Title: In the thick of it: a commentary on the strength of evidence for thickened fluids.

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Abstract

Purpose: The efficacy of thickened fluids for individuals with dysphagia has come under increasing scrutiny among healthcare professionals. This commentary provides a critical appraisal of the research evidence and presents a balanced argument on the benefits and limitations of thickened fluids in dysphagia management. By doing so, we aim to engage the readership to think critically about this controversial topic and make informed, patient-centered decisions regarding the use of thickened fluids in dysphagia management.

Results/ Conclusion: We argue that, while the research evidence for the use of thickened fluids in dysphagia management continues to grow, perhaps our problem lies in trying to find one pure answer – to thicken or not to thicken. We encourage clinicians to move past arguments about the controversies of thickened fluids and, rather, use the current evidence-base, including research evidence, clinical expertise, and patient preferences to support individuals with dysphagia to make informed choices about their oral intake, in the short and long term.

In the thick of it: a commentary on the strength of evidence for thickened fluids.

The efficacy and benefits of thickened fluids for individuals with dysphagia has been a long debated topic among healthcare professionals. A recent publication by Hansen and colleagues (Hansen et al., 2022) "*Second update of a systematic review and evidence-based recommendations on texture modified foods and thickened liquids for adults with oropharyngeal dysphagia*" received widespread attention on social media. According to altmetric data, the paper was in the top 5% of all research outputs, and was re-tweeted over 100 times across 10 different countries within six months of publication (https://www.altmetric.com/). The paper concluded that "there is no convincing evidence that thickened liquids or texture modified diets prevent death or pneumonia nor improves quality of life, nutritional status, or oral intake in individuals with oropharyngeal dysphagia" (Hansen et al., 2022, p. 551). These findings have raised questions amongst healthcare professionals about the common practice of using of thickened fluids in dysphagia management and its impact on clinically relevant outcomes. Subsequent published responses ensued, including a comprehensive expert opinion piece on the ethics of thickened fluid recommendations (O'Keeffe et al., 2023), and a position statement from The Royal College of Speech Language Therapists highlighting the necessity of patient-centered care, patient involvement in the decision making process, and evidence informed decision making (Royal College of Speech Language Therapists, 2023).

To deliver evidence-based care, we are trained to critically evaluate research evidence to inform our clinical decision making. Systematic reviews are considered gold standard for healthcare decision-making due to the rigorous search strategies and methodical appraisal of included studies (Page et al., 2021). However, findings of systematic reviews can remain

unclear, with limitations due to the methodological rigour and the quality of the included studies. Such limitations raise concern over the certainty of the conclusions for clinical practice.

This aim of this commentary is to provide a critical appraisal of the systematic review by Hansen and colleagues (2022). This is followed by a balanced argument on the benefits and limitations of thickened fluids in dysphagia management, supported by other research evidence and clinical expertise. By doing so, we aim to engage the readership to think critically about this controversial topic and to make informed, patient-centred decisions regarding the use of thickened fluids in dysphagia management. As clinician-researchers, we have no vested interest in the use of thickened fluids but, rather, seek to critically synthesise and optimise the translation of the best available research evidence into our clinical practice.

Critical appraisal of the research evidence

Hansen et al. (2022) is an update of two previously published systematic reviews on the use of texture modified foods and fluids by the same research group (Andersen et al., 2013; Beck et al., 2018). However, there are differences in the inclusion criteria and search strategies across the three reviews. In the first 2013 review (Andersen et al., 2013), sixteen papers – ten RCTs, two cohort studies and four systematic reviews – met the inclusion criteria, seven of which were deemed "good quality'" research (p. 130-131). The authors recommended that a "chin down procedure and thin fluids should be the first choice" in individuals with chronic dysphagia and "individual counselling with follow up and adjustment of the consistency of texture modified food and thickened fluid should be given" for individuals with acute dysphagia (Andersen et al., 2013) (p. e127). This finding was supported by the highest level of evidence ("A") based on the Centre for Evidence Based Medicine (Oxford Centre for Evidence-Based Medicine, 2011)

An updated review by Beck and colleagues was conducted in 2018. Only two randomised controlled trials (RCTs) met the new inclusion criteria. The authors limited the publication year to 2010 onwards and excluded papers that did not meet their assessment of methodological quality (Beck et al., 2018). These criteria excluded a number of "good quality" studies, according to the authors' rating (Andersen et al., 2013, p. 130), that were included in their previous review. Both included RCTs in the 2018 review were from 2008, despite their inclusion criteria being from 2010. Both studies evaluated the immediate risk of aspiration (Logemann et al., 2008) and long term development of aspiration penumonia with thin fluids and a chin down posture, compared with thickened fluids without a chin down posture in individuals with dementia and Parkison's Disease (Robbins et al., 2008). The methods of statistical analysis that were performed in the review were not provided; therefore, it is difficult to evaluate how the risk ratios for each outcome were calculated. However, the authors made "a weak recommendation against the use of texture modified liquids" (Beck et al., 2018, p. 1986). This finding was supported by "low" or "very low" levels of evidence (using the GRADE criteria), indicating very little confidence in the estimated effect (Guyatt et al., 2011, p. 1984). In contrast to the 2013 review, no differentiation in recommendations for individuals with acute versus chronic dysphagia was made.

An accelerated search strategy was conducted for the Hansen et al. (2022) review in which only RCTs and systematic reviews were included for analysis. Three RCTs met the updated inclusion criteria, with one (Sezgin et al., 2018) being of "very low" quality (Hansen et al., 2022, p. 554). Although RCTs are considered high levels of research design, their utility is controversial in evaluating public health interventions such as thickened fluids, which require a greater understanding of patient perspetives and contextual factors (Sanson-Fisher et al., 2007). Furthermore, random allocation to texture modification regardless of swallowing pathophysiology lacks research equipoise and, subsequently, findings are difficult to translate

into clinical practice. The rationale for excluding research evidence other than RCTs and systematic reviews is not provided by the authors. In the study's registration on PROSPERO, qualitative studies were specified for inclusion (CRD42016047336). Similar to the 2018 review, methods of statistical analysis were not well described by Hansen et al. (2022). The PROSPERO protocol described their plan to use I^2 for heterogeneity testing. However, this testing was not reported in the published paper, challenging the certainty of the findings. The authors concluded that "there is no convincing evidence that thickened liquids or texture modified diets prevent death or pneumonia nor improves quality of life, nutritional status, or oral intake in individuals with oropharyngeal dysphagia" (p. 551). This conclusion is based on very low to moderate levels of evidence (Guyatt et al., 2011).

The measures chosen to evaluate the effectiveness of an intervention are an important consideration. Hansen and colleagues evaluated the relative risk of normal diet or usual care (which constituted thin fluids with a chin down posture) compared to texture modification on critical health outcomes, such as death, pneumonia, quality of life, as well as important clinical outcomes, such as aspiration, dehydration, weight loss, dislike, adherence, and functional oral intake (Hansen et al., 2022). In contrast to the study's conclusions, which were not supportive of thickened liquids, a non-significant decrease in the risk of critical and important health outcomes such as death, pneumonia and aspiration was found for thickened liquids (Hansen et al., 2022), a finding supported by a low to moderate levels of evidence. A significant decrease in quality of life was observed for thickened fluids, and non-significant increase in dehydration, weight loss and dislike, findings which were supported by low-to-moderate evidence. Outcomes related to quality of life and hydration are based on a sample size of twenty-two patients, all from one "low quality" study, according to the authors' rating (Hansen et al., 2022, p. 554). Therefore, results and conclusions should be interpreted with caution. These findings may highlight the need to incorporate a person-centered approach in increasing the palatability,

visual appeal and taste of thickened fluids when they are required as a short term compensatory mechanism.

The use of critical health outcomes such as death, pneumonia, and quality of life are challenging in dysphagia research. Death and pneumonia are multifactorial and the diagnosis of aspiration pneumonia is challenging in itself (Langmore et al., 1998). It is unclear whether covariates known to influence death and pneumonia in patients with dysphagia (i.e., oral health, mobility, medication use, and number of comorbidities) (Langmore et al., 1998) were accounted for in the statistical analysis as the methods were not definitively described in the paper. All results were based on individual study findings alone, with relatively small sample sizes. This is not accounted for in the authors' discussion (Hansen et al., 2022) despite being an important consideration in assessing the methodological quality of systematic reviews.

Benefits and limitations of thickened fluids

This is not the only research group to attempt to systematically review the research evidence for thickened fluids. In 2015, Barbon and Steele reviewed six papers on the efficacy of thickened fluids for eliminating aspiration in head and neck cancer (Barbon & Steele, 2015). They cautiously concluded that, overall, the evidence was limited and more research was needed. Kaneoka and colleagues reviewed six mixed aetiology studies comparing thick fluids to thin water protocols and found no significant difference in risk of pneumonia in aspirating patients (Kaneoka et al., 2016). Painter and colleagues found similar results in aged care residents, with 22 studies included in their review (Painter et al., 2017). While penetration-aspiration scores for thickened fluids compared to thin fluids were reduced on videofluoroscopy, pneumonia was not (Painter et al., 2017). This finding was supported by Flynn and colleagues in a Cochrane Review in individuals with dementia (Flynn et al., 2018). Multiple other publications have provided narrative reviews, expert opinion, and commentary

on this controversial topic of thickened fluids (Cichero, 2013; McCurtin et al., 2020; O'Keeffe, 2018; Steele et al., 2015; Werden Abrams et al., 2023). The consistent message is that there is insufficient evidence for the use of thickened fluids to prevent aspiration pneumonia, and clinicains need to consider the risks and benefits to make informed, patient-centered decisions. Yet, clinicians continue to use thickened fluids as their most common compensatory strategy in many countries (Rumbach et al., 2018). Following, we discuss a number of possible reasons for this discrepancy between current clinical practice and research evidence.

First, the patient population is vital to interpreting studies' results, conclusions, and implementation into clinical practice. In Hansen and colleagues, the three studies in the review included individuals with Parkinson's Disease, dementia, and head and neck cancer (total maxillectomy). Patient diagnosis is a vital consideration for the use of thickened fluids. Based on clinical expertise, we also know that the management goals of acutely ill patients will differ to those living with long-term, chronic diseases. Failure of Hansen and colleagues to explicitly acknowledge that their conclusion relate to individuals living with long-term, chronic dysphagia is misleading.

Second, thickened fluid research has shown that altering bolus viscosity, texture and volume can alter lingual-palatal pressure, pharyngeal pressure, timing and extent of upper oesophageal sphincter relaxation and speed of bolus transit (Butler et al., 2009; Chi-Fishman & Sonies, 2002; Dantas et al., 1989; Hind et al., 2012; Pouderoux & Kahrilas, 1995). Such evidence would suggest that thickened fluids could be a clinically useful short-term compensatory strategy to prevent aspiration and enable patients with acute dysphagia (e.g., as a result of a neurological injury or upper airway surgery) to recommence / consume oral intake. This may be particularly useful strategy for those finding thin fluids distressing to swallow due to coughing or in those who are immunocompromised and at higher risk of developing

pneumonia (Diniz et al., 2009). However, the use of thickened fluids needs to be taken with careful critical reasoning. The results from the Robbins et al. (2008) RCT indicated that there was an increased risk and severity of pneumonia with very thick fluids compared to thin fluids with a chin tuck. Thus, while aspiration may be reduced in quantity with thickened fluids, the effect of thickener on lung health may be of greater concern. This is highlighted in an animal study in 2017 that found a mild increase in intra-alveolar haemorrhage in rabbits instilled with cornstarch thickened water compared with regular water ($p<.05$), and greater pulmonary inflammation, pulmonary interstitial congestion, and alveolar oedema in rabbits instilled with xanthan-gum thickened water compared with water ($p<.05$) (Nativ-Zeltzer et al., 2018). Another paper by Miles et al. (2018) proposed that while patients may be less likely to aspirate thickened fluids than thin fluids, they were more likely to silently aspirate thick fluids compared to thin fluids, thus, potentially increasing risk to the lungs.

Another counter-balanced argument is that, while thickened fluids may reduce risk of aspiration pre- or mid-swallowing, there is increased pharyngeal residue with thicker viscosities compared to thin, increasing the risk of aspiration of residue post-swallow (Newman et al., 2016). Such a finding suggests that clinicians should avoid thickened fluids for patients who also have pharyngeal impairments leading to accumulation of residue. The same argument could be made for patients at risk of delayed oesophageal motility; the greater the viscosity, the longer the oesophageal transit time (Miles et al., 2016). In a retrospective clinical audit of >600 patients and 140 healthy adults, even when controlled for age, patients with a stroke had significantly longer oesophageal transit times than healthy adults, and these increased oesophageal transit times were associated with aspiration (Miles et al., 2019).

Finally, patients with specific medicine regimes may also need special consideration. The lining of the oesophagus can be damaged by more corrosive medicines if they do not transit

quickly to the stomach suggesting caution with use of thickened fluids for their administration (Cichero, 2013). Cichero also explains that certain medications, such as those used to treat inflammatory, autoimmune disorders and congestive heart failure, have been implicated for poor bioavailability when combined with thickened liquids. Further, the absorption of some regularly prescribed drugs (e.g., penicillin) has been shown to be delayed by increasing concentrations of gum-based thickened fluids and that this may be exacerbated if the medicine has a film coating.

Conclusions

While many research groups have built our evidence-base for the use of thickened fluids in dysphagia management, perhaps our problem lies in trying to find one pure answer – to thicken or not to thicken. Patients have different risk factors, pathophysiology, needs and wishes. We have evidence that thicker viscosities transit more slowly through the pharynx and oesophagus. Dy doing so, thickened fluids can provide the necessary time to facilitate timely airway closure during bolus transit, contributing to swallowing safety. However, thickened fluids are also associated with an array of negative health and quality of life consequences. It is up to the clinician to assess each individual patient and consider whether thickened fluids might be of benefit, or not, based on their synthesis of available information about the patient, their patient's context and wishes, and the published evidence. Questions that clinicians need to consider for each patient include: Are they high risk of developing pneumonia based on their other risk factors? Do they aspirate thin fluids? Do they aspirate thick fluids? Do they have considerable residue with thick fluids? Do they take corrosive medicines or have greater need for controlled medicine absorption? Do they choose to drink thin fluids despite aspirating? Do they enjoy the reduced distress that a thicker consistency provides them? We encourage clinicians to move past arguments 'to thicken or not to thicken' and. instead, use the current

evidence-base to support patients to make truly balanced and informed choices about their oral intake, whether in the short or long term.

Disclosure Statement

The authors report there are no competing interests to declare.

Declaration of Interest

The authors report no financial or non-financial declarations of interest.

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