

Unless otherwise noted, the publisher, which is the American Speech-Language-Hearing Association (ASHA), holds the copyright on all materials published in Perspectives on Swallowing and Swallowing Disorders (Dysphagia), both as a compilation and as individual articles. Please see Rights and Permissions for terms and conditions of use of Perspectives content:

<http://journals.asha.org/perspectives/terms.dtl>

## Water, Water Everywhere, But Why? Argument Against Free Water Protocols

James L. Coyle

Department of Communication Science and Disorders, University of Pittsburgh  
Pittsburgh, PA

*Free water protocols have become common in the management of patients with dysphagia. Their popularity has blossomed in the near-complete absence of any empirical data regarding their safety, efficacy and effectiveness. Proponents point to anecdotal reports and opinion pieces, while recent peer-reviewed investigation shows a mixed bag of safety and efficacy outcomes. This paper presents the argument against administration of “free water” without consideration of numerous factors besides the presence of dysphagia, and strongly urges the developers of the method to submit their data to peer review.*

### Fads, Science, and Protocols

Water, water, every where,  
And all the boards did shrink;  
Water, water, every where,  
Nor any drop to drink.

—Excerpt from “The Rime of the Ancient Mariner” by Samuel Taylor Coleridge (1798)

Numerous web pages and magazine articles describe the fantastic benefits of various fads, including weight-loss methods, hair-loss remedies, and wrinkle-removal methods. Yet, particularly as we age, we continue to suffer from obesity, baldness, and wrinkles. Consumers are attracted to these remedies because they want to be able to take a pill to make the problem go away. Some of these fads are fueled primarily by the manufacturers’ desire for financial gain and reflect a growing trend to market health products directly to the consumer. Consumers now go to their physicians or other health-care providers and ask for the pill they heard about on TV or the Internet. Like the client, the speech-language pathologist (SLP) is bombarded by nonscientific information about products and clinical treatments. Magazine articles and web pages feature descriptions of the popular water protocol and its purported benefits. One striking similarity exists between these fad remedies and the popular water protocol: a lack of scientific evidence supporting their use.

It is understandable that a layperson, who wants to lose weight but may have little understanding of scientific methods, could be convinced by advertising and testimonials about the effectiveness of a weight-loss method. But, it is not appropriate for health-care professionals to employ methods that are not scientifically based. SLPs are ethically obligated to use evidence-based methods of clinical decision-making. This process requires the blending of best clinical evidence with sound clinical judgment and patient values and expectations. Yet, thousands of clinicians in the United States employ the popular water protocol without evidence of its safety, efficacy, or effectiveness.

A *protocol* is defined by Webster's as "a detailed plan of a scientific or medical experiment, treatment, or procedure" (Merriam-Webster, 2011). Medical protocols typically include criteria for eligibility, rules and criteria for decision-making at each step of the procedure, and end-points for termination of the protocol; they are developed from a deep base of evidence that benefits significantly outweigh risks. An excellent example is the protocol-guided ventilator weaning (Alia & Esteban, 1999; Girard & Ely, 2008). Adoption of clinical methods without sufficient scientific justification does not make sense if we are what we claim to be: health-care professionals.

## **Free Water Protocol Arguments**

When looking westward, I beheld  
A something in the sky. (Coleridge, 1798)

The popular *free water protocol* has been in existence for more than 25 years. It was developed from observations of patient and caregiver inconvenience and noncompliance with thickened liquid preparation and recommendations. The developers listed why the protocol was created:

- People need water, and people with dysphagia will be more hydrated if they are allowed to drink water even if they aspirate it.
- People don't comply with thick liquid recommendations; people like water better than thick liquids.
- Water is safe to aspirate because it passes out of the alveoli without adverse events.

Later, after good evidence was published (Langmore et al., 1998), this protocol added another component: aggressive oral hygiene.

Bits and pieces of evidence about the safety of bronchoalveolar lavage, the detrimental effects of dehydration, and quality-of-life issues were strung together to justify these beliefs. The main literature-based justification provided by free water protocol proponents has been a small study by Garon, Engle, and Ormiston (1997). This study investigated two groups of 10 patients each—one assigned to thick liquids and the other to the water protocol (sans oral hygiene). After 30 days, follow-up revealed no differences between groups in pneumonia, hydration, and complications and no significant difference in fluid intake. The only significant difference was that control patients drank more thickened liquids than did water-protocol patients, which is not surprising because that is all they were allowed to drink (Garon et al., 1997).

It is interesting to note that the study's abstract states, "Until further larger scale research utilizing water intake with known aspirators is conducted, it is recommended that water (and ice chips) be given presently only in instances of patient refusal to drink thickened liquids or when hydration issues cause medical concern" (Garon et al., 1997). The only popular dysphagia treatment method with less underlying scientific evidence is deep pharyngeal neuromuscular stimulation, for which there are no published studies.

Thick liquids are the primary comparison intervention used by water protocol proponents, almost as if they consider thick liquids the only intervention for prandial aspiration. It is like giving a pill. Replace the aspirated thin liquid with a thick liquid and tell the patient that she/he must drink it. Prescribing a pill to solve a health problem is an attractive option because it requires no active patient participation and is easy for the clinician to employ. People do not have to exercise and eat healthy foods to prevent heart attack and stroke due to hypercholesterolemia. They can simply take the pill and continue to eat ice cream and bacon—a very attractive alternative. Speech-language pathology evolved as a rehabilitative profession, one whose practice requires the patient's active participation to restore effective communication. There has never been a speech pill. Why have we so quickly forgotten about active intervention?

## **Reasons for Development**

### **Compliance**

And all at once their breath drew in,  
As they were drinking all. (Coleridge, 1798)

The water protocol has been suggested for several main reasons. First, patients prescribed thickened liquids were observed to be less than compliant. If patients prescribed thick liquids do not see an immediate benefit in their comfort or other indices of improved swallowing function or health due to thick liquids, their motivation to continue using them quickly dissipates, and noncompliance with an intervention renders the intervention useless (Panther, 2005). They also correctly point to evidence that patients prescribed thickened liquids do not like them or want to drink them (Garcia, Chambers, & Molander, 2005; Karagiannis, Chivers, & Karagiannis, 2011; Whelan, 2001). Thick liquids are the only comparison to the water protocol that we read about. When did we stop involving patients in learning to protect the airway and participate actively in their own health maintenance?

### **Quality of Life**

My lips were wet, my throat was cold,  
My garments all were dank;  
Sure I had drunken in my dreams,  
And still my body drank. (Coleridge, 1798)

A second justification put forth in favor of the water protocol is quality of life. Well, it is true that patients just prefer thin liquids over thick liquids. Using a neutral inflection pattern, I ask each of my patients who are prescribed thickened liquids, “How do you like that?” They do not. Patient expectations, values, and preferences are top priorities in evidence-based clinical decision-making. However, is this scenario sufficient to justify allowing the unlimited aspiration of thin liquids? Perhaps I should stop performing swallow studies and simply eliminate the use of thick liquids for all referred patients who don’t like them. This would improve my productivity immensely.

### **Hydration**

And every tongue, through utter drought,  
Was withered at the root;  
We could not speak, no more than if  
We had been choked with soot. (Coleridge, 1798)

The third reason the water protocol has been advocated is hydration. The human body needs water; this is true. The average adult requires more than 2 liters of water per day to remain healthy. It has been suggested that, due to some properties of the thickening agent itself, thickened liquids dehydrate the consumer. This has been shown to be a false assumption. Artificially thickened liquids are absorbed 95% as completely as are thin liquids (Sharpe, Ward, Cichero, Sopade, & Halley, 2007).

### **Safety**

Like one that hath been seven days drowned  
My body lay afloat . . . (Coleridge, 1798)

A fourth justification is safety and the absence of negative consequences of alveolar water aspiration; this argument was expressed as, “Aspiration of water is a benign event—we’ve known that for quite some time” (Mosheim, 2006). Water in small amounts is easily absorbed through small specialized proteins in the alveolar epithelium called *aquaporins*. These specialized channels in alveolar epithelium enable transfer of water between capillaries and airspace within the alveoli. In small amounts, clearance of water into the circulatory system

has no consequence. If larger volumes of water enter the circulatory system in a short period of time, as in the near-drowning scenario, the blood becomes diluted (or hypotonic), causing the red blood cells to take on water. Hemolysis, the bursting of the red blood cells, can occur if sufficient dilution of plasma takes place (de Boer, Biewenga, Kuipers, & den Otter, 1970; Gbaanador et al., 1992; Tsokos, Cains, & Byard, 2008).

Aspirated water is less likely to cause dangerous consequences than are most other liquids that humans consume, which are typically hypertonic solutions (fluids containing a lower concentration of water than contained in the blood on the other side of the respiratory membrane) or are more acidic or alkaline than water. Hypertonic, irritant solutions (and those of a high or low pH, containing pathogens, proteins, or other large molecules) that are aspirated cause a rapid influx of water from the blood into the alveoli, thereby adding to the aspirated infiltrate's volume and obstructing respiration within those alveoli. So, it is correct to say that water aspiration is safer than is aspiration of other dietary fluids.

### ***Causes for Jumping On or Off the Bandwagon***

God save thee, ancient Mariner,

From the fiends that plague thee thus! (Coleridge, 1798)

At the 2008 annual Convention of the American Speech-Language-Hearing Association (ASHA), two technical sessions described research on free water protocols. These sessions had been accepted following a peer-review process. One, a retrospective intervention trial, compared previously treated patients who had completed a water protocol to two groups of patients who did not participate in a water protocol (one concurrent, the other an historical control); the water protocol patients were found to have lower pneumonia incidence than non-water-protocol patients had (Bronson-Lowe et al., 2008). It is interesting to note that there was no difference in fluid intake between groups, which suggested that the availability of water did not result in more water drinking. Clinicians should consider the limitations of the nonrandomized, retrospective nature of this study, including the unbalanced representation of diagnoses between groups.

A second prospective, randomized study was presented by Becker, Tews, and Lemke (2008). These investigators randomly assigned 26 patients who were dysphagic and aspirating liquids to prescribed thickened dietary liquids or the water protocol. The study's design was clean, investigators were blinded, and, although the sample size was small, the quality of evidence was very good. All patients received aggressive oral care and were followed to observe incidence of pneumonia and urinary tract infections (UTIs), fluid intake, and mortality. One patient in each group developed pneumonia, and two in each group developed UTIs. It is interesting to note that patients who were able to get their own drinks of water drank significantly less than those who were dependent on caregivers to offer it to them. Two patients in the water protocol group died. The fact that mortality occurred in patients treated with this method cannot be ignored. In both cases, the patients had pulmonary disease, but the inclusion criteria for the protocol were the same as advocated by the protocol's developers at the time of the study; this underscores the importance of the clinician's exercising good judgment and carefully weighing risks, in lieu of following a protocol.

Very recently, two studies were published on this controversial method. In one, 6 of the 42 patients randomly assigned to a free water protocol developed pneumonia or respiratory symptoms, compared to none of the patients assigned to the thickened-liquid-only control group (Karagiannis et al., 2011). In the other study, no adverse events were observed in either water protocol patients or controls (Carlaw et al., 2011). Both studies showed that water protocol patients received slightly more hydrating fluids while on the water protocol. Conflicting findings with different designs produce sources of uncertainty that clinicians must wade through when making important decisions about intervention methods for their patients.

## **Alternate Methods**

There passed a weary time. Each throat  
Was parched, and glazed each eye (Coleridge, 1798)

In patients with dysphagia, we are attempting to accomplish two goals: (a) restoration of nutrition and hydration and (b) prevention of adverse events. Pneumonia prevention is extremely important. As an example, individuals after stroke who develop pneumonia following onset have a seven-fold higher risk of dying, compared to those who remain free of pneumonia (Katzan, Cebul, Husak, Dawson, & Baker, 2003). The addition of oral hygiene to water protocol methods acknowledges the preventive role of decreasing oral bacterial populations and should be applauded. But, because no controlled studies have been published either before or after the inclusion of aggressive oral hygiene (and all evidence to date is anecdotal), we really do not know whether oral hygiene alone would provide the protective benefits purported by water-protocol proponents. Because the water-protocol purveyors have yet to publish a study and are currently treating so many patients, and because there is plenty of evidence supporting oral hygiene in the prevention of pneumonia (Adachi, Ishihara, Abe, & Okuda, 2007; Azarpazhooh & Leake, 2006; Garcia, 2005; Senpuku et al., 2003), a recommended randomized trial might include water protocol with aggressive oral hygiene, versus ordinary care with aggressive oral hygiene, versus water-protocol with ordinary oral hygiene. That study would be an important addition to our evidence base.

Hydration and nutrition restoration is the other goal mentioned above. Again, in the population that has suffered a stroke, as an example, other methods to restore intake have been investigated in the early post-onset period. Individuals who receive enteral supplementation after stroke onset consume significantly more fluids, protein, and nutrients that provide energy than consumed by those who do not receive enteral supplementation. Energy is badly needed in the rehabilitative process (Foley, Finestone, Woodbury, Teasell, & Greene, 2006). Likewise, patients after stroke given intravenous or enteral fluids have significantly more fluid intake than do those dependent on oral means alone (Finestone, Foley, Woodbury, & Greene-Finestone, 2001). Unlike in the United States, in other countries, *hypodermoclysis*, the method of subcutaneous water injection, has been in widespread use in the treatment of mild to moderate dehydration (Remington & Hultman, 2007). This method has been investigated for decades and found to carry absolutely no risks associated with the aspiration of oral contents. Other methods of restoring nutrition and hydration have been investigated, but water-protocol methods have not. We deserve evidence regarding the exact effectiveness and efficacy of this method.

## **Summary**

Wisdom comes from evidence and not from belief. If we do not become wiser and make increasingly better decisions as our careers progress, we miss important opportunities to improve care to our patients. We cannot disregard the importance of good, solid evidence in our clinical decision-making in the interest of expediency. It is not enough to say that a randomized study cannot now be conducted because the free water protocol has been in existence for years. Unlike the overwhelming majority of medical treatments, the current version of clinical water protocols originated without a single published study demonstrating its efficacy or safety. There is plenty of evidence that water, hydration, and patient choice and satisfaction are all good things. There is also evidence that some aspirating patients have died when placed on the water protocol. Likewise, if we cause dehydration or renal failure by prescribing thick liquids because we think we are preventing aspiration, what have we gained? We need to strike a balance when deciding whether a patient is a good candidate for unlimited water or its alternatives, and a "protocol" does not take into consideration the numerous individual risk

factors within each individual patient. When a patient asks, “Will I be better off on this protocol?” we are obligated to answer him/her using evidence.

The claims of reported pneumonia rates in patients who aspirate while assigned to free water protocols are not credible. In a *Perspectives* article a few years ago, the author reported that, based on anecdotal evidence, the incidence of pneumonia in patients treated with the water protocol was 2/234 patients or less than 1% (Panther, 2005). Stroke-related pneumonia incidence was reported as 10.5% (Chumbler et al., 2010) and, in other groups of people with dysphagia, 11–22% (Langmore et al., 1998; Robbins et al., 2008). If these figures are accurate, then the free water protocol is a miracle preventive cure for dysphagia-related pneumonia. Of course, this is a silly argument; it is impossible that pneumonia incidence in patients with dysphagia can be reduced by 90% by drinking unlimited water, yet that is the assertion, based on anecdotal retrospective observations by the method’s developers.

If it is true that people with dysphagia who aspirate and drink unlimited water are equally as well-off as those who do not, then, naturally, we want them to have water. Developers of medical “protocols” are obligated to produce evidence supporting their claims. Maybe, there is no difference between free water and ordinary care. If that is the case, we all need to know that. However, the fact that two treated patients in a water protocol study died should serve as a warning that we must think clearly about which patients we select for these protocols. Whether it is a free water protocol or electrical stimulation, medical procedures must be prescribed on the basis of a reasonable expectation the patient will benefit from, not be harmed by, the treatment. That expectation comes from scientific evidence, which we combine with our clinical judgment. Either alone is insufficient justification, and both together must be understood and approved by the patient to complete the circle of evidence-based practice. All interventions have advantages and disadvantages, risks and benefits. No method has just advantages and benefits. *Caveat emptor*; let the buyer beware. Let’s let evidence prevail.

He went like one that hath been stunned,  
And is of sense forlorn:  
A sadder and a wiser man  
He rose the morrow morn. (Coleridge, 1798)

## References

- Adachi, M., Ishihara, K., Abe, S., & Okuda, K. (2007). Professional oral health care by dental hygienists reduced respiratory infections in elderly persons requiring nursing care. *International Journal of Dental Hygiene*, 5(2), 69–74.
- Alia, I., & Esteban, A. (1999). Protocol-guided weaning: A key issue in reducing the duration of mechanical ventilation. *Intensivmed*, 36(5), 429–435.
- Azarpazhooh, A., & Leake, J. L. (2006). Systematic review of the association between respiratory diseases and oral health. *Journal of Periodontology*, 77(9), 1465–1482.
- Becker, D. L., Tews, L. K., & Lemke, J. H. (2008). *An oral water protocol in rehabilitation patients with dysphagia for liquids*. Available online at [www.asha.org/Events/convention/handouts/2008/1877\\_Tews\\_Lisa.htm](http://www.asha.org/Events/convention/handouts/2008/1877_Tews_Lisa.htm)
- Bronson-Lowe, C. R., Leisling, K., Bronson-Lowe, D., Lanham, S., Hayes, S. M., Ronquillo, A. M., & Blake, P. M. (2008). *Effects of a free water protocol for patients with dysphagia*. Available online at [www.asha.org/Events/convention/handouts/2008/1876\\_Bronson-Lowe\\_Christina.htm](http://www.asha.org/Events/convention/handouts/2008/1876_Bronson-Lowe_Christina.htm)
- Carlaw, C., Finlayson, H., Beggs, K., Visser, T., Marcoux, C., Coney, D., & Steele, C. M. (2011). Outcomes of a pilot water protocol project in a rehabilitation setting [Online version]. *Dysphagia*. doi:10.1007/s00455-011-9366-9
- Chumbler, N. R., Williams, L. S., Wells, C. K., Lo, A. C., Nadeau, S., Peixoto, A. J., . . . Bravata, D. M. (2010). Derivation and validation of a clinical system for predicting pneumonia in acute stroke. *Neuroepidemiology*, 34(4), 193–199.

- Coleridge, S. T. (1798). The rime of the ancient mariner. In W. Wordsworth & S. T. Coleridge (Eds.), *Lyrical ballads with a few other poems* (1st ed.). London, UK: Authors.
- de Boer, J., Biewenga, T. J., Kuipers, H. A., & den Otter, G. (1970). The effects of aspirated and swallowed water in drowning: Sea-water and fresh-water experiments on rats and dogs. *Anesthesiology*, *32*(1), 51–59.
- Finestone, H. M., Foley, N. C., Woodbury, M. G., & Greene-Finestone, L. (2001). Quantifying fluid intake in dysphagic stroke patients: A preliminary comparison of oral and nonoral strategies. *Archives of Physical Medicine & Rehabilitation*, *82*(12), 1744–1746.
- Foley, N., Finestone, H., Woodbury, M. G., Teasell, R., & Greene, F. L. (2006). Energy and protein intakes of acute stroke patients. *Journal of Nutrition, Health & Aging*, *10*(3), 171–175.
- Garcia, J. M., Chambers, E., & Molander, M. (2005). Thickened liquids: Practice patterns of speech-language pathologists. *American Journal of Speech-Language Pathology*, *14*(1), 4–13.
- Garcia, R. (2005). A review of the possible role of oral and dental colonization on the occurrence of health care-associated pneumonia: Underappreciated risk and a call for interventions. *American Journal of Infection Control*, *33*(9), 527–541.
- 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 Neurologic Rehabilitation*, *11*(3), 139–148.
- Gbaanador, G. B., Stothert, J. C., Basadre, J. O., Traber, L., Linares, H. A., & Traber, D. L. (1992). Comparison of the pulmonary lymphatic and hemodynamic changes of near-drowning in a sheep model. *Circulatory Shock*, *38*(4), 245–252.
- Girard, T. D., & Ely, E. W. (2008). Protocol-driven ventilator weaning: Reviewing the evidence. *Clinics in Chest Medicine*, *29*(241), 252.
- Karagiannis, M. J. P., Chivers, L., & Karagiannis, T. C. (2011). Effects of oral intake of water in patients with oropharyngeal dysphagia. *BMC Geriatrics*, *11*, 9.
- Katzan, I. L., Cebul, R. D., Husak, S. H., Dawson, N. V., & Baker, D. W. (2003). The effect of pneumonia on mortality among patients hospitalized for acute stroke. *Neurology*, *60*(4), 620–625.
- Langmore, S. E., Terpenning, M. S., Schork, A., Chen, Y., Murray, J. T., Lopatin, D., & Loesche, W. J. (1998). Predictors of aspiration pneumonia: How important is dysphagia? *Dysphagia*, *13*(2), 69–81.
- Mosheim, J. (2006). Frazier water protocol. *Advance for Speech-Language Pathologists & Audiologists*, *16*(24), 6.
- Panther, K. (2005). The Frazier free water protocol. *Perspectives on Swallowing and Swallowing Disorders (Dysphagia)*, *14*(1), 4–9.
- Protocol. (2011). Merriam-webster.com. Merriam Webster, Inc. Retrieved October 1, 2011, [www.merriam-webster.com/dictionary/protocol](http://www.merriam-webster.com/dictionary/protocol)
- Remington, R., & Hultman, T. (2007). Hypodermoclysis to treat dehydration: A review of the evidence. *Journal of the American Geriatrics Society*, *55*(12), 2051–2055.
- Robbins, J., Gensler, G., Hind, J., Logemann, J. A., Lindblad, A. S., Brandt, D., . . . Miller Gardner, P. J. (2008). Comparison of 2 interventions for liquid aspiration on pneumonia incidence: A randomized trial. *Annals of Internal Medicine*, *148*(7), 509–518.
- Senpuku, H., Sogame, A., Inoshita, E., Tsuha, Y., Miyazaki, H., & Hanada, N. (2003). Systemic diseases in association with microbial species in oral biofilm from elderly requiring care. *Gerontology*, *49*(5), 301–309.
- Sharpe, K., Ward, L., Cichero, J., Sopade, P., & Halley, P. (2007). Thickened fluids and water absorption in rats and humans. *Dysphagia*, *22*(3), 193–203.
- Tsokos, M., Cains, G., & Byard, R. W. (2008). Hemolytic staining of the intima of the aortic root in freshwater drowning: A retrospective study. *American Journal of Forensic Medicine & Pathology*, *29*(2), 128–130.
- Whelan, K. T. (2001). Inadequate fluid intakes in dysphagic acute stroke. *Clinical Nutrition*, *20*(5), 423–428.