Dysphagia Treatment Post Stroke: A Systematic Review of Randomised Trials

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Posted 08/18/2008

Abstract and Introduction

Abstract

Background: dysphagia is common following stroke and is associated with the development of pneumonia. Many dysphagia treatment interventions are available, some still experimental and others already rooted in common practice. Previous reviews of these treatment interventions have highlighted the need for rigorous evaluation of the evidence available, some still experimental and others already rooted in common practice. Previous reviews of these treatment interventions have highlighted the need for rigorous evaluation 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 use of pooled analyses. Descriptively these findings present emerging evidence associated with a higher risk of death compared to percutaneous feeding tubes; and general dysphagia therapy 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 introduction of new treatments and outcomes thereby limiting the evidence to support the medical effectiveness of common dysphagia interventions, current evidence suggests a potential benefit of percutaneous feeding tubes compared to nasogastric feeding tubes in the acute stage of stroke.

Introduction

Dysphagia is prominent across the continuum of stroke recovery and its presence is likely to result in pulmonary complications. Despite the perceived association between dysphagia treatment and a reduction of serious complications including pneumonia, there is a lack of standardised assessment approaches and little high quality evidence for the benefit of either non-invasive or endoscopic gastrostomy (PEG) feeding tubes. Given limitations in study design and sample size, definitive conclusions could not be drawn. At the same time a Cochrane review was conducted assessing the benefit of dysphagia treatment interventions only five trials and concluded that PEG feeding appeared to be more beneficial compared with nasogastric feeding tubes. The purpose of this systematic review is to 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 therapies for dysphagia following stroke. The following databases were searched: The Cumulative Index to Nursing and Allied Health Care (CINAHL), Embase and the Cochrane Library. Search dates depended on the database but ranged from 1966 to August 2007. Search terms included: deglutition disorders, dysphagia, cerebrovascular disorders/or cerebrovascular accident, random placebo or random. The search was limited to the terms human, adult or aged. The reference lists of all included articles were 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 designed trials were included, provided the order of treatments was randomly assigned. Only studies in which the subjects were recovering from stroke and who were identified as dysphagic by the study investigators were included. Studies assessing pharmacological treatments were included regardless of the length of time the intervention was provided or the outcome assessed. Non-English language studies and studies in which patients were not assigned randomly, by chance, to either a treatment group or placebo group were excluded. Abstracts and Letters to the Editor were excluded because of lack of reporting detail. Opinion articles and case reports were excluded.

Two reviewers (NF and KS) independently assessed each abstract for potential inclusion. The original articles were read in full for the nature of the subject's illness or the study design was not clear based on the information provided in the abstract. Differences between treatment groups on primary and secondary outcomes, as identified by the study's authors at the time of the study, were 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, 39 were review articles, commentaries of previously published studies, or abstracts of conference proceedings. The remaining 63 were assessed for eligibility. The most common reason for exclusion was that no intervention was evaluated. Five randomised controlled trials were not dysphagic or some subjects with conditions other than stroke were included. Non-English language studies and studies in which patients were not assigned randomly, by chance, to either a treatment group or placebo group were excluded. Abstracts and Letters to the Editor were excluded because of lack of reporting detail. Opinion articles and case reports were excluded. Two reviewers (NF and KS) independently assessed each abstract for potential inclusion. The original articles were read in full for the nature of the subject's illness or the study design was not clear based on the information provided in the abstract.

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 of participants to treatment groups. The mechanism for adequately concealed allocation was reported in all studies. The outcome assessor was blinded in six studies; both subjects and outcome assessors were blinded. Three studies used an 'intention-to-treat' analysis. Differences between treatment groups on primary and secondary outcomes, as identified by the study's authors at the time of the study, were described and presented in table form. Similar interventions across studies were compared and common outcomes assessed.

Patient Characteristics

The mean ages of patients enrolled in all studies ranged from 67 to 86 years. The diagnosis of stroke was confirmed by examination and a magnetic resonance imaging (MRI) or computed tomography (CT) scan. An eligibility criterion with respect to stroke history was explicitly stated in five trials. In three of these trials, only subjects with a history of stroke were eligible to participate and subjects with stroke recurrence were eligible to participate in the remaining trials. Stroke type was reported in five trials as either ischaemic or both ischaemic and haemorrhagic. Small percentage of subjects (<1%) were found not to have experienced stroke in two trials. Initial stroke severity scales were based on the reported information severe, moderate to severe and mild stroke were recruited. No details of initial stroke severity were reported.

trials.

**Assessment of Dysphagia**

In nine studies, the diagnosis of dysphagia was made on the basis of videofluoroscopic (VFS) examination,\[14,17,20]\ or by both methods.[24] The authors of one of these trials stated that subjects diagnosed with dysphagia on the basis excluded.[25] In four other trials, the authors stated that they enrolled patients taking a texture-modified diet, or those \ 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](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—provicing point[14,17] for the duration of their hospital stay or until the treatment was no longer required.[12,15,17,21,25] In the remaining trials, terms 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 completion of treatment. The choice of target outcome included measurements of swallowing physiology,\[16,22-24\] swallowing tube failures and fewer declines in nutritional status

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 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.[18] See Table 3 (available online at the journal’s website [http://ageing.oxfordjournals.org](http://ageing.oxfordjournals.org)) 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 fell into clinical practice. The outcomes assessed in these trials were usually of clinical relevance, including death, return of full swallowing function, and improvement in feeding for patients with dysphagia. Some outcomes were of clinical interest, such as swallowing physiology,\[16,22-24\] swallowing tube failures and fewer declines in nutritional status.

Three RCTs compared the outcomes of acute stroke patients who were fed using NG or PEG feeding tubes.[15,20,21] One of these studies was a multicentre trial.[15] In this trial, patients randomised to the NG group were less likely to experience dysphagia than those 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 outcomes. The heterogeneity of the interventions, even within the same broad treatment categories, is 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 strength

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-swallowing texture-modified diets that have been shown during a VFS assessment to be effective in reducing aspiration or improvements. There were similarities between the two studies inasmuch as both included three groups providing treatment at varying frequencyplications,\[11,14\] did not include a true control condition, to enable treatment comparisons, we presumed the group receiveing 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 to one acutely, within 7 days\cite{12} and the other, at 41/2 weeks\cite{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 and 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 associated 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.\cite{11,17,19,25} All reviewed evaluated a common outcome (pneumonia), we were still unable to summarise the overall benefit of treatment evidence due to heterogeneity of interventions, timing and duration of therapy and stage of recovery of study participants, ranging from 20\cite{17} to 56\cite{11} and the event rates for pneumonia were low in two of the three studies.\cite{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 excluded 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 dysphagia evidence of its medical effectiveness.

Four RCTs were designed to improve the physiological aspects of swallowing by means of three different intervention channel blocker,\cite{22} olfactory stimulation (aromatherapy) with black pepper oil\cite{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,\cite{24} the reported statistical comparisons,\cite{22} the use of more than one treatment\cite{24} or control group\cite{16} and the failure to identify\cite{22,23} or achieve\cite{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 where impossible to achieve.\cite{26} The single RCT\cite{13} we reviewed evaluating this technique specifically within the stroke population effective compared with the intravenous route for maintaining serum osmolality within a normal range for three consecutive hydration remains uncommon practice likely due to its disadvantages that include the risk of tissue damage and the liquid safety administered.\cite{26} Although the use of hypodermoclysis is not a treatment for dysphagia per se, the single trial exclusion 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 been investigated critically setting requiring artificial ventilation, where it has been shown to reduce the incidence of nosocomial infection. Modified version of this intervention, whereby SDD was applied only as a topical gel rather than one component of a treatment, was evaluated specifically for use in patients recovering from stroke in a single trial.\cite{18} SDD was associated 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 rigorous study is required patients recovering from stroke.

This systematic review sought to review all published RCTs evaluating therapeutic swallowing interventions for dysphagia quality and scope of the empirical evidence. Although the literature search was extensive and we believe all potential possibilities that some were missed. Since this review was restricted to RCTs, the most rigorous study design, we did not use a traditional hierarchical approach that typically includes non-RCTs. Additionally, the contribution to the literature 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 subjected.

**Conclusions**

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

<table>
<thead>
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<th>Exclusions:</th>
<th>Medline</th>
<th>Embase</th>
<th>CCTR</th>
<th>Cinahl</th>
<th>Total</th>
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<td>—</td>
<td>1</td>
<td>—</td>
<td>6</td>
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<tr>
<td>Some/all subjects had not suffered a stroke</td>
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<td>4</td>
<td>3</td>
<td>—</td>
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<td>Some/all subjects not dysphagic</td>
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<td>—</td>
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<tr>
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<td>RCTs remaining</td>
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<td>1</td>
<td>1</td>
<td>15</td>
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Table 2. PEDro Criteria and Final Scores of 15 Included Trials

<table>
<thead>
<tr>
<th>Article</th>
<th>Random assignment</th>
<th>Concealed allocation</th>
<th>Baseline comparisons</th>
<th>Between group comparison</th>
<th>Patient</th>
<th>Clinician</th>
<th>Assessor</th>
<th>Adequa follow-up</th>
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### References


**Sidebar: Key Points**

- Fifteen RCTs have evaluated the benefit of general dysphagia therapy programmes, non-oral feeding, medicalement stimulation in the treatment of post stroke dysphagia.
- The risk of death associated with the use of nasogastric and percutaneous endoscopic gastrostomy (PEG) tubes: 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 stroke setting.
- Despite the recent addition of several newly published RCTs, few utilise the same treatment and outcomes; thus continue to be limited.

**Funding Information**

This research was supported by funds received from the Canadian Stroke Network. The financial sponsors played no role in the interpretation of data or writing of the study.

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Disclosure: Rosemary Martino is supported by a Canadian Institutes of Health Research New Investigator Award in A

Conflicts of Interest: None