

Evidence Table

Clinical Area: Dysphagia: electrical stimulation.
Keywords: Electrical stimulation, dysphagia, stroke.
Reference: Freed ML, Freed L, Chatburn RL et al. Electrical stimulation for swallowing disorders caused by stroke. *Respir Care* 2001;46:466-474.

Study Type: Longitudinal. (The study was pseudo-randomized).
Study Aim: To assess the safety of electric stimulation (ES) treatment, and to compare its effectiveness to that of thermal tactile stimulation (TS) treatment for patients with dysphagia caused by stroke.

Outcomes:

- *Primary:* Improvement in swallow score.

Design:

- *Number of subjects:* N=110 enrolled, and 99 patients completed the study (n=63 in the electrical stimulation (ES) group, and n=36 in the thermal-tactile stimulation (TS) group).
- *Description of study population:* The study included stroke patients referred to a hospital in Cleveland Ohio, for swallowing disorder between September 1993, and January 1995. Their ages ranged from 49 to 101 years with a mean of 78.1 years for the TS group, and 75.7 years for the ES group. 46% were women, 9% had a concomitant CHD, 6% COPD, and 3% dementia.
- *Inclusion criteria:* Primary diagnosis of stroke, and a swallowing disorder confirmed by modified barium swallow (MBS).
- *Exclusion criteria:* Inability to complete at least 2 consecutive days of treatment, behavioral disorder that would interfere with treatment, substantial reflux from feeding tube, and /or dysphagia from drug toxicity.
- *Power:* Not discussed.
- *Method of randomization:* Patients were not randomized but alternately assigned to one of the two treatment groups.
- *Intervention:* All patients underwent an initial MBS to evaluate the swallowing severity and assign a swallow score. Treatment with electrical stimulation (ES) using the Freed Bioelectric dysphagia Treatment Device, or tactile stimulation (TS) was started 24 hours later. Inpatients underwent a daily one-hour of treatment, and 10 minutes of challenge/assessment until achieving a swallow score of at least 5, or premature discharge from the hospital. Outpatients were treated 3 times /week until they achieved a swallow score of 6, or no more progress was made. TS was administered by a speech pathologist, and consisted of touching the base of the anterior faucial arch with an ice-chilled metal probe. ES was administered by a physical therapist and a speech pathologist, and consisted of delivering transcutaneous electrical stimulation applied through a pair of electrodes positioned on the neck. Patients were monitored by electrocardiography, and pulse oximetry.
- *Blinding:* The patients and speech pathologists were apparently not blinded to the treatment received. The radiologists who assigned the swallow scores were blinded to the treatment received.
- *Source of outcome data (e.g. patient self-report, doctor report, lab result):* Swallow function was assessed by auscultation on each treatment day to check for silent aspiration. Follow-up data were obtained from medical records for re-admissions, consultation with patients, families, physicians, or nursing home therapists.
- *Length of follow-up:* Patients were followed for up to three years. The authors did not provide more data on follow-up.
- *Completeness of follow-up:* 90% of the patients completed the study.

Validity

- *Is the study type appropriate for the questions being asked?* No, a randomized trial would be more appropriate.
- *Was the study population typical of patients with this disease?* Only for patients referred for treatment of dysphagia following stroke.
- *Were the treatment/control groups comparable at baseline?* Yes.
- *Was the intervention compared to placebo and/or best accepted intervention?* Yes.
- *Was there compliance with the intervention?* Yes.
- *Was there equal intensity of observation of study and control subjects?* Yes.
- *Was the process of observation likely to affect the outcome?* Probably. The trial was unblinded.
- *Intention to treat analysis?* No.

Conclusions regarding validity of methods:

The study was a pseudo-randomized, controlled trial. It had a relatively small size, 10% dropouts, and the analysis was not based on intention to treat. Patients were alternately and not randomly assigned to the treatment groups, which may be a potential source of bias. The authors did not discuss the ratio at which patients were alternately assigned to the treatment groups (there were 63 patients in the ES group and 36 patients in the TS group). They reported that there were 11 dropouts without discussing their allocation group. Moreover the patients and speech pathologists were not blinded to the treatment provided, but the radiologists who assigned the swallow scores were blinded which may reduce, but not eliminate the observation bias.

Results:

Mean swallow scores* before and after treatment

	<i>Initial swallow score</i>	<i>Final swallow score</i>	<i>p value</i>
<i>Electrical stimulation (n=63)</i>	0.76 ± 1.04	4.52 ± 1.69	<0.0001
<i>Thermal-tactile stimulation (36)</i>	0.75 ± 1.20	1.39 ± 1.13	0.0048
<i>P value for diff between the 2 groups (obtained from fig.)</i>	p=0.74	p<0.0001	

*Swallow function score based on safe liquid consistency on a scale of 0-6 with 0 and 1 indicating profound deficit, and 6 normal (0: nothing safe (aspirates saliva), 1: saliva, 2: pudding, paste, ice slush, 3: honey consistency, 4: Nectar consistency, 5: thin liquids, 6: water)

62 (98%) of the patients in the electrical stimulation (ES) group showed some improvement.

17 (27%) of the patients in the thermal stimulation (TS) remained at the initial swallow score, and 4 (11%) got worse.

There were no cases of laryngospasm or decrease in oxygen saturation level.

Follow-up data:

	Thermal stimulation (n=33)	Electrical stimulation (n=52)
Retained swallow function >2y	67%	89%
Improved within 2 year	0.0%	14%
Aspiration or percutaneous enterostomal gastric tube	24%	0%

No tests of significance for the difference between the two groups were provided.

Authors' conclusion:

The authors concluded that transcutaneous electrical stimulation appears to be safe and effective in treating patients with dysphagia due to stroke, and that it leads to better improvement in swallow function than tactile stimulation.

Reviewer's Conclusions:

The study does not provide sufficient evidence to determine that transcutaneous electric stimulation is more effective than tactile stimulation in improving swallowing among patients with dysphagia after a stroke attack. The results show that both groups of patients treated with TS or ES significantly improved, but the mean swallow scores were higher in the ES group. However, the study was not randomized, and subject to selection and observation bias. Patients and speech pathologists were not blinded to the treatment, and outcomes were mainly subjective.