Evaluating the use of oral trials for inpatient dysphagia management: a cross-sectional database study

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Abstract

Rationale, aims and objectives: Oral trials, otherwise known as swallow trials or tasters, are widely used in dysphagia management. However, to date, no studies have investigated the effectiveness of oral trials or outlined how the approach is utilised in everyday practice. This paper aims to (1) Identify the patient demographics and environments in which oral trials are used in hospital. (2) Explore clinical decision-making around the approach. Method: A cross-sectional examination of 118 patients on the dysphagia caseload of a UK-based inpatient Speech and Language Therapy team was conducted. Statistical analysis explored demographic differences between oral trials groups and the rest of the dysphagia caseload. Results: 19.5% (23/118) of individuals on the caseload were or had been on oral trials during admission. Individuals in the oral trials group were significantly more likely to have a neurological diagnosis than the full oral intake group (78.3% vs 30.5%, $p<0.001$). There was a lack of uniformity in oral trials recommendations and the rationale behind quantity and types of diet or fluids offered was unclear. Conclusions: This study begins to evidence the use of a dysphagia therapy not previously explored within existing literature. It highlights the wide use of oral trials within the hospital observed. Neurological diagnosis was a key predictor of belonging to the oral trials group. Further research into the effectiveness and implementation of oral trials is warranted.
Keywords: dysphagia, swallowing, rehabilitation, speech and language therapy, oral trials.

Introduction

Swallowing is a complex process and individuals can present with breakdown at various levels, which can affect control, coordination or strength of swallowing [1]. Swallowing difficulties (dysphagia) can affect health in a variety of ways, including malnutrition and dehydration [2] and life-threatening illnesses such as aspiration pneumonia [3]. Safe swallowing is essential both to maintain life and also to maintain quality of life [4].

The complexity of swallowing and its heterogeneity in presentation can make evaluating the true effect of treatment methods challenging; there is limited evidence on the effectiveness of the range of therapy approaches available [5,6]. Alongside this, there is poor uptake of interventions which demonstrate a good evidence-base, with Speech and Language Therapists (SLTs) relying heavily on clinical experience and anecdotal evidence [6–8].

The following study aims to investigate the use of 'oral trials', a commonly used dysphagia management approach. Although this initiative has been documented in research and practice [6,9–12], the terminology has not been officially defined. For the purpose of this study it has been defined as: a dysphagia management approach whereby specified, limited amounts of oral diet or fluids are recommended for those at risk of aspiration or choking if full amounts are taken orally. Oral trials are recommended for a specified reason, such as rehabilitation or quality of life.

A recent survey of SLTs working in stroke rehabilitation identified that supervised 'swallow trials' were recommended 'frequently or always' by 73% of respondents [6]. A further survey in Australia found that swallow trials were the only rehabilitation approach being used in dysphagia management with a high

degree of consistency[12]. The use of oral trials is also included in a range of outcome measurement tools, such as the Functional Oral Intake Scale (FOIS) [9], Dysphagia Severity Rating Scale (DSRS)[11] and Therapy Outcome Measures (TOMS)[10]. A further three conference abstracts identify the use of oral trials within SLT approaches [13–15]. However, in spite of its documented use, a search of the literature found no further research into the use or efficacy of oral trials.

This study is part of a mixed methods research project exploring the use of oral trials in hospital. This paper reports on phase one: an observational, cross-sectional study evaluating the dysphagia caseload within one inpatient hospital. Phase two is reported in a separate paper and involves qualitative data collection via focus groups with SLTs, to explore the clinical reasoning behind this quantitative data. Phase one aims to identify where and with which patients oral trials are currently being offered. Given that oral trials have documented use in stroke rehabilitation, it is hypothesised that oral trials are used most commonly within neurological rehabilitation. Data collected will begin to inform how and why oral trials are used widely within dysphagia management, despite their lack of evidence.

Methods

The study took place at a large acute hospital and its partner community rehabilitation hospital in one city in the UK. The hospital has three neurological wards (an acute stroke unit, stroke rehabilitation and neurological rehabilitation wards), a team of around 20 SLTs and a videofluoroscopy clinic. The study was approved by an ethics panel at the University of Lincoln (reference number 2020-2210) and the local NHS Research and Development team. Patient data was accessed via the electronic patient record and anonymised at the point of collection. Research is reported in accordance with STROBE guidelines (see appendix one) [16].

Data collection

All inpatients receiving dysphagia input who were registered on the electronic patient record of the SLT caseload on the 12th March 2020 were eligible for inclusion. All SLT documentation for the patient since admission was reviewed; this included the case history, which highlighted diagnosis and previous medical history, as recorded from the medical notes. Patient demographics and dysphagia treatment decisions were recorded. A questionnaire to guide data collection and define diagnostic categories was produced prior to data collection (see appendix two). Due to the snapshot nature of data collection, details of previous recommendations were not recorded and only most recent oral trial recommendations (where applicable) were outlined.

Data analysis

Data was entered into the Statistical Package for the Social Sciences (SPSS) version 26. The sample was separated into groups based on the treatment approach (full oral intake, oral trials or nil by mouth). Due to the small sample size of the nil by mouth group (n=6), it was not possible to draw statistical comparisons between this group. For the purposes of exploring differences between the oral intake group and the rest of the dysphagia caseload, all individuals not on oral trials were therefore grouped for statistical comparisons. Clinical rationale was used to select clinical predictors of treatment groups. Chi-squared test analysis was used for frequency variables and two-tailed independent samples t-tests for continuous variables. Hierarchical logistic regression analysis was carried out to further investigate predictors of belonging to the treatment group. A $p < 0.05$ cut-off was used to define statistical significance.

Results

Demographics

Of a total of 1,273 beds across the acute and community hospital, 118 patients were on the dysphagia caseload. 13 patients were receiving oral trials, 10 other patients had been on oral trials previously during their stay and six patients were nil by mouth and had never been on oral trials. No missing data was

recorded during data collection. Patients were seen across a range of specialisms and presented with a variety of diagnoses (see table 1).

Comparisons between treatment groups (see table 2) show that patients on oral trials were significantly more likely to have a neurological diagnosis (78.3% vs 30.5%, p<0.001), be on a neurological ward (69.6% vs 25.3%, p<0.001), live independently (73.9% vs 42.1%, p=0.006) and were less likely to have dementia (17.4% vs 37.9%, p=0.027). There was a significant difference between age, with individuals in the oral trials group being younger on average (66.70 vs 77.14 years old, p=0.003). The UK uses a pay banding system to grade the levels of responsibilities of SLTs (range band 5-8), band 5 SLTs will usually be newly qualified and have up to 5 years' experience. Individuals seen by Band 5 SLTs were more likely to be on full oral intake (36.8% vs 8.7%, p=0.009), whilst those seen by mixed SLTs were more likely to be on oral trials (65.2% vs 29.5%, p=0.001).

There was a considerable overlap between some variables measured. Younger individuals were significantly more likely to live independently (p<.001) and individuals with a neurological diagnosis were significantly more likely to be on a neurological ward (p<.001). Individuals with a neurological diagnosis were also younger on average than those admitted for other reasons (68.45 vs 79.51, p<0.001).

Hierarchical logistical regression analysis shows that when neurological diagnosis is included, age and being seen by mixed SLTs were no longer significant predictors of being on oral trials (see table 3). Having a neurological diagnosis was the key statistically significant contributor to the model, with individuals with a neurological diagnosis being over four times more likely to be on oral trials when controlled for age and treating SLT. The model as a whole explained between 17.0% (Cox and Snell R squared) and 27.2% (Nagelkerke R squared) of the variance in treatment group and correctly classified 79.7% of cases.

Oral trials recommendations

There was a wide variety of types of oral trials offered, with a range of consistency, quantity and frequency of diet or fluid trials being recommended (see table 4). Two patients were receiving SLT-led oral trials. In all other cases it was not specified who should supervise oral trials. The reasons for oral trials and whether risks of aspiration were accepted for trials were not usually documented. Within the group of individuals on oral trials, 11 individuals were on limited amounts of oral intake alongside non-oral feeding and a further two individuals were on oral trials of increased texture diet (regular or easy to chew trials) alongside full amounts of modified diet. Of individuals who had been on oral trials previously during admission, 9/10 had trials discontinued due to improvements in swallowing and they were managing full amounts orally. Trials were discontinued for the remaining patient, who had returned to be nil by mouth due to a deterioration in their swallow.

Discussion

Data demonstrates the widespread use of oral trials across the hospital, with 19.5% (N=118) of patients on the dysphagia caseload being offered oral trials. Neurological diagnosis appears to be a defining factor to whether oral trials are offered. Due to the limited sample size and interaction between variables, it is not possible to determine the extent to which other factors contribute independently to treatment group. However, data begins to reveal clear trends as to when and where oral trials are offered.

Oral trials in stroke and neurological rehabilitation

Results highlight that individuals on oral trials were more likely to have a neurological diagnosis and be on a neurological ward, supporting findings that oral trials are used within stroke rehabilitation[6]. One explanation for this may be that in the case of neurological damage, remaining nil by mouth in the early stages may limit the opportunities for recruitment and reorganisation of neurological pathways in contralateral brain regions[17]. Oral trials may therefore help to stimulate the neuromuscular system in the early stages of recovery. Oral trials support key principles of neuroplasticity in their approach, including 'use it or lose it', 'use it and improve it' and 'specificity'[12,18]. Oral trials also utilise compensatory strategies with active rehabilitation to enable access to neural adaptation in the early stages of recovery [18].

Oral trials were also offered to patients on general medical, surgical, respiratory and intensive care wards, suggesting that the approach is not limited exclusively to neurological rehabilitation. One reason for dysphagia in these situations could be that reduced oral intake in critical care can cause muscle atrophy or deconditioning[1,13,19,20]. In these situations, oral trials may be used in active rehabilitation or at a 'maintenance dose' to reduce risk of deconditioning.

Individual factors

Results suggest that younger individuals were more likely to be offered oral trials, although when controlling for neurological diagnosis, age was no longer a significant predictor of treatment group. Individuals with a neurological diagnosis were significantly younger than other groups. Early dysphagia input may be particularly beneficial for younger, previously independent individuals due to increased responsiveness to neural plasticity [18,19].

The oral intake group also included significantly fewer individuals with a dementia diagnosis. Non-oral feeding for individuals with dementia is a complex issue and there may be established ceilings of care for this population [21]. This may contribute to readiness for SLTs to consider oral trials which require non-oral feeding. Furthermore, the cognitive capacity of patients was found to be a key indicator for treatment decisions in dysphagia management[12], therefore certain dysphagia approaches may not be considered for this group. It is important for dysphagia therapy to take a holistic approach, by recognising the limitations, premorbid factors, attitudes and support systems for the individual [22]and it is likely that a range of individual factors are considered in clinical decision-making around oral trials.

Ward environment

In the hospital studied, 'ward nutrition assistants' who are trained to support patients at mealtimes, are available on stroke and care of the elderly wards. Results suggest that the presence of a ward nutrition assistant was not a significant factor for allocation of treatment group. However, presence of specialist support staff may contribute to frequency of dysphagia therapy offered – an outcome not measured in this study. The National Clinical Guidelines for Stroke[23] highlight that patients should receive a minimum of 45 minutes of each therapy required at least five days a week. Availability of specialist staff to assist SLTs can support management of dysphagia in the acute hospital setting [24] and when direct SLT input is limited, oral trials may provide an opportunity for dysphagia therapy to be delivered by a range of staff within the multi-disciplinary team and across the 24-hour picture of a patient's care.

Types of diet/fluids offered as oral trials

There was a lack of consistency in the types and quantities of oral trials offered and no standard approach was identified to guide decision-making around oral trials offered. Interestingly, one individual who was on full meals but NBM for fluids was documented as 'oral trials', showing inconsistency in terminology and delivery of this approach. Some recommendations gave more precise recommendations such as, '5 sips' whilst others left more breadth in recommendations, for example '10-15 teaspoons'. There is a general lack of uniformity in treatment strategies in the SLT community, which is evident both in treatment approaches and intensity of treatment [6,25].

The range of quantity and type of oral trials recommendations may reflect clinical judgements regarding how to provide adequate challenge or 'load' to the swallow system. Different viscosities and volumes of boluses have been found to provide specific sensory input, which consequently affects the nature of swallow physiology by altering the load, intensity or volume of exercise [26]. This is the mechanism behind the McNeill Dysphagia Therapy Program (MDTP) which focuses on the use of swallowing as an exercise and involves offering food or fluid boluses of varying viscosity and volume in a hierarchical fashion to improve strength and skill of swallowing[27]. Decision-making is often informed by 'practice-based rules' which are established through experience[28] and, although there is no evidence-base to guide decision making within oral trials, there may be a range of unwritten rules established. Further research is indicated to explore this.

SLT experience

Results show that patients in the oral trials group were more likely to be assessed by 'mixed SLTs', suggesting a degree of supervision or shared-working between SLTs in the team. When controlled for neurological diagnosis, SLT experience is no longer significant. This suggests that SLT experience is related to types of patients being seen or ward speciality rather than being a predictor for treatment decisions made. SLT experience can influence dysphagia treatment taken and less experienced SLTs may lack the confidence to try novel dysphagia therapies [28,29]. A variety of patients and availability of clinical supervision has been recognised as essential for the development of dysphagia skills [30]. Results may reflect how supervision is used in the hospital studied to support dysphagia management in more complex cases.

Videofluoroscopy was not a significant factor between treatment groups and had only been carried out on 11.0% of patients on the caseload. This may highlight the clinical decision-making process taking place at bedside assessment or may reflect resource limitations. Over half of SLTs working in stroke rehabilitation report using instrumental assessments 'rarely or never' before recommending exercises[6]. This suggests that decision-making around dysphagia therapies relies on other clinical measures and judgments within practice.

Outcomes of oral trials

Although the sample size was limited, outcomes of oral trials were generally positive, with only one patient returning to be nil by mouth following oral trials. Further research is required to determine efficacy of this treatment approach versus other established dysphagia therapies.

Limitations

A key limitation is the sample size. The current study only represents one hospital trust and SLT team in the UK, therefore it may not reflect practice within the wider SLT community. Evidence suggests that oral trials are being used globally with FOIS outcome measures being developed in the United States [9], documented use in Australia [12] and mention of oral trials in conference abstracts from Ireland [13] and India[15]. This suggests that a larger study, looking at how oral trials are delivered nationally and internationally, is indicated.

Data collection did not consider the wider context of an individual's health status. The study did not have access to the original medical notes and due to the absence of standardised assessments on the electronic patient record, cognitive ability, frailty measures or extent of co-morbidities were not recorded. As demonstrated in statistical analysis, although the model explains some of the variance, there are likely other factors contributing to outcomes. Therefore, other aspects affecting clinical decision making may have been overlooked.

Due to the nature of quantitative data, results are unlikely to reflect the complexity of clinical reasoning when managing oral trials. Further research is therefore required to investigate the clinical decision-making process. Moreover, although results begin to illustrate the ways in which oral trials are used, they do not evidence their effectiveness. SLT practice should use the highest level evidence to support practice [8] and given the scarcity of research in this field, randomised control trials are warranted.

Conclusion

Although this study only reflects practice within one inpatient hospital caseload, results begin to systematically explore a popular dysphagia therapy approach in which research is sorely lacking. The study highlights that oral trials are widely used in this inpatient caseload, with trials being offered primarily, although not exclusively, to patients with a new neurological diagnosis. Individual patient factors, ward environment and experience of treating SLT are all likely to contribute to decision-making around offering oral trials.

There was no standardised approach identified regarding delivery of oral trials; decision-making regarding quantity or consistency of diet and fluids is unclear. Further research is required to explore the use of oral trials across other inpatient and community settings and to evaluate their effectiveness.

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Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Conflict of interest statement

The authors certify they have no affiliations with or involvement in any organisation or entity with financial or non-financial interest in the subject matter or materials discussed in this paper.

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Appendices

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