Dysphagia Treatment Post Stroke: A Systematic Review of Randomise

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Abstract and Introduction

Abstract

Background: dysphagia is common following stroke and is associated with the development of pneumonia. Many dy available, some still experimental and others already rooted in common practice. Previous reviews of these treatment available studies. Recently, more trials have been published warranting a re-examination of the evidence.
Objective: a systematic review of all randomised controlled trials (RCTs), updating previous work and evaluating a br interventions intended for use in adults recovering from stroke and dysphagia.
Methods: using multiple databases, we identified RCTs published between the years 1966 and August 2007 examini following stroke. Across studies, results of similar treatments and outcomes were compared and evaluated.
Results: fifteen articles were retrieved assessing a broad range of treatments that included texture-modified diets, ge non-oral (enteral) feeding, medications, and physical and olfactory stimulation. Across the studies there was heteroge the outcomes assessed that precluded the use of pooled analyses. Descriptively these findings present emerging evi not associated with a higher risk of death compared to percutaneous feeding tubes; and general dysphagia therapy p reduced risk of pneumonia in the acute stage of stroke.
Conclusions: dysphagia is known to be a common and potentially serious complication of stroke. Despite the recent same treatment and outcomes thereby limiting the evidence to support the medical effectiveness of common dysphag recovering from stroke.

Introduction

Dysphagia is prominent across the continuum of stroke recovery and its presence is likely to result in pulmonary comp Despite the perceived association between dysphagia treatment and a reduction of serious complications including as well-established evidence to support the use of any of the available treatments. In 1999, the Agency for Health Care P commissioned a large-scale, evidence-based report on the diagnosis and treatment of dysphagia in adult patients wit a lack of standardised assessment approaches and little high quality evidence for the benefit of either non-invasive sv endoscopic gastrostomy (PEG) feeding tubes. Given limitations in study design and sample size, definitive conclusion could not be drawn. At the same time a Cochrane review was conducted assessing the benefit of dysphagia treatmer identified only five trials and concluded that PEG feeding appeared to be more beneficial compared with nasogastric (studies have been published enabling a re-examination of the evidence. Therefore, the purpose of this systematic rev evaluate a broader range of therapeutic interventions intended for use in adults recovering from stroke and dysphagia

Methods

Search Strategy and Selection Criteria

A systematic review of the literature was conducted to identify all randomised controlled trials (RCTs) evaluating thera of dysphagia following stroke. The following databases were searched: The Cumulative Index to Nursing and Allied H Embase and the Cochrane Library. Search dates depended on the database but ranged from 1966 to August 2007. S databases but included: *deglutition disorders, dysphagia, cerebrovascular disorders/or cerebrovascular accident, rand placebo* or *random*. The search was limited to the terms *human, adult or aged.* The reference lists of all included artic studies not identified through the original literature search.

Inclusions and Exclusions

This review was restricted to original parallel group RCTs published in peer-reviewed journals conducting subject-leve designed trials were included, provided the order of treatments was randomly assigned. Only studies in which the san recovering from stroke and who were identified as dysphagic by the study investigators were included. Studies asses pharmacological treatments were included regardless of the length of time the intervention was provided or the outcor

Non-English language studies and studies in which patients were not assigned randomly, by chance, to either a treatr excluded. Abstracts and Letters to the Editor were excluded because of lack of reporting detail. Opinion articles and c

Two reviewers (NF and KS) independently assessed each abstract for potential inclusion. The original articles were re the nature of the subject's illness or the study design was not clear based on the information provided in the abstract. used to resolve conflicts over eligibility of potential articles. A single investigator (NF) abstracted data from all articles investigators (EK, RM) confirmed for accuracy. Additionally, three authors (KS, RM and NF) independently evaluated study using the Physiotherapy Evidence-Based Database (PEDro) scale.[4] The PEDro scale awards a maximum of 1 validity. Disagreement in scores among raters was resolved through consensus.

Differences between treatment groups on primary and secondary outcomes, as identified by the study's authors at the described and presented in table form. Similar interventions across studies were compared and common outcomes a

Results

Literature Retrieved

The search strategy yielded 147 hits from all four databases, of which 45 were duplications, leaving 102 citations. Of t they were found to be review articles, commentaries of previously published studies, or abstracts of conference proce are presented in Table 1 . The most common reason for exclusion was that no intervention was evaluated. Five randc the participants were not dysphagic or some subjects with conditions other than stroke were included.[5-9] Fifteen RCT process. Of these, one study was excluded as it reported additional outcomes from a previously identified trial.[10] Har identified via the search strategy.[11] Therefore, a total of 15 articles met our inclusion criteria and were reviewed.[11-25]

Methodological Quality of the Evidence

Total PEDro scores ranged from 3 to 8. Owing to the selection criteria, all studies received one point for random alloc description of a mechanism for adequately concealed allocation. The outcome assessor was blinded in six studies; bu pharmacological interventions, were both subjects and outcome assessors blinded. Three studies used an 'intention-t individual studies are presented in Table 2 .

Patient Characteristics

The mean ages of patients enrolled in all studies ranged from 67[23] to 86 years.[16] The diagnosis of stroke was confir examination and a magnetic resonance imaging (MRI) or computed tomography (CT) scan[12,14,19-21,25] or was based An eligibility criterion with respect to stroke history was explicitly stated in five trials. In three of these trials, only subje stroke were eligible to participate,[17,18,22] and subjects with stroke recurrence were eligible to participate in the remair or clinical syndrome were provided in seven
trials.[12,14,17,19,20,22,23] Stroke type was reported in five trials as either ischaemic[20,22,23] or both ischaemic and haemor small percentage of subjects (<1%) were found not to have experienced stroke in two trials.[12,15] Initial stroke severity scales (Table 3, available online at the journal's website http://ageing.oxfordjournals.org). On the reported information severe,[13,15,21,22,25] moderate to severe[12,14,16] and mild stroke[20] were recruited. No details of initial stroke severity w

trials.

Assessment of Dysphagia

In nine studies, the diagnosis of dysphagia was made on the basis of videofluoroscopic (VFS) examination,[14,17,20] or [25] or by both methods.[24] The authors of one of these trials stated that subjects diagnosed with dysphagia on the bas excluded.[25] In four other trials, the authors stated that they enrolled patients taking a texture-modified diet, or those 'v study used swallowing difficulties identified by the patient, family member or healthcare provider to identify dysphagic latency of swallowing reflex greater than 3 s to indicate the presence of dysphagia (Ebihara, personal communication

Evidence Supporting Dysphagia Treatments

The 15 articles selected for review included a broad range of treatments. See Table 3 (available online at the journal's http://ageing.oxfordjournals.org) for a description of interventions and outcomes. Treatment was initiated within either weeks of stroke.[14,17,20,21] The time the intervention was initiated following stroke was either highly variable[11,23] or was not stated in the remaining trials. In some of the trials, treatment was of variable duration—provic point[14,17] for the duration of their hospital stay or until the treatment was no longer required.[12,15,21,25] In the remainin term of one to three treatments,[13,23,24] 1 week[19] or for 3 weeks to 1 month.[11,16,18,20,22] Five trials assessed outcome of treatment that varied from 6 weeks[21] to 6 months[11,12,15] to 1 year.[14] The outcomes in the remaining trials were e completion of treatment. The choice of target outcome included measurements of swallowing physiology;[16,22-24] swal [11,12,14,17,18,25] malnutrition;[14,20,21] and dehydration.[14,17]

In terms of study design, nine RCTs were of two-group parallel design[11,13,17-22,25] and four trials included three or mo one randomised crossover study[23]and two separate, but related trials, each of a two group parallel design, which we Sample sizes varied from 17[22] to 859.[15] See Table 3 (available online at the journal's website http://ageing.oxfordjou and results.

Discussion

Of the 15 studies identified and reviewed, the most commonly evaluated interventions were based on dietary texture m cations,[11,17,19,25] general dysphagia therapy programmes[12,14] and enteral feeding;[15,20,21] all forms of interventions t clinical practice. The outcomes assessed in these trials were usually of clinical relevance, including death, return of fu Other therapies evaluated in this review such as thermal[23,24] or olfactory stimulation,[16] and pharmacotherapy[22] aim aspects of swallowing, are currently considered to be experimental and are not yet in routine use. Finally, two interver digestive tract[18] and subcutaneous hydration,[13] have been used, historically, in conditions other than stroke. The ma provided during the first several weeks following stroke, although some were provided in the chronic stage when patie [11,16] Although the review was restricted to RCTs, the methodological quality of the trials was generally only fair. Only design elements most often associated with decreased risk of bias. (concealment of the randomisation schedule, blin intention-to treat analysis). The heterogeneity of the interventions, even within the same broad treatment categories, a outcomes assessed made pooled analyses inappropriate; therefore, the results were presented descriptively. For two swallowing treatment programmes there were a sufficient number of trials available to enable comment on the strengt

Three RCTs compared the outcomes of acute stroke patients who were fed using NG or PEG feeding tubes.[15,20,21] C designed multicentre trial.[15] In this trial patients randomised to the NG group were less likely to experience either dea compared to patients fed with a PEG tube (P = 0.05), and were no more likely to develop pneumonia. However, these two other smaller RCTs reviewed,[20,21] where NG tubes were associated with a higher risk of death and worse outcor more feeding interruptions due to mechanical failures, blockages and dislodgements when compared with PEG tubes giving greater consideration to the FOOD trial with its larger sample size and higher methodological quality score, sug tube feeding is not associated with a greater risk of death compared with PEG feeding. However, PEG tube feeding a tube failures and fewer declines in nutritional status

Two RCTs were identified that assessed the effectiveness of general swallowing treatment programmes.[12,14] Typical and executed by speech-language pathologists. They comprise of a variety of compensatory and treatment-swallowin texture-modified diets that have been shown during a VFS assessment to be effective in reducing aspiration or impro There were similarities between the two studies inasmuch as both included three groups providing treatment at varyin the trials[14] did not include a true control condition, to enable treatment comparisons, we presumed the group receivir the control group. Unfortunately, the authors of this study did not report the actual treatment intensity patients receive

differed from that described since patients were permitted additional instruction upon request. The studies provided tr one acutely, within 7 days[12] and the other, at 41/2 weeks[14] post stroke with differing degrees of intensity. One of the arm that provided swallowing exercises in addition to compensatory swallowing techniques. Two outcomes, death an assessed in both studies. No deaths were reported in the trial assessing subjects in the rehabilitative phase of stroke, were conflicting in terms of reductions in pneumonia. Even though the sample sizes were small and statistical signific [14] reported that patients receiving the lowest intensity of therapy had the lowest incidence of pneumonia. In contrast, patients receiving the lowest intensity of treatment (usual care) had a significantly higher incidence of chest infection t more intensive therapies. In summary, the overall evidence suggests that swallowing treatment programmes are assc pneumonia in at least the acute stage of stroke; however, a larger, adequately powered study is required to establish rehabilitation phase of stroke.

The benefit of dietary texture modifications and/or alteration of fluid viscosity was evaluated in four trials.[11,17,19,25] Alt reviewed evaluated a common outcome (pneumonia), we were still unable to summarise the overall benefit of treatme evidence due to heterogeneity of interventions, timing and duration of therapy and stage of recovery of study participa small, ranging from 20[17] to
56[11] and the event rates for pneumonia were low in two of the three studies.[17,25] The external validity of at least one that the inclusion criteria were highly restrictive such that almost five times the number of available patients were excl simultaneous manipulation of solid textures and fluid viscosities makes it difficult to establish which component (solid pulmonary benefit. In summary, although modifications in dietary textures and fluid viscosities are a common dysphag evidence of its medical effectiveness.

Four RCTs were designed to improve the physiological aspects of swallowing by means of three different intervention channel blocker,[22] olfactory stimulation (aromatherapy) with black pepper oil[16] and the use of a cold stimulus on the plausible mechanism through which treatment could be predicted to improve physiological aspects of the swallow was the evidence from these trials is weakened by small sample sizes, the lack of a no treatment control group,[24] the rep statistical comparisons,[22] the use of more than one
treatment[24] or control group[16] and the failure to identify[22,23] or achieve[24] a clinically significant treatment effect. In required before recommending the clinical application of any of these three treatments.

Hypodermoclysis or subcutaneous hydration has been evaluated primarily in the elderly and palliative populations wh impossible to achieve.[26] The single RCT[13] we reviewed evaluating this technique specifically within the stroke popul effective compared with the intravenous route for maintaining serum osmolality within a normal range for three consec hydration remains uncommon practice likely due to its disadvantages that include the risk of tissue damage and the li safely administered.[26] Although the use of hypodermoclysis is not a treatment for dysphagia *per se*, the single trial ev inclusion criteria and was included.

The use of anti-microbial agents as a means to reduce the colonisation of pathogenic organisms in portions of the dig patients groups other than stroke. The use of selective decontamination of the digestive tract (SDD) has been investig critical care setting requiring artificial ventilation, where it has been shown to reduce the incidence of nosocomial infec modified version of this intervention, whereby SDD was applied only as a topical gel rather than one component of a r approach, was evaluated specifically for use in patients recovering from stroke in a single trial.[18] SDD was associate pneumonia, particularly for patients with an abnormal swallow; however, there was no difference in mortality between were reported, it remains to be established if the treatment is cost-effective. A larger and more rigours study is require patients recovering from stroke.

This systematic review sought to review all published RCTs evaluating therapeutic swallowing interventions for dysph quality and scope of the empirical evidence. Although the literature search was extensive and we believe all potentiall possible that some were missed. Since this review was restricted to RCTs, the most rigorous study design, we did not using a traditional hierarchical approach that typically includes non-RCTs. Additionally, the contribution to the literatur considered in this review. Some forms of experimental dysphagia treatment, such as lingual strengthening exercises, biofeedback, electrical stimulation and others were not evaluated in this review since they have not yet been subjecte

Conclusions

This updated review of all treatments for dysphagia, a common and potentially serious complication of stroke, identifie of treatments including texture-modified diets, swallowing therapy programmes, non-oral feeding, medications and ph associated with the small number of trials as well as heterogeneity of treatments evaluated and outcomes assessed p have definitive implications for clinical practice, with two exceptions. First, NG tubes do not appear to be associated w compared with PEG feeding tubes. Second, general swallowing treatment programmes are associated with a reduced

of stroke. Until further evidence emerges, we will be forced to rely on clinical experience and consensus opinions as t
Although evidence of effectiveness is lacking for many swallowing therapies and interventions now in current practice
discontinued, since current treatments have their roots in clinical experience and approaches that are physiologically
clear and pressing need for high-quality research to identify effective dysphagia treatments post stroke.

Table 1. Literature Search Outcome

	Medline	Embase	CCTR	Cinahl	Total
Hits on database	52	37	48	10	147
Exclusions:					
Duplication between database	—	14	26	5	45
Review articles	4	4	0	1	9
Non-English language	2	2	1	—	5
No intervention evaluated	18	5	2	1	26
No control group	2	—	—	—	2
Non-random assignment	5	—	1	—	6
Some/all subjects had not suffered a stroke	1	4	3	—	8
Some/all subjects not dysphagic	1	5	1	—	7
Commentary or letter to editor	9	—	1	2	12
Abstract of conference proceeding	—	—	12	—	12
RCTs remaining	10	3	1	1	**15**

Table 2. PEDro Criteria and Final Scores of 15 Included Trials

					Blinding			
Article	**Random assignment**	**Concealed allocation**	**Baseline comparisons**	**Between group comparison**	**Patient**	**Clinician**	**Assessor**	**Adequa follow-u**
Carnaby *et al.* 2006 [12]	X	X	X	X	—	—	X	X
Challiner *et al.* 1994 [13]	X	X	X	X	—	—	—	X
DePippo *et al.* 1994 [14]	X	—	X	X	—	—	—	X
Ebihara *et al.*	X	—	X	X	—	—	—	X

2006 [16]								
The FOOD trial, 2005 [15]	X	X	X	X	—	—	—	X
Garon *et al.* 1997 [17]	X	—	X	X	—	—	—	X
Gosney *et al.* 2006 [18]	X	X	X	X	X		X	X
Goulding and Bakheit 2000 [19]	X	—	X	X	—	—	X	X
Groher 1987 [11]	X	—		X	—	—	—	X
Hamidon *et al.* 2006 [20]	X	—	X	X	—	—	—	X
Norton *et al.* 1996 [21]	X	X	X	X				X
Perez *et al.* 1998 [22]	X		X	—	X		X	X
Rosenbek *et al.* 1996 [23]	X	—	—	X	—	—	X	X
Rosenbek *et al.* 1998 [24]	X	X		X			X	X
Whelan 2001 [25]	X		—	X	—	—	—	X

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Sidebar: Key Points

- Fifteen RCTs have evaluated the benefit of general dysphagia therapy programmmes, non-oral feeding, medi stimulation in the treatment of post stroke dysphagia.
- The risk of death associated with the use of nasogastric and percutaneous endoscopic gastrostomy (PEG) tub declines in variables associated with nutritional status are associated with the use of PEG tubes.
- There is emerging evidence that general dysphagia programmes reduce the risk of pneumonia in the acute st
- Despite the recent addition of several newly published RCTs, few utilise the same treatment and outcomes; th continue to be limited.

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