Oropharyngeal dysphagia, free water protocol and quality of life: an update from a prospective clinical trial

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Abstract

Oropharyngeal dysphagia, typically associated with older adults, represents a spectrum of swallowing disorders with potentially serious complications and a negative impact on quality of life. A major complication of dysphagia is caused by aspiration, predominantly of thin liquids, which may cause aspiration pneumonia. Given that thin liquids are typically aspirated, the conventional therapy involves altering the diet to one consisting of modified solid consistencies and thickened fluids. While it is well known that this approach is appropriate for aspiration, it does represent difficulties with compliancy and quality of life. We have undertaken a relatively large scale clinical trial to investigate the relationships between the effects of free access to water and the development of aspiration, aspects of hydration and issues related to quality in people with dysphagia. Along with clinical observations and findings from others we have previously stratified people with dysphagia, namely those that are immobile or who have low mobility and severe degenerative neurological dysfunction, at highest risk of developing aspiration pneumonia following intake of water. In the present study, we have extended our previous clinical results. Our findings indicate that following purposeful selection of people with dysphagia with their own mobility and relatively healthy cognitive function, free access to water did not result in aspiration pneumonia, improved measures of hydration and in particular, significantly increased quality of life when compared to a diet consisting of thickened fluids only. Overall, we conclude that in people with good mobility and cognitive ability, there is no need to deviate from the Frazier Rehabilitation Centre free water protocol, which allows for the provision of water to people with dysphagia with strict guidelines particularly in relation to good physical ability.

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Introduction

Oropharyngeal dysphagia refers to a range of swallowing disorders and is a common clinical problem, affecting mainly older adults [1]. It is typically associated with cerebrovascular conditions (CVA; stroke), degenerative neurological dysfunction and certain advanced cancers, particularly those of the head and neck [2-7]. Major complications of oropharyngeal dysphagia include severe malnutrition, dehydration and in certain cases a specific type of pneumonia, referred to as aspiration pneumonia may develop [8-11]. Indeed, the causal relationship between aspiration and the development of pneumonia is well-established [12]. In certain cases, postural interventions have been shown to be beneficial, particularly in less advanced cases [13, 14]. However, given that thin liquids are the most likely consistency to be aspirated conventional treatment, particularly at early stages, involves dietary modifications. Typically, intervention entails the prescription of a diet consisting of modified solids and in most cases to thickened liquids ranging from extremely to moderately and mildly thick consistencies [15]. Although from a strictly clinical perspective modified diets successfully alleviate swallowing problems and decrease the risk of aspiration, issues with quality of life are major concerns. The dissatisfaction of people prescribed thickened fluids is very difficult to ignore and in many cases reaches the point of non-compliance [16, 17]. These issues have created an enduring debate and sometimes confusion in the clinical management of people with dysphagia.

We designed a relatively large-scale prospective study to investigate the effects of the provision of water to people with dysphagia on the risk of aspiration, hydration status and quality of life. To date, we have recruited >120 people with oropharyngeal dysphagia and our findings from the first cohort of studies have been reported previously [18]. Briefly, we identified a subset of people with dysphagia, namely those that are immobile or who have low mobility and severe degenerative neurological dysfunction that should be strongly encouraged to adhere to modified diet [18]. Importantly, we have not observed evidence of complications from aspiration in people with relatively healthy cognitive function and who have relatively good mobility. Therefore, following the initial clinical, only suitable people have been placed on a free water protocol for assessment of issues related to quality of life. As described below, our findings related to quality of life are intriguing, with the perceived improvement of quality of life not requiring statistical analysis for significance. The findings from the present study confirm our previous findings and further highlight the improvement in quality of life associated with the provision of the free water protocol.

Methods

The present trial was conducted at the West Wimmera Health Service, a regional hospital, approximately 360 kilometres from the capital city Melbourne, in western Victoria, Australia. In this arm of the trial (St John of God Hospital reference number: JLG:DMSDir/HREC11Dec08/5.1) we have recruited 16 people (6 female and 10 male). The mean and standard deviation of ages were 84±6 years and 85±11 years for females and males, respectively. The major underlying clinical condition was diagnosed on admission by qualified physicians. Oropharyngeal dysphagia was diagnosed by an experienced clinical speech pathologist. People with dysphagia generally suffered from multiple ailments, the most common being CVA with an accompanying neurodegenerative condition or mood variation (depression, anxiety).

In the first of two separate phases of the study design, thorough education was provided to medical, nursing and other allied health staff who are part of the multi-disciplinary team providing healthcare to people with dysphagia. An important aspect was implementation of an appropriate oral hygiene protocol prior to the provision of water. Oral toilet was identical for all the people recruited to the study and required that water be provided only 30min after a meal following thorough brushing of teeth or cleaning of dentures. Pharmacy provided chlorhexidine gluconate (0.12%) solution was used as a rinse was to ensure thorough cleaning of the oral cavity prior to the provision of water. In the second phase, recruited people were monitored carefully for five days while they consumed the modified diet consisting of the prescribed thickened fluids which ranged included extremely thick (puree), moderately thick (smooth puree) and mildly thick (minced) consistencies (designated pre-intervention). Following this five day period participants continued the consumption the prescribed thickened modified diet and were allowed access to water as requested under strict nursing guidance. Participants were monitored carefully for an additional five days (designated post-intervention).

Apart from daily chest examinations by experienced medical staff, full blood examinations and nasal swabs to detect for pneumococcal a-b, respiratory syncytial virus and influenza A/B were performed on the final days of the pre- and post-intervention stages. Further, total fluid intake (thickened fluids and water) for each of the participants was measured and recorded daily. Simple but informative quality of life surveys were administered, also on the final days of the pre- and post-intervention stages.

Statistical analysis

Paired t-tests were performed to calculate p-values for evaluating statistical significance for the hydration and quality of life surveys.

Results

The characteristics of the people with dysphagia recruited in this study, including the prescribed thickened fluid diet and underlying clinical conditions are summarized in Table 1.

Table 1. *De-identified characteristics of people with dysphagia recruited in this study*

Patients	
Total	16
Age (mean ± SD)	81±11
Female	6
Male	10
Underlying condition*	
CVA**	6
Mild (early) dementia	3
Cancer	3
Parkinson's disease	2
Ischemic heart disease	1
Traumatic brain injury	1
Oral	
Own teeth	4
Dentures	9
No teeth	3
Modified Diet	
Mildly thick	7
Moderately thick	4
Extremely thick	5

*People typically had multiple ailments and underlying condition refers to the major presenting disease

**CVA = cerebrovascular accident (stroke)

The results from the accredited pathological service were unremarkable with all nasal swabs returning negative results. Similarly, chest and full blood examinations were unremarkable. With respect to hydration, four (25%) people

required intravenous fluid for the entire ten day period with typically 2000mL being administered per day. A further, three people (18.8%) required intravenous administration for between one to three days throughout the study; two of these participants received two days of intravenous fluid only during the pre-intervention phase. As anticipated and highlighted in Figure 1, fluid intake was variable for each participant over the 10 day period. Overall, the results indicate a significant difference in fluid intake with a mean±standard deviation of 1241±209mL and 1629±313mL (P<0.001), for the total intake during pre- and post-intervention stages, respectively (Fig. 1).

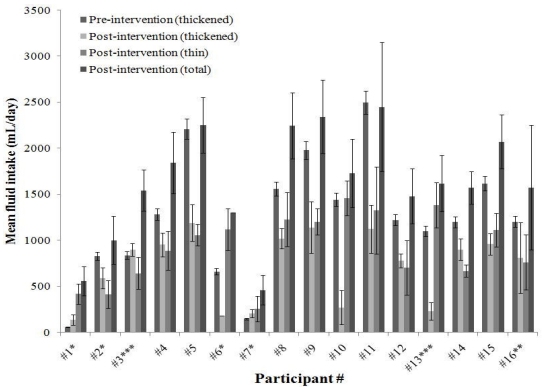

Figure 1. Daily oral fluid intake by the participants in the study. Comparison of the mean total daily oral fluid intake by people in the pre- (thickened fluid only) and post-intervention (thickened fluid and free access to water) stages of the study. * These participants required intravenous fluid administration for the duration of the study. ** Participant required intravenous fluid administration for two days in the pre-intervention phase and one day in the post-intervention phase. *** Participants required intravenous fluid administration for one day each in the pre-intervention phase.

A total of 11 (69%) participants completed both the pre- and post-intervention surveys. The surveys comprised of four simple questions and an adaption of the Wong and Baker, 1986, faces rating chart was used to calculate scores [19]. Scores ranged from 0-10, were designed to assess general well-being and satisfaction and lower scores on the scale indicating higher levels of contentedness. Although the scores for general well-being were similar for the pre- and post-intervention stages (4.5 and 4.2, respectively), remarkable differences were evident for responses to questions related to the quality of drinks (6.9 and 1.1, respectively; P<0.001), hydration (6.5 and 1.3, respectively; P<0.001) and oral mouth care (6.7 and 1.8, respectively; P<0.001) (Fig. 1).

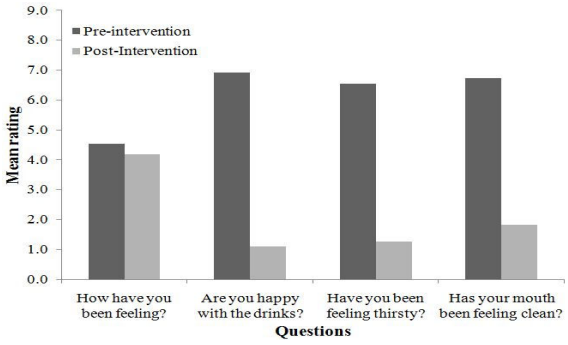

Figure 2. Mean ratings for the quality of life surveys given on the final day of the pre-intervention and final day of the post-intervention phase of the study. Scores represent the mean of each group on the basis of the Wong and Baker, faces rating chart; the lower scores representing greater satisfaction.

Discussion

Overall the results from clinical parameters including chest examination, full blood analysis and nasal swabs did not differ between the pre- and post-intervention periods of the study. This is most likely due to the fact that only people with diagnosed oropharyngeal dysphagia who were mobile and had relatively good cognitive ability were recruited to the study. Similarly, the measurements of fluid intake per day were not extraordinary, indicating that access to water in addition to the prescribed modified diet results in a significant increase in overall fluid intake, when compared to the intake during the thickened fluid only period.

An important clinical aspect related the management of people with dysphagia is related to the intense dissatisfaction to diets consisting of only thickened fluids or modified solid consistencies [16, 17]. The associated problems, not only with respect to ethical considerations and quality of life but also to non-compliance and the risk of severe dehydration are well-known. To overcome these problems an authoritative protocol was designed and established at the Frazier Rehabilitation Centre in Louisville, United States almost three decades ago. Essentially, the free water

protocol provides strict guidelines for the provision of water to people with dysphagia who are 1) able to tolerate three hours of physical rehabilitation daily for six days per week and have 2) adequate insurance coverage. Despite these recommendations, solid scientific evidence is still lacking and there is confusion in many clinical settings.

Our current findings, indicating that aspiration pneumonia did not develop when the free water protocol was used are in accordance with our previous observations when we consider mobile patients with relatively good cognitive ability. Further, our findings are in agreement with an important study published in the field in 1997, which relationships between the effects of access to water, aspiration pneumonia, hydration and quality of life in people with dysphagia [20]. In short, the one-year randomised study in people with an acute stroke (within 3 weeks) indicated that access to water did not result in any instances of pneumonia, dehydration or other complications. However, like our findings, a marked increase in the quality of life of patients allowed access to water was evident [20].

In conclusion, given that people with degenerative neurologic dysfunction who are immobile or have low mobility were purposefully not recruited in this study on the basis of our previous findings, the suggestion remains that a thickened fluid or modified solid consistency diet should be strongly encouraged for people at highest risk for the developing serious complications. However, taken together, our clinical studies, which to date includes the assessment of >120 people with dysphagia, along with the extensive clinical experience and documentation of issues related to quality of life, we may conclude that there is now sufficient evidence in favour of the Frazier Rehabilitation Centre free water protocol. Indeed, relatively low risk people, particularly for those in rehabilitation from an acute condition, should have a choice to free access to water, after being well-informed with respect to appropriate oral hygiene and to the relative risk. Finally, future research directions may be aimed at further stratifying people with dysphagia into high-, moderate- and low-risk in relation to complications from aspiration. Further, there now are numerous proprietary products (e.g. salivary substitutes and salivary stimulants), that may alleviate from some of the conditions that may exacerbate dysphagia, such as xerostomia. Investigation of the effects of these formulations may also form the basis for further research.

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The authors declare that they have no conflicts of interest.

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