Electrical Stimulation for Swallowing Disorders Caused by Stroke

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BACKGROUND: An estimated 15 million adults in the United States are affected by dysphagia (difficulty swallowing). Severe dysphagia predisposes to medical complications such as aspiration pneumonia, bronchospasm, dehydration, malnutrition, and asphyxia. These can cause death or increased health care costs from increased severity of illness and prolonged length of stay. Existing modalities for treating dysphagia are generally ineffective, and at best it may take weeks to months to show improvement. One common conventional therapy, application of cold stimulus to the base of the anterior faucial arch, has been reported to be somewhat effective. We describe an alternative treatment consisting of transcutaneous electrical stimulation (ES) applied through electrodes placed on the neck. OBJECTIVE: Compare the effectiveness of ES treatment to thermal-tactile stimulation (TS) treatment in patients with dysphagia caused by stroke and assess the safety of the technique. METHODS: In this controlled study, stroke patients with swallowing disorder were alternately assigned to one of the two treatment groups (TS or ES). Entry criteria included a primary diagnosis of stroke and confirmation of swallowing disorder by modified barium swallow (MBS). TS consisted of touching the base of the anterior faucial arch with a metal probe chilled by immersion in ice. ES was administered with a modified hand-held battery-powered electrical stimulator connected to a pair of electrodes positioned on the neck. Daily treatments of TS or ES lasted 1 hour. Swallow function before and after the treatment regimen was scored from 0 (aspirates own saliva) to 6 (normal swallow) based on substances the patients could swallow during a modified barium swallow. Demographic data were compared with the *t* test and Fisher exact test. Swallow scores were compared with the Mann-Whitney U test and Wilcoxon signed-rank test. RESULTS: The treatment groups were of similar age and gender ($p > 0.27$), co-morbid conditions ($p = 0.0044$), and initial swallow score ($p = 0.74$). Both treatment groups showed improvement in swallow score, but the final swallow scores were higher in the ES group ($p > 0.0001$). In addition, 98% of ES patients showed some improvement, whereas 27% of TS patients remained at initial swallow score and 11% got worse. These results are based on similar numbers of treatments (average of 5.5 for ES and 6.0 for TS, $p = 0.36$). CONCLUSIONS: ES appears to be a safe and effective treatment for dysphagia due to stroke and results in better swallow function than conventional TS treatment. *Key words: swallowing, dysphagia, electrical stimulation, stroke, modified barium swallow.* [Respir Care 2001;46(5):466–474]

Background

An estimated 15 million adults in the United States[1] are affected by difficulty in swallowing (dysphagia). The prevalence of dysphagia in certain diseases may approach 90% (eg, amyotrophic lateral sclerosis, Parkinson's disease, and certain types of stroke).[2] Severe dysphagia predisposes to

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Members of the research team have applied for and received a patent on the technique and device described herein, with further claims now pending. As of this date, there has been no money promised or received from any business group. The study was funded in total by the authors and the research team.

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medical complications such as aspiration pneumonia, bronchospasm, dehydration, malnutrition, and asphyxia. These can cause death or increased health care costs from increased severity of illness, prolonged length of stay, readmissions, respiratory support, tracheotomy, and percutaneous enterostomal gastric (PEG) tube placement plus related nutritional supplements and equipment.[2–4] Aside from the physical complications of aspiration, patients often suffer severe depression because of the loss of the swallow function and the disruption of normal activities of daily living.

Existing treatments for dysphagia are unable to restore complete swallow function in patients with the most severe disorders. Physical maneuvers to compensate for the deficiency (such as tucking the chin and suck swallow) are considered generally ineffective.[5,6] Thermal-tactile stimulation (TS) (ie, application of cold to the anterior faucial arch[7,8]) and biofeedback[9] have success rates ranging from 0% to 83%.[5,9–11] Studies reporting high success rates with stroke patients generally do not include the most severe forms of dysphagia, in which patients initially aspirate everything, including their own saliva. Often, these studies simply state that improvement was resumption of oral intake, but they do not describe the consistency of the oral intake. The type of oral intake is important because it affects not only hydration and nutrition but also the psychosocial impact on the patient. The minimum goal of treatment should be to achieve sufficient oral intake to prevent or remove a PEG tube, with its attendant difficulties of reflux aspiration and complications associated with infections. The ultimate goal should be restoration of normal swallow.

Current modalities have long treatment times: 2–52 weeks (average 15 weeks) for severe dysphagia using tactile and thermal-tactile stimulation[5] and 3–29 weeks using biofeedback.[9] A 4-fold increase in pneumonia has been documented during treatment, compared to the post-treatment period.[5] Lengthy treatment of swallowing disorders is thus risky and may potentially interfere with treatment of other medical problems.

Spontaneous improvement in swallowing may occur in certain acute diseases that cause mild dysphagia.[12] However, in the United States only 2% of patients with neurologic disorders and PEGs returned to full oral feeding after one year, suggesting that spontaneous improvement is rare for cases of severe dysphagia.[3]

Electrical stimulation (ES) has been reported as a treatment for dysphagia.[13,14] Park et al[15] applied electricity through a prosthetic device on the soft palate, aiming to re-educate neural pathways associated with the swallowing reflex. They reported a 50% success rate in improving the swallow of patients already capable of oral feeding. Transcutaneous application of electrical current to the neck with a nerve stimulator has also been successful in improving swallow function, but has rarely been used, because of assumed concerns for safety.[6,16]

We report a new treatment for dysphagia, consisting of transcutaneous ES applied through electrodes placed on the neck. The purpose of this study was to compare the effectiveness of ES to TS in patients with dysphagia caused by stroke, and to assess the safety of the technique. Because ES is a more direct stimulus than TS to nerves and muscles associated with swallowing, we hypothesized that ES would result in better swallow function than TS in patients with comparable conditions of dysphagia. We also monitored patients after treatment to investigate the long-term effects of treatment and the potential for spontaneous recovery.

Methods

The study was conducted at Hillcrest Hospital, a 280-bed acute care hospital in a suburb of Cleveland, Ohio. All new referrals who met entry criteria and signed the consent form were enrolled during the study period. The study period was September 23, 1993, through January 24, 1995. The study population included both in-patients and out-patients. Entry criteria included:

- primary diagnosis of stroke
- confirmation of swallowing disorder by modified barium swallow (MBS)

Exclusion criteria were:

- inability to complete at least 2 consecutive days of therapy
- any behavioral disorder that interfered with administration of therapy
- substantial reflux from feeding tube
- dysphagia from drug toxicity

Duration of swallow dysfunction did not limit eligibility. Written, informed consent, as approved by the institutional review board, was obtained from all patients.

Stroke patients with possible swallowing disorder were alternately assigned to one of the 2 treatment groups (TS or ES) independent of any other information and before being seen by the speech-language pathologist. After assignment, the speech-language pathologist performed the MBS with a radiologist to determine the severity of the swallowing disorder and to assign a swallow score (see assessment protocol below). If it was confirmed that the patient did not meet any exclusion criteria, the treatment regimen was begun. No patients were excluded from the study because of the severity of dysphagia. After the course of treatment, another MBS was performed and a final swallow score assessed.

Assessment Protocol

Each patient's swallow function was evaluated via standardized MBS,[8,17] with the addition of following the bolus

into the stomach to identify esophageal reflux that could result in aspiration. Patients swallowed various consistencies of food mixed with barium powder while being observed under fluoroscopy. Food consistencies progressed from thick to thin, until aspiration occurred. Penetration was defined as entry of the bolus into the laryngeal vestibule. Aspiration was defined as passage of barium below the level of the vocal cords. The results of the MBS were interpreted as a swallow score according to the criteria listed in Table 1.

The swallow score was assigned as follows. The speech therapist would perform the MBS and send the videotape of the procedure to a designated radiologist. The radiologist would then provide a narrative interpretation of the tape in terms of what type of liquid could be safely swallowed. That narrative report was sent back to the speech therapist, who then assigned the corresponding score (Table 1). There were 3 radiologists who assigned scores, and at the time of scoring they did not know which treatment a patient had received.

The MBS procedure we used was standard except for 2 items. First, instead of barium paste, we used barium powder, because it has less effect on the consistency and taste of the liquid it is mixed with. The idea is to create mixtures of different, realistic consistencies but with as much of the original taste as possible. Paste has a greater tendency to thicken the mixture than powder and also has a more objectionable taste. The second difference was in the order of consistencies presented to the patient. Standard references suggest using thin liquid (eg, water), then pudding, and then cookie.[18] The problem with this order is that thin liquids may be (but are not always) the most easily aspirated.[18] Thus, if the patient aspirates early in the procedure because thin liquid was used first, then (a) the airway becomes contaminated with barium, making visualization of aspiration for other substances difficult, and (b) because of the aspiration, the procedure may be terminated without determining what consistency can be safely swallowed.

Table 1. Swallow Function Scoring System*

Swallow Function Score	Safe Liquid Consistency	Clinical Implication	Level of Swallow Deficit
0	Nothing safe (aspirates saliva)	No solid or liquid is safe	Profound
1	Saliva	Same as above (candidate for PEG)	Profound
2	Pudding, paste, ice slush	—	Substantial
3	Honey consistency (liquid with thickener or premixed product like *Resource* brand liquid nourishment)	—	Moderate
4	Nectar consistency (pureed fruit juice such as apricot, peach, pear)	—	Mild
5	Thin liquids (eg, cream soups, orange juice, carbonated beverage)	No coffee, tea, thin juice (eg, apple), or water	Minimal
6	Water	All liquids tolerated	Normal

*This system identifies the consistency of liquid that the patient can swallow without aspiration.

During treatment, the speech-language pathologist auscultated the right main bronchus during inspiration. A normal swallow was a single or polysyllabic sound of 1–2 seconds duration, representing the movement of food through the pharyngeal area and into the esophagus, and consisted of only clear breath sounds.[19] This technique enabled the therapist to identify abnormal swallowing or so-called silent aspiration by airway sounds, including rales and rhonchi, during post-swallow inspiration. Silent aspiration is a condition in which food or liquid enters the airway but does not produce any obvious signs of aspiration (ie, there is no cough during or after the swallow).[20] The use of auscultation of the right bronchus during inspiration and following ingestion of the food or liquid bolus aided in hearing changes in lung sounds and changes in the rate of respiration, which often trigger concern about silent aspiration and justify an MBS. Swallow function (by auscultation) was assessed each day of treatment protocol to check for silent aspiration.

Treatment Protocols

General Treatment Protocol. In-patient treatment (either ES or TS) began within 24 hours of initial evaluation. Duration was 1 hour per day of treatment and 10 minutes of challenge/assessment. If a patient became fatigued, treatment was continued later in the day, as often as necessary, to obtain the full hour. Treatment continued on consecutive days until a swallow function score of at least 5 was achieved or the patient was discharged because of insurance constraints. Those patients discharged before achieving a score of 5 avoided a PEG if they could achieve a score of at least 2 on consistency of liquid.

Out-patients were treated 3 times per week for 1 hour per treatment. Treatment continued until they achieved a swallow score of 6 or it was judged that no more progress would be made.

Follow-up on patients was based on medical records (for readmission) or consultation with the patient, family, physician, or nursing home therapists, for up to 3 years.

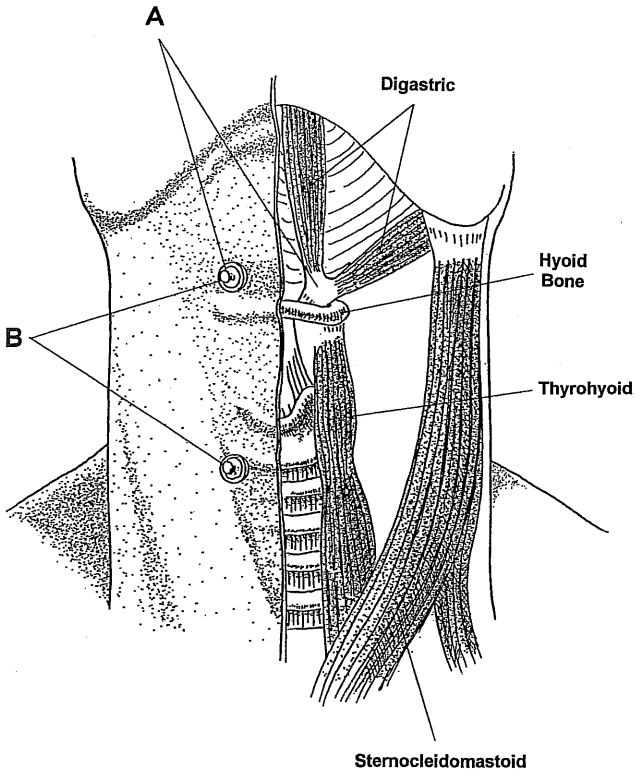

Fig. 1. Diagram of the throat showing placements for pairs of snap electrodes. One of two placements was used: (A) On either side of the midline, above the lesser horns of the hyoid bone, on the digastric muscle. (B) On either side of the midline (preferably on right side) with upper electrode above lesser horns of the hyoid bone, on the digastric muscle, and lower electrode on the thyrohyoid muscle at the level of the top of the cricothyroid cartilage. Position A was used for patients with tracheostomies or those whose anatomy prevented using the other position. Position B was used for everyone else.

Thermal-Tactile Stimulation Treatment Protocol. TS was given in three 20-minute intervals daily. A speech pathologist (one of the authors, MLF) used the standard methodology[8] for TS, including verbal coaching. TS was applied with a size 00 oral examination mirror cooled by immersion in ice. The base of the anterior faucial arch was lightly touched with the mirror back. The mirror was removed, and the patient was asked to close his or her mouth and attempt to swallow saliva (dry swallow). TS and verbal coaching continued. If a dry swallow was elicited, the patient was challenged with thickened liquids (pudding viscosity).

Electrical Stimulation Treatment Protocol. ES was administered by a physical therapist in conjunction with a speech pathologist (MLF), using a modified hand-held battery-powered electrical stimulator (Staodyn EMS +2, Staodyn Inc, Longmont, Colorado). Electrodes were placed on the neck in one of two positions (Fig. 1) and were repositioned until muscle fasciculations occurred or the strongest contraction was observed during the swallow response. Neuromuscular ES consisted of a symmetric rectangular alternating current passing between positive and negative snap skin electrodes. Frequency and pulse width were fixed at 80 Hz and 300 microseconds. Current intensity was set to the patient's tolerance and comfort level. Tolerance and comfort differed among individuals. The sensation most patients experienced first was a very slight tingling or crawling sensation. As the intensity was increased (in 2.5 mA increments from a start of 2.5 mA up to a maximum of 25.0 mA), the individual perceived a strong vibration or the sensation that the electrodes were coming loose from the neck. Most individuals accommodated rapidly enough to the sensations that the intensity could be continuously increased until contractions were consistently audible (designated the therapy current level). When ES was successful in obtaining a voluntary swallow response, the patient was asked to attempt a swallow with a specific oral consistency. ES was delivered at the therapy current for a total of 60 minutes per treatment, in the continuous mode, with a 1.0 second pause between each minute.

All patients were monitored continuously by electrocardiography and pulse oximetry. A pulse oximetry-measured blood oxygen saturation (S_{pO_2}) decrease of more than 2% was considered a desaturation due to aspiration. Laryngospasm was defined as a spasmodic closure of the glottis with severely limited ability to ventilate. Laryngospasm was judged by the speech therapist, during treatment, based on audible or visible signs of respiratory distress. All recordings were reviewed and interpreted by the medical chief of staff of the acute care facility.

Data Analysis

Unpaired *t* tests were used to compare the mean ages and the total number of treatments in the two groups. The Fisher exact test was used to compare the proportions of females to males in each group. The similarity of co-morbid conditions was evaluated with Kendall's tau test (ie, if a high proportion of TS patients have a co-morbid condition, do a high proportion of ES patients also have the co-morbid condition, and vice versa). The proportions of confounding factors (ie, brainstem vs hemispheric vs multiple strokes) in the 2 groups were compared with the chi-square test. The Mann-Whitney U test was used to compare the initial swallow scores (ie, to determine if the initial degree of dysphagia on entering the study was the same for both groups) and the distributions of final swallow scores (ie, to determine if one treatment group showed greater improvement). The change in swallow scores (ie, initial vs final) was evaluated with the Wilcoxon signed-rank test. Analyses were performed with StatView software (SAS Institute Inc, Cary, North Carolina). Statistical significance was set at $p < 0.05$.

Results

One hundred twenty-five patients were screened for possible inclusion in the study. Fifteen refused to sign consent after meeting entry criteria, leaving 110 who were enrolled. Ninety-nine patients completed the study (Table 2). All TS patients were in-patients. All but 6 ES patients were in-patients, and one was both an in-patient and out-patient. Eleven patients dropped out of the study: 6 had drug toxicity from other treatments, 2 were transferred to other hospitals, and 3 dropped out for unrecorded reasons.

The 2 treatment groups were comparable in terms of mean age and gender distribution and in co-morbid conditions that would affect treatment outcome (see Table 2). The condition that would most negatively affect the conventional treatment group was dementia, and the prevalence was identical in the 2 groups. The presence of confounding factors related to the type of lesion (ie, brainstem vs hemispheric stroke vs multiple strokes) was similar in both groups (Table 3). The TS and ES treatment groups had similar distributions of initial swallow score ($p = 0.74$). There were aphasic patients in both groups, but aphasia did not affect their treatment. There were no patients in the study with apraxia of swallowing. There were 7 ES versus 6 TS patients with dysarthria, but in no case did dysarthria appear to affect outcome.

Both treatment groups showed improvement in swallow score (Table 4). However, Figure 2 shows that ES resulted in more people having higher final swallow scores than TS ($p < 0.0001$). In addition, all but one of the ES patients showed some improvement (98%; the one patient remained at a swallow score of 2), whereas 17 (27%) of TS patients remained at initial swallow score and 4 (11%) got worse.

ES patients with +6 changes progressed from swallow function 0 (completely dysphagic) to swallow function 6 (normal swallow). ES patients with +5 changes included 3 patients who progressed from swallow function 1 (tolerates saliva only) to 6, and 6 patients who progressed from swallow function 0 to swallow function 5. Other step changes less than +5 include some ES patients who achieved swallow functions 5 or 6, but these patients started with swallow function greater than 1. No TS patient, regardless of initial swallow function, achieved a final swallow function greater than 4. These results are based on similar numbers of treatments (average of 5.5 for ES and 6.0 for TS, $p = 0.36$).

Several focused comparisons illustrate further differences between ES and TS. For patients starting at swallow scores 0 and 1, achieving swallow score 2 or higher indicated successful treatment, in that PEG was not required. Only 52% (15 of 29) of TS patients experienced successful treatment, compared to 95% (41 of 43) of ES patients ($p < 0.0001$). ES treatments were also more successful than TS treatments, based on achievement of complete swallow score 6 (35% of ES patients vs 0% of TS patients, $p < 0.0002$), each starting at swallow score 0 or 1. In addition, 4 TS patients (11%) required a PEG during treatment. None of the 58 ES patients required a PEG during treatment, and a swallow score of 2 was achieved within 1–2 treatments in all ES patients.

Twenty-five bedside evaluations performed by the therapist (ie, auscultation of the right bronchial tree for evi-

Table 2. Treatment Groups with Respect to Demography and Health

Variable	Thermal Stimulation ($n = 36$)	Electrical Stimulation ($n = 63$)	p
Average age	78.1	75.7	0.27
Maximum age	91	101	—
Minimum age	65	49	—
Female (%)	44	48	0.83
Co-morbid conditions*	(%)	(%)	
Stroke	8	11	
Coronary artery disease	8	8	
Congestive heart failure	14	8	
Chronic obstructive pulmonary disease	6	5	
Hypertension	17	19	
Dementia	3	3	
Diabetes mellitus	6	8	
Parkinson's disease	0	2	
Cancer	25	10	
Multiple sclerosis	3	0	

*Patients often had more than one co-morbid condition (ie, proportions were not mutually exclusive), and proportions were significantly correlated by Kendall's tau ($p = 0.0044$).

Table 3. Frequencies of Types of Lesions*

Treatment	Brainstem	Hemispheric	Multiple Strokes
Electrical stimulation	7	29	24
Thermal-tactile stimulation	1	19	8

*Not all patients were evaluated for type of lesion. The proportion of observations in the different categories is not significantly different than would be expected from random occurrence ($p = 0.183$).

Table 4. Mean Swallow Scores Before and After Treatment

Treatment	Initial Swallow Score	Final Swallow Score
Electrical stimulation	0.76 ± 1.04	4.52 ± 1.69
Thermal-tactile stimulation	0.75 ± 1.20	1.39 ± 1.13

Values are ± standard deviation.

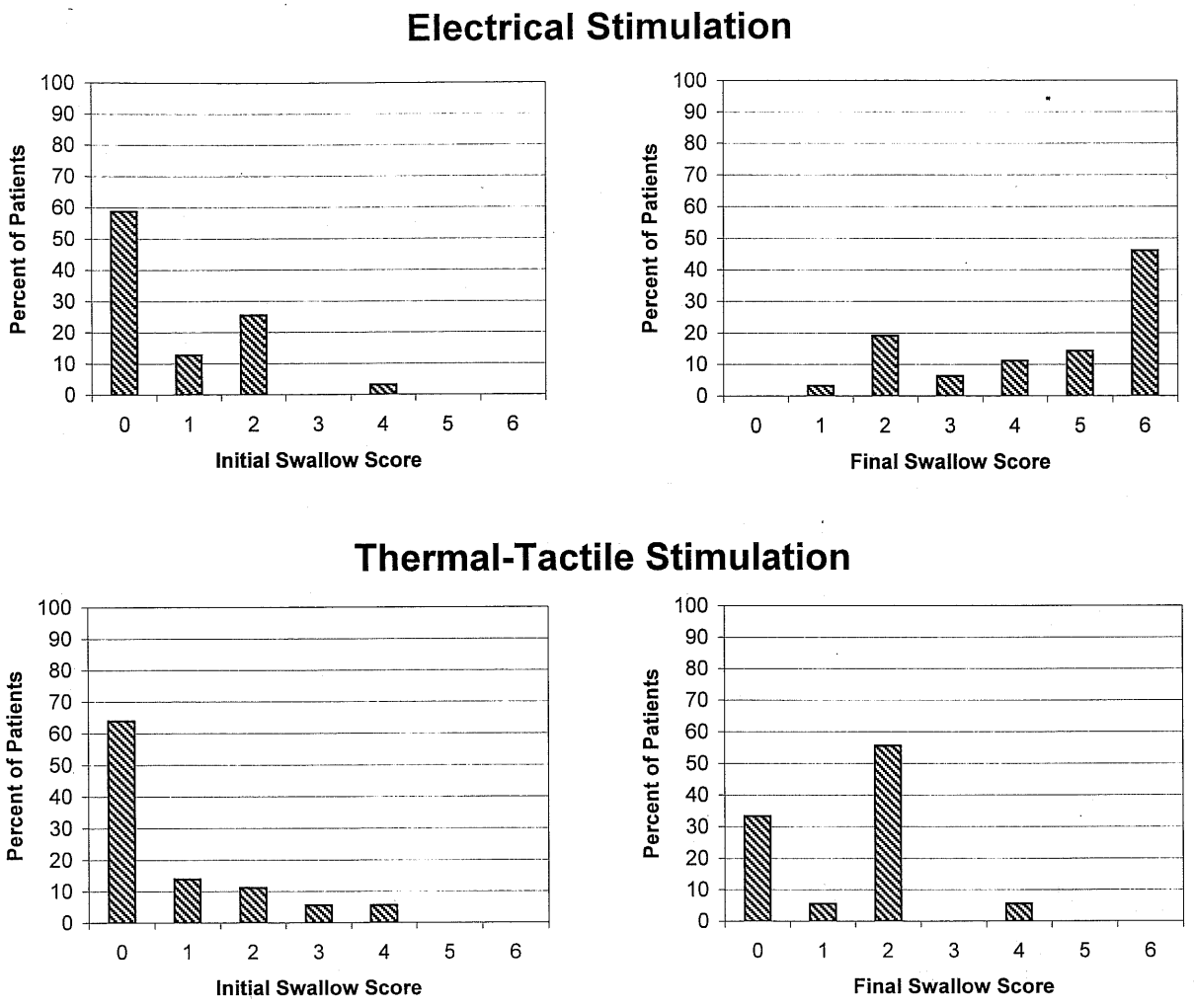

Fig. 2. Distributions of initial and final swallow scores for electrical stimulation and thermal-tactile stimulation treatment groups. A higher score means better swallow function. Initial swallow scores for the two groups were similar ($p = 0.74$). Both groups showed improvement in score (thermal-tactile stimulation $p = 0.0048$; electrical stimulation $p < 0.0001$). The electrical stimulation group had higher final scores ($p < 0.0001$).

dence of rhonchi or change in ventilatory pattern) were compared with corresponding MBS studies interpreted by a radiologist. Only one of the 25 comparisons disagreed: the therapist judged silent aspiration that was not confirmed by MBS. This yields the decision matrix shown in

Table 5. Analysis of Agreement between Bedside Assessment of Silent Aspiration and Results of Modified Barium Swallow

Bedside Evaluation	MBS Interpretation	
	Aspiration Present	Aspiration Absent
Aspiration present	24	1
Aspiration absent	0	0

MBS = modified barium swallow.

Table 6. Proportions of Patients in Post-Treatment Categories

Category	Thermal Stimulation ($n = 33$)	Electrical Stimulation ($n = 52$)
No change for >2 y, alive	0.061	0.289
No change for <2 y, lost*	0.242	0.269
No change for <2 y, died*	0.364	0.250
Improved within 2 y	0.000	0.077†
Aspiration or PEG	0.242	0.000
New episode of dysphagia‡	—	0.115
Received ES after TS‡	0.091	—

*Average time of follow-up >1 year.
†Proportion is 0.143 of 28 electrical stimulation patients with final swallow function < 6.
PEG = percutaneous enterostomal gastric tube
ES = electrical stimulation
TS = thermal-tactile stimulation
‡Full swallow function restored after electrical stimulation.

Table 5. The positive predictive value was 24/25 = 96%; the true positive rate was 24/24 = 100%; the false positive rate was 1/25 = 4%.

Follow-up data show that the effects of treatments administered during the study generally persisted (Table 6). Most patients retained their final swallow function for over 2 years (89% for ES and 67% for TS). Loss of swallow function during the post-treatment period for ES patients was based on new episodes of the problems that caused the dysphagia. None of the TS patients showed improved swallow function, whereas 4 (14%) of ES patients improved (3 confirmed by MBS). There was a high rate of aspiration (24%) in TS patients, compared with no aspiration in ES patients. Two of the aspirating TS patients received a PEG.

A total of 318 applications of ES were administered to patients during this study. Not a single case of laryngospasm or decrease in S_{pO_2} was observed. No change in heart rhythm occurred, based on electrocardiograph rhythm strip recordings.

Discussion

The demographic similarities between the two groups (Table 2) indicate that the desired properties of randomization from the same underlying population were in fact achieved for the two treatment groups, despite the fact that a strict randomization scheme was not used.[21] There was, however, one general difference between the two groups: the ES group was treated much longer after stroke than the TS group. This is because most of these patients had already failed conventional therapy, which was the reason they were referred for the study. The longer the period after the stroke, the less success is expected with dysphagia treatment. Despite this potential bias against the ES treatment, the ES group showed better results than the TS group.

Bedside evaluations are important in determining the safety of treatment, to estimate the patient's progress during the treatment period, and to justify further MBS studies. In our study, auscultation was used to detect silent aspiration during treatment. The ability to detect aspiration by this method was evaluated by comparison with radiographic evidence of aspiration. However, MBS procedures were done only for patients who were suspected of aspiration (silent or not). Therefore, we collected no data from which negative predictive value could be estimated, yet the high positive predictive value suggests that auscultation deserves further study as a potentially useful screening test for silent aspiration. More research should be done to identify the optimum bedside evaluation technique and to compare its accuracy with the gold standard, MBS.

Application of ES to muscles associated with swallowing links swallowing therapy with physical therapy. A fundamental principle of physical therapy is 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.[22] Loss of muscle tone is identified by physical therapists as little or no measurable contractility or strength. When attempts at exercise alone fail to result in contraction of an atrophied muscle, ES may enhance tone to the point where exercise may strengthen or activate the muscle.

There may be an analogy with dysphagia. A medical event such as stroke may block the primary neural pathway for swallowing. There are fewer myofibrils per motor unit of the laryngeal muscles relative to larger muscles (4–6 vs 4,000), and there are numerous small muscles of this type that participate in the oropharyngeal phase of swallow.[23] In addition, the motor units within each laryngeal muscle tend to fire asynchronously during a normal swallow, contrasting with the more synchronous firing of larger muscles designed for strength.[23] Under this model, even a few days without the typical 600–2,400 normal swallows per day[24,25] could lead to long-term dysphagia. Though this design of small muscles might make them more susceptible to failure from lack of use, it is possible that this design can respond more fully to ES. Perhaps this is a reason why ES of the neck restores effective swallow with fewer treatments than required for restoration of appropriate function by ES of other muscles of the body.[26] Alternatively, fewer treatments might be associated with stimulating a reflex, since swallowing is a complex action that is usually initiated voluntarily but is always completed as a reflex involving afferent and efferent cranial nerves[27,28] and primary and secondary swallow centers in the cortex.[29] These muscle tone and reflex hypotheses also pertain to the success of ES in treating urinary incontinence.[30] Much research is required to determine whether ES, applied at a sensory level in our study, works via a peripheral nerve, a direct effect on the small muscles, the central nervous system, or a combination of these factors.

Our data directly address issues of safety. ES of the head and neck, discussed in the recent third edition of Charles Darwin's *The Expression of the Emotions in Man and Animals*,[31] has been the subject of major recent debate about safety. Possible risks include arrhythmia, hypotension, interference with pacemaker, laryngospasm, glottic closure, burns, and tumor growth.[27] However, one successful study that applied external ES to a nerve of the neck had no complications.[16] Other studies also observed no change in vital signs, electrocardiograph, or other adverse effects in patients who received implantable recurrent laryngeal and vagal nerve stimulators used to treat spastic dysphonia or control epilepsy.[27,28] External application of ES with a muscle stimulator within the settings used in our study appears safe, at the sensory level of application. Standard electrode placement in our study purposely avoids the carotid body. In addition, the voltage

and current used in our device are lower than is delivered by a standard neuromuscular stimulator, assumed by other authors concerned over the safety of ES.

The most important theoretical risk of ES is laryngospasm. In an animal study, laryngospasm was achieved with repetitive suprathreshold ES, but not with single-shock excitation of the superior laryngeal nerve.[27] As stimulus frequency went above 32–64 Hz, there was a decrease in adductor after-discharge and glottic pressure.[28] In our study, suprathreshold levels of stimulation of the superior laryngeal nerve did not occur, because of the level of therapeutic current, limits on the maximum current of the stimulator, and attenuation by soft tissues of the neck. The high-frequency stimulation of ES for dysphagia exceeded 64 Hz and may be one of the factors protecting against laryngospasm. In addition, the constant current stimulator automatically dropped the voltage to maintain a constant current dose in the event of decreased electrode or tissue resistance. With these safeguards, a device as configured for our study is apparently safe. The hypothetical concerns about safety are not supported by our data.

Although there are reports in the literature that stroke patients can recover their swallow spontaneously,[12] tube feedings were needed for 15–60 weeks.[5,9,10] Howard et al[3] indicated that 30% of all patients continued on total tube feeding at one year after stroke. The patients who received ES in our study began eating following 3 treatments and did not require tube feeding thereafter. ES may initiate muscle reeducation prior to the beginning of spontaneous recovery and prevent the need for tube feeding.

In an age when extensive efforts are made to reduce health care costs, the ES protocol can contribute substantially to those efforts. Between 300,000 and 600,000 new cases of dysphagia occur each year in stroke patients.[24] In 1992, the cost of United States enteral nutrition in neurologic disease alone exceeded 330 million dollars per year.[3] Since the ES protocol restored swallow function to a score of 2 within 1–2 days of treatment, a hospitalized stroke patient who lost swallow function in association with the underlying medical problem could eat on his or her own or with reduced assistance as an in-patient. Six treatments of one hour each day, for in-patients or out-patients, would be expected to restore normal swallow in 35% of the most severe cases of stroke and 45% of all stroke cases. The medical implications for patients include reduced amounts of therapy (fewer sessions, less traveling), avoidance of surgery for PEG (and attendant complications), avoidance of specialized dietary regimens, normal liquid intake, and reduced risk of aspiration pneumonia. Caregivers benefit from increased efficiency. Corrected dysphagia would interfere less with treatments for other medical problems while improving cost effectiveness for health care facilities. The social implication of lower medical bills and less restricted social activities associated with eating is higher quality of life for both the patient and the family.

A potential limitation of this study is that, though the scoring of swallow function was fairly objective (see Table 1), it does not preclude subjective bias. However, we compared the distribution of final swallow scores of 29 TS patients from our study with that of 53 patients treated with TS by Neumann et al[5] and found no difference (Kolmogorov-Smirnoff test KS = 0.2531, p = 0.13). Therefore the difference between TS and ES was probably not due to bias against TS. The physical evidence of MBS reveals no bias in favor of ES. In addition, the swallow function score we used is no more subjective than the score validated and published by Rosenbek et al.[25] The major difference with our score is that we did not record the trajectory of the bolus, but only whether it was aspirated and the consistency of liquid aspirated. Because consistency affects risk of aspiration, the purpose of the score is to rank the consistency of liquid that can be safely swallowed. This is the type of information referring physicians prefer to see as an interpretation of the MBS procedure because it helps them formulate instructions for the patient.

Conclusions

Transcutaneous ES appears to be a safe and effective treatment for dysphagia caused by stroke, and it results in better improvement in swallow function than does thermal-tactile stimulation. Normal swallow function was restored to 35% of the most severely dysphagic patients in less than a week of daily treatment, to 45% of patients at all levels of severity, and the restoration persisted until a new episode of dysphagia occurred. The only limitations of ES are that it cannot be done on patients who talk continuously (such as is found in some severely demented patients), patients who have beards must be willing to shave them for ES, and TS treatment requires the patient's cooperation in opening the mouth and in following verbal commands.

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