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SYSTEMATIC REVIEW

Dysphagia treatment post stroke: a systematic review of randomised controlled trials

Norine Foley[1], Robert Teasell[2], Katherine Salter[1], Elizabeth Kruger[1], Rosemary Martino[3]

[1]Research Associate, Aging, Rehabilitation and Geriatric Care Program, Lawson Health Research Institute, Parkwood Hospital, Rm B-3019b, 801 Commissioner's Rd. E. London, ON N6C 5J1, Canada
[2]Department of Physical Medicine and Rehabilitation, Parkwood Hospital, 801 Commissioner's Rd. E. London, ON N6C 5J1, Canada
[3]Graduate Department of Speech-Language Pathology, Rehabilitation Sciences Building, Centre for Function and Well Being, Faculty of Medicine, University of Toronto, 500 University Ave, 10th floor, Toronto, ON M5G 1V7, Canada

Address correspondence to: Norine Foley. Tel: 1 (519) 685-4292 ext 42738; Fax: (519) 685-4036.
Email: norine.foley@sjhc.london.on.ca

Abstract

Background: dysphagia is common following stroke and is associated with the development of pneumonia. Many dysphagia treatment options are available, some still experimental and others already rooted in common practice. Previous reviews of these treatments were limited due to a dearth of 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 broader range of therapeutic 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 examining the efficacy of dysphagia therapies 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, general dysphagia therapy programmes, non-oral (enteral) feeding, medications, and physical and olfactory stimulation. Across the studies there was heterogeneity of the treatments evaluated and the outcomes assessed that precluded the use of pooled analyses. Descriptively these findings present emerging evidence that nasogastric tube feeding is not associated with a higher risk of death compared to percutaneous feeding tubes; and general dysphagia therapy programmes are associated with a 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 newly published RCTs, few utilise the same treatment and outcomes thereby limiting the evidence to support the medical effectiveness of common dysphagia treatments used for patients recovering from stroke.

Keywords: *literature review, deglutition disorders, treatment, outcome, cerebrovasular disorders, elderly*

Introduction

Dysphagia is prominent across the continuum of stroke recovery and its presence is likely to result in pulmonary complications, particularly pneumonia [1]. Despite the perceived association between dysphagia treatment and a reduction of serious complications including aspiration pneumonia, there is yet no well-established evidence to support the use of any of the available treatments. In 1999, the Agency for Health Care Policy and Research (AHCPR) commissioned a large-scale, evidence-based report on the diagnosis and treatment of dysphagia in adult patients with acute stroke [2]. The results identified a lack of standardised assessment approaches and little high quality evidence for the benefit of either non-invasive swallowing therapy and/or percutaneous endoscopic gastrostomy (PEG) feeding tubes. Given limitations in study design and sample size, definitive conclusions with regard to swallowing therapy could not be drawn. At the same time a Cochrane review was conducted assessing the benefit of dysphagia treatment

following stroke [3]. This review identified only five trials and concluded that PEG feeding appeared to be more beneficial compared with nasogastric (NG) feeding. More recently, several studies have been published enabling a re-examination of the evidence. Therefore, the purpose of this systematic review was to update previous work and 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 therapeutic interventions for the treatment of dysphagia following stroke. The following databases were searched: The Cumulative Index to Nursing and Allied Health Literature (Cinahl), Medline, Embase and the Cochrane Library. Search dates depended on the database but ranged from 1966 to August 2007. Search terms varied slightly across databases but included: *deglutition disorders, dysphagia, cerebrovascular disorders/or cerebrovascular accident, randomised controlled trial, double-blind, placebo* or *random*. The search was limited to the terms *human, adult or aged*. The reference lists of all included articles were hand searched for any 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-level interventions. Planned crossover designed trials were included, provided the order of treatments was randomly assigned. Only studies in which the sample was comprised entirely of patients recovering from stroke and who were identified as dysphagic by the study investigators were included. Studies assessing both pharmacological and non-pharmacological treatments were included regardless of the length of time the intervention was provided or the outcome(s) assessed.

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

Two reviewers (NF and KS) independently assessed each abstract for potential inclusion. The original articles were reviewed if the intervention under study, the nature of the subject's illness or the study design was not clear based on the information provided in the abstract. Consensus following discussion was used to resolve conflicts over eligibility of potential articles. A single investigator (NF) abstracted data from all articles selected for review, which two other investigators (EK, RM) confirmed for accuracy. Additionally, three authors (KS, RM and NF) independently evaluated the methodological quality of each study using the Physiotherapy Evidence-Based Database (PEDro) scale [4]. The PEDro scale awards a maximum of 10 points for indicators of internal 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 end of the follow-up period, are described and presented in table form. Similar interventions across studies were compared and common outcomes assessed.

Results

Literature retrieved

The search strategy yielded 147 hits from all four databases, of which 45 were duplications, leaving 102 citations. Of these, a further 33 were rejected when they were found to be review articles, commentaries of previously published studies, or abstracts of conference proceedings. Reasons for further exclusions are presented in Table 1. The most common reason for exclusion was that no intervention was evaluated. Five randomised trials were eliminated because the participants were not dysphagic or some subjects with conditions other than stroke were included [5–9]. Fifteen RCTs remained following the initial review process. Of these, one study was excluded as it reported additional outcomes from a previously identified trial [10]. Hand-searching yielded one RCT not 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 allocation; however, only 6 provided a description of a mechanism for adequately concealed allocation. The outcome assessor was blinded in six studies; but in only three studies, all of pharmacological interventions, were both subjects and outcome assessors blinded. Three studies used an 'intention-to-treat analysis'. PEDro scores for the 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 confirmed either by both a clinical examination and a magnetic resonance imaging (MRI) or computed tomography (CT) scan [12, 14, 19–21, 25] or was based on the results from a CT scan alone [22]. An eligibility criterion with respect to stroke history was explicitly stated in five trials. In three of these trials, only subjects who had experienced their first stroke were eligible to participate [17, 18, 22], and subjects with stroke recurrence were eligible to participate in the remaining two [15, 23]. Details of stroke location 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

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

Article	Random assignment	Concealed allocation	Baseline comparisons	Between group comparison	Blinding			Adequate follow-up	Intent -to- treat	Point estimate and variability	PEDro score
					Patient	Clinician	Assessor				
Carnaby *et al.* 2006 [12]	X	X	X	X	—	—	X	X	X	X	8
Challiner *et al.* 1994 [13]	X	X	X	X	—	—	—	X	—	X	6
DePippo *et al.* 1994 [14]	X	—	X	X	—	—	—	X	X	—	5
Ebihara *et al.* 2006 [16]	X	—	X	X	—	—	—	X	—	X	5
The FOOD trial, 2005 [15]	X	X	X	X	—	—	—	X	X	X	7
Garon *et al.* 1997 [17]	X	—	X	X	—	—	—	X	—	X	5
Gosney *et al.* 2006 [18]	X	X	X	X	X		X	X			7
Goulding and Bakheit 2000 [19]	X	—	X	X	—	—	X	X	—	X	6
Groher 1987 [11]	X	—		X	—	—	—	X	—	—	3
Hamidon *et al.* 2006 [20]	X	—	X	X	—	—	—	X	—	X	5
Norton *et al.* 1996 [21]	X	X	X	X				X		X	6
Perez *et al.* 1998 [22]	X		X	—	X		X	X		X	6
Rosenbek *et al.* 1996 [23]	X	—	—	X	—	—	X	X	—	X	5
Rosenbek *et al.* 1998 [24]	X	X		X			X	X		X	6
Whelan 2001 [25]	X		—	X	—	—	—	X	—	X	4

and haemorrhagic [12, 19]. Following randomisation a small percentage of subjects (<1%) were found not to have experienced stroke in two trials [12, 15]. Initial stroke severity was assessed using a variety of scales (Table 3, available online at the journal's website http://ageing.oxfordjournals.org). On the reported information, it appeared that subjects with severe [13, 15, 21, 22, 25], moderate to severe [12, 14, 16] and mild stroke [20] were recruited. No details of initial stroke severity were presented in the remaining six trials.

Assessment of dysphagia

In nine studies, the diagnosis of dysphagia was made on the basis of videofluoroscopic (VFS) examination [14, 17, 20], or clinical assessment [12, 18, 19, 21] by either [25], or by both methods [24]. The authors of one of these trials stated that subjects diagnosed with dysphagia on the basis of a screening test only were excluded [25]. In four other trials, the authors stated that they enrolled patients taking a texture-modified diet, or those 'with dysphagia' [11, 13, 15, 22]. A single study used swallowing difficulties identified by the patient, family member or healthcare provider to identify dysphagic subjects [23], while yet another used a latency of swallowing reflex greater than 3 s to indicate the presence of dysphagia (Ebihara, personal communication 2007).

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 website http://ageing.oxfordjournals.org) for a description of interventions and outcomes. Treatment was initiated within either 7 days [12, 13, 15, 18] or between 4 and 6 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—provided until patients reached a study end point [14, 17] for the duration of their hospital stay or until the treatment was no longer required [12, 15, 21, 25]. In the remaining trials, treatment was given for a fixed 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 outcomes after a gap following the completion 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 evaluated immediately following completion of treatment. The choice of target outcome included measurements of swallowing physiology [16, 22–24]; swallowing function [17]; lung infection [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 more study groups [12, 14, 16, 24]. There was one randomised crossover study [23]and two separate, but related trials, each of a two group parallel design, which were reported in a single publication [15]. Sample sizes varied from 17 [22] to 859 [15]. See Table 3 (available online at the journal's website http://ageing.oxfordjournals.org) for details of study design and results.

Discussion

Of the 15 studies identified and reviewed, the most commonly evaluated interventions were based on dietary texture modifications [11, 17, 19, 25], general dysphagia therapy programmes [12, 14] and enteral feeding [15, 20, 21]; all forms of interventions that have become well-established in clinical practice. The outcomes assessed in these trials were usually of clinical relevance, including death, return of functional swallowing and/or pneumonia. Other therapies evaluated in this review such as thermal [23, 24] or olfactory stimulation [16], and pharmacotherapy [22] aimed primarily at improving physiological aspects of swallowing, are currently considered to be experimental and are not yet in routine use. Finally, two interventions, selective decontamination of the digestive tract [18] and subcutaneous hydration [13], have been used, historically, in conditions other than stroke. The majority of the interventions were provided during the first several weeks following stroke, although some were provided in the chronic stage when patients were residing in a nursing home [11, 16]. Although the review was restricted to RCTs, the methodological quality of the trials was generally only fair. Only a single trial [12] included all of the design elements most often associated with decreased risk of bias. (concealment of the randomisation schedule, blinding of the outcome assessor and used intention-to treat analysis). The heterogeneity of the interventions, even within the same broad treatment categories, as well as the timing and nature of the outcomes assessed made pooled analyses inappropriate; therefore, the results were presented descriptively. For two interventions, enteral tube feeding and swallowing treatment programmes there were a sufficient number of trials available to enable comment on the strength of the evidence.

Three RCTs compared the outcomes of acute stroke patients who were fed using NG or PEG feeding tubes [15, 20, 21]. One, the FOOD trial, was a large, well-designed multicentre trial [15]. In this trial patients randomised to the NG group were less likely to experience either death or poor functional status when compared to patients fed with a PEG tube ($P = 0.05$), and were no more likely to develop pneumonia. However, these findings conflicted with those from the two other smaller RCTs reviewed [20, 21], where NG tubes were associated with a higher risk of death and worse outcomes such as being malnourished and more feeding interruptions due to mechanical failures, blockages and dislodgements when compared with PEG tubes. In summary, the strength of evidence, giving greater consideration to the FOOD trial with its larger sample size and higher methodological quality score, suggests that unlike previous findings NG tube feeding is not associated with a greater risk of death compared with PEG feeding. However, PEG tube feeding appears to be associated with fewer tube failures and fewer declines in nutritional status

Two RCTs were identified that assessed the effectiveness of general swallowing treatment programmes [12, 14]. Typically, such programmes are prescribed and executed by speech-language pathologists. They comprise of a variety of compensatory and treatment-swallowing techniques in combination with texture-modified diets that have been shown during a VFS assessment to be effective in reducing aspiration or improving bolus flow for a particular patient. There were similarities between the two studies inasmuch as both included three groups providing treatment at varying

degrees of intensity. Since one of the trials [14] did not include a true control condition, to enable treatment comparisons, we presumed the group receiving the lowest intensity of therapy to be the control group. Unfortunately, the authors of this study did not report the actual treatment intensity patients received in this group, which might have differed from that described since patients were permitted additional instruction upon request. The studies provided treatment at different stages of recovery, one acutely, within 7 days [12] and the other, at 41/2 weeks [14] post stroke with differing degrees of intensity. One of the studies [12]also included a treatment arm that provided swallowing exercises in addition to compensatory swallowing techniques. Two outcomes, death and the incidence of pneumonia were assessed in both studies. No deaths were reported in the trial assessing subjects in the rehabilitative phase of stroke [14], limiting comparability. The results were conflicting in terms of reductions in pneumonia. Even though the sample sizes were small and statistical significance was not achieved, DePippo *et al.* [14]. reported that patients receiving the lowest intensity of therapy had the lowest incidence of pneumonia. In contrast, Carnaby *et al.* [12]. reported that patients receiving the lowest intensity of treatment (usual care) had a significantly higher incidence of chest infection than patients receiving either of the more intensive therapies. In summary, the overall evidence suggests that swallowing treatment programmes are associated with a reduced risk of pneumonia in at least the acute stage of stroke; however, a larger, adequately powered study is required to establish a benefit of therapy during the 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]. Although three [11, 17, 25] of four studies reviewed evaluated a common outcome (pneumonia), we were still unable to summarise the overall benefit of treatment or comment on the strength of evidence due to heterogeneity of interventions, timing and duration of therapy and stage of recovery of study participants. Sample sizes across studies were 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 of these RCTs [17] is questioned given that the inclusion criteria were highly restrictive such that almost five times the number of available patients were excluded. In another trail [11], the simultaneous manipulation of solid textures and fluid viscosities makes it difficult to establish which component (solid or liquid) was associated with pulmonary benefit. In summary, although modifications in dietary textures and fluid viscosities are a common dysphagia intervention there is scant empirical evidence of its medical effectiveness.

Four RCTs were designed to improve the physiological aspects of swallowing by means of three different interventions: the use of nifedipine, a calcium channel blocker [22], olfactory stimulation (aromatherapy) with black pepper oil [16] and the use of a cold stimulus on the faucial pillars [23, 24]. A biologically plausible mechanism through which treatment could be predicted to improve physiological aspects of the swallow was described in each study. However, the evidence from these trials is weakened by small sample sizes, the lack of a no treatment control group [24], the reporting absence of between group 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 summary, additional research is 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 where intravenous access is difficult or impossible to achieve [26]. The single RCT [13] we reviewed evaluating this technique specifically within the stroke population found the method equally effective compared with the intravenous route for maintaining serum osmolality within a normal range for three consecutive days. However, this method of hydration remains uncommon practice likely due to its disadvantages that include the risk of tissue damage and the limited volume of fluids that can be safely administered [26]. Although the use of hypodermoclysis is not a treatment for dysphagia *per se*, the single trial evaluating this intervention met our 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 digestive tract has also been studied in patients groups other than stroke. The use of selective decontamination of the digestive tract (SDD) has been investigated primarily among patients in a critical care setting requiring artificial ventilation, where it has been shown to reduce the incidence of nosocomial infections and to reduce mortality [27]. A modified version of this intervention, whereby SDD was applied only as a topical gel rather than one component of a more comprehensive treatment approach, was evaluated specifically for use in patients recovering from stroke in a single trial [18]. SDD was associated with reductions in the incidence of pneumonia, particularly for patients with an abnormal swallow; however, there was no difference in mortality between groups. Although no adverse events were reported, it remains to be established if the treatment is cost-effective. A larger and more rigours study is required to conclude on the benefit of SDD in patients recovering from stroke.

This systematic review sought to review all published RCTs evaluating therapeutic swallowing interventions for dysphagia following stroke to evaluate the quality and scope of the empirical evidence. Although the literature search was extensive and we believe all potentially eligible studies were captured, it is possible that some were missed. Since this review was restricted to RCTs, the most rigorous study design, we did not evaluate the strength of evidence using a traditional hierarchical approach that typically includes non-RCTs. Additionally, the contribution to the literature from unpublished RCTs was not considered in this review. Some forms of experimental dysphagia treatment, such as lingual strengthening exercises, electromyographic (EMG)

biofeedback, electrical stimulation and others were not evaluated in this review since they have not yet been subjected to investigation by an RCT.

Conclusions

This updated review of all treatments for dysphagia, a common and potentially serious complication of stroke, identified 15 RCTs assessing a broad range of treatments including texture-modified diets, swallowing therapy programmes, non-oral feeding, medications and physical stimulation. Limitations associated with the small number of trials as well as heterogeneity of treatments evaluated and outcomes assessed precluded conclusions being drawn that have definitive implications for clinical practice, with two exceptions. First, NG tubes do not appear to be associated with an increased risk of death compared with PEG feeding tubes. Second, general swallowing treatment programmes are associated with a reduced risk of pneumonia in the acute stage of stroke. Until further evidence emerges, we will be forced to rely on clinical experience and consensus opinions as the basis for treatment decisions. Although evidence of effectiveness is lacking for many swallowing therapies and interventions now in current practice, we do not suggest that they be discontinued, since current treatments have their roots in clinical experience and approaches that are physiologically based. In the meantime, there is a clear and pressing need for high-quality research to identify effective dysphagia treatments post stroke.

Key points

- Fifteen RCTs have evaluated the benefit of general dysphagia therapy programmmes, non-oral feeding, medications, and physical and olfactory stimulation in the treatment of post stroke dysphagia.
- The risk of death associated with the use of nasogastric and percutaneous endoscopic gastrostomy (PEG) tubes is equal. Fewer tube failures and 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 stage of stroke.
- Despite the recent addition of several newly published RCTs, few utilise the same treatment and outcomes; thereby comparisons across studies continue to be limited.

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Conflicts of interest

None

Supplementary data

Supplementary data for this article are available online at http://ageing.oxfordjournals.org.

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