

## Evidence-based systematic review: Oropharyngeal dysphagia behavioral treatments. Part V—Applications for clinicians and researchers

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**Abstract**—Evidence-based practice (EBP) involves the integration of three essential principles: (1) the current best available research, (2) the clinician's experience and expertise, and (3) the patient's values and preferences. This report is the last in a series that presents the culmination of a collaborative effort between the American Speech-Language-Hearing Association and the Department of Veterans Affairs to examine the state of the evidence on seven behavioral swallowing interventions. This article addresses how speech-language pathologists treating individuals with oropharyngeal dysphagia can incorporate EBP into their clinical decision-making process. A fictitious patient scenario is presented and discussed as an example of the clinical application of the findings from the three systematic reviews in this series on evidence for the use of behavioral swallowing interventions. Also, recommendations for researchers studying dysphagia treatment are discussed, with the overall goal of facilitating the generation of a stronger evidence base for clinicians.

**Key words:** chin-tuck posture, dysphagia, effortful swallow maneuver, evidence-based practice, evidence-based systematic review, head-rotation posture, Mendelsohn maneuver, side-lying posture, speech-language pathologist, super-supraglottic swallow maneuver, supraglottic swallow maneuver, treatment.

### INTRODUCTION

Sackett et al. defined the underlying principles of evidence-based medicine that have been incorporated into the framework of evidence-based practice (EBP) [1].

Conceptualized in the **Figure**, the goal of EBP is to provide optimal treatment by incorporating (1) clinical expertise, (2) best current evidence, and (3) client/patient values to provide high-quality services reflecting the preferences of the individuals served [1–2]. These three distinct but interdependent principles of EBP are essential to clinicians engaging in evidence-based clinical decision making to treat oropharyngeal dysphagia.

Knowledge of the current best evidence informs the clinician of efficacious treatments that have been verified through rigorous research investigation. The speech-language pathologist (SLP) should be guided by scientific evidence when choosing dysphagia treatment methods for

**Abbreviations:** ASHA = American Speech-Language-Hearing Association, CPRS = Computerized Patient Record System, CVA = cerebrovascular accident, EBP = evidence-based practice, EBSR = evidence-based systematic review, EMG = electromyographic, N-CEP = National Center for Evidence-Based Practice in Communication Disorders, sEMG = surface electromyography, SLP = speech-language pathologist, VA = Department of Veterans Affairs, VISN = Veterans Integrated Service Network.

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**Figure.**  
Components of evidence-based practice (EBP).

specific patient populations. Clinical expertise includes not only the clinician's knowledge base of treatments but also his or her experiences and capabilities. SLPs working in the area of dysphagia receive specialized training in swallowing and swallowing disorders. This expertise grows further through clinical experience and observation of patient outcomes. Finally, client/patient values play an integral role in the success of dysphagia treatment. Client preferences (e.g., the desire to eat by mouth or to avoid placement of feeding tubes) and capabilities should be considered. For example, complex treatment maneuvers may be impractical for some patients with dementia, while posttreatment anatomy may preclude the use of certain treatment postures or maneuvers in patients with head and neck cancer. The SLP and patient should discuss and weigh the patient's preferences before establishing a treatment plan. Current best evidence in conjunction with the SLP's clinical expertise and the patient's individual circumstances and preferences help determine the optimal course of treatment.

Making evidence-based clinical decisions as illustrated by the trilateral principles in the **Figure** seems straightforward; however, in reality, its application is quite complex. Recently, a number of sources have shown that SLPs value the importance of EBP; however, limited time and resources for searching and analyzing the scientific literature have made integrating evidence into the clinical decision-making process difficult for them [3–5]. Moreover, SLPs reported the lack of available evidence as a major barrier to EBP, citing that evi-

dence was nonexistent, conflicting, or irrelevant in many aspects of treatment [3].

In response to its members, the American Speech-Language-Hearing Association (ASHA) has initiated evidence-based systematic reviews (EBSRs) on clinically relevant topics in communication sciences and disorders research. These reviews employ specific and transparent methods to systematically search and critically appraise a body of scientific literature and describe the extent to which a particular treatment or diagnostic approach is supported by the evidence; they are often considered the highest form of evidence in many levels-of-evidence schemes. The specific clinical question(s) to be addressed, the inclusion/exclusion criteria, and the search parameters are set a priori to reduce the likelihood of bias (see Frymark et al., this issue, Part I, p. 175). The information gleaned from EBSRs provides a valuable and time-saving resource to clinicians seeking evidence. In addition, EBSRs have practical applications for researchers by identifying discrepancies and gaps in the evidence, which helps determine future research needs.

This article provides information to clinicians and researchers that can be used in their clinical practice for oropharyngeal dysphagia treatment. This article is the last in a series reporting the results of a collaborative project between ASHA and the Department of Veterans Affairs (VA). This review group examined the state of the evidence on seven behavioral swallowing postures and maneuvers for disordered and nondisordered populations. The findings from three EBSRs are presented elsewhere in this series (Wheeler-Hegland et al., this issue, Part II, p. 185; Ashford et al., this issue, Part III, p. 195; and McCabe et al., this issue, Part IV, p. 205) along with a separate report (Frymark et al., this issue, Part I, p. 175) that presents the methodology used for the systematic reviews. A fictitious case scenario will be presented to illustrate how SLPs can incorporate evidence into the clinical decision-making process. Limitations in the methodological quality of the evidence will also be discussed in order to prompt a future research agenda for specific populations and treatments.

## CASE SCENARIO

A 44-year-old male was referred to SLP services for swallowing evaluation and treatment secondary to squamous cell carcinoma of the laryngeal area. Medical

history indicated a small stage I tumor along the left superior margin of the epiglottis. Surgical excision included the complete superior segment of the epiglottis to the floor of the valleculae. At the time of referral, the patient was 10 days postoperative with no radiation or chemotherapy treatment provided; he received all feeding and hydration via a nasogastric tube. Initial bedside assessment indicated the patient was awake, alert, oriented, and able to follow complex commands.

### Seeking Evidence

Before assessing this patient, the SLP should investigate the published research regarding various behavioral swallowing interventions used with the population with head and neck cancer. An analysis of the scientific evidence through systematic reviews will help determine the most appropriate treatments to explore with this patient. The ASHA compendium of guidelines and systematic reviews [6] includes the EBSR on oropharyngeal dysphagia behavioral treatments applied in normal control subjects (see Wheeler-Hegland et al., this issue, Part II, p. 185) and for individuals with structurally based dysphagia (see McCabe et al., this issue, Part IV, p. 205). The latter reports findings from studies examining five behavioral interventions (chin tuck, effortful swallow, Mendelsohn maneuver, supraglottic swallow, and super-supraglottic swallow) and the impact of these interventions on physiological and functional swallowing outcomes. The EBSR provides some support for the use of swallowing postures and maneuvers, specifically, the Mendelsohn maneuver (Valsalva maneuver during swallow) for individuals after head and neck cancer treatment [7–9]. However, the studies were exploratory and the subject characteristics were not identical to this patient (e.g., time postonset, medical intervention, age, severity). However, the EBSR for normal control subjects directs the SLP to behavioral treatments that alter specific aspects of swallow physiology. While the effortful swallow (exaggerated muscle movement during swallow) was not indicated in an EBSR for patient groups, data from control subjects suggest that the effortful swallow should (among other physiological effects) increase the amplitude and duration of lingual pressure generated during swallowing, which may improve swallow function in this case [10–11]. Ultimately, both EBSRs can help the SLP prioritize trials of the treatments; however, before treatment is initiated, the SLP must determine the nature of this patient's dysphagia in order to choose appropriate treatment trials.

### Making Treatment Decisions

The patient's baseline pretreatment swallowing performance was examined under videofluoroscopy [12], which revealed normal function of the lip, mandible, and palate and normal anterior tongue mobility but reduced strength and mobility with posterior tongue retraction. Laryngeal penetration (movement of some portion of the bolus into the laryngeal area) occurred with puree, soft solids, and masticated solids. Aspiration (movement of some portion of the bolus below the level of the true vocal folds into the proximal trachea) occurred with thin and thick liquids and puree consistencies. The patient exhibited some throat clearing and coughing reflexes paired with aspiration events, indicating an intact sensory system of the upper-airway area.

The Mendelsohn and effortful swallow maneuvers were attempted under fluoroscopy based on the evidence that the Mendelsohn maneuver reduces aspiration and improves oral intake for individuals with head and neck cancer and that the effortful swallow has an effect on lingual pressures in normal subjects. During the trial treatment, the Mendelsohn maneuver offered some reduction in penetration and aspiration, while effortful swallowing showed less benefit. Although the patient expressed a strong desire to return to oral feeding, the SLP discussed the consequences of aspiration and recommended that the patient remain on nasogastric tube feeding and begin using the Mendelsohn maneuver as an exercise to improve swallow function. Additionally, the SLP employed surface electromyography (sEMG) in conjunction with the Mendelsohn maneuver based on findings from the Crary et al. study [7] and the clinician's knowledge and experience with sEMG as a means of monitoring patient performance.

### Applying Evidence-Based Practice Principles

This case highlights the integration of the EBP triangle into the clinical decision-making process with use of two systematic reviews from this series. The EBSR reported limited data to support treatments in head and neck cases; therefore, the SLP had to draw hypotheses regarding other possible treatments from studies on normal subjects based on observed physiological changes induced with the various behavioral techniques. Based on the EBSR on studies of normal participants, the effortful swallow was a logical option given this patient's symptoms. Clinical judgment and observation on instrumental evaluation of swallow supported the decision to use the

Mendelsohn maneuver as the most optimal treatment approach. Because the EBSR reported that the evidence was exploratory and existing data were limited in methodological rigor, the outcome was in question and treatment was initiated on a trial basis. The individual patient's diagnoses and dysphagia symptoms were also considered. For example, had this patient presented with the diagnosis of cerebrovascular accident (CVA), the clinician would apply findings from the EBSR on populations with neurological disorders (Ashford et al., this issue, Part III, p. 195) or from other external evidence. For example, safety concerns regarding possible cardiac complications in CVA patients may negate the use of the Mendelsohn maneuver [13]. Clinical evaluation and expertise may support other treatment options that are not supported by scientific evidence (e.g., concurrent use of exercises and maneuvers, use of combined maneuvers and/or postures in conjunction with diet modification). While SLPs should proactively seek scientific research, they should also apply evidence carefully and thoughtfully so as to meet the individual and unique needs of the patient being served.

## IMPLICATIONS FOR FUTURE RESEARCH

Based on the results of all three EBSRs conducted by ASHA and the VA, the evidence for dysphagia treatment is in its infancy and requires further exploration for many postural- and maneuver-based treatments. The first review in this series included physiological outcome measures on normal subjects for dysphagia treatment techniques that can be used as evidence for potential benefits for disordered populations. For example, results of multiple studies reported increased submental muscle activation during healthy subjects' performance of the effortful swallow. Based on those results, the effortful swallow may be applied in the treatment of dysphagia that results from submental muscle weakness and manifests as reduced hyolaryngeal excursion during the swallow. The effortful swallow is thought to increase the volitional load placed on the submental muscles, as evidenced by increased electromyographic (EMG) activation of those muscles during the swallow. Therefore, according to the overload principle of exercise training [14], the effortful swallow may increase the strength of the submental muscles over time. This is a good example of basic research

guiding applied research in terms of matching a treatment hypothesis to a patient population.

One problem that may be encountered in the transition from basic to applied research is the nature and consistency of basic research findings. In the case of effortful swallow studies, while each study that included EMG measures of submental muscles concluded that activation of those muscles increased, other outcome measures differed between the studies. Specifically, during effortful swallow, one study found increased hyoid movement [10] and another, decreased hyoid movement [11]. These conflicting results are presumably due to methodological differences that should be considered in future research of the effortful swallow. The EBSR found that the extent of hyoid movement is inconclusive with regard to the effect of the effortful swallow, while the submental muscles, which are the primary movers for superior-anterior hyoid excursion during swallowing, are activated more during effortful swallowing. Thus, the data suggest that patients with dysphagia with decreased hyoid movement may benefit from the effortful swallow maneuver because of the increased submental activation. This hypothesis is based on physiological outcomes from available data and requires appropriate testing.

Bridging the basic-applied research gap is challenging, and designing research protocols can be particularly difficult, especially in the field of dysphagia, for which the ethics of withholding treatment or using repeated baseline measures of aspiration must be considered. The potential risks/harms and clinical benefits must be carefully considered when dysphagia research is being conducted. According to a five-phase model of clinical research outcomes described by Robey, applied research should be approached systematically to reach levels of efficacy and then effectiveness [15]. Generally, treatment studies in the pilot stage (phase I) that demonstrate an intervention effect in a relatively small number of subjects should establish treatment safety and help further develop hypotheses. The next step should determine in a larger patient group whether the demonstrated treatment effect sufficiently warrants additional testing (phase II), and then an efficacy study should be implemented to determine whether the treatment is effective under controlled conditions (phase III). A randomized control trial would be considered such a phase III study. A phase IV study determines treatment effectiveness in a less controlled, "real world" setting with typical patients, and a phase V study examines treatment efficiency in patient subpopulations

[15]. In the current EBSRs, no study included research phase IV or V; however, two studies on populations with neurological disorders were considered phase III [16–17].

Results of this EBSR indicate that studies fall short of achieving higher levels of evidence in several areas. Specifically, study design, random participant sampling and allocation, and assessor blinding are key areas that need improvement in order to achieve the highest quality-marker rating (Table).

### Study Design

The majority (75%) of the 28 studies included in this series of reviews were case series reports. These were pre/post studies involving a sequence of individual cases with an uncontrolled description of events and outcomes. Other designs included control trials, case-control studies, and case studies. According to the levels-of-evidence criteria [18] detailed in Table 2 of Frymark et al. (this issue, Part I, p. 175), control trials were given the highest quality-marker rating for study design. Control or comparison groups are needed to identify placebo effects, and failure to include them can be a fatal flaw for any experimental study. Most of the studies reviewed for the EBSRs were either nonexperimental or quasi-experimental and, thus, raise questions regarding reported outcomes. Use of a sham treatment group and/or crossover of treatment groups are solutions for decreasing the chances that a significant placebo effect will influence differences detected in outcome measures.

Adequate participant recruitment to fill the subject number requirements for each group presents a first challenge for researchers interested in using a controlled trial design. Finding subjects who not only meet inclusion/

exclusion criteria, including age, sex, race, diagnoses, and dysphagia type and severity, but also agree and consent to participate can be a challenging and lengthy process. The VA healthcare system offers a unique and desirable setting for implementation of studies with these subject requirements because of the number of veterans with dysphagia of different etiologies. The VA Computerized Patient Record System (CPRS) is integrated across Veterans Integrated Service Networks (VISNs) and could greatly assist the development of large multicenter trials. These systems enable scientists to identify subpopulations of patients for inclusion and stimulate collaborative relationships between researchers and clinicians at different institutions.

Other design issues may not be uniquely inherent to control trials but certainly affect the capability of the study to adequately examine the experimental treatment. The collection of baseline data is one topic for consideration, since most research groups are moving toward the collection of multiple baselines because of the inherent variability in human performance across time. Collecting two, three, or even upward of five baselines at specific times of day, with or without certain medication, caffeine, nicotine, etc., are all important aspects of collecting valid and reliable baseline data. Variables that may affect performance of a given task for which outcome measures will be derived should be considered and controlled to ensure that treatment effects are due to the experimental treatment and not performance variability.

### Participant Sampling and Allocation

The majority of participants in our reviews were selected as a convenience sample, and only three studies

**Table.**

Highest quality markers for the 28 studies included in evidence-based systematic reviews of oropharyngeal dysphagia treatments.

Quality Indicator	Highest Quality Marker	No. of Studies Meeting Highest Quality Marker
Study Design	Controlled trial.	2
Blinding	Assessors blinded.	2
Sampling/Allocation	Random sample adequately described.	3
Groups/Participants	Groups/participants comparable at baseline on important factors (between-subject design) or participant(s) adequately described (within-subject design).	26
Outcomes	At least one primary outcome valid and reliable.	14
Significance	<i>p</i> -Values reported or calculable.	22
Precision	Effect size and confidence interval reported or calculable.	20
Intention to Treat	Analyzed by intention to treat.	2/2 (controlled trials only)

described random-sampling procedures (**Table**). In the purest sense, a random sample means that any member of a subject population has equal chance of participating in a study. If a researcher operates within the VA system (or any closed hospital system), he or she clearly does not have access to every patient (anywhere) in a particular patient group. This limitation is further confounded when other inclusionary criteria are considered. For example, not only does the patient need to have a particular disorder but also be of a certain age, sex, race/ethnicity, smoking status, etc. One way to expand the sampling availability would be the use of the CPRS across VISNs. Such use would greatly facilitate the application of random sampling.

One aspect of sampling that can be more easily controlled is the assignment of research subjects to participant groups. In a control trial with an experimental and control group, subjects should be randomly assigned to a group. That is, each subject enrolled has equal likelihood of being in the experimental or control group. If inclusionary criteria were met by all participants and group assignment was truly random, the groups should be appropriately matched in terms of subject characteristics and baseline measures in order to ensure any effects seen are not due to group differences before treatment initiation.

With this random assignment comes the ethical obligation of intention to treat. This concept must be incorporated into the study design and can usually be accomplished through cross over design components or otherwise ensuring that those in the control group receive the treatment if that treatment proves effective.

### **Assessor Blinding**

Blinding is intended to control for bias during data collection and/or analysis. Ideally, when measuring data points, study assessors should not know to which treatment group the subject has been assigned. One barrier to blinding is the need for experienced raters. If the study is employing traditional markers, such as hyoid movement, many experienced researchers and clinicians will know treatment is being applied (if it is being demonstrated on videofluoroscopy), making blinding impossible. During the posttreatment stage of a study, blinding is much easier and care should be taken so that the rater is not cognizant as to which treatment group subjects were assigned.

Another barrier to blinding is knowledge of what treatment is being administered during a study. For example, if a study is investigating chin tuck versus effortful

swallow, the technique being applied is perfectly clear to the clinician delivering treatment. Therefore, if that clinician has any personal biases toward one treatment or another, these may be unintentionally conveyed during treatment to the patient and may affect the results.

Some solutions exist for these kinds of biases, whether they stem from data collection and measurement or treatment delivery. Experienced persons delivering study treatment without knowledge of study goals or hypotheses may help to eliminate some treatment delivery bias. This approach would also be appropriate with regard to data measurement when treatment group assignment cannot be hidden based on the types of measures that are taken (for example, rater blinding would be difficult if the chin tuck and effortful swallow were recorded on a videofluoroscopic examination). Additionally, during data analysis, the use of multiple raters allows a measure of reliability that may control for biases existing for just one rater. Measurement of interrater reliability should be included in the data of these studies. Ultimately, several ways to attempt to control for treatment delivery and measurement biases exist and should be integrated into studies as much as is reasonable given study goals, design, methods, and measures.

### **CONCLUSIONS**

An understanding of all aspects of EBP and the utility of EBSRs makes the clinician a valuable team member who is instrumental in facilitating change to promote the best possible outcome for the patient. The findings from the three EBSRs reported in this series of articles should be considered and weighed with other important aspects of clinical decisions, including the expertise of the treating clinician and the preferences of the patient. The limitations of the available evidence should form the basis for future research in the field of dysphagia. The VA healthcare system, including the CPRS, provides an excellent environment for addressing limitations in study design and inadequate subject sampling. Future research, whether basic or applied, should include interrater reliability measures; good design principles; and quantifiable, relevant outcome measures in the study of postural alterations and maneuvers for the treatment of oropharyngeal dysphagia.

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