MEASURING DYSPHAGIA OUTCOMES

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Introduction

It is my distinct pleasure to return to Japan. It particular, it is an honor to once again address the Japanese Society of Dysphagia Rehabilitation. Much has happened in four years. In discussions I have had with your colleagues, it is clear to me that this Society has made great strides toward educating medical personnel, and dysphagic patients and their families about the diagnosis and treatment of the dysphagic condition. I would congratulate the planning committee for the selection of this years’ theme, “the right to eat”.

Personally, I have made a philosophical, but I think medically relevant change in my own thinking about dysphagia treatment. Rather than emphasizing the need to prevent aspiration pneumonia, our focus should be on allowing patients to continue eating in the safest manner possible. The implication of this philosophical stance is that we must take very seriously the impact of taking away a patient’s right to oral alimentation. In the United States, dysphagia services are paid for by insurance companies. The regulation of the policies for financial reimbursement is monitored by the Health Care Financing Administration. This group has asked the American Speech, Language, and Hearing Association to provide outcome data on the benefit of our services with dysphagic patients. Unfortunately, there are few data on this subject. To gather the data we have to decide what to measure and how to measure it. What I will talk about today is our preliminary thinking on this topic.

Levels of Outcome Measurement

The measurement of health care outcomes traditionally has focused on the documentation of physiologic changes secondary to a primary medical diagnosis with a known severity level. In this approach, baseline measurements are made of physiologic performance, and are compared with the same measures of physiology following treatment. For instance, in disorders of deglutition one might document that the tongue or lips are weak on physical examination (physiologic level of impairment), and that this physiologic impairment results in the cause for dysphagia (level of disability). The measurement of swallowing performance at the level of disability would focus on the improvement in the patient’s ability to produce a safe swallow as a function of the improvement in the muscles of deglutition. Recently, there has been a shift away from the measurement of the disability to the measurement of the effect of the disability on the patient’s quality of life (handicap level). That is, how does the swallowing disability interfere with the patient’s interaction with the environment, or with their psychological well-being? For instance, does your swallowing problem keep you from eating in public? Measurement of swallowing performance at the level of handicap is most appealing to insurance companies who are paying for dysphagia treatment.

The measurement of outcomes following treatment for dysphagia may not be possible using a single measurement...
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scale, although a dysphagia rating scale that encompasses many parameters into a single swallowing index would be ideal. Swallowing performance scales should attempt to measure physiologic changes, the effect of therapy on health status, the patient’s functional improvements such as dietary level, their satisfaction with the quality of services, and the overall impact of treatment on their quality life. Clearly, some aspects of measurement of these parameters would have overlapping concerns. Information gathered may be redundant such as that information gathered in the measurement of the patient’s satisfaction with their treatment, and their judgment of their quality of life. Nonetheless, these broad areas of outcome measurement appear appropriate for patients with dysphagia. The cost of achieving each outcome, such as improvement in health or functional eating status is calculated to compare the expense one incurs for achieving a particular outcome. For instance, a dysphagia treatment program may be too costly if it only improves the patient’s functional oral intake at the expense of good health outcomes such as pulmonary safety and nutrition and hydration adequacy.

Which type of dysphagia scale to use may be dependent on the health care setting. For clinicians working in acute care, chances of achieving measurable changes in functional status or quality of life may not be an accurate barometer of change due to the short length of stay. However, changes in physiologic status (improved tongue control, better secretion management) or in health status (improved nutrition and hydration) may be the type of outcome scale more suited to the acute care environment. Functional measurement scales and measurement of the patient’s overall quality of life may be better suited to the patient in the rehabilitation or home care setting.

Comparisons of dysphagia treatment outcomes across health care settings only are possible if those comparisons are made between groups with similar clinical profiles. Specific determinants of clinical outcomes that require documentation if comparisons are to be made among different health care settings include: (1) a measure of initial severity that includes a statement of prognosis (2) elucidation of the diagnostic tests used to define the disorder and determine the treatment (3) a thorough description of the treatments employed including their intensity and risk (4) a description of clinician experience, and overall patient motivation, and (5) documentation of the patient’s compliance with treatment.

Severity. Scales of dysphagia severity have not been validated. Most research publications operationally define severity by disease stage, physiologic status, and eating and drinking status. Most frequently, severity is referenced as a function of oral intake, such as the scale developed by Groher and Crary (unpublished, 1998):

1. Totally tube fed
2. Tube fed with minimal attempts at oral feeding
3. Relies on tube feeding, but takes some things by mouth
4. Takes most food orally, but limited to a single consistency
5. Takes multiple consistencies, but with some food class restrictions
6. Takes a regular diet with limitations on certain items, like can not take thin liquids
7. No restrictions on oral intake

Diagnostic tests used. Comparisons of outcomes among dysphagic groups can be judged best if the diagnostic test or combination of tests is known. For instance, are outcomes improved if one plans the dysphagic treatment on the basis of three tests instead of one? To date, only one study has been done to examine the influence of videofluoroscopy in the treatment planning of patients who were dysphagic secondary to head and neck cancer (Logemann et al., Dysphagia, 1992). In this study, patients were put into two groups; Group 1 was treated based on videofluorographic findings, and Group 2 was treated based on the clinical examination only. Both groups received videofluorographic swallowing studies at 3 months. Measurement of outcomes for both groups included the number that achieved total oral intake, the time it took to achieve full oral alimentation, and the number of medical complications in the first three months. The group that received treatments based on the clinical evaluation achieved full oral alimentation faster than the group who received the videofluorographic evaluation. Also, there were fewer medical complications in this group.

Treatments employed. To date there are no studies that document the efficacy of behavioral dysphagia treatment. There are numerous studies that have shown positive changes following treatment for chronic dysphagia, however, there was no control group. In these studies,
subjects served as their own control. One such study was done by Crary (Dysphagia, 1995). Using biofeedback assisted therapy for three weeks, he was able to restore oral feeding in 5 of 6 brainstem stroke patients who prior to therapy had not been eating orally. Not only did their functional intake improve, but there was demonstrated physiologic change. At 6 months and at one year following therapy, all patients maintained their level of intake.

**Therapist competence/patient motivation.** While there are published guidelines for those skills necessary to treat patients with oropharyngeal dysphagia, there are no guidelines for how to measure therapist competence in applying diagnostic and treatment procedures. The judgment of therapist competence is made difficult because there is confusion over how specific swallowing maneuvers are applied. For instance, it is well known that a chin down posture aids in airway protection, however, there is no clear definition of how much flexion is necessary to achieve this protection. Clinician agreement on treatment planning also is not uniform. Wilcox et al., (Journal of Speech and Hearing Research, 1996) showed that following videofluorographic swallowing studies clinicians were unable to agree on their treatment recommendations.

The American Speech, Language, and Hearing Association has formed a task force to develop scales that measure the outcomes of dysphagic treatments. Results of the first meetings have focused on the development of a functional outcome scale. Such a scale should be able to measure the effectiveness of dysphagia treatment, provide some type of predictive data, and be easily understood by patients and insurance companies. A functional outcome swallowing scale is a scale that measures a patient's performance in eating and drinking. What one eats and drinks, and how one eats and drinks are the two major components of the functional outcome scale.

What one eats and drinks includes the dietary level (from tube feeding to a regular diet), the amount of intake, saliva management success, and measures of success in taking medications orally. How one eats and drinks is defined by measures of independence, efficiency, and interactions with the environment.

**Independence.** Eating and drinking independence can be assessed by measures of the amount of supervision needed, and the type of assistance that is required. Assistance required can be further defined as the number of auditory and/or visual cues needed at each meal, and the presence or absence of the need for special prosthetic devices.

**Efficiency.** Measurement of eating and drinking efficiency is defined by four variables: (1) the amount of time necessary to complete the meal (2) the number of meals in a day necessary to meet nutritional requirements (3) the need for behavioral treatment strategies, and (4) the amount of difficulty and/or fatigue associated with the ingestion effort.

**Environment.** This variable is defined by the presence or absence of restrictions on with whom someone eats, or where they eat. For instance, some dysphagic patients do not eat with their families, or avoid eating in public.

Measurement of a patient’s health status is an important outcome variable to consider following dysphagia treatment. Of particular concern is the morbidity and mortality associated with the dysphagic condition. Three areas of morbidity of most concern are pulmonary integrity, nutritional status, and hydration. Hydration and nutritional status can be objectified by appropriate laboratory chemistry. Objective pulmonary measurements are difficult to obtain and are, therefore, more subjective. They may be defined simply as either the presence or absence of aspiration pneumonia, although this diagnosis often is controversial and somewhat presumptive.

One measure of physiologic status related to pulmonary integrity and dysphagia is a measurement scale developed by Rosenbek and colleagues (Journal of Speech and Hearing Research, 1998). This scale is useful because its reliability and validity are known. Eating and swallowing performance during videofluorography is scored on an eight point scale:

1. No material enters the airway
2. Enters airway above vocal folds and is ejected
3. Enters airway above the vocal folds and is not ejected
4. Enters airway, contacts vocal folds and is ejected
5. Enters airway, contacts vocal folds, and is not ejected
6. Enters airway below the vocal folds and is ejected
7. Enters airway below the vocal folds and is not ejected
8. Enters airway below the vocal folds and there is no attempt to eject

To date, there are no outcome scales that measure the impact of dysphagia specifically on the patient’s quality of life. The FACT scale (Harrison et al., Head and Neck, 1997) does include speech, diet, and aspects of eating in public as part of a scale that measures the quality of life in patients
who have been treated for head and neck cancer.

The cost associated with dysphagia management is important in assessing whether or not the benefits of particular outcomes are cost-efficient. In addition to a calculation of the resources (time, materials, equipment) needed to treat dysphagic patients, calculations of the cost-savings (reduced need for surgery, fewer medical complications, fewer readmissions) should be considered.

Final outcome measurements ideally should be accomplished by clinicians blinded to the patient’s condition in order to avoid bias in data interpretation. Measurement end points should be extended beyond the immediate treatment period, to periods up to one year in order to fully assess the benefits of treatment.

Ideally, we should begin work toward developing a single swallowing index score that would be reflective of outcomes associated with dysphagia management. Variables to consider should include: (1) the percent of oral/nonoral nutrition and hydration (2) the diet level (3) the time it takes to complete a single meal (4) the necessity for prosthetic devices and behavioral intervention, and (5) the need for, and type of supervision required.

In conclusion, I want to encourage and challenge you to spend time designing dysphagia outcome scales that are reliable and valid. If they do not meet these basic criteria we will not be able to make a rationale judgment of the effects of our treatments. We will not be able to determine differences in treatment outcomes unless we use similar measures. In the United States, we are just beginning to develop these measures in order to collect the amount of data we will need to justify the treatment resources devoted to dysphagic persons.