Electrical stimulation of the pharyngeal swallow: Does the evidence support application in clinical practice?

La relation entre la communication et la qualité de vie chez des locuteurs alaryngés

Catriona M. Steele

Abstract
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Keywords: Swallowing, Dysphagia, Therapy, Electrical Stimulation, Evidence-Based

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1. Was the assignment of patients to treatment randomized?
2. Were all patients who entered the trial properly accounted for and attributed at its conclusion?
3. Were patients, their clinicians, and study personnel “blind” to treatment?
4. Were the groups similar at the start of the trial?
5. Aside from the experimental intervention, were the groups treated equally?

Part B of the U of A EBMT addresses questions regarding the statistical strength of the results reported in a study. Specifically, this section explores the risk of type I and type II error by considering the magnitude and power of a reported treatment effect. Finally, part C of the U of A EBMT explores the applicability of research findings to clinical practice. This section is intended to guide clinicians in determining whether a particular experimental treatment would be appropriately applied to their clinical caseload. Specific questions in this section ask whether the reported results can reasonably be generalized to a clinician’s practice setting, whether the reported outcomes were clinically significant, and whether treatment benefits appear to outweigh any risk of harm or costs involved.

**Neurophysiology of Swallow Initiation**

Neurophysiological control of swallowing has been attributed to a central pattern generator (CPG) located in the brainstem. Numerous neurophysiological studies in animals have demonstrated that pools of motoneurons in the motor nuclei of cranial nerves V, VII, IX, X and XII and interneurons located in two medullary subgroups (dorsal and ventrolateral) are active during swallowing (Jean, 2001; Miller, 1987; Miller, Bieger, & Conklin, 1997). Jean (2001) argues that neurons in the dorsal subgroup, located in the nucleus tractus solitarii (NTS), function as preswallowing or trigger neurons with a re-excitation loop that allows them to fire repeatedly until the threshold for swallow initiation is achieved. The ventrolateral subgroup of interneurons, integral to the swallowing CPG, is found in the region of the nucleus ambiguus (NA). Jean (2001) proposes that this ventral subgroup distributes the swallowing drive from the NTS to the various pools of motoneurons involved in swallowing. Once initiated, the central swallowing network fires in a linear rostrocaudal sequence, corresponding somatotopically to the proximal-distal anatomy of the alimentary tract.

At a muscular level, the onset of the pharyngeal phase of the swallow is demarcated by activity in a leading complex of muscles, beginning with the mylohyoid and followed, after a delay of 30-40 ms, by contractions of the anterior digastric, internal pterygoid, genioglossus, geniohyoid, stylohyoid, styloglossus, posterior tongue, superior constrictor, palatoglossus, and palatopharyngeus muscles (Jean, 2001; Lowe & Sessle, 1973). At a behavioural level, contraction of the mylohyoid with a fixed jaw position instigates first an upward and then an anterior movement of the hyoid bone (Chi-Fishman & Sonies, 2000; Logemann, 2000). Anterior displacement of the hyolaryngeal complex is thought to generate traction that assists with biomechanical opening of the upper esophageal sphincter (Ishida, Palmer, & Hiiemae, 2002). Additionally, anterior movement of the hyolaryngeal complex widens the pharyngeal lumen to facilitate epiglottic deflection and facilitates safe positioning of the laryngeal inlet, out of the direct pathway of the bolus (Vandaele, Perleman, & Cassell, 1995).

The onset of the pharyngeal phase has classically been defined as the point in time when the leading edge of the bolus, viewed radiographically, passes through the faucial arches (Logemann, 1983). The onset of hyoid movement has been proposed as a radiographic marker of the biomechanical onset of the pharyngeal phase of swallowing (Kendall, McKenzie, Leonard, Goncalves, & Walker, 2000; Lof & Robbins, 1990). The latency between the arrival of the bolus head at the faucial pillars and the onset of hyoid elevation has been measured by some scientists as a durational variable in swallowing, known as stage transition duration (Lof & Robbins, 1990). With liquids, stage transition duration (STD) is usually a negative value, reflecting anticipatory onset of hyoid movement prior to bolus arrival in the pharynx (Lof & Robbins, 1990). STDs greater than zero have traditionally been considered abnormal and are interpreted either to reflect impaired transmission of sensory input from the glossopharyngeal junction or impaired control of bolus propulsion in the tongue (Logemann, 1983). The therapeutic application of sensory stimulation techniques for swallowing is predicated on the first of these two interpretations and the related logic that priming or heightening sensory input to the swallowing CPG may elicit earlier onset of the motor components of the pharyngeal swallow.

Neuroanatomical studies support the premise that sensory detection of bolus presence at the glossopharyngeal junction is a component of the pharyngeal swallow initiation process. An elegant histological study has recently mapped the complex distribution of the sensory pharyngeal branches of cranial nerves IX and X in a human cadaver, demonstrating a plexus of rich innervation in the posterior tonsillar pillar (Mu & Sanders, 2000). Tract tracing studies in animals have used cholera toxin horseradish peroxidase (CT-HRP) to confirm that palatal, pharyngeal, and laryngeal afferent fibres from the glossopharyngeal and vagal nerves terminate in the intermediate and intermediate subnuclei of the NTS, where they synapse with the premotor pre-swallow or trigger neurons (Broussard & Altschuler, 2000; Jean, 2001). Storey (1967) has proposed that different kinds of stimuli might be differentially effective in eliciting swallowing at different locations in the upper aerodigestive tract. This premise is consistent with evidence from a 1928 study by...
Pommerenke (cited by Storey, 1967), in which light tactile contact was shown to be highly effective in eliciting swallows when applied to the faucial pillars; by contrast, heavy tactile contact was required in order to elicit swallowing through stimulation of the posterior pharyngeal wall, an area demonstrated by Mu and Sanders (2000) to have a relatively sparse afferent nerve supply.

**Indications for Swallow Stimulation Therapy**

**What Constitutes a Delayed Pharyngeal Swallow?**

Traditional teaching regarding the timing of pharyngeal swallow initiation argued that it was abnormal for the bolus to be located distal to the faucial pillars at the time of hyolaryngeal excursion (Logemann, 1983). However, subsequent research has shown that there are conditions in which it is normal for the bolus to reach the valleculae or even the pyriform sinuses prior to the initiation of the pharyngeal phase of the swallow. Masticated solid foods are now known to collect in the valleculae prior to the onset of the pharyngeal swallow, which is assumed to trigger contingent on the vallecular accumulation of a critical volume or mass of bolus material (Hiiemae & Palmer, 1999). In the case of thin liquids, preswallow bolus presence deep in the hypopharynx has been reported during sequences of repeated sequential swallows, using either cup or straw administration (Chi-Fishman & Sonies, 2000, 2002; Chi-Fishman, Stone, & McCall, 1998; Daniels & Foundas, 2001). These data no longer support the original description (Lazzara et al., 1986), the technique is assumed to trigger contingent on the vallecular accumulation of a critical volume or mass of bolus material (Hiiemae & Palmer, 1999). In the case of thin liquids, preswallow bolus presence deep in the hypopharynx has been reported during sequences of repeated sequential swallows, using either cup or straw administration (Chi-Fishman & Sonies, 2000, 2002; Chi-Fishman, Stone, & McCall, 1998; Daniels & Foundas, 2001). These data no longer support the initial report provided data on the timing of swallow elicitation with and without prior stimulation (Lazzara et al., 1986); however, these studies were criticized for their failure to control for order effects. Subsequent studies, with improved experimental design, demonstrated immediate post-stimulation reductions in swallowing latency in almost 70% of the participants studied (Rosenbek et al., 1996). However, these effects were short-term and did not lead to generalized improvement (Rosenbek et al., 1991), even with an aggressive treatment schedule involving 600 stimulation trials per week over a two week course of therapy (Rosenbek et al., 1998). The technique has evolved across experiments, with the original chilled laryngeal mirrors being replaced by iced water sticks. Nonetheless, several questions remain unanswered regarding optimum technique. In the absence of an asymmetric palatal gag response, how should the clinician determine which side of the faucial pillar to stimulate? Does the presence or strength of a palatal gag response correlate with the integrity of pharyngeal swallow elicitation? Is there a limited stimulation-to-response time window within which a stimulation effect can be optimally identified? And, is it preferable to measure the influence of stimulation on swallowing latency for the subsequent bolus swallow as reported by Lazzara et al. (1986) and Rosenbek et al. (1991, 1996, 1998) or on subsequent dry swallows as reported by Selinger, Prescott, and Hoffman (1994) and Kaatzke-McDonald, Post, and Davis (1996)?

Interestingly, Kaatzke-McDonald and colleagues (1996) failed to demonstrate differential swallowing stimulation effects between a single 5 second duration steady contact and repetitive downward stroking of the anterior faucial pillars with a laryngeal mirror. In the same experiment, reduced latency-to-swallow-onset were significantly more common following stimulation with a laryngeal mirror chilled to 0° Celsius than with a mirror warmed to body temperature (37° Celsius) (Kaatzke-McDonald et al., 1996). However, there is some reason to question whether the thermal nature of the stimulus is critical to results reported to date, given that ice-chilled probes have been shown to warm rapidly to minimal cold sensation levels by the time contact with the faucial pillars is achieved (Selinger et al., 1994). With repeated faucial pillar contact during stimulation, these probes are demonstrated to warm further, achieving a neutral or even warm temperature within 6 seconds of removal from the ice-bath (Selinger et al., 1994).

**Stimulation Techniques and Evidence**

**Thermal tactile stimulation.**

Thermal tactile stimulation is a therapeutic intervention strategy for dysphagia in which exteroceptive stimulation of the faucial pillar is provided with the objective of eliciting a timely pharyngeal swallow response (Fujiu, Toleikis, Logemann, & Larson, 1994; Lazzara, Lazarus, & Logemann, 1986; Rosenbek et al., 1998; Rosenbek, Robbins, Fishback, & Levine, 1991; Rosenbek, Roecker, Wood, & Robbins, 1996). In its original description (Lazzara et al., 1986), the technique was performed using a laryngeal mirror, which was first cooled in a container of ice chips. The clinician was instructed to lightly stroke the faucial pillars in an ascending direction, beginning at their base. The initial report provided data on the timing of swallow elicitation with and without prior stimulation (Lazzara et al., 1986); however, these studies were criticized for their failure to control for order effects. Subsequent studies, with improved experimental design, demonstrated immediate post-stimulation reductions in swallowing latency in almost 70% of the participants studied (Rosenbek et al., 1996). However, these effects were short-term and did not lead to generalized improvement (Rosenbek et al., 1991), even with an aggressive treatment schedule involving 600 stimulation trials per week over a two week course of therapy (Rosenbek et al., 1998). The technique has evolved across experiments, with the original chilled laryngeal mirrors being replaced by iced water sticks. Nonetheless, several questions remain unanswered regarding optimum technique. In the absence of an asymmetric palatal gag response, how should the clinician determine which side of the faucial pillars to stimulate? Does the presence or strength of a palatal gag response correlate with the integrity of pharyngeal swallow elicitation? Is there a limited stimulation-to-response time window within which a stimulation effect can be optimally identified? And, is it preferable to measure the influence of stimulation on swallowing latency for the subsequent bolus swallow as reported by Lazzara et al. (1986) and Rosenbek et al. (1991, 1996, 1998) or on subsequent dry swallows as reported by Selinger, Prescott, and Hoffman (1994) and Kaatzke-McDonald, Post, and Davis (1996)?

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**Intra-oral and intra-pharyngeal electrical stimulation.**

Sensory stimulation for delayed swallow initiation has also been attempted via the intra-oral administration of electrical current. Reported studies of this method.
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have used specially designed palatal prostheses that deliver the electrical stimulation bilaterally to the faucial pillars, thus targeting the sameglossopharyngeal afferent pathways as those targeted in thermal-tactile stimulation (Park, O’Neill, & Martin, 1997; Power et al., 2002). Similarly, electrical stimulation has been applied directly to the pharyngeal mucosa using a pair of bipolar ring electrodes on an intraluminal catheter (Fraser et al., 2002). In the first of these, reports (Park et al., 1997), four dysphagic individuals with videofluoroscopic evidence of delayed pharyngeal swallow initiation showed impressiveresponses in the form of shorter overall transit times and reduced pooling, penetration, and aspiration immediately post stimulation. While STD data were not specifically measured, the implication of the reported reductions in overall oropharyngeal transit time is that STD was reduced in the post stimulation videofluoroscopies. Of particular interest in the latter two studies (Power et al., 2002; Fraser et al., 2002) was the finding that response patterns to electrical stimulation might differ depending on the frequency of the stimulus provided. Intraorally, a 0.2 Hz stimulus was reported to be excitatory, while a 5 Hz stimulus was inhibitory, actually resulting in prolonged latencies to pharyngeal swallow initiation (Power et al., 2002). In the pharynx, application of a 5 Hz stimulus at 75% of maximum tolerance for a period of 10 minutes was reported to be most effective in increasing the amplitude of evoked pharyngeal swallowing EMG (Fraser et al., 2002). Importantly, increased pharyngeal excitability following electrical stimulation in dysphagic individuals was correlated with radiographic evidence of functional improvements in swallowing, in the form of both reduced swallowing latency times and reduced aspiration. However, stimulation at 10, 20 and 40 Hz frequencies were all observed to be inhibitory (Fraser et al., 2002). Thus, certain frequencies of electrical stimulation applied to the faucial pillars may actually be detrimental to facilitation of the swallowing process. Interestingly, Fraser et al. (2002) also demonstrated that the pharyngeal excitability following intrapharyngeal electrical stimulation continued to grow for at least 90 minutes following the end of stimulation. Clearly, this technique has powerful potential to influence neurophysiological pathways involved in swallowing. However, further careful study is needed to determine dose-response effects, response durations, and which frequencies of stimulation involve risk of harm in the form of further delayed swallow elicitation. This technique should be considered experimental for the time being.

**Transcutaneous electrical stimulation**

Transcutaneous electrical stimulation (e-stim) applied to the supra- and infrahyoid musculature has been reported to yield positive treatment outcomes for dysphagic individuals with a wide variety of etiologies (Freed, Freed, Chatburn, & Christian, 2001). Freed’s technique, marketed under the name VitalStim™, involves repeated delivery of 60-second long trains of electrical current at a frequency of 80 Hz. Stimulus intensity is adjusted to participant tolerance, and increased in 2.5 milliamp increments until contractions of the supra- and infrahyoid musculature are evoked; maximum intensity does not exceed 25 milliamps. Internet advertisement for VitalStim™ treatment claims a “proven 97% success rate in clinical trials to return a patient from dependent tube feeding to full oral intake in an average of 14 sessions” (VitalStim, 2004). A single published outcome study is available regarding the VitalStim™ technique (Freed et al., 2001), in which treatment outcomes were compared for patients receiving either e-stim or thermal tactile stimulation. Unfortunately, careful review of this study reveals a substantial number of experimental design concerns that raise doubts as to the validity of reported treatment benefits. These concerns (detailed below) include concerns regarding the physiological rationale guiding the site of stimulation, subject eligibility criteria and similarity, failure to control for spontaneous recovery, randomization, validity of the measure used to determine outcome, and experimenter bias.

The first question regarding Freed’s use of e-stim relates to the intended physiological treatment effect (Freed et al., 2001). As previously discussed, the theoretical basis for swallowing stimulation techniques advocates their application specifically to remedy delayed initiation of pharyngeal swallowing. Neither the selection criteria for subjects in Freed’s study nor the reported outcomes were specific to the physiological feature of delayed pharyngeal swallow. Rather, it appears that the intended mechanism of effect is one of enhancing the strength of muscle response. Applying this rationale to the current understanding of oropharyngeal swallowing physiology, it would be most logical to target the suprahypoid muscles for stimulation, thereby enhancing hyolaryngeal excursion and upper esophageal sphincter opening. Freed et al. (2001) report inconsistency in the site of electrode placement across participants in her study, with the most common site being over the infrahyoid musculature (i.e., muscles that are not directly involved in the pharyngeal phase of swallowing). Consequently, the physiological rationale behind the reported treatment and its effects remains unclear.

The majority of the 110 subjects enrolled in Freed’s study (Freed et al., 2001) were inpatients on the stroke unit of an acute care hospital. Detailed information regarding the specific physiological nature of dysphagia in these individuals was not reported. Consequently,
it is not possible to determine whether the proposed treatment was physiologically appropriate for these participants (i.e., did participants present with deficits either in the timing or strength of pharyngeal swallowing?). Disturbingly, there was no attempt to ensure similarity of subjects in the various treatment arms, either at the outset or during conduction of the study (Freed et al., 2001). Some subjects were reportedly enrolled in the study within 24 hours of their initial swallowing evaluation in the acute care hospital. Others had dysphagia of long-standing and participated in treatment on an outpatient basis. The e-stim group reportedly included some subjects with tracheostomy, while this population was not included in the thermal stimulation group. The authors fail to acknowledge the possibility that spontaneous recovery contributed to positive outcomes in some subjects, or that patient complexity might have contributed to less favourable outcomes in others. The duration of treatment was not equal in the different groups, and was acknowledged to be “much longer” for the e-stim group. Consequently, failure of the thermal stimulation technique to achieve similar outcomes to the e-stim technique might simply be a factor of the amount of treatment provided. A significant subject drop-out rate was reported, but it remains unclear whether this occurred equally in both treatment arms. And, most seriously, the original article failed to report that subjects in the e-stim group also underwent esophageal dilatation as part of their treatment, although this has been verbally disclosed in subsequent oral presentations and is discussed on the VitalStim™ website (Freed, 2002).

Additional concern is warranted by the fact that randomization was not properly performed (Freed et al., 2001). Treatment assignment decisions were made prior to conducting the videofluoroscopic assessment that confirmed eligibility of the subject to participate in the study (i.e., presence of dysphagia). It appears that subjects who proved not to require treatment at their intake assessment were included either as missing data points or as subjects with positive outcomes in the subsequent statistical analysis. Furthermore, 7 of the subjects with long-standing dysphagia (who had failed to recover with previous courses of traditional treatment) were all assigned to the electrical stimulation treatment arm on compassionate grounds. This was also the case for all subjects with tracheostomies. Consequently, the reader is left with the impression that the experimenters began this study with the bias that the thermal tactile stimulation treatment would be unlikely to yield favourable results, and may not have pursued this control intervention with the same enthusiasm as they did for the e-stim technique.

Experimenter bias is also a concern with respect to the analysis and interpretation of the outcome measure used in Freed’s study (Freed et al., 2001). Treatment effects were evaluated using a 6-point rating scale of diet texture tolerance during videofluoroscopic swallowing assessments. The scale was developed by Freed herself, and was not validated prior to use. Importantly, the six levels of impairment reported on this tool relate to overall swallowing safety, and are not specific either to the timing of swallowing or to the presumed target deficit, a weak pharyngeal swallow. The clinician who scored and interpreted both the baseline and post-treatment videofluoroscopies was not blind to treatment assignment or the timing (pre vs. post-treatment) of the studies she was evaluating. No information regarding intra-rater reliability was provided. In short, Freed’s research (Freed et al., 2001) falls seriously short of providing substantive evidence to support her claims of treatment efficacy.

A second report of transcutaneous electrical stimulation can be found in a recent issue of Laryngoscope (Leelamanit, Limskul, & Geater, 2002). This study used a custom made device to deliver electrical pulses to the thyrohyoid muscle, via two 2 x 2 cm square electrodes positioned bilaterally over the thyrohyoid muscle, 1 cm lateral to the midline just inferior to the hyoid bone. Importantly, each of these pulses were timed to closely follow the onset of spontaneous submental muscle contraction, detected by simultaneous surface EMG channels built into the device. Rather than heightening sensory input to the swallowing central pattern generator, the hypothesized mechanism of treatment effect in this study was one of enhancing the strength of muscle contraction, range of laryngeal elevation, and associated upper esophageal sphincter opening achieved during the swallow (Leelamanit et al., 2002).

Like the Freed et al. (2001) study, Leelamanit et al.’s (2002) study suffers from several methodological problems with regard to subject selection criteria, experimental bias, and the presumed physiological mechanism of effect. These concerns necessitate caution when interpreting the reported results. Twenty-three participants with dysphagia were enrolled in this study. As in Freed’s study, the pre-treatment duration of dysphagic symptoms was not controlled, ranging from 3 to 12 months. Etiologies were mixed and included aging as the primary diagnosis in 10 of the 23 subjects. All subjects underwent videofluoroscopic swallowing evaluation (VFSS) at baseline and following treatment; ratings were performed by the first author, and no intra-rater reliability data were reported. Unfortunately, the rater was not blinded to the time-point of each VFSS during rating. Participants were grouped based on the severity of their swallowing difficulty; however, little information is provided regarding the criteria by which severity was judged.

There was no control group in the Leelamanit et al. (2002) study, and thus no randomization of subjects. All subjects underwent four hours of electrical stimulation on a daily basis; insufficient information is provided to permit replication of the treatment protocol. Treatment progress was judged clinically, based on the subject’s ability to tolerate 3 cc water swallows without...
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...treatment protocol achieves its intended outcome. Not succeed in reporting convincing evidence that their measure treatment outcome, Leelamanit et al. (2002) do was judged effective. Given the mixed etiologies of the course of 3 to 8 treatment sessions in these individuals was reported in 5 subjects, within 2 to 9 months. A second subjects. Of those who responded to treatment, a relapse (2002) to the thyrohyoid rather than geniohyoid or displacement of the hyoid (Ishida et al., 2002). Therefore, it seems reasonable to question whether the improvements noted in Leelamanit et al.'s subjects included differences in both anterior and upward excursion of the hyolaryngeal complex. A recent hooked-wire electrode study has suggested that the geniohyoid muscle, rather than the thyrohyoid, contributes most significantly to anterior displacement of the hyoid (Burnett, Mann, Cornell & Ludlow, 2002). Therefore, the specificity of the reported treatment effects in Leelamanit et al.’s study (2002) to the thyrohyoid rather than geniohyoid or other muscles remains questionable.

Leelamanit et al. (2002) reported a successful treatment outcome following 2-9 days of treatment in all except 4 subjects. Of those who responded to treatment, a relapse was reported in 5 subjects, within 2 to 9 months. A second course of 3 to 8 treatment sessions in these individuals was judged effective. Given the mixed etiologies of the subjects, and the largely subjective evaluations used to measure treatment outcome, Leelamanit et al. (2002) do not succeed in reporting convincing evidence that their treatment protocol achieves its intended outcome.

Conclusions

This review of the rationale and existing evidence supporting therapeutic swallowing stimulation techniques has identified many unanswered questions. With specific reference to the current data on electrical stimulation of swallowing, the existing literature is insufficient to demonstrate credible evidence of validity or treatment outcomes according to the criteria in sections A and B of the U of A EBMT. In light of the absence of clear answers to those questions, it certainly seems premature to consider applying electrical stimulation techniques to those with swallowing disorders except in the context of carefully controlled research. Indeed, the data reported by Power et al. (2002) and Fraser et al. (2002) suggest that potential harm issues must be carefully considered and closely scrutinized in future electrical stimulation experiments. For the time being, we propose that electrical stimulation of the oropharyngeal swallowing process should not be adopted in clinical settings.

Author Notes

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