Critical Review:
The effects of a free-fluid protocol on individuals with thin-liquid dysphagia

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This critical review examines the effects of free-fluid protocols on individuals with thin-liquid dysphagia. A literature search was completed resulting in two studies, four abstracts, and one book chapter that met the inclusion criteria. Study designs included randomized control trials, nonrandomized between groups, and single group. Overall, the research suggests that free-fluid protocols do not increase risk of pneumonia or other adverse events. Suggestions for future research and clinical implications are also discussed.

Introduction

Dysphagia, or swallowing difficulty, is especially common in stroke populations and is associated with complications such as dehydration, weight loss, malnutrition, and aspiration. One of the most serious complications arising from aspiration is aspiration pneumonia, which can have serious and life-threatening consequences (Chernoff, 1994; Langmore et al., 1998).

The goals of dysphagia management include balancing nutrition and hydration needs while reducing risk of aspiration. Typically, this is accomplished by modifying the consistency of the patient's diet, in particular by thickening liquids (Mills, 2008; Logemann, 1998). In fact, thickening thin liquids is one of the most common recommendations made by clinicians (Garcia, Chambers, & Molander, 2005) as it is assumed they move more slowly through the swallowing mechanism allowing the patient more time to trigger a complete and adequate swallow. However, the use of thickened liquids poses several challenges for patient satisfaction and compliance. Several studies have found that patients dislike thickened fluids, leading to a refusal to drink which causes decreased fluid intake and dehydration (Colodny, 2005; Garcia et al., 2005; Logemann et al., 2008; Macqueen, Taubert, Cotter, Stevens, & Frost, 2008). In her qualitative study, Colodny (2005) found that typical complaints toward thickened fluids include: aversion to taste, feeling full, and constant thirst sensation. In addition, modified foods and liquids are socially stigmatizing and largely impact social participation and quality of life (QOL) (Davis, 2007). Therefore, considering patient preference when selecting an intervention may not only improve compliance, but also quality of life (Colodny, 2005; Davis, 2007).

Free-fluid protocols attempt to combat these obstacles through the combination of oral administration of water between meals and strict oral care. In theory, the literature supports free-fluid protocols. Langmore et al. (1998) determined that the number one predictor of pneumonia was dependency for feeding (not aspiration or dysphagia). Further, when combined with oral care, water's neutral, safe pH does not cause damage to the lungs, and if aspirated (as one may do when swimming), aquaporins, or water channels in the lungs enable safe water absorption (Effros et al., 1997). Despite these facts, the safety of using water for individuals with dysphagia is highly debated among physicians and swallowing experts especially because research specifically addressing free-fluid protocols is limited.

Objectives

The primary goal of this paper is to conduct a critical evaluation of the current research literature investigating the effects of free-fluid protocols on individuals with thin-liquid dysphagia. A second objective is to offer evidence-based practice recommendations for speech-language pathologists and health care providers.

Methods

Search Strategy

Computerized databases, including PubMed, CINAHL, Google Scholar, and SCOPUS were searched using the following criteria:

> (dysphagia OR swallow OR deglutition disorder) AND (aspiration) OR (aspiration pneumonia) AND (free-fluid protocol) OR (frazier free water protocol) OR (free water protocol) OR (water protocol) OR (hydration) OR (oral care) OR (oral hygiene).

Due to the relatively limited results, an informal search using the aforementioned key words was completed via Google Web.

Selection Criteria

The articles included within this evaluation were written in English, with no limits on the publication date. All studies were required to examine or discuss free-fluid

protocols. There were no limits based on differences in protocols.

Data Collection

Results of the literature search and above selection criteria yielded the following study designs: randomized control trial (RCT) (3), nonrandomized between groups (1), and single group studies (3). The analyzed studies consisted of two peer-reviewed articles, two abstracts from published proceedings, two abstracts available online, and one book chapter.

Results

The studies discussed below are organized in accordance with the Oxford Center of Medicine's (2011) levels of evidence. The strength of the evidence is categorized into three levels: suggestive (possible), preponderant (probable) and conclusive (definitely true) (Smith, 1981).

Randomized Control Trials

Randomized control trials are the gold standard of experimental research, or level 1 evidence. Randomization reduces the likelihood that groups differ before the study and thus increases the confidence that any differences noted after the study can be attributed to the variable investigated. Therefore, the conclusions drawn from these studies can be considered high levels of evidence.

Garon, Engle, and Ormiston (1997) investigated whether patients with dysphagia would increase oral fluid intake without developing pneumonia if allowed access to water between meals. A randomized control trial was employed for this study and included stroke patients with documented aspiration of thin liquids. Participants were randomly assigned to either the treatment group (thickened fluids and water between meals; n=10), or the control group (thickened fluids only; n=10). Outcome measures included occurrence of aspiration pneumonia, occurrence of dehydration, need for intravenous fluid, amount of thickened fluid and water consumption, time to "no aspiration" status, and patient satisfaction. Following the study and 30 day follow-up, none of the participants developed pneumonia, dehydration, or other complications. While specific analytic procedures were not described, data analyses were reported to reveal a significant difference in the amount of thickened fluid consumed between the two groups. None of the other dependent variables resulted in significant differences. The patient questionnaire revealed high satisfaction among the treatment group and low satisfaction in the control group.

Participants were recruited based on documented aspiration verified by videofluoroscopic study. Subject inclusion and exclusion criteria were well documented and participant characteristics were well-described. Independent, dependent, and modifier variables were discussed and experimental procedures were thoroughly outlined. Staff and family members were well-educated regarding the study procedures and recording of fluid intake data, but none were blinded, nor were any inter-rater reliability measures reported.

Despite the high validity, there were some limitations with respect to sample size, reproducibility, and generalizability. Garon et al. (1997) acknowledged small sample size as one limitation of the study, stating that some of the findings may have been significant had the sample size been larger. Patient participation was also limited to those who were able to sufficiently consent to the study. Additionally, reproducibility would be difficult as documentation of statistical methods was absent and a thorough description of the questionnaire was not provided. Thus, the findings can be considered preponderant evidence, suggesting that a free water protocol improves patient satisfaction and does not increase risk of aspiration pneumonia for individuals with adequate cognitive capacity.

Carlaw et al. (2010) examined the effectiveness of the GF Strong Water Protocol on fluid intake, satisfaction, QOL, and adverse events for individuals with thin-liquid dysphagia in an unpublished randomized control trial. This research is presented in an abstract as well as an online presentation. All outcome measures were assessed prior to initiation of the study, which increases the validity of the results. The researchers found that none of the participants experienced adverse events (e.g. pneumonia, acute care hospitalization). The study also revealed that participants assigned to the water intake group experienced a 5% increase in fluid intake when compared to the control group ($p=0.03$). On the quality of life measure (SWAL-QOL), those in the treatment group had overall improved scores and significant improvements on the symptom and fear subscales. Documentation of statistical methods was not reported, which may be a result of the unpublished format.

All participants had confirmed aspiration on videofluoroscopy. Exclusion criteria were clearly outlined. Six of the included subjects were randomly assigned to the control group (no water) and eight to the treatment group (water access). Subsequently, five of the control participants crossed-over to water access. Details regarding intention to treat analysis and additional information regarding participant characteristics were not provided.

A strength of this study is its ease of reproducibility. The researchers provided a very thorough outline of the methods of selection, water protocol, and oral care protocol employed in this study. Additionally, the researchers used outcome measures (SWAL-QOL, fluid intake) that have documented reliability and validity (Davis, 2007). While the design employed is excellent, the data remains incomplete as it has not been peer assessed. Thus, the results of improved quality of life, increased fluid intake, and lack of adverse events for the individuals receiving free-fluid protocols must be considered preponderant at present.

Becker, Tews, and Lemke (2008) studied whether the use of oral water protocols would yield differences in adverse event rates, physical, cognitive, and swallowing recovery, and length of hospitalization among patients with thin liquid dysphagia. The investigators used a randomized control trial; however the results were reported in an unpublished format, which limits the strength of the evidence. All 26 participants had confirmed thin-liquid dysphagia by videofluoroscopy and were stratified into independent versus assisted feeders prior to randomization in either the control group (no water) or the treatment group (unlimited oral access to water outside of meals). A thorough description of patient factors was provided, which showed some initial differences between the groups. In the description of follow-up analyses, the researchers indicated controlling for these pre-treatment differences, but specific methods of analysis were not reported. Results of the data analyses did not reveal any differences between the groups in adverse events, physical and cognitive recovery, or swallowing recovery. However, the treatment group had significantly decreased duration of hospital stay ($p=0.003$). Interestingly, it was also determined that the independent feeders consumed significantly less daily fluid than the assisted feeders, regardless of group.

This study included the analysis of an important variable (assisted vs. independent feeding) in patient characteristics, which improves generalization. Unfortunately, the small sample size places limitations on overall generalizability and, in combination with the intrinsic limitations of unpublished research, the evidence that free fluid protocols did not cause adverse events and decreased length of hospitalization should be considered as preponderant evidence. Thus, the clinical application of these findings must be done with caution.

Non-randomized between group comparison

Non-randomized between group comparisons enable researchers to compare the effects of two different treatments. However, they are subject to many biases, particularly confounding and selection.

Bronson-Lowe et al. (2008) presented findings of an unpublished between group comparison evaluating fluid intake, risk of dehydration, and pneumonia development. This research is presented in an abstract and an online presentation. The researchers used historical chart data as the control group and following the intervention, a concurrent control was added. This consisted of patients who were eligible for the intervention but did not receive it during the time of the study. The addition of a concurrent control group adds validity to the findings, however, because it was done retrospectively there are limitations based on patient selection and true group differences. Participants were deemed eligible based on restriction from thin liquids for at least one day. The study consisted of 101 participants (30 historical controls, 46 treatment group, and 25 concurrent controls). The selection criteria for the treatment group were not reported. Researchers reported no significant intergroup differences, except that the treatment group consisted of more individuals with Parkinson's disease. Results of the study found a significant difference in occurrence of pneumonia in favour of the treatment group when compared to the concurrent group, but not the historical controls. There were no differences on gross measures of dehydration, but significant improvement in fluid intake for the free-fluid group when compared to both controls.

While this study employs a level 2 research design, there are many limitations that reduce the strength of the results. There are no pretest measures, thus, despite the use of controls it is difficult to verify the change as it is uncertain whether the groups were initially different. There was no discussion regarding the selection of treatment group subjects. The treatment and data collection procedures were not reported and the statistical methods were not described. Further, the study is unpublished. All of the aforementioned weaknesses in methodology require that the results be interpreted with caution. The findings of improved fluid intake and lack of adverse events for those on the free fluid protocol must be considered borderline preponderant.

Single Group Studies

Single group designs are often employed in descriptive studies where the researchers observe the effects of a particular event. This is important in obtaining "real life" data and detailed information, which can then be used in future experimental studies. There is no control group and numerous threats to internal and external validity exist. Thus, single group studies constitute level 4 evidence.

Panther (2005) employed a retrospective single group study investigating the occurrence of pneumonia among

individuals placed on the Frazier Free Water Protocol. She looked at 234 charts over an 18-month period, and through visual inspection, identified two patients who developed aspiration pneumonia. The methodology employed by this study was limited as only one effect of the protocol was analyzed. However it specifically addressed the research question and thus was appropriate in this study.

The large sample size suggests that this study is representative of the target population. However, participant characteristics and the specific selection criteria for inclusion were not discussed. The fact that 232 patients did not develop pneumonia can be considered preponderant evidence, however, significant selection bias and limited reproducibility reduces the confidence with which one can generalize and apply these results to clinical practice.

Scott and Benjamin (2010) used a prospective single group study to evaluate the effects of a free fluid protocol for dysphagic residents in a long-term care facility. Sixteen males and ten females were given free fluid over a ten month period. Through visual inspection, the researchers found that none of the participants developed pneumonia, nor did anyone suffer from any new acute illnesses. Three patients died due to pre-existing medical conditions.

Information on subject selection and experimental procedures was limited and although the authors discussed the types of patients included in the study, the specific characteristics were not reported. Additionally, there was no mention of statistical procedures performed, this is especially important in this study as three participants died during the study period. While there are inherent limitations to single group studies, more sophisticated statistical analyses could have strengthened the validity of this study.

In conclusion, Scott and Benjamin (2010) completed a study with many methodological limitations, thus the claim that free fluid protocols do not increase adverse events can only be considered suggestive.

Nevitt (2010) investigated the effects of the Frazier Free Water Protocol on 15 patients with thin liquid dysphagia in an unpublished abstract. Replication of the study was limited in several ways: the procedures were only outlined in moderate detail and participant selection, characteristics, and statistical procedures were not discussed. The reported results indicated no cases of pneumonia and increased patient satisfaction. The unpublished nature of this study makes it difficult to critically analyze and limits the confidence with which these results can be applied to clinical practice. Therefore, this evidence is deemed suggestive.

Discussion

A review of the available evidence regarding the effects of free fluid protocols on individuals with thin liquid dysphagia revealed that, in general, individuals receiving free access to water do not have an increase in adverse events, specifically pneumonia. Additionally, individuals on the protocol appear to have increased patient satisfaction and quality of life. Interestingly, one study found that the free fluid protocol decreased length of hospitalization (Becker et al., 2008). It is difficult to claim increased fluid intake, however, since not all studies reported similar findings.

While all studies had intriguing results, there were a number of weaknesses that limit the application into clinical practice. The biggest limitation was the lack of peer-reviewed studies. Peer-reviews ensure a high quality of evidence and require that the researchers adhere to specific standards. Thus, four of the reviewed articles could not be fully critiqued, which limits their contribution to the overall findings.

Other weaknesses were found in the design and procedure of the studies, including small sample size, potential participant selection bias, poor demographic data and a lack of sophisticated statistical analyses. Experimenter bias, performance bias, and placebo effects were of particular concern since none of the studies mentioned the use of blinding procedures. Some of this limitation is inherent to the question being studied as subjects will always know whether or not they are allowed access to water, however evaluators and participants could have been blinded to the purpose of the study. Therefore, it is difficult to say whether the positive results were truly due to water access or participants' positive feelings toward their treatment.

An additional confounder was the concurrent oral hygiene component. None of the studies discussed whether or not the control groups were receiving the same oral care protocols. Thus, perhaps some of the positive results (i.e. decreased hospitalization, improved quality of life) were a result of the increased attention to oral hygiene and not access to water.

Further, many of the studies have limited generalizability, as patient selection excluded a large number of participants (super coughers, patients with dementia, patients on ventilators, etc). Additionally none of the studies included fidelity measures, which would ensure fluid intake measures, diagnosis of

pneumonia, and oral care procedures were conducted consistently without introducing additional variables.

Conclusion

Future research

It is recommended that future research be conducted to clarify and confirm the effects of free-fluid protocols on individuals with thin liquid dysphagia. In order to improve the level of evidence that is currently in the literature, the following considerations should be made:

a) Future research should include power calculations as well as confidence interval calculations when differences are found. This ensures large enough samples for finding true differences and is particularly important when binomial distribution (presence/absence of aspiration) is being considered.
b) Incorporating measures of feeding dependence and patient compliance as additional variables is necessary in order to further the understanding of free-fluid protocol effectiveness and appropriate candidates.
c) Future studies would benefit from expanding outcome measures to include patient satisfaction surveys, length of hospitalization, and swallowing ability. Thus, additional purposes or uses of free water access may be observed and incorporated into dysphagia management.
d) Baseline measures of fluid intake, swallow rating (ie: penetration aspiration scale,) and quality of life (SWAL-QOL) should be included to ensure true group differences.
e) Incorporating fidelity measures would strengthen the generalizability and reliability of the findings.
f) Discussion of cost-benefit relationship between thickened fluid and free fluid protocols may assist policy makers when deciding whether to implement these protocols.

Clinical Implications

It has been noted that conclusive evidence may not always be available, especially in health care. However, the appraised studies have provided evidence that enable informed decisions, which are "certainly better than no informed conclusions at all" (Smith, 1981; p. 278). Thus, while the literature is lacking in strong proof, there is a growing and consistent body of evidence supporting the positive effects of free fluid protocols, including patient satisfaction and improved QOL. This is an important aspect of dysphagia management. Speech-Language Pathologists (SLP) should consider the potential positive impact of free fluid protocols when determining treatment. Further, none of the studies revealed an increase in adverse events with the protocol. Based on the appraised research, it seems most appropriate that SLPs exercise caution when implementing free fluid protocols, but that such protocols can be implemented safely. The best way to accomplish this is through patient, family, and staff education regarding the importance of oral hygiene and compliance with protocol procedures. Further, SLPs must commit to careful monitoring and appropriate patient selection.

References

Becker, D.L., Tews, L.K., & Lemke, J.H. (2008) [Convention presentation]. Retrieved from http:// www.asha.org/Events/convention/handouts/2008/ 1877_Tews_Lisa.htm

Bronson-Lowe, C.R., Leising, K., Bronson-Lowe, D., Lanham, S., Hayes, S., Ronquillo, A.M., & Blake, P.A. (2008, March). Effects of a Free Water Protocol for patients with dysphagia. In *Dysphagia Research Society: 17th Annual Dysphagia Research Society Meeting*, New Orleans, Louisiana, March 4-7, 2009. (pg 23). Dysphagia Research Society; Continuing Medical Education Resources Inc.

Carlaw, C., Finlayson, H., Beggs, K., Marcoux, C., Visser,T., Coney, D., & Steele, C. (2010, March). Implementation of a water protocol in clients with thin liquid dysphagia: preliminary results of a randomized trial. In *Dysphagia Research Society: 18th Annual Dysphagia Research Society Meeting*, San Diego, California, March 3-6, 2010 (pg 39). The Dysphagia Research Society; Continuing Medical Education Resources Inc.

Chernoff, R. (1994). Meeting the nutritional needs of the elderly in the institutional setting. *Nutrition Reviews*, 52 (4); 132-136.

Colodny, N. (2005). Dysphagic independent feeders' justifications for noncompliance with recommendations by a speech-language pathologist. *American Journal of Speech- Language Pathology*, 14, 61-70.

Davis, L.A. (2007). Quality of life issue related to dysphagia. *Topics in Geriatric Rehabilitation*, 23(4); 352-365.

Effros, R.M., Darin, C., Jacobs, E.R., Rogers, R.A., Krenz, G., & Schneerberger, E.E. (1997). Water transport and the distribution of aquaporin-1 in pulmonary air spaces. Journal of Applied Physiology, 83; 1002-1016.

Garcia, J. M., Chambers, E., & Molander, M. (2005). Thickened liquids: practice patterns of speech-language pathologists. *American Journal of Speech-Language Pathology, 14*, 4-13.

Garon, B.R., Engle, M., & Ormiston, C. (1997). A randomized control study to determine the effects of unlimited oral intake of water in patients with identified aspiration. *Journal of Neurological Rehabilitation*, 11; 139-148.

Langmore, S. E., Terpenning, M.S., Schork, A.,Chen,

Y., Murray, J., & Loesche, W.J. (1998). Predictors of Aspiration Pneumonia: How Important is Dysphagia? *Dysphagia* 13; 69-81.

Logemann, J.A., Gensler, G., Robbins, J., Lindblad, A.S., Brandt, D., Hind, J.A., Kosek, S… Miller Gardner, P.J. (2008). A randomized study of three interventions for aspiration of thin liquids in patients with dementia or parkinson's disease. *Journal of Speech, Language, and Hearing Research*, 51; 173-183.

Logemann, J.A. (1998). Evaluation and Treatment of Swallowing Disorders. Pro-Ed Inc. Texas, USA.

Macqueen, C.E., Taubert, S., Cotter, D., Stevens, S., Frost, G.S. (2003). Which commercial thickening agent do patients prefer? *Dysphagia*, 18:46–52.

Mills, R.H. (2008). Dysphagia Management: Using thickened liquids. *The ASHA Leader*. Retrieved from http://www.asha.org/Publications/leader/2008/081014/f081014a4.htm

Nevitt, J. (2010). The Frazier Free Water Protocol improves compliance with modified diets. Online Abstract. Retrieved from www.nurseweb.ucsf.edu /conf/cripc/ebpabstract/nevitt/.pdf.

OCEBM Table of Evidence Working Group. (2011). The oxford 2011 table of evidence. *Oxford Centre for evidence based medicine*. Retrieved from http://www.cebm.net/index.aspx?o=5653

Panther, K. (2005). The Frazier Free Water Protocol. *Swallowing and Swallowing Disorders*. 4-9

Scott, A., & Benjamin, L. (2010). Implementation of a free fluid protocol in an aged care facility. In Roddam, H., & Skeat J. (Eds.), *Embedding evidence-based practice in speech and language therapy: International examples* (pp 184-188). UK: John Wiley & Sons Ltd.

Sharpe, K., Ward, L. Cichero, J., Sopade, P., & Halley, P. (2007). Thickened fluids and water absorption in rats and humans. *Dysphagia, 22*, 193-203.

Smith, N.L (1981). The certainty of judgments in health evaluations. *Evaluation and Program Planning 4(3-4)*; 273-278.