Title: Oropharyngeal Dysphagia Assessment and Treatment Efficacy: Setting the record straight. (Response to Campbell-Taylor).

Running Title: *Response to Campbell-Taylor.*

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Key Words

Dysphagia; swallowing; videofluoroscopy; evidence-based medicine

Abstract

In September, 2008, an article was published in the *Journal of the American Medical Directors Association*, criticizing current dysphagia assessment and management practices performed by speech-language pathologists in Long-Term Care (LTC) settings¹. In the same issue, an editorial invited dialogue on the points raised by Campbell-Taylor². We are responding to this call for dialogue. We find Campbell-Taylor's interpretation of the literature to be incomplete and one-sided, leading to misleading and pessimistic conclusions. We offer a complementary perspective to balance this discussion, on the four specific questions raised: 1) Is the use of videofluoroscopy warranted for evaluating dysphagia in the LTC population? 2) How effective are thickened liquids and other interventions for preventing aspiration and do they contribute to reduction of morbidity? 3) Can aspiration be prevented and is its prevention important? and 4) Is there sufficient evidence to justify dysphagia intervention by Speech Language Pathologists?

Key Words

Dysphagia; swallowing; videofluoroscopy; evidence-based medicine

We are writing to comment on two articles from the September, 2008 issue of the *Journal of the American Medical Directors Association*: the article entitled “Oropharyngeal Dysphagia in Long-Term Care: Misperceptions of Treatment Efficacy” by Campbell-Taylor¹, and the associated editorial by Thomas, entitled “Hard to Swallow: Management of Dysphagia in Nursing Home Residents”². The article by Campbell-Taylor takes the extreme position that current approaches to the assessment and intervention for oropharyngeal dysphagia (swallowing difficulties) are essentially futile in the Long-Term Care (LTC) setting, arguing that the available evidence does not support the benefits of instrumental examination, a link between the aspiration of food and liquid during swallowing and subsequent aspiration pneumonia, nor the effectiveness of common interventions such as texture modification, postural modifications or enteral feeding in reducing the occurrence of aspiration pneumonia. Campbell-Taylor is especially critical of the knowledge base and competency of speech-language pathologists as key players on the dysphagia team. The editorial by Dr. Thomas invites dialogue on the points raised by Campbell-Taylor. We are responding as speech-language pathologists engaged in dysphagia research and practice; many of us have been cited by Campbell-Taylor. Overall, the evidence cited by Campbell-Taylor is not inaccurate; however, the evidence has been selectively chosen to support an extremely negative perspective. We find this regrettable, and wish to contribute a more balanced and optimistic interpretation of the same and related evidence. We will focus on four questions in this letter:

- 1) Is the use of videofluoroscopy warranted for evaluating dysphagia in the LTC population?
- 2) How effective are thickened liquids for preventing aspiration and pneumonia?
- 3) Can aspiration be prevented, and is it important to do so?

4) Is there evidence to support the field of dysphagia intervention?

Is the use of videofluoroscopy warranted for evaluating dysphagia in the LTC population?

Campbell-Taylor criticizes the use of videofluoroscopy (also known as the modified barium swallow procedure) to evaluate swallowing in LTC residents, arguing that the procedure does not deserve to be considered a “gold standard” due to its potential to yield both false negative and false positive results with respect to identifying aspiration (the entry of material into the airway below the level of the vocal folds). Campbell-Taylor argues that the sensitivity and specificity of a full bedside examination to detecting aspiration is adequate and does not justify further examination using instrumentation.

We concur with Campbell-Taylor that a thorough bedside examination can provide strong suggestive inference that dysphagia or aspiration exist. We would like to point out, however, that a swallowing assessment seeks to do much more than identify the presence or absence of aspiration. While a videofluoroscopy is not always required to confirm the presence of dysphagia, a bedside swallowing test is usually not adequate for defining the nature and severity of dysphagia, particularly when pharyngeal phase abnormalities are suspected, or in cases of silent aspiration (aspiration without overt clinical signs such as cough)³. Furthermore, in the case of pharyngeal phase abnormalities, which include such impairments as inadequate airway protection or incomplete and inefficient transport of material through the pharynx into the esophagus, the videofluoroscopy provides a direct opportunity to evaluate the effectiveness of compensatory maneuvers that may reduce the impact of these abnormalities on airway protection and the delivery of nutrients to the digestive system. Until recently, the majority of dysphagia interventions were viewed by most clinicians as potentially beneficial, or, at worst, benign. However, Campbell-Taylor correctly points out that some dysphagia interventions may be

unhelpful or even maladaptive for particular patients (e.g. ⁴⁻⁷). This reality further underscores the importance of testing and observing the effect (and effectiveness) of specific interventions with instrumentation prior to recommending them for patients. The risks of implementing dysphagia interventions without instrumented demonstration of beneficial effect are increasingly recognized in regulatory documents such as the Practice Standards and Guidelines for Dysphagia of the College of Audiologists and Speech-Language Pathologists of Ontario⁸, and the guidelines published by the American College of Radiology⁹.

How effective are thickened liquids for preventing aspiration and pneumonia?

Campbell-Taylor makes reference to two recent articles in the dysphagia literature, reporting results from the largest randomized clinical trial of dysphagia interventions completed to date¹⁰⁻¹¹. This study (known to many as “Protocol 201”), Logemann, Robbins and colleagues evaluated the effectiveness of the chin tuck posture and of nectar-thick and honey-thick liquids in preventing aspiration in individuals who were confirmed to aspirate thin liquids in videofluoroscopy. Unlike the majority of the dysphagia literature, this study was not conducted with individuals recovering from stroke, but rather with individuals with either Parkinson’s Disease and/or dementia. Consequently, the results are of direct importance to LTC settings. The study was conducted in two phases. In part I, aspiration on thin liquids was confirmed in 711 participants (the majority of whom were over the age of 80), and the three experimental conditions were then tested in random order¹⁰. In summarizing the results of this study, Campbell-Taylor jumps to the results of the second phase of the project, in which the effectiveness of these interventions in preventing pneumonia was explored¹¹. In doing so, she neglects two extremely important details. First, phase one of the study¹⁰ confirmed that all three of the interventions successfully eliminated aspiration in 25% of the participants. Additionally, in

a further 26%, one of the three interventions was found to eliminate aspiration better than the other two. The honey-thick liquid was significantly more effective than nectar-thick liquid, which was more effective than the use of a chin-tuck posture with thin liquid. These results show that one or more of these three interventions were successful in effectively eliminating aspiration in 51% of the participants. To dismiss this finding as showing that thickened liquids “do not work” is an inaccurate and unnecessarily bleak interpretation. Perhaps the most correct interpretation of this study is that overall, 49% of senior individuals with Parkinson’s Disease and/or dementia failed to show favorable response to any of the three interventions tested and continued, therefore, to be at risk of aspiration and its consequences. Surely this does not negate the positive benefit demonstrated in the other 51% of participants.

The second detail that Campbell-Taylor conveniently omits from her summary of this work is the fact that aspiration was eliminated by one of the three interventions investigated in 25% of the patients evaluated in Part I of the study. The researchers were ethically obliged to exclude these patients from entering Part II of the trial because one of the three interventions in Part I eliminated aspiration while the other two interventions did not¹¹. These individuals were advised to implement the intervention that had proven most effective for them, but their health status outcomes were not monitored over the subsequent 3 months. Thus, we still do not know for certain whether implementation of an intervention that is shown to be effective in videofluoroscopy translates to better outcomes in the LTC population. Part II of the study proceeded as a true randomized control trial¹¹, with videofluoroscopic evidence (from Part I¹⁰) that the 515 participants had truly equal chances of responding favorably (or unfavorably) to the experimental interventions. As such, this study stands as a stellar example of impeccable design; few randomized controlled trials are able to demonstrate such equality in opportunity for either

positive or negative response in their participants. However, it must also be recognized that 2/3 of the participants in this phase of the study continued to aspirate in part I, despite any of the tested interventions; if such continuing aspiration constituted a direct risk for the development of pneumonia in the ensuing 3-month period, then one could have expected the pneumonia incidence in part II of the study to approach 66%. The cumulative incidence of pneumonia experienced in part II of the study was, in fact, much lower: 8% for those on nectar-thick liquids; 12% for those employing the chin-tuck posture; and 15% for those on honey-thick liquids¹¹. To put these numbers in context, they should be compared to population estimates of pneumonia incidence, which are reported at 1% for the population at large over the age of 65, and ten-fold that number for individuals aged 75 or older residing in nursing homes¹². Other undesirable health status outcomes (dehydration, urinary tract infection and fever) were also relatively rare in the Protocol 201 Part II population (none of these conditions occurred at rates higher than 6%)¹¹. While it is interesting, indeed, to ask new scientific questions about the relative risks demonstrated in the three experimental conditions, one must note that overall the incidence of health status complications was impressively low in a population of individuals at clear risk.

Can aspiration be prevented, and is it important to do so?

Campbell-Taylor argues that it is a misconception that aspiration can and must be prevented. We beg to differ. We concur that the use of dysphagia intervention techniques is unlikely to address or limit occurrences of aspiration of saliva or gastroesophageal reflux. However, we emphatically disagree that prandial aspiration (aspiration during the swallowing of food and liquid) cannot and does not need to be prevented. Prandial aspiration is among the most likely sequelae of dysphagia and serves as a direct vehicle for transporting pathogenic bacteria (which colonize the oropharynx and are typically present in oropharyngeal secretions) into the

respiratory system¹³⁻¹⁶. Researchers have shown that aspiration of colonized bacteria contained in saliva is one of the most predictable risk factors for pathogenesis of pneumonia in patients who have a history of aspiration¹⁷⁻¹⁹. Patients with laryngeal penetration, tracheobronchial aspiration, or silent tracheobronchial aspiration on videofluoroscopy have been found to be approximately four times ($p = 0.008$), 10 times ($p < 0.0001$), and 13 times ($p < 0.0001$), respectively, more likely to develop pneumonia in the ensuing 6 months than those with normal swallowing²⁰.

Therefore, when aspiration of food and/or liquid is confirmed during swallowing assessment, it is surely incumbent upon us to further explore any interventions that successfully limit the aspiration of those items and to recommend the adoption of these interventions in order to limit the prandial portion of the opportunities by which bacteria and harmful substances travel to the lungs. DePippo and colleagues²¹ investigated the effect of modest and high intensity traditional treatment of post-stroke dysphagia, compared to a control group that received no formal therapy. All patients were dysphagic, and received treatment for oropharyngeal dysphagia that included an oral diet supplemented by one or more traditional compensatory or rehabilitative maneuvers. Patients were randomized to a control or minimal intensity group (single visit counseling session), or one of two treatment groups (i.e., moderate or high intensity) after videofluoroscopic examination revealed aspiration on at least 50% of all consistencies assessed. This study identified a 22% reduction in the odds of pneumonia, dehydration and mortality of patients, during institutionalization and at three, six, and 12 months follow up, in the patients receiving intensive therapeutic interventions when compared to the no-treatment group. Likewise, Hinchey et al.²² identified a significant reduction in the odds of pneumonia in

institutions employing a formal dysphagia screening and management protocol for patients with stroke, compared to institutions in which no institutional dysphagia protocol was present.

When assessment shows that aspiration cannot be prevented by the available interventions, then this provides the justification for exploring the patient and family's wishes regarding nutritional support at the end of life. We agree with Campbell-Taylor that it is essential that clinicians of all disciplines recognize the complexities of this difficult situation and not misrepresent enteral feeding as a means of preventing aspiration pneumonia.

Acknowledging that certain interventions do not have a good track record in preventing aspiration pneumonia does not mean that attempts to prevent aspiration pneumonia are not worth pursuing. On the contrary, a modest reduction in pneumonia incidence would produce an enormous economic benefit and increased survival, justifying management of dysphagia²³. According to the Centers for Disease Control and Prevention²⁴, the seventh leading cause of death in the United States was attributed to influenza and pneumonia, the latter producing the majority of their combined mortalities. In 2005, annual pneumonia-related deaths totaled 63,001 and occurred at rates of 36, 142 and 594 per 100,000 in adults aged 65-74, 75-84 and over 85, respectively²⁵. Pneumonia is the most frequent cause of death by infectious disease in the United States²⁶.

In a large, population-based study of 11,286 stroke patients without co-occurring terminal disease or advance directives requiring "do not resuscitate" management, the mortality rate was six times higher (26.9%) in patients who developed pneumonia after onset of stroke compared to those that did not develop pneumonia (4.4%)²⁷. After adjustments for various underlying factors affecting mortality, the relative risk of death (RRD) of stroke patients who developed pneumonia

within 30 days post-onset was 2.99 (i.e., the probability of death was about three times higher) compared to stroke patients without pneumonia.

Baine and colleagues²⁸ reviewed 5% of all Medicare hospital inpatient bills from 1991 through 1998 to determine the estimated number of hospitalizations for aspiration pneumonia in the United States. Their 5% sample revealed that aspiration pneumonia constituted 15.5% of all Medicare pneumonia admissions, and ranked second only to ‘unspecified causes of pneumonia’ as coded in hospital discharge summaries. Extrapolating these data to the population, an estimated 743,000 pneumonia admissions occurred in 1998, with aspiration pneumonia constituting 115,120 or 15.5% of Medicare hospital admissions for pneumonia that year. Aspiration pneumonia carried the highest case-fatality rate during hospitalization (23.1%) of all pneumonia diagnoses.

In another analysis of Medicare source data, Niederman and colleagues²⁹ determined that more than \$8 billion was spent treating hospital inpatients for community acquired pneumonia (CAP), at an average cost per stay of \$6,000 to \$7,000 (in 1998 US dollars). Combining information from both of the aforementioned Medicare review studies, the proportion of CAP inpatient hospital cost for aspiration pneumonia was 15.5% of \$8.4 billion, or approximately \$1.3 billion. Given these figures, the impact of a modest ten percent reduction in either hospital admissions or in length of stay for aspiration pneumonia could save the health care system hundreds of millions of dollars each year, and eliminate thousands of deaths annually.

Is there evidence to support the field of dysphagia intervention?

Campbell-Taylor lodges harsh criticism against the field of dysphagia intervention, citing a relative lack of evidence, a paucity of randomized controlled trials, and questionable applicability of results from research of better-studied population groups (i.e. stroke) to other

groups (i.e. individuals in LTC). These same criticisms can also, however, be fairly lodged against the interventions that Campbell-Taylor appears to favor (such as oral hygiene) though they are widely accepted. Similarly, the criticisms that she makes of our profession (speech-language pathology) with respect to inadequacies in dysphagia training, credentialing and competency can also be lodged against other professions. The singling out of one discipline for such criticism is biased. A major component of the research enterprise is to identify needs of a field of study or a profession for continued growth and development. Healthcare professions and medicine are always changing and evolving and developing new techniques and treatments as our knowledge improves and changes. Our speech-language pathology literature admits to such shortcomings in articles published with the intent of encouraging higher standards, e.g.³⁰. It would be unethical to stay with the *status quo* and not identify or admit to training needs. Such admission surely reflects an admirable commitment to promoting higher scientifically based standards for a profession.

With respect to the current level of evidence for dysphagia interventions, we would like to remind the reader that many accepted medical practices have lacked robust evidence throughout history. The current trend of evidence based medicine has spawned much insight regarding the importance of external evidence, but it has also produced a small, zealous constituency that believes external evidence in the form of randomized, controlled trials, is the only acceptable evidence to justify medical interventions. While randomized controlled trials have become the accepted “gold standard”, they are not always necessary to demonstrate effect (either positive or negative). We offer a few examples for consideration:

- Willow bark was prescribed by Hippocrates to relieve pain, fever, and inflammation, as long ago as 400BC, and its eventual derivative, aspirin, gained widespread acceptance

though research into its effects did not begin until the mid 20th century. Aspirin has now been shown, through continued investigation, to possess numerous beneficial properties.

- Thalidomide was developed in the 1950's for nausea associated with pregnancy. In 1962, a single physician noted numerous birth defects in children born to his patients to whom he had prescribed the drug. His letter³¹, not a randomized trial, spawned worldwide awareness of the negative effects of thalidomide.
- Users of the parachute have universally accepted it as an intervention to reduce morbidity and mortality caused by “gravitational challenge”, though it has never been put to a randomized controlled trial³².

It is also important to remember that dysphagia therapy is designed to reduce adverse sequelae, but complete elimination of sequelae is not possible in any disease/disorder treatment.

We do not dispute the importance of adequate academic and clinical preparation of health care professionals managing dysphagic patients, nor do we disagree that there are underqualified clinicians involved in dysphagia management. There are underqualified physicians, dentists, pharmacists and lawyers practicing as well. Speech-language pathology has recognized this important issue and has established Specialty Board Recognition in Swallowing Disorders which is no different, except in name, from Board Certification. Specialty Board Recognition has established a bar well above minimum entry-level competencies, in order to offer the referring physician and the consumer alike, a benchmark of competence against which to measure their dysphagia clinician.

Campbell-Taylor commits a classic Aristotelian material fallacy, the “call to perfection” throughout her manuscript. This fallacious form of argument is committed when one contends to postpone some action or policy until some unlikely event or impossible change is achieved. The

most egregious employment of this fallacy is in Campbell-Taylor's assault on the Veterans Health Administration (VHA) efforts to streamline and standardize the assessment of patients with suspected dysphagia³³⁻³⁴. The guidelines developed by VHA provide comprehensive direction to clinicians to enable a uniform approach to assessment and treatment of patients with dysphagia. The VHA is not alone in promoting standardization in dysphagia practice. Notably, a new standardized evaluation tool for the videofluoroscopic assessment of swallowing impairment is currently in press³⁵. This tool, the MBSImp, has been rigorously tested in a heterogeneous, representative, cross-sectional sample of patients referred for videofluoroscopy based on scored observations of physiologic and bolus flow measures. Use of the MBSImp was characterized by high inter- and intra-rater reliability following standardized training for SLP clinicians with a minimum of 3 years post-certification experience. Such efforts to contain, steer and standardize what has previously been perceived and demonstrated to be inconsistent and variable clinical practice should be saluted rather than denigrated.

Evidence-based medicine relies on the combined contributions of best external evidence, best clinical judgment, and patient values and expectations³⁶. We submit that clinicians and scientists working with dysphagic patients, who maintain optimal clinical competency, continuing education and professional preparation, are qualified to make judgments regarding the value of dysphagia interventions. We acknowledge Campbell-Taylor's adoption of the principles of evidence-based medicine; we cannot, however, sanction the manner in which she has cherry-picked data from selected research, expert opinion, commentary, and comments from the discussion sections of published research, to support her premise.

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Conflicts of Interest:

None of the authors have any conflicts of interest to declare with respect to this manuscript.