



SPECIAL INTEREST DIVISION 13

Swallowing and Swallowing Disorders (Dysphagia)

Frequently Asked Questions Regarding the Use of Electrical Stimulation to Treat Feeding and Swallowing Disorders in the Pediatric Population

This document was developed by the Pediatric Advisory Committee of Special Interest Division 13 (Swallowing and Swallowing Disorders) of the American Speech-Language-Hearing Association (ASHA). Members of the committee were Rita Bailey, EdD, CCC/SLP, BRS-S, Kara Fletcher, MA, CCC/SLP, Memorie Gosa, MS, CCC/SLP, Jeri L. Miller, PhD, CCC/SLP, Jeanne Saavedra, MHS, CCC/SLP, Donna Scarborough, PhD, CCC/SLP, and Claire Kane Miller, PhD, CCC/SLP BRS-S (chair). Additional information and input to the document were provided by Christy L. Ludlow, PhD, CCC/SLP. This document expresses the opinions and views of the individual authors and does not represent any official position or policy of ASHA or any ASHA Special Interest Division. Reference herein to any specific program, product, process, service, or manufacturer does not constitute or imply endorsement or recommendation by ASHA or any ASHA Special Interest Division.

1.1. What is electrical stimulation?

Electrical stimulation (commonly referred to as “e-stim” and also known as neuromuscular electrical stimulation [NMES] and transcutaneous electrical stimulation [TES]) involves the use of electrical current to stimulate the nerves or nerve endings that innervate muscle beneath the skin. Electrical stimulation may be applied superficially on the skin (transcutaneously) or directly into a muscle or muscles (intramuscularly) for the primary purpose of enhancing muscle function. The basic theoretical premise is that if the peripheral nerve can be stimulated, the resulting excitation impulse will be transmitted along the nerve to the motor endplates in the muscle, producing a muscle contraction. Therefore, patients with central nervous system abnormalities but intact peripheral nerve function may be candidates for electrical stimulation.

Historically, electrical stimulation has been used as a rehabilitation method to treat a variety of conditions, including spinal cord injuries, temporal mandibular joint dysfunction, impaired hand function, muscle spasms, muscle atrophy, incontinence, and gastroparesis, as well as for wound care and even relief of pain. Increased range of motion, improved strength, improved patterns of muscle contraction, and increased functional movements have been reported following application of electrical stimulation (Peckham, 1999).

There has been a recent surge of interest in the application of surface electrical stimulation to assist with swallowing rehabilitation. Small surface electrodes are placed on specified regions of the neck to ensure a targeted delivery of a low-voltage current to peripheral nerve endings. Subsequent excitation of the motor nerves results in contraction of muscles close to the skin surface (Ludlow, 2008).

1.2. Is the use of electrical stimulation within the scope of practice for speech-language pathologists practicing in pediatric dysphagia? What training is available for providing electrical stimulation? Does ASHA recommend the use of electrical stimulation or specific products for this technique?

The ASHA *Scope of Practice in Speech-Language Pathology* (available at www.asha.org/policy) outlines what a speech-language pathologist is trained to evaluate and treat in general terms but does not identify or recommend use of specific techniques or modalities. The ASHA Code of Ethics provides a number of guidelines, such as Principle I, Rule F: “Individuals shall fully inform the persons they serve of the nature and possible effects of services rendered and products dispensed, and they shall inform participants in research about the possible effects of their participation in research conducted.” Clinicians may also refer to Principle I, Rule G: “Individuals shall evaluate the effectiveness of services rendered and of products dispensed and shall provide services or dispense products only when benefit can be reasonably expected.” Lastly, Principle II, Rule B states, “Individuals shall engage in only those aspects of the professions that are within the scope of their competence, considering their level of education, training, and experience.”

In response to the many inquiries ASHA has received about electrical stimulation, ASHA’s National Center for Evidence-based Practice in Communication Disorders (N-CEP) is currently

completing a systematic review of evidence on the effectiveness of electrical stimulation. This review will address four key areas related to electrical stimulation and its effect on aspiration, functional swallowing outcomes, drooling/secretion management, and neurological activation during swallowing. (For more information, contact N-CEP via e-mail at ncep@asha.org.)

A number of workshops and training sessions that focus on the use of electrical stimulation are currently offered to practicing speech-language pathologists. However, to date, there is scant evidence to support the use of electrical stimulation as a treatment strategy for dysphagia in either the adult or pediatric population. ASHA is strongly committed to evidence-based practice and urges members to consider the best available evidence before utilizing any product or technique. ASHA does not endorse any products, procedures, or programs, and therefore does not have an official position on the use of electrical stimulation or specific workshops or products associated with electrical stimulation.

1.3. What information is currently available about the use of electrical stimulation to assist with swallowing function? How should requests regarding electrical stimulation be handled? How do you determine who qualifies for this technique and who is not a candidate?

The effects of electrical stimulation and its benefits as a treatment modality are current topics of interest in the field of speech-language pathology. Questions as to whether pediatric patients (defined broadly as preterm infants to children) with swallowing dysfunction as a result of neurological insult or other conditions may benefit from surface electrical stimulation remain unanswered. Empirical data regarding the effect of electrical stimulation specific to swallowing function primarily in adults are beginning to appear in peer-reviewed publications. Some of the results are conflicting, and there appears to be mixed evidence in regard to electrical stimulation's rehabilitative effects on swallowing recovery. References to studies conducted in adults are summarized at www.asha.org/slp/clinical/dysphagia/e-stim.htm. At this time, there are no published data specific to pediatrics that provide evidence supporting use of the technique as a therapeutic strategy. There are some centers that are conducting feasibility studies; however, no results have been published to date. Therefore, speech-language pathologists who receive referrals or requests to provide electrical stimulation to assist specifically with swallowing dysfunction are faced with questions for which there are no definitive answers at this time. In addition, there are currently no objective guidelines to determine which pediatric patients qualify as "candidates" for electrical stimulation to treat swallowing dysfunction.

1.4. Is it possible for there to be adverse outcomes when using electrical stimulation with children? Are there specific concerns regarding electrical stimulation in the neurologically developing infant? At what age is it safe to use the device?

Food and Drug Administration (FDA) clearance (Class 2—Special Controls) was obtained to expand the use of electrical stimulation devices to include swallowing therapy. It should be noted that the role of the FDA is limited to clearance for use of the device only. FDA clearance is only relevant to safety issues and does **not** refer to whether results of clinical trials confirm the efficacy within specific patient populations. The FDA has issued 510(k) clearance documents for only two products for stimulation in the throat area, the VitalStim battery-powered device and the Experia device (FDA, 2007). These were cleared for the indication of “Muscle re-education by application of external stimulation to the muscles necessary for pharyngeal contraction.” Neither of these products was specifically cleared for any particular population, and therefore they cover use in both adults and children. A different level of review would be required to specify the safety of use in specific populations.

According to the FDA’s *Guidance Document for Powered Muscle Stimulator 510(k)s* (FDA, 1999), caution should be used when applying powered muscle stimulators in patients with suspected or diagnosed heart problems or epilepsy, as well as following acute trauma or fracture, or recent surgical procedures.

Therefore, the advisability and possible detrimental effects of applying electrical current to a developing neurological system must be considered. Premature or medically fragile infants in the neonatal intensive care unit as well as other high-risk environments (e.g., pediatric intensive care) may have medical conditions or developmental needs that may limit the child’s candidacy for electrical stimulation therapy. In vulnerable nervous systems that are developmentally immature, the use of any electrical current without knowledge of the dynamic range of safe stimulation has the potential to result in deleterious effects. Infants who may have undiagnosed metabolic or other degenerative disease may also not be able to overcome the effect of stimulated contractions.

Further, many of these children have aerodigestive structures that are still developing (Miller, Sonies, & Macedonia, 2003) and are structurally arranged in ways very unlike adults. In Ludlow et al. (2007), patients who had reduced aspiration and penetration during swallowing with stimulation had greater hyoid depression during stimulation at rest, suggesting that electrical stimulation may act to resist adults’ hyoid elevation during swallowing. Unfortunately, there are few clear diagnostic protocols that determine aspiration in premature infants, whose structural organization and related functional movements of the hyoid in swallowing are biomechanically different than adults.

1.5. For children who are nonverbal (either because of age or cognitive level), how do you determine the strength of the input? Should the frequency of the input used in children be the same as adults?

The appropriate intensity of the electrical input for maximal effect in conjunction with overall patient comfort will vary from patient to patient, and will differ between electrodes and devices. Behavioral pain scales such as CHEOPS (Children’s Hospital of Eastern Ontario Pain Scale) or

Oucher (self-report scale) are clinical tools that subjectively assess a patient's level of pain or discomfort during any type of medical procedure. However, normative standards for premature or medically fragile patients have not been developed. This is an important issue because premature infants' response to pain, such as during heel stick procedures, may not result in audible cries. Instead, clinicians often rely on nonaudible, behavioral signs of physiological discomfort. Early research using infant animal models provides some clues that stimulation at inappropriate levels can pose risks for apnea and a variety of upper airway reactions (Sutton, Taylor, & Lindeman, 1978; Taylor, Sutton, Larson, Smith, & Lindeman, 1976). Such findings point to the need for careful and systematic research to further understand physiological responses of the entire aerodigestive system during stimulation therapy.

1.6. How is improvement measured before and after electrical stimulation treatment by clinicians researching its effects?

Published investigative reports (studying adults) cite the use of videofluoroscopic and endoscopic evaluation of swallowing before and after electrical stimulation as a means of objectively determining the degree of change or improvement with swallowing function. Though not objective, there are numerous anecdotal reports citing either swallowing improvement or no improvement of swallowing following electrical stimulation treatment. Patient testimonials have been circulated on the Web, in e-mail lists, and in published material that advocate the use of electrical stimulation for treatment of swallowing dysfunction.

1.7. Does the size of the electrode change the effects of the device? Are infants placed at greater risk for stimulating the carotid sinus? Should stimulating vasovagal responses be a concern?

A company that markets electrical stimulation for treatment of swallowing dysfunction in adults and children provides two different sizes of electrodes: pediatric, with a 1.7-cm round active area, and adult, with a 2.1-cm round active area. The number of electrodes recommended for placement with children is generally two, whereas four electrodes are recommended for adults. Various placements are described to improve swallowing dysfunction. The use of electrical stimulation in the carotid sinus area should be avoided and is a warning mentioned by the FDA (1999); though no adverse effect reports have been documented, inadvertent stimulation of the carotid sinus is known to cause unwanted fluctuations in blood pressure. Vasovagal responses are possible in adults as well as children and infants, and can be elicited as a reaction to a variety of stimuli including application of electrical stimulation. There are currently no published reports that document specific adverse outcomes associated with the use of surface electrical stimulation. There are anecdotal reports in adults of skin reddening or irritation associated with the surface electrode placement. Currently, smaller electrodes are being marketed for use in youth populations. If smaller surface electrodes are used in children at similar current levels to those used in adults, the current density may be greater given that a smaller skin surface area is being stimulated, potentially increasing the risk of adverse effects such as skin irritation or burns.

1.8. What type of research is needed to define the efficacy of electrical stimulation as a treatment technique?

Clearly, more research is necessary to determine whether electrical stimulation is beneficial in the adult populations. To date, no peer-reviewed research is available to support the use of transcutaneous electrical stimulation in children/infants. Research designs that encompass different etiologies and different treatment approaches in combination with electrical stimulation are needed. The primary focus should be on careful patient selection to ensure that electrical stimulation is being used only in situations where there is no possibility of inducing untoward effects.

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