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Editor’s Corner

Lori A. Davis

The last issue of Perspectives for 2011 is presented in a point/counterpoint format, with authors discussing positive and negative aspects of two current treatment options for dysphagia. Controversy can make us uncomfortable, but it also can make us think critically about practices that we may have unquestionably adopted and which we may want to revisit. Alternatively, controversy can be a distraction from more important questions. This Perspectives deals with two controversial interventions for patients with dysphagia: neuromuscular electrical stimulation and free water protocols.

These methods have many things in common. They are in widespread use by thousands of speech-language pathologists in the United States and elsewhere. They both have enthusiastic proponents and opponents. There is much public testimonial for each of them. In addition, their evidence bases range from equivocal to nearly nonexistent.

Jennifer Carter and Ianessa Humbert take opposing views on the use of neuromuscular electrical stimulation for treatment of dysphagia. James L. Coyle and Susan E. Langmore debate pros and cons of the free water protocol. Jeri A. Logemann concludes the issue with a discussion of evidence-based practice in relation to care of patients with dysphagia. We offer these debates to provide the readers with opposing viewpoints that are effectively presented and can be persuasive, regardless of the amount or level of evidence (including pseudo- or unscientific arguments) to support them.

This issue would not have been possible without the support and reviews from the Editorial Committee: Sheryl Amaral, Krisi Brackett, Elizabeth Callaway, Todd Coleman, James Coyle, Cindy DuBose, Jane Mertz-Garcia, Jo Puntiil-Sheltman, Dave Zirlen, and our Continuing Education Content Manager, Julie Blair.

This is my final issue of Perspectives as Editor. I appreciate the opportunity to have served Special Interest Group 13, Swallowing and Swallowing Disorders (Dysphagia) in this role, for it has truly been a fabulous learning experience. Please welcome Donna Edwards to the job for the next 3 years as she continues the tradition of providing excellence in continuing education. Suggestions from affiliates for future topics are always welcome. Please e-mail Donna at edwardsd@childrensdayton.org to share any topic suggestions or other comments.
Editor’s Note/Disclosure of Proprietary Interest: Please be advised that the author of this paper had a financial interest in the program she describes (i.e., she served as clinical dysphagia consultant to DJO Global, the manufacturer of VitalStim Therapy, on a contract basis and as VitalStim Certification course instructor for CIAO Seminars, which is not affiliated with DJO).

Point/Counterpoint: Electrical Stimulation for Dysphagia: The Argument for Electrical Stimulation for Dysphagia

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Abstract

This article is one side of the debate about the use of neuromuscular electrical stimulation (NMES or “VitalStim”) in dysphagia treatment and presents the case supporting the use of this modality. I present published results of clinical trials examining the effectiveness of NMES and acknowledge some flaws in the trials. The evidence shows that, when added to traditional therapy, NMES makes a statistically significant positive difference for a variety of traditional treatment approaches to which it may be added.

Given the body of research published in the last 10 years about the use of neuromuscular electrical stimulation (NMES or “VitalStim”) in dysphagia treatment, there is increasing acceptance in the profession that there is some impact from NMES on swallowing function. However, NMES is still not universally accepted as a treatment modality for dysphagia.

As the body of research grows, speech-language pathologists should periodically re-examine the arguments for and against the use of this modality. As with any clinical intervention, clinicians should consider the information presented on both sides of the debate and make clinical decisions that are appropriate for each patient.

In this article, I present the case for use of the NMES modality, beginning with a summary of the application of NMES in rehabilitation practice. Next, I present the published evidence demonstrating the safety of NMES in dysphagia treatment. In the discussion, I differentiate between evidence gathered through research and assertions that are not necessarily supported by the evidence. Then, I present published results of clinical trials that examined the effectiveness of NMES and acknowledge some flaws in the trials. The evidence shows that, when added to traditional therapy, NMES makes a statistically significant positive difference for a variety of traditional treatment approaches to which it may be added.

The research shows that clinicians can improve patient outcomes by adding NMES to their treatment regimes. But, is the amount of research published sufficient? To offer an answer to that question, I conclude with recommendations for future research focused on
identifying which patients will benefit most from NMES and which traditional therapy approaches are most enhanced by the addition of NMES. The future of our evidence-based practice lies in asking not “Does NMES provide benefit?” but, instead, “What combination of NMES and traditional treatments optimize treatment cost and patient benefit?”

**Evolution of NMES in Rehabilitation**

NMES is an adjunctive modality that has been added to exercise during rehabilitation by allied health professionals for decades (Hainaut & Duchateau, 1992). When using NMES, clinicians deliver electrical current through externally placed electrodes to stimulate the peripheral nerves that innervate a muscle. When of sufficient intensity, this stimulation creates an action potential, which travels through the motor neuron and evokes a muscle contraction.

Exercise without NMES initially evokes mostly type 1 (slow-twitch) muscle fibers. The therapeutic benefit of a contraction evoked by NMES is its ability to elicit the contraction of type 2 (fast-twitch) muscle fibers sooner than would be elicited during regular exercise alone (Wijting, 2011). The authors of a published review of the physical therapy literature on the use of NMES during rehabilitation concluded that the addition of NMES can “optimize recovery of muscle strength” during rehabilitation, because it “induces the activity of those motor units which are difficult to activate during voluntary contraction” (Hainaut & Duchateau, 1992, p. 110). The authors of this study and others concluded that NMES is complementary to voluntary exercise, in that it evokes a strength response critical to voluntary exercise and results in shortened rehabilitation time when used in conjunction with voluntary exercise (Hainaut & Duchateau, 1992; Paillard, 2008).

On the basis of the well-documented experience in physical therapy practice and the supporting evidence on the effectiveness of adding NMES to exercise during rehabilitation, speech-language pathologists began using NMES with a device specifically cleared by the Food and Drug Administration (FDA) in 2002 for use on the anterior neck for dysphagia treatment (Department of Health and Human Services, 2002).

**NMES and Swallowing**

Since the adoption of NMES in dysphagia treatment in 2002, much has been learned about NMES and swallowing. In this section, I describe the numerous published physiological studies that showed NMES is safe for patients and the treatment studies that documented improved patient swallowing function.

**Physiological Studies**

Any new medical treatment must be proven to be safe before it is used on patients. In the case of NMES for dysphagia treatment, there are two key questions:

1. Is it safe to apply electrical current to the anterior portion of the neck?
2. Does the addition of NMES negatively affect swallowing function?

To address general patient safety, Freed (1998) tested for changes in pulse oxymetry readings and cardiac function (heart rate, blood pressure). The treatment data she submitted to the FDA showed no adverse reactions to NMES for any of the 892 patients in the clinical trial. In subsequent treatment studies published since then (as of September 2011), there have been no reported occurrences of adverse reactions across all patient diagnoses.

However, some of the debate around the use of NMES for swallowing stems from the findings of physiology studies. For example, in one study (Ludlow et al., 2007), researchers measured hyoid movement at rest and during swallowing in patients with chronic, severe dysphagia. One of the statistically significant findings was that when NMES was applied at the maximum level tolerated by each patient, some of the 11 subjects experienced hyoid depression at rest. Because the hyoid normally elevates and protracts during a swallow, it is logical to
expect that lowering of the hyoid would increase laryngeal penetration and tracheal aspiration, thereby making swallowing function worse. However, the researchers reported "no group change in aspiration was noted on either [Penetration-Aspiration scale (Pen-Asp scale) or NIH Swallowing Safety Scale (NIH-SSS) during swallowing] scale" (Ludlow, 2007, p. 8). Instead, the evidence showed that the patients with the greatest at-rest hyoid depression had the greatest immediate improvements on the Pen-Asp scale and the NIH-SSS during swallowing. Despite the evidence showing that aspiration did not increase (and, in some cases, actually improved), the study authors assert that NMES may put patients at a greater risk of aspiration. Clinicians must consider many factors when deciding if a patient is appropriate for bolus trials, and it is inappropriate to assert that NMES puts patients at greater risk during such trials when this assertion is not supported by published data.

Another assertion that is contradicted by the evidence gathered during clinical trials but continues to cloud the debate on NMES is that, given the nature of surface NMES devices, this modality is incapable of making positive changes to swallowing function. The speculation is that some of the infrahyoid muscles that depress the hyoid receive greater stimulation than the deeper thyrohyoid muscle that elevates the larynx toward the hyoid (Ludlow, 2010). However, the muscles of swallowing work together as a system, and the impact of NMES on swallowing must be assessed as such. So, rather than teasing out which muscle is doing what in response to stimulation, researchers should choose a different, better indicator of the effectiveness of this stimulation: treatment study outcomes over the course of several treatment studies. Conclusions about treatment are most appropriately made from treatment studies.

The evidence presented in all physiological and treatment studies published to date shows that NMES is safe to use in swallowing therapy; there have been no published treatment studies documenting harm, worsening swallow function, or increased aspiration when NMES is applied during therapy.

**Treatment Studies**

It is well supported in the physical therapy literature that NMES is not a stand-alone treatment and is “not a substitute for but a complement of voluntary exercise for disused muscles” (Hainaut & Duchateau, 1992, p. 101). Given that NMES is an addition to (rather than a replacement for) traditional therapy techniques, the most appropriate question to ask with respect to the validity of using NMES in dysphagia treatment is, “Does the addition of NMES to traditional dysphagia treatment make a significant difference?”

Randomized controlled trials are regarded as the gold standard of research and can be designed to specifically address this question. To best answer the question, a randomized controlled study will compare similar groups of patients with a control group that receives traditional treatment and an experimental group that receives NMES in addition to an identical course of traditional treatment.

In the last few years, six randomized controlled trials have been published about NMES and dysphagia (Bulow, Speyer, Bajens, Woisard, & Ekberg, 2008; Lim, Lee, Lim, & Choi, 2009; Permsirivanich et al., 2009; Ryu et al., 2008; Xia et al., 2011). Of these studies, only three provided identical treatment to both the control and the experimental group with NMES being added to the experimental group (Lim et al., 2009; Ryu et al., 2008; Xia et al., 2011).

First, with respect to the studies that did not compare identical treatment, it is worth noting that some of the control groups were given isolated exercises (Bulow et al., 2008; Permsirivanich et al., 2009) and home exercise programs (Bulow et al., 2008; Lin et al., 2009) that were not given to the NMES experimental group. Despite this omission, the experimental (NMES) groups in the Permsirivanich et al. (2009) and Lin et al. (2009) studies still showed statistically significant greater improvement on some outcome measures, thereby demonstrating the effectiveness of NMES. However, it cannot be known for sure whether the difference in outcomes would have been even greater if the experimental group had received all
the treatments that the control group received. Researchers can answer this question only by comparing outcomes of identical traditional therapy with and without NMES; such studies are the subject of the remainder of this section.

In the Lim et al. (2009) study, 36 patients who were post-stroke were randomly assigned to experimental and control groups. A total of 28 patients completed the study. The control group received thermal-tactile stimulation treatment only and the experimental group received the same thermal-tactile stimulation treatment with the addition of NMES. The groups were statistically similar with regard to stroke type, location of lesion, number of months since onset, and initial swallow score. Thermal-tactile stimulation alone has not been found to be effective in past clinical trials and, not surprisingly, the slight improvements in swallowing function noted in the control group were not statistically significant. However, the experimental group with NMES added to thermal-tactile stimulation therapy did make statistically significant changes on the Pen-Asp scale and pharyngeal transit time. This study is worth noting because, even when NMES was combined with less-than-ideal traditional treatment, the researchers observed statistically significant improvements in swallowing measures.

In Ryu et al. (2008)’s prospective, double-blind case control study, 46 patients following head and neck cancer treatment were randomly assigned to either a control group of traditional therapy with sham stimulation (low-intensity transcutaneous electrical nerve stimulation [TENS]) or an experimental group of traditional therapy plus NMES (VitalStim). A total of 26 patients completed the study. After 2 weeks of treatment, the experimental group made statistically significant greater improvements on the functional dysphagia scale (FDS) compared to performance by the control group.

In the largest of the randomized controlled trials to date (Xia et al., 2011), the researchers assessed 120 patients who were post-stroke with dysphagia and randomly assigned to one of three groups: traditional swallowing therapy alone, NMES alone, or NMES plus traditional swallowing therapy. There were no statistically significant differences in age, time since onset, or severity of the dysphagia among the groups. Outcomes were measured with a standardized swallowing assessment (SSA), maximum amplitude of surface electromyography (sEMG) when swallowing 2 milliliters of water, a videofluoroscopic swallowing study (VFSS), and the swallowing-related quality of life (SWAL-QOL) questionnaire. Because all patients were less than 2 weeks post-onset of dysphagia, it is to be expected that all groups would make some degree of progress through spontaneous recovery. However, the experimental group, which received NMES added to traditional therapy, made statistically significant greater improvements in all four outcome measures. No significant difference was noted between groups receiving the therapy alone and those receiving NMES alone. This study demonstrates that the addition of NMES to traditional therapy resulted in better patient outcomes than did traditional therapy alone.

Though all of the studies presented above are randomized controlled trials, each study deviates from the ideal. In an ideal study, the control group and experimental group would have received identical and appropriate traditional therapy with and without the addition of NMES. An ideal study would also be limited to patients who were several months post-onset to eliminate the spontaneous recovery element. And, as any researcher will attest, an ideal study will include more patients.

Do clinicians have to wait for the publication of a perfectly designed, large, randomized controlled study before adopting a treatment intervention? Much of the debate about the use of NMES in dysphagia treatment stems from differences of opinion regarding how much research is needed. In an examination of evidence-based practice in general, Dollaghan (2004) noted that, because “few studies meet all the critical appraisal criteria, reasonable people can disagree about the quality of evidence from a particular study, making it important for individuals to think independently about the validity, importance, and precision of results from empirical studies as a prelude to applying them to clinical care.”
When one examines past research, it becomes apparent that, for many other treatment techniques, the research is limited to just a handful of studies. When deciding how much research must be published about NMES and dysphagia treatment for it to be evidenced-based practice, clinicians should hold NMES to the same standard as other already accepted treatments. Given the limited research supporting many traditional therapy techniques, clinicians have needed to apply all elements of evidence-based practice, research, clinician experience, and patient experience to make therapeutic decisions. The same should be done for the use of NMES.

The existing studies on adding NMES to treatment for dysphagia—however imperfect—represent the current state of the practice and encompass more evidence than is available for many traditional treatment techniques. It is time for researchers to move past asking if NMES should be used and begin answering questions of when and how NMES can best be used to achieve treatment goals.

**Moving Forward**

No matter how many studies are published about NMES and dysphagia treatment, or any other clinical intervention, there will always be questions to be answered with further research. Such research is how our evidence-based practice advances; without it, our profession would stagnate, and we would simply continue to do what we’ve always done.

**Cost-Benefit Analysis**

As in many industries, medical professionals are increasingly asked to do more with less. With hospital stays shortening and outpatient insurance benefits shrinking, clinicians need to be mindful of ways to increase the effectiveness of treatment to obtain greater outcomes in less time and at lower cost. More effective treatments can lead to a decreased number of sessions and, thus, a decreased cost to achieve the desired outcome.

Research in physical therapy has already shown that NMES leads to shorter lengths of rehabilitation, so a cost-benefit analysis of NMES treatment for dysphagia appears warranted. An ideal study would quantify not only the costs associated with therapy time, devices, and consumables, but also track the benefits associated with—and other costs avoided by—accelerated recoveries and improved outcomes. Until such an ambitious study to this effect can be completed, clinicians should track outcomes with their clients to quantify the “clinician experience” portion of the evidence-based practice triad. By doing so, clinicians can start to identify which treatments are most cost-effective and tend to produce the greatest outcomes in the shortest amount of time.

**The Complementary Nature of Traditional and NMES Modalities**

Given the nature of NMES as an adjunctive modality, perhaps the most important clinical question to answer moving forward is how to define the best treatment intervention to provide while the NMES is being applied. The wide range of treatments that have been seen in the NMES research thus far is likely a reflection of the fact that no single best or most effective dysphagia treatment in general has been determined. However, the broad range of interventions applied during NMES in the studies that show a statistically significant difference suggests that adding NMES to a variety of treatments can still increase the effectiveness of a particular treatment. So, clinicians can use NMES in treatment without having to wait for the ideal research study to document the perfect treatment to use in conjunction with NMES.

This argument supporting the use of NMES as a treatment tool for dysphagia in no way suggests that NMES should be used with all patients. Like all other speech-language pathology treatment tools, the use of NMES is not a panacea that will work for all patient types. No matter how sound the evidence supporting the use of NMES, as with all treatment interventions, clinicians must always apply clinical judgment to the decision-making process. In the case of NMES, the clinician must evaluate the published evidence as well as the patient’s condition, symptoms, and needs in determining how (or if) NMES can provide benefit to that
patient. As the body of published research continues to grow, a fresh review (and perhaps another debate) will continue to advance the state of the profession to the benefit of all.

References


Point/Counterpoint: Electrical Stimulation for Dysphagia: The Argument Against Electrical Stimulation for Dysphagia

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Abstract

Surface electrical stimulation for dysphagia is still a controversial subject. Some studies tout the benefits of using electrical stimulation (e-stim) for improving a disordered swallow. It is important to ensure that the discussion about e-stim is balanced. In this article, I discuss selected counterpoints, including e-stim’s intended use, the objective findings of scientific findings, and whether speech-language pathology training in the area of swallowing anatomy and physiology adequately prepares clinicians to use e-stim for dysphagia. Overall, clinicians are urged to take into account all sides of this debate and make educated decisions about whether it should be a part of their clinical practice.

In this article, I will discuss three points that support the argument against the use of electrical stimulation (e-stim) for dysphagia:

- **Point 1:** The intended clinical use of e-stim for swallowing is not clear.
- **Point 2:** Objective, scientific findings do not support e-stim’s marketed outcomes.
- **Point 3:** Speech-language pathologists’ (SLP) training in swallowing is insufficient for most physiologically based treatments for dysphagia.

Unclear Clinical Use of E-Stim

What is the intended use of e-stim for dysphagia? Can anyone clearly summarize it? There are many vague hypotheses, such as “to improve swallowing,” or “to increase oral intake of food,” or “because nothing else worked, and we were desperate.”

The problem is that e-stim for swallowing (like compensatory strategies) should serve a specific purpose. For example, many patients aspirate on thin liquids because of delayed onset of the pharyngeal swallow response. When a clinician recommends replacing thin liquids with thickened liquids for such a patient, the expected outcome (reduced aspiration) and rationale (thickened liquids move more slowly, thereby minimizing the negative effects of a delayed response to the bolus) are fairly well known and logical.

Now, let’s consider this same patient diagnosis (delayed onset of the pharyngeal swallow resulting in aspiration on thin liquids) with respect to e-stim. Under what circumstances would you decide that e-stim is appropriate? What stimulation intensity would be appropriate? What electrode array would be most likely to succeed? Should the patient actively swallow during this time or engage in non-swallowing, if any, activities? What about patient selection; is e-stim likely to be more useful for individuals with particular diagnoses? To answer any of these questions, one first has to determine the physiological cause of the diagnosis. In other words,
why is the patient’s pharyngeal phase so delayed? This is a question that is not completely understood by swallowing experts. So, when there is uncertainty about the cause of the diagnosis, why should a clinician apply electrical stimulation (an additional unknown entity) to the equation without first pursuing some logical thought process about its intended use and identifying a clear rationale for why it should be successful?

What is the marketed intended use of e-stim by VitalStim®? Currently, the most commonly used device for delivering e-stim in a clinical setting is VitalStim®. The manufacturer’s website includes a description of e-stim’s intended use:

   The VitalStim® Therapy System is an adjunctive modality to traditional exercise that unites the power of electrical stimulation with the benefits of swallowing exercises. Combining VitalStim and traditional therapy allows clinicians to accelerate strengthening, restore function, and help the brain remap the swallow. Research has demonstrated that combining these therapies results in better outcomes than using either one alone. (VitalStim Dysphagia, 2011)

These strong claims give rise to many questions. What exactly is the “power” of e-stim? How does the brain “remap” a swallow? Though some studies have reported that e-stim is beneficial, others show that it is either not beneficial or produces outcomes no different from those produced by traditional swallowing treatment alone (discussed further below). Also, studies that report cortical mapping after e-stim involve highly technical methodologies (neural stimulation and imaging) after direct stimulation of the pharyngeal mucosa in patients (Jayasekeran et al., 2010). On the other hand, Gallas, Marie, Leroi, and Verin (2010) found no differences in cortical mapping in patients after submental electrical stimulation.

What is the intended use of electrical stimulation (e-stim) in other fields? E-stim is widely used and accepted in the field of physical therapy. In fact, the Federation of State Boards of Physical Therapy (FSBPT), which develops and administers the National Physical Therapy Examination, includes content on the use of e-stim for physical therapy as part of the exam’s Therapeutic Modalities section (FSBPT, 2007, 2010). Its intended use in physical therapy is broadly defined and includes pain management (Fuentes, Armijo Olivo, Magee, & Gross, 2010), improving function after spinal injury (Gater, Dolbow, Tsui, & Gorgey, 2011), avoiding atrophy after paralysis (Gater et al., 2011; Needham, Truong, & Fan, 2009), and improving strength (Monaghan, Caulfield, & O’Mathuna, 2010). Despite extensive published research on e-stim for these purposes, meta-analyses and systematic reviews (that combine the results of several studies to draw one larger conclusion about a treatment) report inconsistent evidence of the benefits of e-stim for pain, strengthening, or post-stroke hemiparesis (Ada, Dorsch, & Canning, 2006; Bax, Staes, & Verhagen, 2005; Fuentes et al., 2010; Glanz, Klawansky, Stason, Berkey, & Chalmers, 1996; Mello, Nobrega, & Lemos, 2011; Scianni, Butler, Ada, & Teixeira-Salmela, 2009). Of course, e-stim is not the only widely used treatment in any particular field that does not have strong scientific evidence to support its use. This treatment conundrum probably exists in all clinical fields. However, the difference between a PT’s use of e-stim and an SLP’s use of e-stim, at this time, appears to be reflected in the professional’s time, clinical experience, educational preparation, and clear goals for its intended use based on a thorough understanding of the complex system being treated (more about SLP preparation in Point 3 below).

It is critical that the clinician establish the goals of applying e-stim before using it. One requires a clear dysphagia diagnosis, an understanding of the cause for the pathology, and a working knowledge of e-stim’s ability to reduce the pathology, along with the expected clinical outcomes. Actually, this should be the case when the clinician considers any dysphagia treatment. At this time, e-stim is being marketed to clinicians and patients with strong claims of its benefits. In another rehabilitation discipline, physical therapy, e-stim is considered to be a standard treatment modality; numerous scientific studies have been carried out on the topic, yet conflicting evidence of its outcomes remains. The fields of both speech-language pathology and physical therapy will continue to advance their scientific and clinical pursuits for answers
about e-stim as a treatment. Though published evidence related to e-stim use has not been conclusive, clinicians will continue to use e-stim for dysphagia; therefore, they are cautioned to do so thoughtfully.

**Lack of Evidence-Based Support**

The second point I want to make is that objective, scientific findings do not support e-stim’s marketed outcomes.

The VitalStim® company reports that e-stim will “accelerate strengthening, restore function, and help the brain remap the swallow” (VitalStim Dysphagia, 2011). E-stim for dysphagia has been an intriguing and controversial subject ever since it was first advertised for dysphagia treatment. However, the excitement surrounding the potential of a new treatment should not overshadow the importance of learning about both sides of the argument, which includes benefits as well as risks.

To date, the studies that have been published on the effects of e-stim on swallowing have been conducted in healthy individuals and individuals with dysphagia over both short- and long-term periods. Short-term studies in healthy individuals and adults with dysphagia typically examine the immediate physiological effects of e-stim on the neck and/or the submental region. In summary, short-term physiological studies in healthy individuals and patients report hyo-laryngeal descent when stimulation induces muscle contractions in the anterior neck. Also, when swallowing with concurrent stimulation that causes a muscle contraction, healthy adults and patients had significantly reduced hyo-laryngeal elevation (Humbert et al., 2006; Ludlow et al., 2007). The clinician who does not understand why hyo-laryngeal descent occurs needs to seek out more information about the principles of surface e-stim and about swallowing anatomy and physiology. This finding directly contradicts the information in the VitalStim® training manual, which states that significant laryngeal elevation is expected within the first e-stim session in patients (Wijting & Freed, 2003).

The online, marketed information also lists benefits reported in long-term studies, including that e-stim is safe and effective for patients (Carnaby-Mann & Crary, 2007); accelerates the recovery time from a restricted diet (Blumenfeld, Hahn, Lepage, Leonard, & Belafsky, 2006); and helps patients achieve sustained improvement and long-term results, even when traditional therapy alone has not been effective. However, other studies do not report the same benefits (Bulow, Speyer, Baijens, Woisard, & Ekberg, 2008; Freed, Freed, Chatburn, & Christian, 2001; Kiger, Brown, & Watkins, 2006). Many studies are limited by a small sample size (< 40 patients) and/or the presence of heterogeneous etiologies of dysphagia, lack of a control or comparison group, and a focus on functional measures as the primary outcome. Functional measures (oral intake, weight gain) are important indicators of success. However, they cannot be directly tied to e-stim as the cause for such changes, unless physiological measures (i.e., timing and range of motion of the structures involved in swallowing) are considered alongside functional gains. After all, physiology is responsible for bolus flow.

For instance, a study that compares two treatments (Treatment A and Treatment B) at two time points (1 week and 8 weeks post-stroke) might show that, at 1 week, all patients are on a restricted diet or *nil per os* (NPO). This outcome is functional (diet). If, after 8 weeks of treatment, one patient group has a diet that is significantly improved and the other’s has not changed much, then one might conclude that the treatment with the most significant improvement in oral intake is superior. But, suppose the physiological changes between the two groups are identical, meaning that neither treatment affected the disordered physiology (i.e., laryngeal movement, delayed swallow)? What explains this change in oral intake? Because rehabilitative swallowing treatments, such as e-stim, are expected to improve swallowing physiology and, thus, improve bolus flow, the physiological effects must be measured before one can claim strong benefits have been achieved. In addition, diet changes are subjective.
measures and, therefore, difficult to standardize. Therefore, researchers should be cautious in drawing conclusions of improvement based on their e-stim studies, unless those studies include (a) an appropriate control group, (b) an objective physiological measure that can explain the more subjective outcome measures such as oral intake, and (c) explicitly stated means for minimizing investigator biases by ensuring that subjective decisions (recommending a less restrictive diet) are reached without the researcher’s knowledge of the patients’ treatment groups. In an evidence-based systematic review of e-stim for swallowing, Clark, Lazarus, Arvedson, Schooling, and Frymark concluded that 10 of the 14 studies on this topic were exploratory, with significant methodological flaws, and that more high-quality studies are needed before firm conclusions can be made (Clark et al., 2009).

New dysphagia treatments offer clinicians and clients hope that the complexities of the pharyngeal phase of swallowing can be addressed and impairments remedied. Because improving a patient’s swallowing ability is an urgent goal, clinicians usually recommend compensatory techniques (bolus change, postural adjustments) or rehabilitation options that have emerged into clinical practice ahead of supportive, empirical evidence. This is because the scientific process often moves more slowly than the influx of patients with conditions that lead to dysphagia with immediate needs. So, it is not surprising that treatments are applied though scientific evidence is unsupportive or conflicting. As mentioned before, speech-language pathology is not the only field with such a dilemma. Nonetheless, the onus is upon each clinician who uses e-stim to determine both the benefits and risks before administering it to patients.

**Insufficient Training in Physiology**

The third point I will discuss is that SLP training in swallowing is insufficient for most physiologically based treatments for dysphagia.

The training and education for SLPs who want to focus on swallowing and swallowing disorders as part of a medical model is limited, even though it is within the scope of the SLP’s practice. The curriculum for speech-language pathology requires high linguistic content to prepare graduates to practice in educational settings (articulation and phonology, aural rehabilitation, child language and development, literacy, language and learning). There is some content on the sensory-motor based systems (fluency and fluency disorders, voice and voice disorders, swallowing and swallowing disorders), although these might not be taught strictly from a medical perspective. Taken together, these required topics are broad, and many do not directly facilitate learning about swallowing. Furthermore, the required neurophysiology and anatomy and physiology courses, some at the undergraduate level, focus on speech, language, and hearing systems and rarely delve into swallowing physiology.

Recently, the American Speech-Language-Hearing Association (ASHA) outlined requirements for dysphagia content for the graduate curriculum (2007). However, this does not affect SLPs who have been practicing for many years—our most seasoned clinicians. The 2005 Omnibus survey reported that approximately 87% of respondents self-identified as primary care providers of dysphagia services (ASHA, 2005).

The anatomy in the neck is complex and the swallowing sensorimotor system (particularly its neurophysiology) is not thoroughly understood. Muscles in the neck and face are small, interdigitated, in close proximity to one another or superimposed upon one another, and may serve different functions depending upon the task. Surface e-stim activates all tissues that can be stimulated in its electrical current and, thus, lacks specificity. This is particularly challenging for stimulating muscles of the anterior neck and submental regions, because a nonspecific electrical field can activate so many diversely functioning muscles (although research, to date, points to one primary outcome: hyo-laryngeal descent). In other words, when stimulating muscles on the neck, clinicians should be aware that they could be stimulating many different muscles, because the electrical current is likely larger than any single
superficial muscle in the neck. Before any clinical use of e-stim is initiated, it is imperative that clinicians have a solid understanding of normal swallowing anatomy and physiology.

The limited training in swallowing can be a potential constraint for even the accepted swallowing treatments or compensatory mechanisms. For instance, the clinician must understand the structural changes in the upper-aerodigestive tract caused by a head turn to the right or to the left before he/she chooses this technique. Studies show that a sour bolus and biofeedback can change swallowing kinematics (Ding, Logemann, Larson, & Rademaker, 2003) and are also associated with different cortical patterns of activity during swallowing (Humbert & Joel, 2011). There are abundant continuing education opportunities for clinicians who are interested in increasing their knowledge of swallowing physiology, neurophysiology, and electrical stimulation. However, much of what has been published, even if read and thoroughly understood, does not answer many of the critical questions (discussed in Point 1, above) about e-stim for swallowing. Therefore, given the limited professional training on swallowing, clinicians’ limited understanding of the principles of e-stim, and limited scientific evidence about e-stim’s physiological outcomes in patients, widespread, liberal use of e-stim in a clinical setting is contraindicated. One would not recommend a chin tuck to every dysphagia patient without considering whether it is appropriate. The choice of e-stim should be made with even greater caution because it is more complex than many compensatory strategies; because e-stim has the potential to alter function (for better or for worse), the clinician should possess substantial knowledge about swallowing physiology to avoid potential negative outcomes (i.e., hyo-laryngeal descent).

Summary

E-stim for swallowing is a controversial topic. Studies show that it has the potential to immediately alter swallowing physiology, although the outcomes were not positive. Many long-term, therapeutic studies in patients have not been carried out in a scientifically rigorous manner, thereby limiting researchers’ ability to draw conclusions of beneficial outcomes for swallowing. Although e-stim for swallowing has many studies dedicated to it, its intended use is largely undefined in the clinical and scientific realms. Some continue to make general claims about its ability to improve swallowing. All of these circumstances likely exist because of limited understanding about swallowing in both the scientific literature and clinical practice. Swallowing is a complex function, is more challenging to study compared to the limbs, and has been steadily gaining attention only in recent decades. The principles of e-stim are to be reconsidered when applying it to the neck versus the quadriceps because swallowing muscles are small and multifunctional. Therefore, clinicians are cautioned about the marketing of e-stim’s benefits in isolation. Take into account all sides of this debate and make an educated decision about whether it should be a part of your clinical practice.

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Water, Water Everywhere, But Why? Argument Against Free Water Protocols

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Free water protocols have become common in the management of patients with dysphagia. Their popularity has blossomed in the near-complete absence of any empirical data regarding their safety, efficacy and effectiveness. Proponents point to anecdotal reports and opinion pieces, while recent peer-reviewed investigation shows a mixed bag of safety and efficacy outcomes. This paper presents the argument against administration of “free water” without consideration of numerous factors besides the presence of dysphagia, and strongly urges the developers of the method to submit their data to peer review.

Fads, Science, and Protocols

Water, water, every where,
And all the boards did shrink;
Water, water, every where,
Nor any drop to drink.
—Excerpt from “The Rime of the Ancient Mariner” by Samuel Taylor Coleridge (1798)

Numerous web pages and magazine articles describe the fantastic benefits of various fads, including weight-loss methods, hair-loss remedies, and wrinkle-removal methods. Yet, particularly as we age, we continue to suffer from obesity, baldness, and wrinkles. Consumers are attracted to these remedies because they want to be able to take a pill to make the problem go away. Some of these fads are fueled primarily by the manufacturers’ desire for financial gain and reflect a growing trend to market health products directly to the consumer. Consumers now go to their physicians or other health-care providers and ask for the pill they heard about on TV or the Internet. Like the client, the speech-language pathologist (SLP) is bombarded by non-scientific information about products and clinical treatments. Magazine articles and web pages feature descriptions of the popular water protocol and its purported benefits. One striking similarity exists between these fad remedies and the popular water protocol: a lack of scientific evidence supporting their use.

It is understandable that a layperson, who wants to lose weight but may have little understanding of scientific methods, could be convinced by advertising and testimonials about the effectiveness of a weight-loss method. But, it is not appropriate for health-care professionals to employ methods that are not scientifically based. SLPs are ethically obligated to use evidence-based methods of clinical decision-making. This process requires the blending of best clinical evidence with sound clinical judgment and patient values and expectations. Yet, thousands of clinicians in the United States employ the popular water protocol without evidence of its safety, efficacy, or effectiveness.
A protocol is defined by Webster’s as “a detailed plan of a scientific or medical experiment, treatment, or procedure” (Merriam-Webster, 2011). Medical protocols typically include criteria for eligibility, rules and criteria for decision-making at each step of the procedure, and end-points for termination of the protocol; they are developed from a deep base of evidence that benefits significantly outweigh risks. An excellent example is the protocol-guided ventilator weaning (Alia & Esteban, 1999; Girard & Ely, 2008). Adoption of clinical methods without sufficient scientific justification does not make sense if we are what we claim to be: health-care professionals.

**Free Water Protocol Arguments**

When looking westward, I beheld
A something in the sky. (Coleridge, 1798)

The popular *free water protocol* has been in existence for more than 25 years. It was developed from observations of patient and caregiver inconvenience and noncompliance with thickened liquid preparation and recommendations. The developers listed why the protocol was created:

- People need water, and people with dysphagia will be more hydrated if they are allowed to drink water even if they aspirate it.
- People don’t comply with thick liquid recommendations; people like water better than thick liquids.
- Water is safe to aspirate because it passes out of the alveoli without adverse events.

Later, after good evidence was published (Langmore et al., 1998), this protocol added another component: aggressive oral hygiene.

Bits and pieces of evidence about the safety of bronchoalveolar lavage, the detrimental effects of dehydration, and quality-of-life issues were strung together to justify these beliefs. The main literature-based justification provided by free water protocol proponents has been a small study by Garon, Engle, and Ormiston (1997). This study investigated two groups of 10 patients each—one assigned to thick liquids and the other to the water protocol (sans oral hygiene). After 30 days, follow-up revealed no differences between groups in pneumonia, hydration, and complications and no significant difference in fluid intake. The only significant difference was that control patients drank more thickened liquids than did water-protocol patients, which is not surprising because that is all they were allowed to drink (Garon et al., 1997).

It is interesting to note that the study’s abstract states, “Until further larger scale research utilizing water intake with known aspirators is conducted, it is recommended that water (and ice chips) be given presently only in instances of patient refusal to drink thickened liquids or when hydration issues cause medical concern” (Garon et al., 1997). The only popular dysphagia treatment method with less underlying scientific evidence is deep pharyngeal neuromuscular stimulation, for which there are no published studies.

Thick liquids are the primary comparison intervention used by water protocol proponents, almost as if they consider thick liquids the only intervention for prandial aspiration. It is like giving a pill. Replace the aspirated thin liquid with a thick liquid and tell the patient that she/he must drink it. Prescribing a pill to solve a health problem is an attractive option because it requires no active patient participation and is easy for the clinician to employ. People do not have to exercise and eat healthy foods to prevent heart attack and stroke due to hypercholesterolemia. They can simply take the pill and continue to eat ice cream and bacon—a very attractive alternative. Speech-language pathology evolved as a rehabilitative profession, one whose practice requires the patient’s active participation to restore effective communication. There has never been a speech pill. Why have we so quickly forgotten about active intervention?
Reasons for Development

Compliance

And all at once their breath drew in,
As they were drinking all. (Coleridge, 1798)

The water protocol has been suggested for several main reasons. First, patients prescribed thickened liquids were observed to be less than compliant. If patients prescribed thick liquids do not see an immediate benefit in their comfort or other indices of improved swallowing function or health due to thick liquids, their motivation to continue using them quickly dissipates, and noncompliance with an intervention renders the intervention useless (Panther, 2005). They also correctly point to evidence that patients prescribed thickened liquids do not like them or want to drink them (Garcia, Chambers, & Molander, 2005; Karagiannis, Chivers, & Karagiannis, 2011; Whelan, 2001). Thick liquids are the only comparison to the water protocol that we read about. When did we stop involving patients in learning to protect the airway and participate actively in their own health maintenance?

Quality of Life

My lips were wet, my throat was cold,
My garments all were dank;
Sure I had drunken in my dreams,
And still my body drank. (Coleridge, 1798)

A second justification put forth in favor of the water protocol is quality of life. Well, it is true that patients just prefer thin liquids over thick liquids. Using a neutral inflection pattern, I ask each of my patients who are prescribed thickened liquids, “How do you like that?” They do not. Patient expectations, values, and preferences are top priorities in evidence-based clinical decision-making. However, is this scenario sufficient to justify allowing the unlimited aspiration of thin liquids? Perhaps I should stop performing swallow studies and simply eliminate the use of thick liquids for all referred patients who don’t like them. This would improve my productivity immensely.

Hydration

And every tongue, through utter drought,
Was withered at the root;
We could not speak, no more than if
We had been choked with soot. (Coleridge, 1798)

The third reason the water protocol has been advocated is hydration. The human body needs water; this is true. The average adult requires more than 2 liters of water per day to remain healthy. It has been suggested that, due to some properties of the thickening agent itself, thickened liquids dehydrate the consumer. This has been shown to be a false assumption. Artificially thickened liquids are absorbed 95% as completely as are thin liquids (Sharpe, Ward, Cichero, Sopade, & Halley, 2007).

Safety

Like one that hath been seven days drowned
My body lay afloat . . . (Coleridge, 1798)

A fourth justification is safety and the absence of negative consequences of alveolar water aspiration; this argument was expressed as, “Aspiration of water is a benign event—we’ve known that for quite some time” (Mosheim, 2006). Water in small amounts is easily absorbed through small specialized proteins in the alveolar epithelium called aquaporins. These specialized channels in alveolar epithelium enable transfer of water between capillaries and airspace within the alveoli. In small amounts, clearance of water into the circulatory system
has no consequence. If larger volumes of water enter the circulatory system in a short period of
time, as in the near-drowning scenario, the blood becomes diluted (or hypotonic), causing the
red blood cells to take on water. Hemolysis, the bursting of the red blood cells, can occur if
sufficient dilution of plasma takes place (de Boer, Biewenga, Kuipers, & den Otter, 1970;
Gbaanador et al., 1992; Tsokos, Cains, & Byard, 2008).

Aspirated water is less likely to cause dangerous consequences than are most other
liquids that humans consume, which are typically hypertonic solutions (fluids containing a
lower concentration of water than contained in the blood on the other side of the respiratory
membrane) or are more acidic or alkaline than water. Hypertonic, irritant solutions (and those
of a high or low pH, containing pathogens, proteins, or other large molecules) that are
aspirated cause a rapid influx of water from the blood into the alveoli, thereby adding to the
aspirated infiltrate’s volume and obstructing respiration within those alveoli. So, it is correct to
say that water aspiration is safer than is aspiration of other dietary fluids.

Causes for Jumping On or Off the Bandwagon

God save thee, ancient Mariner,
From the fiends that plague thee thus! (Coleridge, 1798)

At the 2008 annual Convention of the American Speech-Language-Hearing Association
(ASHA), two technical sessions described research on free water protocols. These sessions had
been accepted following a peer-review process. One, a retrospective intervention trial, compared
previously treated patients who had completed a water protocol to two groups of patients who
did not participate in a water protocol (one concurrent, the other an historical control); the
water protocol patients were found to have lower pneumonia incidence than non–water-
protocol patients had (Bronson-Lowe et al., 2008). It is interesting to note that there was no
difference in fluid intake between groups, which suggested that the availability of water did not
result in more water drinking. Clinicians should consider the limitations of the nonrandomized,
retrospective nature of this study, including the unbalanced representation of diagnoses
between groups.

A second prospective, randomized study was presented by Becker, Tews, and Lemke
(2008). These investigators randomly assigned 26 patients who were dysphagic and aspirating
liquids to prescribed thickened dietary liquids or the water protocol. The study’s design was
clean, investigators were blinded, and, although the sample size was small, the quality of
evidence was very good. All patients received aggressive oral care and were followed to observe
incidence of pneumonia and urinary tract infections (UTIs), fluid intake, and mortality. One
patient in each group developed pneumonia, and two in each group developed UTIs. It is
interesting to note that patients who were able to get their own drinks of water drank
significantly less than those who were dependent on caregivers to offer it to them. Two patients
in the water protocol group died. The fact that mortality occurred in patients treated with this
method cannot be ignored. In both cases, the patients had pulmonary disease, but the
inclusion criteria for the protocol were the same as advocated by the protocol’s developers at
the time of the study; this underscores the importance of the clinician’s exercising good
judgment and carefully weighing risks, in lieu of following a protocol.

Very recently, two studies were published on this controversial method. In one, 6 of the
42 patients randomly assigned to a free water protocol developed pneumonia or respiratory
symptoms, compared to none of the patients assigned to the thickened-liquid-only control
group (Karagiannis et al., 2011). In the other study, no adverse events were observed in either
water protocol patients or controls (Carlaw et al., 2011). Both studies showed that water
protocol patients received slightly more hydrating fluids while on the water protocol. Conflicting
findings with different designs produce sources of uncertainty that clinicians must wade
through when making important decisions about intervention methods for their patients.
Alternate Methods

There passed a weary time. Each throat
Was parched, and glazed each eye (Coleridge, 1798)

In patients with dysphagia, we are attempting to accomplish two goals: (a) restoration of nutrition and hydration and (b) prevention of adverse events. Pneumonia prevention is extremely important. As an example, individuals after stroke who develop pneumonia following onset have a seven-fold higher risk of dying, compared to those who remain free of pneumonia (Katzan, Cebul, Husak, Dawson, & Baker, 2003). The addition of oral hygiene to water protocol methods acknowledges the preventive role of decreasing oral bacterial populations and should be applauded. But, because no controlled studies have been published either before or after the inclusion of aggressive oral hygiene (and all evidence to date is anecdotal), we really do not know whether oral hygiene alone would provide the protective benefits purported by water-protocol proponents. Because the water-protocol purveyors have yet to publish a study and are currently treating so many patients, and because there is plenty of evidence supporting oral hygiene in the prevention of pneumonia (Adachi, Ishihara, Abe, & Okuda, 2007; Azarpazhooh & Leake, 2006; Garcia, 2005; Senpuku et al., 2003), a recommended randomized trial might include water protocol with aggressive oral hygiene, versus ordinary care with aggressive oral hygiene, versus water-protocol with ordinary oral hygiene. That study would be an important addition to our evidence base.

Hydration and nutrition restoration is the other goal mentioned above. Again, in the population that has suffered a stroke, as an example, other methods to restore intake have been investigated in the early post-onset period. Individuals who receive enteral supplementation after stroke onset consume significantly more fluids, protein, and nutrients that provide energy than consumed by those who do not receive enteral supplementation. Energy is badly needed in the rehabilitative process (Foley, Finestone, Woodbury, Teasell, & Greene, 2006). Likewise, patients after stroke given intravenous or enteral fluids have significantly more fluid intake than do those dependent on oral means alone (Finestone, Foley, Woodbury, & Greene-Finestone, 2001). Unlike in the United States, in other countries, hypodermoclysis, the method of subcutaneous water injection, has been in widespread use in the treatment of mild to moderate dehydration (Remington & Hultman, 2007). This method has been investigated for decades and found to carry absolutely no risks associated with the aspiration of oral contents. Other methods of restoring nutrition and hydration have been investigated, but water-protocol methods have not. We deserve evidence regarding the exact effectiveness and efficacy of this method.

Summary

Wisdom comes from evidence and not from belief. If we do not become wiser and make increasingly better decisions as our careers progress, we miss important opportunities to improve care to our patients. We cannot disregard the importance of good, solid evidence in our clinical decision-making in the interest of expediency. It is not enough to say that a randomized study cannot now be conducted because the free water protocol has been in existence for years. Unlike the overwhelming majority of medical treatments, the current version of clinical water protocols originated without a single published study demonstrating its efficacy or safety. There is plenty of evidence that water, hydration, and patient choice and satisfaction are all good things. There is also evidence that some aspirating patients have died when placed on the water protocol. Likewise, if we cause dehydration or renal failure by prescribing thick liquids because we think we are preventing aspiration, what have we gained? We need to strike a balance when deciding whether a patient is a good candidate for unlimited water or its alternatives, and a “protocol” does not take into consideration the numerous individual risk
factors within each individual patient. When a patient asks, “Will I be better off on this protocol?” we are obligated to answer him/her using evidence.

The claims of reported pneumonia rates in patients who aspirate while assigned to free water protocols are not credible. In a *Perspectives* article a few years ago, the author reported that, based on anectodal evidence, the incidence of pneumonia in patients treated with the water protocol was 2/234 patients or less than 1% (Panther, 2005). Stroke-related pneumonia incidence was reported as 10.5% (Chumbler et al., 2010) and, in other groups of people with dysphagia, 11–22% (Langmore et al., 1998; Robbins et al., 2008). If these figures are accurate, then the free water protocol is a miracle preventive cure for dysphagia-related pneumonia. Of course, this is a silly argument; it is impossible that pneumonia incidence in patients with dysphagia can be is reduced by 90% by drinking unlimited water, yet that is the assertion, based on anedotcal retrospective observations by the method’s developers.

If it is true that people with dysphagia who aspirate and drink unlimited water are equally as well-off as those who do not, then, naturally, we want them to have water. Developers of medical “protocols” are obligated to produce evidence supporting their claims. Maybe, there is no difference between free water and ordinary care. If that is the case, we all need to know that. However, the fact that two treated patients in a water protocol study died should serve as a warning that we must think clearly about which patients we select for these protocols. Whether it is a free water protocol or electrical stimulation, medical procedures must be prescribed on the basis of a reasonable expectation the patient will benefit from, not be harmed by, the treatment. That expectation comes from scientific evidence, which we combine with our clinical judgment. Either alone is insufficient justification, and both together must be understood and approved by the patient to complete the circle of evidence-based practice. All interventions have advantages and disadvantages, risks and benefits. No method has just advantages and benefits. *Caveat emptor,* let the buyer beware. Let’s let evidence prevail.

He went like one that hath been stunned,
And is of sense forlorn:
A sadder and a wiser man
He rose the morrow morn. (Coleridge, 1798)

References


Why I Like the Free Water Protocol

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Abstract

In this opinion piece, I present my major reasons for advocating for the free water protocol (FWP). Although there is a lack of strong direct evidence in support of the FWP, there are multiple bits of indirect evidence supporting it: patients do not like thick liquids and avoid them; thick liquids are more harmful to the lungs than are thin liquids; feeding tubes are associated with high rates of pneumonia; and thin liquids, especially water, are relatively benign to the lungs. We need solid evidence in the form of a randomized clinical trial, but, in the meantime, decisions regarding allowing free water to patients who aspirate this consistency should be made on a case-by-case basis.

Over 25 years ago, in 1984, Kathy Panther and colleagues began the free water protocol (FWP) at Frazier Rehabilitation Hospital in response to a situation in which patients who resided in their Rehabilitation Center and were “ordered” to refrain from consuming thin liquids drank water anyway. After determining that the overall pneumonia rates in their institution were very low and noting that the compliance rate with water restriction was poor, the clinicians instituted a policy to allow patients who aspirated thin liquids to drink water “freely.” Since the policy was begun, the incidence of pneumonia has continued to be very low at that facility; in fact, over a period of 18 months, only 2 out of 134 patients on the protocol developed pneumonia (Panther, 2005). Over the years, the FWP has undergone several refinements, including the requirement that oral care be given to all patients on the FWP, and has been presented regularly at scientific meetings and seminars. In 2005, Kathy Panther wrote a comprehensive overview of the rationale for this policy and the evidence supporting it in Perspectives on Swallowing and Swallowing Disorders, and I recommend this article to everyone reading this current opinion piece.

Today, many speech-language pathologists (SLPs) have embraced the FWP. It is a formal policy in many rehabilitation hospitals and even in some acute care facilities. Others have declined to consider it, taking the “safe” road and disallowing thin liquids for any patient who aspirates them. What is my position? I am a “believer” in the philosophy of the FWP, but I have not attempted to formally implement it at my medical center. Why not? Because the scientist in me tells me to wait until we have more solid evidence specifying the safety of water aspiration in different populations and conditions. After all, pneumonia is a serious complication and cannot be taken lightly. However, on a case-by-case basis, I frequently endorse a patient’s desire to drink water, in spite of aspirating thin liquids, on a formal dysphagia evaluation. I do this because of indirect evidence supporting the safety of the practice and because it is sometimes critical for a patient’s quality of life (QOL), as has been made apparent to me in conversations with patients with a swallowing problem.
I submit that the FWP should be considered for certain patients and in certain conditions for the interim—that is, until someone conducts a randomized controlled trial that yields strong evidence that supports or refutes the safety of this policy. I base my decision on the following indirect evidence: (a) patients who are restricted to drinking thick liquids may develop pneumonia at comparable or higher rates than patients who drink thin liquids, and patients who are restricted to drinking thick liquids are at high risk of becoming dehydrated; (b) there is evidence that some patients who receive their nutrition via feeding tubes develop higher rates of pneumonia than do patients who drink thin liquids; and (c) some patients who drink (and aspirate) thin liquids may not increase their risk for pneumonia and may be better hydrated and have better QOL.

**The Thick Liquid Alternative**

Prescribing thick liquids is an extremely common recommendation for patients who are suspected of aspirating or are known to aspirate thin liquid. Garcia, Chambers, Clark, Helverson, and Matta (2010) reported that one quarter to three quarters of patients in hospitals, rehabilitation facilities, and nursing homes were ordered this diet, in many cases without the benefit of an instrumental evaluation. Yet, there are known adverse effects of imposing this on patients. Anecdotal evidence from clinicians across the country supports the notion that most people do not like drinking thick liquids. Consequently, patients tend to drink less fluids and, thus, increase their risk of dehydration. This has been documented in hospitalized patients on thick liquids (Vivanti, Harvey, Ash, & Battistutta, 2008) and found to be an even more significant problem for patients ordered to take a “honey thick” liquid (Robbins et al., 2008). Adherence to a thick liquids regimen in this latter study was only fair: 67–73% of patients complied with nectar thick and 56%–91% complied with honey thick liquid recommendations, which suggests that many patients may have been drinking thin liquids instead.

What is the evidence that patients who aspirate thick liquids have an increased risk of pneumonia? Panther (2005) cited two important studies in the 1990s—Schmidt, Holas, Halvorson, and Reding (1994) and Holas, DePipppo, and Reding (1994)—that reported patients who aspirated thick liquids were more likely to develop pneumonia than were patients who aspirated thin liquids only or who did not aspirate. More recently, a study done in the United States with more than 700 patients in nursing homes (Robbins et al., 2008) found patients who aspirated thick liquids had significantly higher rates of pneumonia than did patients who did not aspirate thick liquids. Presumably, thick liquids are harder for the lungs to clear.

**The Percutaneous Endoscopic Gastrostomy Tube (PEG) Alternative**

Does the percutaneous endoscopic gastrostomy tube (PEG) protect against pneumonia? First of all, if aspiration of all consistencies is present and occurs regularly and of sufficient volume, then yes, tube feeding does prevent aspiration of food and liquid. Two such cases in point are (a) a patient with bulbar amyotrophic lateral sclerosis (ALS) whose musculature is too weak to generate an effective swallow and (b) a patient with a brainstem cerebrovascular accident (CVA) who has lost the ability to swallow. These are examples of such severe dysphagia that, not only is aspiration pneumonia a likely complication, but excessive weight loss is likely to occur due to inadequate nutritional intake. However, there are many more patients who aspirate a mild to moderate amount of all consistencies on some or most swallows and are closer to the “fence,” where a decision regarding tube feeding is not so clear cut.

One major reason for hesitating before inserting a feeding tube is that feeding tubes carry their own risks for pneumonia and, so, may not prevent the very complication they were intended to prevent. Why not? Because they do not eliminate aspiration of oral, nasal, and pharyngeal secretions, which can, by themselves, cause pneumonia. Second, they often result in less frequent oral care (because the patient is not eating orally); this, in turn, increases the
bacterial count of the secretions, which, if aspirated, are pathogenic to the lungs. Third, the patient may reduce frequency of dry/saliva swallowing simply because there is no oral intake, which is responsible for stimulating salivary flow. Frequency of spontaneous swallowing will also decrease if the patient’s secretions are suctioned. With less frequent spontaneous swallowing, secretions build up and dry up within the hypopharynx. These thick, tenacious secretions are difficult for the patient to clear and are loaded with bacteria. Finally, tube feeding is known to increase gastroesophageal reflux (Balan et al., 1998) and lead to an aspiration pneumonitis.

One large group of patients who frequently receive feeding tubes are persons in institutions who have chronic progressive neurologic disease with dementia and have become difficult for staff to feed (i.e., the patient who “stops eating” due to dementia). In this group, there is no evidence that PEG protects against pneumonia or malnutrition; in fact, higher rates of pneumonia are generally seen in those patients who get feeding tubes, contrary to the intention of placing them (Croghan, Burke, Caplan, & Denman, 1994; Finucane, Christmas, & Travis, 1999; Mitchell, Kiely, & Lipsitz, 1997).

For all patients with feeding tubes who are told to refrain from drinking water, the clinician should consider the question of comfort and QOL. If you restrict water to the pharynx but continue to deliver adequate hydration, is thirst satisfied? One very interesting study suggests this is not the case. Figaro and Mack (1997) reported on 7 healthy subjects who voluntarily used a nasogastric tube (NGT) to deliver hydration directly to the stomach after exercising to the point of dehydration. All the subjects continued to be thirsty even after they had been given enough fluid to rehydrate them. Apparently, the pharynx needs direct flushing with water to eliminate the “thirsty throat” symptom.

Thin Liquids and Pneumonia

Over the years, several research studies have concluded that aspiration of thin liquids, especially water, does not pose a serious risk for pneumonia (Feinberg, Kneble, & Tully, 1996; Feinberg, Kneble, Tully, & Segall, 1990; Olson, 1970; Splaingard, Hutchins, Sulton, & Chaudhuri, 1988). More recently, two studies lent further support to this conclusion.

In 2008, Robbins and colleagues reported on the results of a large, randomly controlled trial (RCT) that involved 515 nursing home patients with Parkinson’s disease and dementia. The major focus of the study was to determine whether incidence of aspiration pneumonia was significantly different in patients who received chin tuck, as opposed to thick liquids, as an intervention to prevent aspiration of thin liquids. The results of the study showed no difference in outcome of pneumonia between the two groups, with the incidence of pneumonia approximately 10% in each group. As a secondary aim of the study, researchers analyzed a large subset of patients (345) who aspirated thin and thick liquids and for whom neither intervention prevented aspiration. The patients were randomly assigned to receive one of two treatments, with half of the patients receiving thick liquids (and aspirating them) and half of the patients delegated to “chin tuck” while drinking thin liquids (and aspirating them). Outcomes showed that, overall, the patients who aspirated contracted significantly more pneumonia than did the patients who did not aspirate (< .05). When the patients were subdivided into the two different treatment groups, it was found that the incidence of pneumonia was significantly higher in the sub-group of patients who aspirated thick liquids than in the group that did not aspirate thick liquids (p < 0.05). However, the incidence of pneumonia in the sub-group of patients who aspirated thin liquids was not significantly different from the group that did not aspirate thin liquids (Anonymous, personal communication, 2009); thus, one may question whether aspiration of thin liquids was a benign event for this group (Robbins et al., 2008).

Patients with head and neck cancer (HNC) are also frequently found to aspirate thin liquids on a regular basis. In a recent study, researchers looked at outcomes for this group.
They conducted swallow studies and CT scans to assess the lung function of 116 patients who had undergone partial laryngectomy surgeries 3–13 years earlier to treat cancer (Simonelli et al., 2010). All of the patients had pre-existing chronic pulmonary disease (COPD). Results of the modified barium swallow (MBS) or fiberoptic endoscopic examination of swallowing (FEES) studies showed 39% of the patients aspirated, mostly on thin liquids. The researchers compared the swallow studies and CT scans to results for a control group of 45 COPD patients who did not have cancer and did not aspirate on the swallow studies. Results showed no lung abnormalities on CT in the HNC patients that were distinguishable from the control COPD patients and no reported events of aspiration pneumonia. The researchers concluded that HNC patients post-surgery can tolerate small amounts of aspiration.

Aspiration pneumonia, by definition, develops after colonized oropharyngeal material is aspirated into the lungs. Water is not the same as secretions. Far fewer bacteria exist in water—less than in any other drink, food, and, certainly, less than in saliva (100–1000 bacteria/ml in water compared to 1,000,000,000 bacteria/ml in saliva). The bacteria in water are not pathogenic to lungs and are cleared easily by being absorbed into the bloodstream (Feinberg et al., 1990). Thus, the only reasons aspiration of water might cause pneumonia are (a) a huge volume is aspirated, literally causing a drowning episode or (b) the water washed bacteria from the oropharyngeal secretions into the lungs.

Concluding Thoughts

After all these years, why don’t we have more good (conclusive) evidence for this very appealing protocol? There have been three published studies that have supported the FWP. Two studies had weak research designs, being retrospective, cohort studies (Frey, 2011) or single cohort prospective studies (Carlaw et al., 2011). There has been only one very small RCT done by Garon, Engle, and Ormiston (1997), and it was too underpowered to be useful. A proper RCT would be a complex, expensive study and would require experienced researcher-clinicians with the insight, interest, time, and skill to obtain funding. The impact, however, would be huge.

In the meantime, I look at the individual risks for pneumonia faced by each patient I see. Given similar findings on an instrumental swallow study for two patients (including aspiration of thin liquids), but differences regarding other known risks for pneumonia (e.g., a patient who is ambulatory, living at home, and managing his/her own oral care versus a patient who is acutely ill, bedbound, and dependent on nursing for feeding and oral care), one can imagine which patient I am more likely to let drink thin liquids.

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Debates in Dysphagia Management: How Do You Use Evidence-Based Practice in Your Dysphagia Patient Care?

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Evidence-based practice requires astute clinicians to blend our best clinical judgment with the best available external evidence and the patient’s own values and expectations. Sometimes, we value one more than another during clinical decision-making, though it is never wise to do so, and sometimes other factors that we are unaware of produce unanticipated clinical outcomes. Sometimes, we feel very strongly about one clinical method or another, and hopefully that belief is founded in evidence. Some beliefs, however, are not founded in evidence. The sound use of evidence is the best way to navigate the debates within our field of practice.

We are all aware that speech-language pathology has been declared a profession that uses evidence as the basis for our patient care in both evaluation and treatment. The need for evidence-based practice is critical in all areas of our patient care, but particularly in dysphagia, where health-related harm can be done. In addition, we are always looking for the safest and most rapid way to return a patient to full oral intake. It is fortunate that, in the area of dysphagia, we have several approaches that we can use to apply evidence to our patient care decision-making.

The first approach to evidence-based practice in dysphagia is to look at the literature regarding evidence about the effectiveness of specific treatment procedures that may be relevant to each of our patients. There is a potential problem with literature reviews, however; they must extend far enough back (to the 1950s) in order for researchers to find evidence and physiological rationale for all of the behavioral procedures that we use or could use. For example, when considering postural procedures, researchers should be aware that head rotation was first introduced by an otolaryngologist, John Kirchner, in the 1960s. He noted that rotating the head to the more damaged side of the pharynx would close it, changing the path of the bolus flow and directing swallowed food down the more normal side of the pharynx (Kirchner, 1967). If we conduct a search on head rotation in the literature over the past 10 years, we might not find his work. As an example, I recently received an e-mail from a clinician who complained that some of us criticize the use of some new treatment procedures because of a lack of evidence. But, she then said, “I see no evidence for many of our behavioral approaches” (Anonymous, personal communication). Postural change, of course, is a behavioral intervention of which there are six different possibilities (Logemann, 1998; Logemann, Kahrilas, Kobara, & Vakil, 1989; Rasley et al., 1993). Evidence has been published for each of the postural techniques we use, but that literature is spread from the 1950s to the present time. So, we must thoroughly review the literature and evaluate the evidence for the past 60 years, not just the past 5 or 10 years.
The other issue that arises when we review the literature is whether it applies to our patient’s situation (i.e., the patient’s medical diagnosis, age, concomitant diagnoses, motivation level, swallowing biomechanical impairments, etc.). The information from a given manuscript may or may not fit our patient. This leads us to the second method of application of evidence-based practice in management of patients with dysphagia: application of one or more therapy procedures during the evaluation procedure to see the therapy technique’s effectiveness within our individual patient.

During the modified barium swallow, for example, we first identify the patient’s swallowing disorders. Then, we can introduce selected treatment procedures, such as a postural change, a sensory enhancement of the bolus, and/or swallowing maneuvers (voluntary controls) during the swallow, as well as modify food or liquid consistencies or increase the sensation of the bolus by using carbonation, temperature change, and so on. If we identify a treatment procedure that has an immediate positive effect on our patient’s swallow, we can continue to use it during X-ray to validate that it has a consistent effect on improving the patient’s oropharyngeal swallow. In this way, we are applying treatments to our specific, individual patient.

Now that we have the second procedure for testing treatment efficacy, we have the opportunity to move the patient’s swallowing rehab rapidly toward full oral intake. We need to consider the patient’s response, both physiologically and cognitively, to any of the procedures we introduce. And, we must observe enough swallows to conclude that the patient’s function is consistent, his/her improvement with a given procedure is always applicable, and the treatment affects the swallow consistently.

Researchers often find difficulty in judging the efficacy of various treatments for individual patients. We must remember that spontaneous recovery occurs in many patients suffering from stroke, head injury, and some other types of damage affecting swallow. When we use a therapy procedure in the first 4–6 weeks after sudden onset of a disease or condition that causes damaged oropharyngeal swallowing, we must always be aware that the change we see may not be related to what we are doing for the patient, but rather to the patient’s own spontaneous recovery. The same is true when we evaluate research studies that discuss therapy with a given procedure provided in the first 5–6 weeks post-injury. We must realize that, at the very least, the results may be the combined effects of spontaneous recovery and treatment. On these bases, yes, many of us criticize procedures when research studies of their use have been poorly designed and do not account for spontaneous recovery, normal growth, development in children, or other factors that can affect swallow physiology.

This issue of Perspectives contains debates regarding controversial methods of treatment of patients with dysphagia—neuromuscular electrical stimulation and free water protocols—that are currently in widespread use. The debates illustrate opposing, unilateral views of the two subjects. Debate and controversy can be good things. They can fuel inquiry and curiosity and spawn efforts to answer important questions. There are many debates about the best treatment to select for one disorder or another. Some debates are based in the debaters’ beliefs and opinions, and others have more objective evidence to support the debaters’ positions. Clinical science is not the place for belief and opinion to drive decision-making.

Yes, the application of evidence-based practice can be difficult at times and does require that we carefully understand the nature of the patient’s dysphagia, both anatomically and physiologically, and the rationale for the application of each treatment procedure to our specific patient. Selecting effective patient treatments in dysphagia is a thinking clinician’s job. Join us in this challenging area.
References


