Take Two Swallows and Call Me in the Morning

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Several treatments have been proposed for dysphagia management, including the supraglottic swallow (Lazarus, Logemann, & Gibbons, 1993); the Mendelsohn maneuever (Shaker, Kern, & Bardan, 1997); the Masako technique or tongue holding technique (Fujiu & Logemann, 1996; Fujiu, Logemann, & Pauloski, 1995); tongue strengthening exercises (Lazarus, Logemann, Huang, & Rademaker, 2003; Lazarus, 2006; Robbins et al., 2007); and neuromuscular electrical stimulation (Shaw et al., 2007), as well as other techniques and/or maneuvers.

The regimen of these therapies varies by the number of treatments that occurs per day, number of trials practiced per day, and the intended therapeutic target. For example, a therapeutic target might be to strengthen the tongue musculature or to strengthen the submental musculature in order to affect the biomechanical process of swallow or the timing of the swallow process. While each technique seeks to have an effective outcome on swallow function, not all of the techniques have provided equal evidence of their outcomes and some reported outcomes have been largely anecdotal.

As suggested by the literature, a positive relationship exists between increased tongue strength and oral and pharyngeal timing measures in those with head and neck cancer (Lazarus, Logemann, Pauloski, et al., 2000). The Mendelsohn maneuver in particular results in increases in the pharyngeal peak contraction and contraction duration, potentially improving the propulsion of the bolus into the esophagus and/or tongue base posterior motion and pressure. These findings are from single centers, and most single center studies offer both prospective and retrospective data analysis from particular populations of patients. Both sets of results are encouraging and help endorse the role of the speech-language pathologist in the treatment of dysphagia.

However, the literature lacks evidence regarding the dosage issues for these swallow rehabilitation techniques. Issues of dosage are especially important in individuals with dysphagia, given that many of the disorders that cause dysphagia result in generalized fatigue and inability to participate in lengthy rehabilitative regimens. Provided below is a brief discussion regarding dosage and the suitable designs to measure such. The importance of appropriate outcome measurement selection and use, essential in both clinical and research endeavors, is emphasized. Without appropriate selection of outcome measures, change cannot be properly assessed clinically or experimentally.

Exercise-based treatment has recently received much attention in the literature. With any exercise-training paradigm, particularly strength training, experimental manipulation of specific criteria should occur to establish its effectiveness.

The first variable of interest is the *stimulus intensity*. Stimulus intensity is the magnitude of the training stimulus. Whereas some of the exercise-based treatments used in the rehabilitation of dysphagia provide a calibrated method in which to manipulate stimulus intensity, most do not. With regard to using a calibrated load in swallow therapy to exercise muscle, the tongue strengthening technique utilizes a defined load. Defining the stimulus load of a strength training technique is imperative if a valid assessment of the relationship between stimulus intensity, strength gain, and functional outcome is to be determined.

By comparison, the Mendelsohn maneuver is performed by holding the larynx up, either using the muscles of the neck or with the hand, during the swallow for an extended period of time. The actual physiological load placed on the submental muscles and/or other muscles of the head and neck cannot be defined. As such, quantitative recording and manipulation of the relationship between stimulus and outcome is less definitive. Some might argue that offering interpretation at the end of a treatment is less convincing if the manipulation of the independent variable is a subjective procedure rather than an objective function.

The next variable of interest is the *number of exercises per session* that must be completed to achieve the intended outcomes. Ideally, studies should inform clinicians about the number of exercises per session they have to employ to treat a patient. Furthermore, basic science inquiry could assist by providing information about how fatigable a patient becomes in response to an exercise, as well as how the number of exercises used per session should vary as a function of the etiology of the patient's disorder. Currently, it seems that therapies are becoming more structured using a set number of exercises per session, however empirical evidence supporting session frequency relative to patient outcomes has not been reported.

Next, we need to provide information about the *number of sets needed per exercise* to achieve a desired outcome. For example, what happens if a patient, after perform-

ing one complete set of exercise, reaches total failure; that is, the patient finds it impossible to generate the same force and intensity for another complete set of the same exercise? Instructions on how to handle these particular situations and how the number of sets may influence rate of fatigability require careful study within and across the numerous etiologies that contribute to swallow dysfunction.

We have fortunately begun to realize the heterogeneity of particular diseases and recognize the impact a neurodegenerative disease, for example, has on exercise performance. No study to date, however, has experimentally reported on how these variables impact swallow treatment outcomes.

Evidence from strength training studies of the limbs further suggests that it is not always true that volume training (multiple sets) is most effective for gaining strength. Recent research indicates that in order to achieve some exercise outcomes a single set of training is as beneficial as multiple sets of training sessions and may save more energy for other exercises required during the treatment (Byrd et al., 1998; Hass et al., 2000).

The *number of repetitions per set needed to obtain the intended outcome* is the next factor to examine experimentally. Case in point, when a person cycles to exercise, the intensity of the cycling changes and the load imposed by the cycle is altered in order to maintain progression and avoid training plateaus. How might we monitor the training plateaus that occur with swallow therapy? What number of repetitions has been experimentally shown to produce the best treatment effect? These are easy questions to ask, yet difficult answers to find as the complexity of the research designs must be intricate to solve these solutions.

In designing a study on exercise dosage, several factors require consideration. There is a need for careful selection of inclusionary and exclusionary criteria, controlling for confounding variables that could introduce experimental artifact. At the same time, excluding too many factors could be precarious as the generalization of the results will be minimal.

The first place to start in completing a dosage comparison study might be examining the outcome of a particular treatment in a single center, using a prospective research design. Other sound criteria to include in the design are

1. Use of standardized data collection protocols
2. Use of a well-structured and validated instrument for assessment
3. Applying the measurement at similar timing in all study groups
4. Blinding the study participants to the study hypothesis, if possible, and the specific factors being studied
5. Blinding the data measurer to the status of the research participants and the study hypothesis.

These are just some basic recommendations.

Currently, we are examining the outcome of the expiratory muscle strength technique for strengthening the submental musculature in patients with Parkinson's disease. Our therapeutic target is improvement in swallowing, measured by several variables related to the timing and biomechanical measures of the swallow process. The development of strength and muscle is interrelated. That is, strength-training sessions should produce increases in strength that are equal to increases in functional muscle. Numerous investigators have discussed this relationship in the literature (e.g., Abernathy, Jurimae, Logan, Taylor, & Thayer, 1994; Conroy & Earl, 1994; Fleck & Kraemer, 1987; MacDougal, 1993; Narici, Roi, Landoni, Minetti, & Cerretelli, 1989).

The expiratory muscle strength-training technique uses a device to strengthen muscle and the device is set a particular calibrated threshold of a person's maximum expiratory pressure (MEP) generating capability.

The device is currently set at 75% of a person's given MEP and is incrementally increased each week of the training, if the MEP increases over time. However, the particular selection of 75% was not selected prospectively based on a dosage comparison study. Instead, the 75% was pre-selected as the training threshold, based on previous literature that used a similar procedure for strength training the limb muscles.

Additionally, while 75% may result in a positive effect for the outcomes of interest, we will not know whether a different dosage works better. For example, could a patient with Parkinson's disease respond equally well to the training if the device were set at 60% and if the therapy were completed 3 days per week rather than the 5 days per week currently prescribed? Furthermore, would similar treatment effects occur if the number of trials performed on the device differed?

We started to look at this issue in a very tangential way, because we have no systematic clinical trial to examine the impact of dosage using the expiratory muscle strength training technique. We asked participants to perform two swallows (saliva swallow and water swallow) and develop an expiratory pressure set at 25% and 75% of their MEP using the expiratory muscle strength trainer.

Therefore, the only variable manipulated in this study was stimulus intensity. The two device

settings (25% vs. 75%) allowed comparison of muscle activity during both the swallow tasks. The next step in this research is to involve a greater number of experimental groups, randomize them into different stimulus intensity groups and vary the number of sessions they train each week with the device. Once the dosage is properly determined via an appropriately designed clinical trial, the plotting of treatment progress will be the next task.

Plotting treatment progress requires certain considerations. Clinicians and researchers must decide whether to measure outcomes at the impairment level and/or by patient-centered measures of quality of life. Both types of outcome measures have merit. Impairment level measures allow for the acquisition of information about baseline state or change that has occurred to the structure and function of the swallowing mechanism with treatment. Patient-centered measures of quality of life contribute information about the social and functional impact swallowing impairments might have on the patient.

When considering the assessment and management of a patient's swallow function, we indicated that a well-structured and validated instrument for assessment should be part of the speech-pathologist's armamentarium. For some, this might include the clinical swallow evaluation, fiberoptic endoscopic evaluation of swallowing (FEES), and modified barium swallow study (MBSS), among others. Given the MBSS's popularity among clinicians, its practical use clinically, and its ability to allow for sensitive and specific measures of swallow outcomes, data extracted from the MBSS is one particular method that should be used to define impairment level outcomes.

During the MBSS, manipulation of variables including bolus consistency and use of compensatory techniques (e.g., chin tuck, head tilt) are conducted in real time, allowing for the assessment of presence/absence of dysphagia, techniques appropriate for swallowing therapy, and improvement/worsening of swallowing symptoms pre/post swallow therapy, among others.

Data obtained from MBSSs allow for the measurement of impairment level outcomes, specifically biomechanical measures of swallowing. Long described in the dysphagia literature (Logemann, 1985; Logemann et al., 1992; Robbins, Logemann, & Kirschner, 1986), these measures can often be time consuming for clinical practice. Described by Logemann (1983) in her seminal text, measures of bolus movement, temporal measures of movement, and temporal measures of swallow coordination can be useful in the description of swallow dysfunction.

In addition to the measures described above, the presence or absence of penetration and aspiration, also a measure of level of impairment, is essential to the determination of whether a swallow therapy is effective and to the development of the treatment plan. The Penetration-Aspiration Scale (Rosenbek, Robbins, Roecker, Coyle, & Wood, 1996) provides a clear, consistent, and specific method of rating penetration/aspiration severity. The scale is an 8-point scale that is multidimensional, measuring several behaviors including the level to which the material enters or does not enter the larynx and the patient's response to the presence of the bolus.

The scale is ordinal with a score of 1 representing no aspiration/penetration; 2, 3, 4, and 5 levels of penetration; and 6, 7, and 8 levels of aspiration; with the most severe, 8, being silent aspiration. The purpose of developing the scale was to "provide reliable quantification of selected penetration and aspiration events observed during videofluoroscopic swallowing evaluations" (Rosenbek et al., 1996, p. 97). In addition to allowing for the assessment of change over time, this measure provides clinicians and researchers with a common language with which to discuss penetration/aspiration.

Quality of life measures are becoming increasingly important for issues of third-party reimbursement and for the demonstration of treatment efficacy and effectiveness. The SWAL-QOL provides a valid and reliable measure (McHorney, Bricker, Robbins, et al., 2000; McHorney, Bricker, Kramer, et al., 2000; McHorney et al., 2002; McHorney, Martin-Harris, Robbins, & Rosenbek, 2006) to address the above-mentioned issues. The SWAL-QOL is a 44-item questionnaire created to provide clinicians with a patient-centered measure of functioning, especially given the discrepancy that often exists between a patient's perception of his or her disorder and traditional clinical measures. Designed for both the clinical and research environments, the SWAL-QOL and the accompanying SWAL-CARE, a 15-item tool used to assess quality of care and patient satisfaction (McHorney et al., 2002; McHorney, Martin-Harris, Robbins, & Rosenbek, 2006), are disease-specific measures of quality of life and care specific to dysphagia.

Recent literature has focused on the use and importance of patient-centered outcome tools in rehabilitation. Patients showing improvements in impairment levels measures, but with no change in qualitative report of everyday functioning or quality of life, present a dilemma for clinicians. Other times, we must chose which treatment is best for a patient whose severe disease progression may not allow for observational changes in impairments, yet the patient may report improvements in their functioning or quality of life. Patient-centered measures of quality of life and care

allow quantitative measurement of changes (or lack of) in quality of life and functioning in research and treatment planning (e.g., discharge, dosage, etc.).

Impairment and quality-of-life measures both have great utility in the research and clinical environments, yet a combination of the two may be the most appropriate approach to plotting progress. Using an impairment level measure of outcome, in conjunction with a patient-centered measure, might allow clinicians and researchers to assess whether their perception of the patient's condition is consistent with that of the patient.

The use of these outcome measures is also essential for assessment of appropriate dosage. While improvements might be seen in structure and function of swallowing at a given dosage of therapy, there may be side effects or changes to function that can only be measured by patient-centered outcomes. It is our opinion, that the current body of literature lacks sufficient description on the issues of dosage (e.g., intensity, repetitions, sets, etc.) in swallowing therapy. Future studies should consider utilizing outcome measures that will allow for the appropriate description of a patient's baseline function and change with intervention within controlled experimental environments.

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Taking the Temperature of the Dysphagia Research Literature: A Search for Peer-reviewed Publications About Compensatory and Rehabilitative Interventions for Dysphagia

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Introduction

When a new patient with dysphagia is referred to a speech-language pathologist for assessment, it is common to conduct a chart review and to interview the patient to identify relevant events and factors in their past and current medical history. This process is similar to the one each of us might undergo during an annual physical examination with our family physician. A general, but comprehensive consideration of a variety of physical and medical factors contributes to an overall understanding of the general health of the patient and, in the case of a swallowing referral, to an understanding of the factors that might be contributing to the patient's swallowing difficulties.

In this article, we will share with you the results of a similar check-up process, in which we *took the temperature* (as it were) of the current research literature regarding compensatory and rehabilitative interventions for oropharyngeal dysphagia. We will report the results of a preliminary search for (and review of) evidence on this topic; this review was undertaken in association with the development of a local licensing body practice guidelines document for speech-language pathologists practicing in the area of dysphagia (Steele, in press). The intent of the review was to identify literature on dysphagia interventions that might be considered by speech-language pathologists for use in swallowing rehabilitation.

In the December 2006 issue of *Perspectives*, Rob Mullen, founding director of ASHA's National Center for Evidence-Based Practice in Communication Disorders (NCEP), outlined the steps involved in conducting a systematic review of evidence for clinical interventions. We followed a similar process, after consulting the guidelines available from the Cochrane Foundation (www.cochrane.org) on the procedures involved in conducting reviews.

Methods

Search Strategy

The initial step in our inquiry process involved a broad search for articles in the literature using several different search engines. The search engines selected for this process were: CINAHL (Cumulative Index to Nursing & Allied Health Literature); Health and Psychosocial Instruments; Ovid MEDLINE(R); PsycINFO (R); EMBASE: Excerpta Medica (EMEZ, EMED, EMEB, EMEF, EMEM); and the OVID Evidence Based Medicine Reviews (includes American College of Physicians Journal Club, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, and Database of Abstracts of Reviews of Effects).