

Restriction of oral intake of water for aspiration lung disease in children (Review)

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[Intervention Review]

Restriction of oral intake of water for aspiration lung disease in children

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ABSTRACT

Background

Primary aspiration of food and fluid is commonly seen in children with feeding and swallowing difficulties associated with a range of diseases and complex medical conditions. Respiratory sequelae and pneumonia are known to be associated with primary aspiration of ingested material, however causality between primary aspiration of specific food and fluid types and pulmonary effects in children is yet to be established in controlled trials. The relative pulmonary morbidity of aspiration of ingested food and fluid materials versus other causes of respiratory disease such as viral and bacterial causes, secondary aspiration of gastrointestinal contents and predisposing lung conditions such as chronic neonatal lung disease in a developing immune system is also unclear. Current management decisions for children who aspirate have to optimise oral nutrition and hydration, while reducing the risk of aspiration to preserve pulmonary integrity. This generally includes restricting aspirated food or fluids and providing texture-modified diets and thickened fluids. Young children frequently refuse thickened fluids providing a management dilemma for both families and health professionals.

Objectives

Our objective was to evaluate the efficacy of restriction of oral water ingestion on the pulmonary status of children with thin fluid aspiration demonstrated on a modified barium swallow study.

Search methods

The Cochrane Central Register of Controlled Trials (CENTRAL), the Cochrane Airways Collaborative Review Group Specialised Register, MEDLINE, EMBASE and CINAHL databases were searched by the Cochrane Airways Group. The latest search was performed in January 2011.

Selection criteria

All randomised controlled trials comparing restriction of oral intake of water with unlimited oral water ingestion were eligible to be included.

Data collection and analysis

Results of searches were reviewed against a pre-determined criteria for inclusion. No eligible trials were identified for a paediatric population and thus no data were available for analysis. One trial in an adult population was identified and reported.

Main results

No randomised controlled trials examining the efficacy of restriction of oral intake of water in the management of children with thin fluid aspiration were found. In a single study in an adult population with stroke, no significant differences were seen between a control group of oral water restriction and the experimental group of unlimited oral water ingestion on outcomes such as pneumonia, total oral fluid intake and dehydration.

Authors' conclusions

There are no trials that have adequately evaluated the pulmonary effects of allowing or restricting oral water ingestion in children known to have primary aspiration of thin fluids. Thus, there is currently an absence of evidence to support a strict approach of full restriction of oral intake of water or support a more liberal approach of allowing oral water ingestion in children with primary aspiration of thin fluids.

PLAIN LANGUAGE SUMMARY

Restriction of oral intake of water for aspiration lung disease in children

Primary aspiration of food and fluid can cause serious lung consequences in infants and children. Treatment recommendations for children who have primary aspiration of thin fluids includes restriction of thin fluids and provision of thickened fluids. Children often refuse to drink thickened fluids presenting a challenge for families to ensure that the child takes sufficient fluid. Allowing children who have thin fluid aspiration to drink water may assist in providing enough fluid without endangering the lung. This review found no evidence about drinking water in children with primary aspiration of thin fluids.

BACKGROUND

One of the most significant complications of dysphagia or feeding difficulty is aspiration, which is defined as entry of material into the airway below the level of the true vocal folds (Logemann 1983). Primary aspiration is commonly seen in infants and children with feeding and swallowing problems associated with neurological disease, anatomical anomalies and other aetiologies (Weiss 1988; Arvedson 1994; Colombo 1999). Short term manifestations of pulmonary aspiration are cough, wheeze, increased number and prolonged respiratory infections and atelectasis (Colombo 1999; Loughlin 1994). Cough is a common symptom of the above conditions. Long term consequences of pulmonary aspiration include bronchiectasis, bronchiolitis obliterans and follicular bronchiolitis, respiratory distress, airway obstruction, acute or recurrent pneumonia, frequent or long-lasting upper respiratory infections and chronic lung disease (Loughlin 1989; Loughlin 1994; Arvedson 1998; Colombo 1999). Weiss suggested that although aspiration is an important complication in a patient of any age, it may assume particular importance in the developing infant or child with dysphagia (Weiss 1988). He proposed that infants and children may lack some of the compensatory mechanisms that enable adults to protect the airway, thus making early detection

and prevention of aspiration essential in order to avoid severe and possibly irreversible pulmonary morbidity.

Dysphagia may also cause other complications such as failure to maintain an adequate nutritional intake and hydration. A Cochrane review of treatment for dysphagia in chronic muscle disease investigated the effect of various interventions on a primary outcome of nutritional issues including stabilisation of previously documented weight loss (Hill 2004). The reviewers found no RCTs and concluded that "It is therefore not possible to decide on the most appropriate treatment for a given individual based on current evidence". Our review focuses primarily on aspiration and respiratory outcomes.

Currently, there is no gold standard outcome measure for the assessment of primary aspiration. A range of instrumental procedures are available to evaluate the occurrence of primary aspiration. These techniques include the fiberoptic endoscopic evaluation of swallowing (FEES), radionuclide salivagram, nuclear scintigraphy, bronchoscopy and use of the lipid laden macrophage index, static radiographs, upper gastrointestinal studies and the modified barium swallow study (MBS) (Sonies 1991; Bar-Sever 1995; Leder 1998; Bauer 1999; Hartnick 2000; Leder 2000; Ding 2002;

Tohara 2003). Inflammatory changes consistent with neutrophilic inflammation and lipid laden macrophage index are sometimes used as supportive markers of aspiration, but neither marker is specific for aspiration (Bauer 1999; Ding 2002). However, the modified barium swallow study (MBS) is currently the most frequently used tool to detect primary aspiration during feeding in paediatrics (Sonies 1991; O'Donoghue 1999; Miller 2003).

Current practice following detection of aspiration on any consistency during an MBS is to implement swallowing strategies or indirect intervention techniques such as alterations in postural variations and food characteristics such as temperature, viscosity, and texture (Newman 2000; Arvedson 1997; Seddon 2003). Fluid consistencies are the most commonly aspirated material in people with swallowing dysfunction (Arvedson 1994; Rogers 1994; Taniguchi 1994; Morton 1999; Friedman 2000; Lefton-Greif 2000). In the case of thin fluids, texture restriction may entail eliminating the thin fluids from a person's diet and allowing thickened fluids to be orally consumed (Logemann 1983; Newman 2000). Alternative methods of nutrition such as nasogastric or gastrostomy tubes may be necessary to provide hydration needs (Arvedson 1997; Newman 2000). While existing evidence suggests a strong association between aspiration of thick fluid and solid textures with pneumonia (Taniguchi 1994), little evidence exists to prove or disprove a relationship between aspiration of thin liquids, and particularly water, with the development of pneumonia (Taniguchi 1994; Garon 1997). The pathophysiology resulting from aspiration depends on several factors including the presence of particulate matter, a relatively low pH (<2.5), bacterial contamination from the oral or gastrointestinal tracts and volume of gastric aspirate (> 0.3 ml per kilogram of body weight (20-25 ml in adults) (Nahum 1981; Kirsch 1988). Water has a neutral pH of approximately 7, with Australian drinking water requirements recommending a pH value between 6.5 - 8.5 (NHMRC 1996). Small amounts of aspiration of this liquid with a relatively neutral pH should have little pulmonary or health effects if the current literature is to be believed.

In current medical practice, some children who are known to aspirate on thin fluids have full restriction of thin fluids orally, while others are allowed to ingest water orally. There is no research at present that systematically investigates the health effects of water ingestion in children who are known to aspirate thin fluids. Garon and colleagues investigated the development of pneumonia in two groups of adult stroke patients with thin fluid aspiration documented on MBS (Garon 1997). They found that patients allowed unlimited water ingestion did not have increased pulmonary complications compared to those on thickened fluids and full thin fluid restriction (Garon 1997). Furthermore, the group allowed unrestricted water ingestion reported higher satisfaction rates on quality of life measures (Garon 1997). The results of studies by Garon and colleagues and Taniguchi and Moyer have thrown open the debate on the relative effects of ingesting water and possible aspiration on the health and well-being of young children (Garon

1997; Taniguchi 1994). Relative benefits to the quality of life of swallowing impaired children and their families and associated health benefits in providing adequate hydration and negating the need for tubes may far outweigh the relative risks of the primary aspiration itself. Hence, there is a need for systematic evaluation of the effects of water ingestion in children who aspirate thin fluids in terms of pulmonary health and quality of life.

OBJECTIVES

To evaluate the efficacy of restriction of oral water ingestion on pulmonary status of children with aspiration demonstrated on a modified barium swallow.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised controlled trials of water restriction in children with documented aspiration on fluids would be included in the review.

Types of participants

Participants included children aged < 14 years whose modified barium swallow had shown aspiration of thin fluids. There were no exclusion criteria.

Types of interventions

Interventions included all randomised controlled comparisons of oral water restriction. Trials that included the use of other medications or interventions were to be included if all participants had equal access to such medications or interventions.

Types of outcome measures

It was planned to obtain data on at least one of the following outcome measures:

Primary outcome:

a) proportions of participants who were not cured or not substantially improved at follow up (clinical failure).

Secondary outcomes:

b) proportions of participants who were not cured at follow up,

c) proportions of participants who were not substantially improved at follow up,

- d) mean difference in the number of respiratory episodes (defined by diary cards or acute respiratory illness score)
- e) proportions requiring hospitalization for respiratory illness
- f) mean difference in symptoms and signs (mean improvement in clinical state)
- g) proportions developing new respiratory complications such as bronchiectasis, bronchiolitis obliterans, follicular bronchiolitis etc,
- h) proportions experiencing adverse effects of the intervention (e.g., dehydration, gastrostomy button complications etc),
- i) proportions requiring new intervention for management of aspiration e.g., requirement for gastrostomy, diversion surgery, etc. The proportions of participants who failed to improve on treatment and the mean clinical improvement were to be determined by using the following hierarchy of assessment measures (i.e., where two or more assessment measures were reported in the same study, the outcome measure that was listed first in the hierarchy was to be used).
 - i) Objective measurements of cough indices (cough frequency).
 - ii) Symptomatic (Quality of life, Likert scale, visual analogue scale, level of interference of respiratory symptoms such as cough, cough diary) - assessed by child
 - iii) Symptomatic (Quality of life, Likert scale, visual analogue scale, level of interference of respiratory symptoms such as cough, cough diary) - assessed by the parents/carers.
 - iv) Symptomatic (Likert scale, visual analogue scale, level of interference of respiratory symptoms such as cough, cough diary) - assessed by clinicians.
 - v) Radiological assessment of chest (High resolution computed tomography and chest Xray)
 - vi) Relevant airway markers consistent with neutrophilic inflammation or surrogate markers of aspiration such as lipid laden macrophage index.

Search methods for identification of studies

The following topic search strategy was used to identify relevant randomised controlled trials from the listed electronic databases: (“aspiration” OR “aspirate” OR “silent aspiration” OR “dysphagia” OR “feeding difficulties” OR “swallowing difficulties” OR “swallow abnormalities” OR “swallow dysfunction” OR “deglutition” OR “deglutition disorders” OR “oropharyngeal” OR “barium meal” OR “swallow evaluation” OR “videofluoroscopy” OR “modified barium swallow”, all as (textword) or (MeSH)) AND (“water” or “fluid” or “liquid” or “drink”; all as (textword) or (MeSH)) AND (“child” OR “children” OR “infant” as (textword) or (MeSH)) For the full searches see Appendix 1. Trials were identified from the following sources:

1. The Cochrane Controlled Trials Register (CENTRAL) which includes the Airways Collaborative Review Group Specialised Trials Register.
2. MEDLINE (1966-present). Topic search strategy combined with the Medline randomised controlled trial search filter as outlined in the Airways Group module.
3. OLDMEDLINE (1951-1965). Topic search strategy combined with the Medline randomised controlled trial search filter as outlined in the Airways Group module.
4. EMBASE (1980-present). Topic search strategy combined with the Embase randomised controlled trial search filter as outlined in the Airways Group module.
5. CINAHL (R) (1982-present).
6. The list of references in relevant publications.
7. Written communication with the authors of trials was included in the review when necessary.

Data collection and analysis

Retrieval of studies

Two reviewers (KW, AC) independently reviewed the title, abstract and descriptions of studies retrieved in the literature searches to identify potentially relevant trials for full review. Searches of bibliographies and texts were conducted to identify additional studies. The same two reviewers independently selected trials for inclusion from the full text using specific criteria. Agreement was to be measured using Kappa statistics. Disagreement was to be resolved by consensus or third party adjudication (SM).

Assessment of Quality

Studies included in the review were to undergo quality assessment performed independently by all reviewers. Four components of quality would have been assessed:

1. Allocation concealment. Trials will be scored as: Grade A: Adequate concealment, Grade B: Unclear, Grade C: Clearly inadequate concealment (Grade A = high quality).
2. Blinding. Trials will be scored as: Grade A: Participant and care provider and outcome assessor blinded, Grade B: Outcome assessor blinded, Grade C: Unclear, Grade D: No blinding of outcome assessor (Grade A, B = high quality).
3. Reporting of participants by allocation group. Trials will be scored as: Grade A: The progress of all randomised children in each group described, Grade B: Unclear or no mention of withdrawals or dropouts, Grade C: The progress of all randomised children in each group clearly not described (Grade A = high quality).
4. Follow-up. Trials will be scored as: Grade A: Outcomes measured in >90% (where withdrawals due to complications and side-effects are categorised as treatment failures), Grade B: Outcomes measured in 80 to 90%, Grade C: Unclear, Grade D: Outcomes measured in <80% (Grade A = high quality). While only the allocation concealment quality would have been displayed in the meta-analysis figures, all assessments would have

been included in the “Characteristics of included studies” table. Inter-reviewer reliability for the identification of high quality studies for each component were to be measured using the Kappa statistic. Each study would have been assessed using a one to five scale described by Jadad (Jadad 1996) and summarised as follows:

Was the study described as randomised? (1= yes; 0 = no)

Was the study described as double blind? (1= yes; 0 = no)

Was there a description of withdrawals and dropouts? (1= yes; 0 = no)

Was the method of randomisation clearly described and appropriate? (1= yes; 0 = no)

Was the method of double blinding well described and appropriate? (1= yes; 0 = no)

Data Extraction

Trials that satisfied the inclusion criteria were to be reviewed and the following information recorded: study setting, year of study, source of funding, patient recruitment details (including number of eligible children), inclusion and exclusion criteria, randomisation and allocation concealment method, numbers of participants randomised, blinding (masking) of participants, care providers and outcome assessors, intervention (duration and quantification of water restriction), control (types and methods of dietary manipulation), co-morbidities (all medical problems with particular attention to neurological problems and genetic syndromes), existing respiratory problems (asthma, bronchiectasis, cystic fibrosis), co-interventions, numbers of patients not followed up, reasons for withdrawals from study protocol (clinical, side-effects, refusal and other), details on side-effects of therapy, and whether intention-to-treat analyses were possible. Data would have been extracted on the outcomes described previously. Further information was to be requested from the authors where required.

Data Analysis

For the dichotomous outcome variables of each individual study, relative and absolute risk reductions were to be calculated using a modified intention-to-treat analysis. This analysis assumes that children not available for outcome assessment have not improved (and probably represents a conservative estimate of effect). An initial qualitative comparison of all the individually analysed studies was to have examined whether pooling of results (meta-analysis) is reasonable. This takes into account differences in study populations, inclusion/exclusion criteria, interventions, outcome assessment and estimated effect size.

The results from studies that met the inclusion criteria and reported any of the outcomes of interest would have been included in the subsequent meta-analysis. The summary weighted risk ratio and 95% confidence interval (fixed effects model) would have been calculated using the inverse of the variance of each study result for weighting (Cochrane statistical package, RevMan 4.2). Numbers needed to treat (NNT) were to be calculated from the pooled OR and its 95% CI applied to a specified baseline risk using an online calculator (Visual Rx at www.nntonline.net). This calculator converts the risk in the placebo group to the corresponding odds,

applies the OR to estimate the odds in the treated group, and converts that odds to the corresponding risk and calculates the risk difference, the inverse of which is the NNT. The outcome indices would have been assumed to be normally distributed continuous variables so the mean difference in outcomes could have been estimated (weighted mean difference). If studies reported outcomes using different measurement scales, the standardised mean difference would have been estimated. In cross-over trials, if data was combined with parallel studies only data from the first arm would have been used (Elbourne 2002). In addition, for pooled cross-over studies, mean treatment differences would have been calculated from raw data, extracted or imputed and entered as fixed effects generic inverse variance (GIV) outcome to give weighted SD unit difference and 95% confidence intervals (RevMan 4.2). Heterogeneity between the study results would have been tested to see if it reached statistical significance using a chi-squared test. The 95% confidence interval estimated using a random effects model would have been included whenever there were concerns about statistical heterogeneity.

SUBGROUP ANALYSIS:

An a priori subgroup analysis was planned for

1. Age: infants (<12 months) or children (aged 1-14 years)
2. Complete versus partial water restriction
3. Presence of established lung disease (such as cystic fibrosis, bronchiectasis, immunodeficiency, chronic neonatal lung disease, asthma) and gastro-esophageal reflux disease
4. Medical comorbidity (primary neurological problem versus others)
5. Method of primary nutrition intake (oral or non-oral: i.e. nasogastric tube, gastrostomy)

Sensitivity analyses was planned to assess the impact of the potentially important factors on the overall outcomes:

- a) study quality;
- b) study size;
- c) variation in the inclusion criteria;
- d) differences in other medications used in the intervention and comparison groups;
- e) differences in outcome measures;
- f) analysis using random effects model;
- g) analysis by 'treatment received';
- h) analysis by 'intention-to-treat'; and
- i) analysis by study design-parallel and cross over studies.

RESULTS

Description of studies

See: [Characteristics of excluded studies](#).

The original searches in 2005 identified 3 potential studies but none fulfilled the study eligibility criteria. Subsequent searches to

date (January 2011) revealed no relevant studies. The 2011 search identified 182 references. See Appendix 2 for the search history.

Risk of bias in included studies

Not applicable.

Effects of interventions

The initial Airways Group Specialised Register/search identified 1364 potentially relevant titles. After assessing the abstracts, 3 studies were considered for inclusion into review but none fulfilled the study eligibility criteria. Non controlled studies are summarised in the excluded table. A single RCT was identified in an adult population (Garon 1997) who had sustained their first stroke, had good cognitive skills and could follow a rinsing protocol. This study found no difference in the occurrence of pneumonia, dehydration or total fluid intake between a group of adult patients who were allowed unlimited ingestion of oral water and a group on full restriction of thin fluids.

DISCUSSION

No randomised controlled trials on the effects of restriction or allowing orally ingested water in persons with known primary aspiration of fluids in a paediatric population were found. The adult study on stroke patients suggested that free ingestion of water did not increase pneumonia events (Garon 1997). However these results should not be extrapolated to a paediatric population for several reasons. An adult population with stroke is very different from infants and young children who may have either acquired or congenital aetiologies and may have multiple body systems affected. The effects of dysphagia in children are often chronic due to the complexities of developing (maturing) oral-motor competence and feeding milestones using impaired body systems, which may include neurodevelopmental, structural, gastrointestinal and respiratory compromise, in the context of maturing cognition and behaviour in children.

Primary aspiration of food and fluid textures is commonly seen in children with feeding and swallowing difficulties associated with a range of diseases and complex medical conditions. Respiratory sequelae and pneumonia are known to be associated with primary aspiration of ingested material. However causality between primary aspiration of specific food and fluid textures and pulmonary effects in children is yet to be established in controlled trials. Cass and colleagues comment that determination of an intervention for children with suspected primary aspiration of food or fluids requires a three step approach that includes establishing whether aspiration is occurring, quantifying that aspiration and predicting

the long term impact on lung function (Cass 2005). Restriction of oral ingestion of aspirated food and fluid textures and, in the case of fluids, prescribing thickened fluids, are commonly recommended when treating children with feeding and swallowing difficulties (Alper 1996, Logemann 1983). Indeed, current standard practice in most centres for children with MBS documented evidence of fluid aspiration includes the total restriction of all fluids including water. This review has found an absence of evidence for total restriction of water, an intervention that significantly impacts on amount of extra work on carers (thickening all fluids including water) as well as hydration status of the child.

While recurrent primary aspiration of food and fluid textures is commonly believed to lead to “serious and sometimes irreversible pulmonary damage” in infants and young children (Weiss 1988), there is no good data on the direct relationship between severity of aspiration and lung disease. Nevertheless, it is often assumed that a linear relationship exists between the severity of oropharyngeal aspiration and the development respiratory compromise or disease (Cass 2005; Seddon 2003). Taniguchi and Moyer described (using a case control study) that abnormal MBS is a risk factor for pneumonia in children (Taniguchi 1994). However, some children with clinically similar degrees of oropharyngeal aspiration can have quite different pulmonary responses with some children showing no apparent effects while others experience severe acute or chronic complications (Cass 2005). Also, defining pneumonia caused by aspiration is difficult to prove or disprove, especially in the context of a child with chronic CXR changes and the known increased frequency of respiratory infections in children compared to adults (Leder 2003). The increased frequency of respiratory infections is likely related to the relative immaturity of the respiratory and immunological systems of infants and young children. Presence or co-existence of non aspiration related respiratory infections may either mask or alter respiratory responses to primary aspiration of water or other food or fluid substances in this age group. Thus the relative pulmonary morbidity of aspiration of ingested food and fluid materials versus other causes of respiratory disease such as viral and bacterial causes, secondary aspiration of gastrointestinal contents and predisposing lung conditions such as chronic neonatal lung disease in a developing immune system is unclear and needs to be considered in cohort and controlled studies.

AUTHORS' CONCLUSIONS

Implications for practice

Given the lack of evidence, it is not possible to either recommend total restriction or liberalisation of oral water ingestion to 'protect' the pulmonary status of children with thin fluid aspiration demonstrated on a modified barium swallow study. Clinicians should be cognisant that water (with a neutral pH) significantly differs from

other fluids and this review did not examine the effect of non-water fluids.

Implications for research

Randomised controlled trials to determine the effects of restricting or allowing oral intake of water in children with thin fluid aspiration are needed to provide evidence-based guidelines for treating children with oropharyngeal aspiration. The trial(s) should include data on the relative impact of type and severity of oropharyngeal aspiration on the development of aspiration lung disease and respiratory morbidity. Data on likely confounders and other clinically useful outcomes should also be collected. These include mobility, nutritional status, oral hygiene, co-morbidities (e.g. gastroe-

sophageal reflux, neurological impairment and structural anomalies) and exposure to community-based respiratory disease. Such data would provide valuable information on the relative impact of oropharyngeal aspiration in the context of other determinants of respiratory disease in children.

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Weiss 1988

Weiss MH. Dysphagia in infants and children. *Otolaryngologic Clinics of North America* 1988;**21**:727–35.

* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Garon 1997	Randomised controlled trial in an adult stroke population.
Sheikh 2001	No control group. No intervention trial was included.
Taniguchi 1994	A case-control study design. No intervention trial was included

DATA AND ANALYSES

This review has no analyses.

WHAT'S NEW

Last assessed as up-to-date: 27 January 2011.

Date	Event	Description
28 January 2011	New search has been performed	Literature search run. No new included studies identified.

HISTORY

Protocol first published: Issue 2, 2005

Review first published: Issue 4, 2005

Date	Event	Description
9 September 2008	Amended	Converted to new review format.
29 January 2008	New search has been performed	Literature search run; no new studies identified
1 August 2005	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

KW and AC wrote the primary protocol based on previous protocols involving cough as an outcome measure. For the review, KW and AC extracted suitable abstracts on the search conducted by Liz Arnold of the Cochrane Airways Group. Analysis and data extraction was primarily performed by KW with guidance by AC and SM. All authors contributed to writing the review.

DECLARATIONS OF INTEREST

The authors are currently involved in a RCT examining the effect of restricted vs liberalisation of oral water on the pulmonary status of children with dysphagia.

SOURCES OF SUPPORT

Internal sources

- Royal Children's Hospital Foundation, Brisbane, Australia.

External sources

- No sources of support supplied

INDEX TERMS

Medical Subject Headings (MeSH)

*Drinking; Pneumonia, Aspiration [*prevention & control]

MeSH check words

Child; Child, Preschool; Humans; Infant