractions, especially type II muscle fibers, and increase muscle strength[10]. An electrical stimulation device, the VitalStim (Chattanooga Group, Hixson, TN) has been developed specifically for the treatment of dysphagia, receiving 510(k) premarket approval by the U.S. Food and Drug Administration (FDA) in 2001. It is classified as a Class II device by the FDA, and the listed indication for use is muscle re-education by application of external stimulation to the muscles necessary for pharyngeal contraction. Fraser et al[17] initially investigated the effects of pharyngeal electrical stimulation in healthy volunteers with transcranial magnetic stimulation (TMS). They applied the specified stimulation parameters to 10 dysphagic stroke patients while six patients received sham stimulation. The TMS group showed a sustained increase in swallowing motor cortex excitability. Carnaby-Mann and Crary[18] conducted a meta-analysis to evaluate the efficacy of NMES on swallowing rehabilitation. Seven studies met the criteria and were included in the review. The seven studies included 255 patients with dysphagia from multiple etiologies. Therapeutic outcomes were evaluated using various tools including functional oral intake scale, weight gain, or residue on a swallowing X-ray study. The NMES treatments were provided over a variable period of one to 24 weeks, with the number of total treatment sessions varying across the studies. The authors concluded that this preliminary meta-analysis revealed a small but significant summary effect size for transcutaneous NMES for swallowing ($p < 0.05$). This is in agreement with the observation of Steele et al[19] who noted that although ES approaches to the restoration and rehabilitation of swallowing is an exciting area of research that holds promise for future clinically relevant technology and/or therapy, implementation of ES in clinical swallowing rehabilitation settings still remains unclear and studies to date are inconclusive. Kiger et al[20] compared the outcomes using transcutaneous neuromuscular ES (VitalStim therapy) to outcomes using traditional swallowing therapy for deglutition disorders. Twenty-two patients had an initial and a follow-up video-fluoroscopic swallowing study or fiberoptic endoscopic evaluation of swallowing and were divided into an experimental group that received VitalStim treatments and a control group that received traditional swallowing therapy. Outcomes were analyzed for changes in oral and pharyngeal phase dysphagia severity, dietary

consistency restrictions, and progression from non-oral to oral intake. Results of Chi-square analysis showed no statistically significant difference in outcomes between the experimental and control groups. Varying results may result from different study lengths, number of total treatment sessions or different NMES electrode placements. Shaw et al[21] carried out a retrospective analysis of 18 patients with dysphagia who received VitalStim therapy. All subjects underwent evaluation by speech-language pathologists, including a modified barium swallowing examination or functional endoscopic evaluation of swallowing and clinical evaluation of swallowing that included assessment of laryngeal elevation, diet tolerance, and swallowing delay, and were then assigned an overall dysphagia severity score. Sixty-one percent of patients demonstrated some improvement in their swallowing, and 33% of patients improved enough to no longer require a feeding tube. However, of the five patients categorized as having severe dysphagia before therapy, two patients showed improvement, and these patients still required a feeding tube for adequate nutrition. The authors concluded that VitalStim therapy seems to help those with mild-to-moderate dysphagia, as the patients with the most severe dysphagia did not gain independence from their feeding tubes. In contrast, the patients in the present study showed a higher percentage of improved swallowing, and 90% of the dysphagic patients (FOIS 1, 2 or 3) progressed to total oral intake (FOIS levels 4, 5, 6, or 7). These differences may be explained by the authors' larger number of therapy sessions. The further studies should be explored for the effects of NMES on specific biomechanical aspects of pharyngeal swallowing, as well as the best location for electrode adhesion, effects of varying frequencies and amplitude of electrical stimulation on swallowing physiology, duration of each session, and total number of sessions.

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ผลการรักษาเปรียบเทียบระหว่างเวชศาสตร์ฟื้นฟูการกลืนและการใช้เครื่องกระตุ้นกลืนในผู้ป่วยโรคหลอดเลือดสมองที่มีภาวะกลืนลำบาก

วุฒิชัย เพิ่มศิริวาณิชย์, สุทธิพงษ์ ทิพชาติโยธิน, มานิตย์ วงศ์ไชย, วิทูร ลีลามานิตย์, สุวรรณา เศรษฐวัชราวนิช, พรชัย สถิรปัญญา, คณิตพงศ์ ปราบพาล, อุมา จันทวิเศษ, อัจฉรา บุญมีประกอบ

***ภูมิหลัง**: ภาวะกลืนลำบากพบได้บ่อยในผู้ป่วยโรคหลอดเลือดสมอง การรักษาด้วยวิธีทางเวชศาสตร์ฟื้นฟู จัดเป็นวิธีมาตรฐาน การรักษาใหม่ล่าสุด คือ การใช้เครื่องกระตุ้นกลืน จากข้อมูลปัจจุบันไม่พบการศึกษาเปรียบเทียบผลการรักษาระหว่าง 2 วิธีนี้*

***วัตถุประสงค์**: เพื่อเปรียบเทียบผลการรักษาระหว่างการฝึกการกลืนด้วยวิธีทางเวชศาสตร์ฟื้นฟูกับการใช้เครื่องกระตุ้นกลืนในผู้ป่วยโรคหลอดเลือดสมองที่มีภาวะกลืนลำบากเป็นระยะเวลานานกว่า 2 สัปดาห์*

***วัสดุและวิธีการ**: ผู้ป่วยโรคหลอดเลือดสมองที่มีภาวะกลืนลำบาก จำนวน 23 ราย ทำการแบ่งกลุ่มโดยการสุ่มเพื่อทำการฝึกการกลืนด้วยวิธีทางเวชศาสตร์ฟื้นฟูจำนวน 11 ราย และกระตุ้นด้วยเครื่องกระตุ้นกลืน จำนวน 12 ราย ทั้งสองกลุ่มได้รับการรักษาครั้งละ 60 นาที 5 วันต่อสัปดาห์ นาน 4 สัปดาห์ หรือจนกระทั่งกลืนอาหารได้ปกติ โดยเปรียบเทียบผลก่อนและหลังการรักษาด้วยแบบประเมิน Functional Oral Intake Scale (FOIS) และติดตามภาวะแทรกซ้อน*

***ผลการศึกษา**: ไม่พบความแตกต่างอย่างมีนัยสำคัญทางสถิติระหว่างข้อมูลพื้นฐานของทั้งสองกลุ่ม ได้แก่ อายุ เพศ ระยะภายหลังเกิดโรคหลอดเลือดสมอง ชนิดของโรคหลอดเลือกสมอง ข้างที่อ่อนแรง ระดับการรับรู้สติ ค่าคะแนนบาร์เทล ความผิดปกติของการกลืนจากการตรวจด้วยการกลืนสารทึบแสง และค่าคะแนน FOIS ก่อนและหลังการรักษา, ส่วนค่าคะแนนเฉลี่ยที่เพิ่มขึ้นของ FOIS ภายหลังการรักษา พบว่าในกลุ่มที่ได้รับการรักษาด้วยเครื่องกระตุ้นกลืนสูงกว่ากลุ่มที่รักษาด้วยวิธีการทางเวชศาสตร์ฟื้นฟู คือ 3.17 ± 1.27 และ 2.46 ± 1.04 ตามลำดับ ซึ่งมีความแตกต่างอย่างมีนัยสำคัญทางสถิติ ($p < 0.001$) นอกจากนี้ไม่พบภาวะแทรกซ้อนระหว่างการรักษาใน 2 กลุ่ม*

***สรุป**: การรักษาผู้ป่วยโรคหลอดเลือดสมองที่มีภาวะกลืนลำบากเกิน 2 สัปดาห์ด้วยการฝึกการกลืนทางเวชศาสตร์ฟื้นฟูและการใช้เครื่องกระตุ้นกลืน ได้ผลการรักษาที่ดีและไม่พบภาวะแทรกซ้อน*