Standard versus modified postural drainage in infants and young children with cystic fibrosis (Protocol)

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[Intervention Protocol]

Standard versus modified postural drainage in infants and young children with cystic fibrosis

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To compare the effects of standard postural drainage (greater (30° to 45° head down tilt) and lesser (15° to 20° head down tilt)) with modified postural drainage (without head down tilt) with regard to gastroesophageal reflux in infants and young children up to six years old with cystic fibrosis in terms of safety and efficacy.

BACKGROUND

Description of the condition

Cystic fibrosis is a chronic autosomal recessive disease (Robinson 2009). Patients with cystic fibrosis may suffer from: chronic sinusitis; nasal polyps; respiratory infections; infertility (especially in males); and gastrointestinal disorders (such as gastroesophageal reflux, exocrine pancreatic insufficiency, a higher risk of developing diabetes mellitus, poor absorption of nutrients and excessive absorption of fluid) (Ernst 2010). Although cystic fibrosis is a multisystem disorder, pulmonary disease is the most common cause of morbidity and mortality (Flume 2009).

Children with cystic fibrosis are more likely than healthy children to suffer from pathological gastroesophageal reflux (Cucchiara 1991). The mechanism involved in this process is not completely described. However, the high incidence of gastroesophageal reflux in infants and children with cystic fibrosis may be secondary to lung disease (chronic coughing, hyperinflation) as well as being related to delayed gastric emptying and transient lower oesophageal sphincter relaxations which are increased during distension of the gastric fundus, and hyperalimentation of cystic fibrosis infants (Heine 1998; Blondeau 2010).

Conventional chest physiotherapy has been widely used as an adjunctive therapy in the treatment of cystic fibrosis in all populations affected by this disease, contributing to the improved survival of these patients (Button 1997). Conventional chest physiotherapy techniques may include postural drainage, percussion and vibration, huffing and coughing (Main 2005).

Description of the intervention

Postural drainage is especially used in infants from diagnosis up to the moment when they are mature enough to actively participate in other self-administered treatments (Lannefors 2004). The postural drainage technique consists of positioning the patient so that gravity may assist in draining mucus from the lungs (Lannefors 2004). There are 12 postural drainage positions, one for each pulmonary segment. Postural drainage is usually associated with vibration, percussion, inhalation therapy, coughing, and breathing exercises. There are two regimens of postural drainage techniques: standard postural drainage which includes the head-down tilt of 15° to 45°; and modified postural drainage (without the head-down tilt).

How the intervention might work

Chest physiotherapy has been associated with an increase in gastroesophageal reflux episodes in patients with cystic fibrosis. Previous studies have suggested that postural drainage techniques may exacerbate reflux, potentially resulting in aspiration or reflex bronchospasm and further impairment of pulmonary function. Such studies associated the higher incidence of gastroesophageal reflux with the head-down tilt position with different angles in infants with cystic fibrosis (Button 1997; Heine 1998; Button 2004).

Why it is important to do this review

Cystic fibrosis lung disease is characterized by depleted airway surface liquid volume and thickened mucus, which results in impaired mucus clearance (Matsui 1998; Dwyer 2011). Such events promote airway obstruction and colonization with a variety of bacteria, which generates a vicious cycle of infection resulting in airway damage (Robison 2002). Chest physiotherapy is a recommended intervention to promote airway clearance and improve lung ventilation and gas exchange. During physiotherapy sessions, techniques to facilitate airway clearance, such as postural drainage, are used. However, there is a risk of gastroesophageal reflux associated with this technique. Gastroesophageal reflux is increased in cystic fibrosis patients and may contribute to the worsening of pulmonary function among other complications (Mousa 2012). Currently, there is no consensus regarding the type of postural drainage that may avoid gastroesophageal reflux episodes in infants and young children with cystic fibrosis. This review aims to evaluate which postural drainage regimen (standard or modified postural drainage) is the most effective and safe for treating respiratory complications of cystic fibrosis.

OBJECTIVES

To compare the effects of standard postural drainage (greater (30° to 45° head down tilt) and lesser (15° to 20° head down tilt)) with modified postural drainage (without head down tilt) with regard to gastroesophageal reflux in infants and young children up to six years old with cystic fibrosis in terms of safety and efficacy.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials, regardless of year or language of publication.

Types of participants

Children from birth up to and including, six years of age, diagnosed with cystic fibrosis on the basis of clinical criteria and sweat testing or genotype analysis.

Types of interventions

Standard postural drainage (greater (30° to 45° head down tilt) and lesser (15° to 20° head down tilt)) compared with a modified postural drainage (without head down tilt).

Types of outcome measures

Primary outcomes

1. Appearance or exacerbation of gastroesophageal reflux episodes (number and duration of episodes) identified by:
   i) clinical symptoms (e.g. vomiting, regurgitation, rumination)
   ii) clinical tests (e.g. oesophageal pH monitoring, oesophageal impedance-pH monitoring, ultrasonography, oesophagogastric scintigraphy)

Secondary outcomes

1. Airway clearance measured by:
   i) sputum weight
   ii) volume
2. Percentage of peripheral oxygen saturation
3. Number of exacerbations of upper respiratory tract symptoms
4. Number of days on antibiotics (oral, inhaled or intravenous) for acute exacerbations

5. Hospital stays for respiratory problems
    i) number of stays
    ii) duration of stay (days)
6. Chest X-ray scores
7. High-resolution computed tomography (HRCT) scores
8. Pulmonary function tests (immediate and long-term differences)
    i) spirometry
        a) forced vital capacity (FVC)
        b) forced expiratory volume in one second (FEV_1)
        c) forced expiratory flow at 25%-75% (FEF_{25-75})
    ii) lung clearance index (LCI) derived from multiple breath washout (MBW)
    iii) plethysmography
9. Occurrence of adverse events (defined as any undesired outcome due to the intervention)

Search methods for identification of studies

Electronic searches

Relevant studies will be identified from the Cystic Firbosis and Genetic Disorders Group's Cystic Fibrosis Trials Register using the terms: postural drainage and gastroesophageal reflux.

The Cystic Fibrosis Trials Register is compiled from electronic searches of the Cochrane Central Register of Controlled Trials (CENTRAL) (updated each new issue of *The Cochrane Library*), quarterly searches of MEDLINE, a search of EMBASE to 1995 and the prospective handsearching of two journals - *Pediatric Pulmonology* and the *Journal of Cystic Fibrosis*. Unpublished work is identified by searching the abstract books of three major cystic fibrosis conferences: the International Cystic Fibrosis Conference; the European Cystic Fibrosis Conference and the North American Cystic Fibrosis Conference. For full details of all searching activities for the register, please see the relevant sections of the Cystic Fibrosis and Genetic Disorders Group Module.

Trials registers such as ClinicalTrials.gov and the WHO ICTRP will be consulted in order to identify any ongoing trails.

Searching other resources

The reference lists of the relevant articles found by the above methods will be consulted for additional studies.

Data collection and analysis

Selection of studies

Two review authors (KM and DF) will independently read the abstracts identified from the initial search to select studies that meet the inclusion criteria. The full text articles will be retrieved and reviewed to determine eligibility. In cases of disagreement, the two authors will consult a third review author (GF).

Data extraction and management

Two authors (KM and DF) will independently extract data into RevMan 5.1 using a standard data collection form and any disagreements will be resolved by discussion and consensus (RevMan 2011). According to methods described in the *Cochrane Handbook for Systematic Reviews of Interventions*, the authors will collect the following information: participants (total number, age, gender, country); interventions (total number of each groups - standard and modified postural drainage, number of sessions, intervention details which allows its replication); outcomes; and risk of bias (Higgins 2011a).

The authors will analyse studies of up to seven days treatment separately from studies of longer duration. The authors will group outcome data from longer-term studies (more than seven days) into those measured at one, three, six, twelve months, and annually thereafter. If outcome data are recorded at other time periods, then the authors will consider examining these as well.

Assessment of risk of bias in included studies

The authors will assess the risk of bias using the tool developed by the Cochrane Collaboration, which includes the following items: random sequence generation; allocation concealment; blinding of outcome assessors; incomplete outcome data; selective reporting and other sources of bias. The risk of bias will be classified as either high, low or unclear, according to the methods described in chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011b). Authors will resolve any disagreements by discussion and consensus.

Measures of treatment effect

For continuous outcomes, the authors will report the mean difference (MD) with 95% confidence intervals (CI), or the standardised mean difference (SMD) (95% CI) if different units of measurement were used by the studies. For dichotomous outcomes, the authors will report the relative risk (RR) with the corresponding 95% CI.

Unit of analysis issues

In cases of events that can occur several times per person, the authors will calculate the rate ratio (RR), which compares the rate of events in two groups by dividing one by the other (Higgins 2011c).

Cross-over trials

When including both parallel and cross-over studies (with an adequate washout period), the authors plan to use the inverse variance method, as recommended by Elbourne (Elbourne 2002). For the cross-over studies, in this method, the authors will use the results from paired analyses (including an estimate of treatment effect and its standard error).

Cluster-randomised trials

The authors will include data from cluster-randomized trials if the information is available. For cluster-randomized trials, we will adjust results when the unit of analysis in the trial is presented as the total number of individual participants instead of number of clusters. Results will be adjusted using the mean cluster size and intra-cluster correlation co-efficient (ICC) (Higgins 2011c). For meta-analysis, data will be combined from individually randomized trials using the generic inverse-variance method as described in chapter 16.3 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011c).

Dealing with missing data

The authors will contact the trial investigators in cases of incomplete or missing data. If it is not possible to contact the investigators, or if they do not send the requested data, when possible, the authors will include the trial within the review and highlight the missing data or information along with details of when they contacted the investigators. If the review authors cannot adequately assess the eligibility of the trial, they will categorise the trial as a 'study awaiting classification' and will aim to include it in a future update if further information becomes available.

Assessment of heterogeneity

If the authors are able to include a sufficient number of studies, they will assess heterogeneity in the trial results by inspecting the forest plots to detect non-overlapping CIs and by applying the Chi ^{2} test (with a P value of 0.10 indicating statistical significance). In addition to this the authors will use the I^2 statistic with a categorisation of heterogeneity as follows: up to 50% as a moderate level; and above 50% as a substantial level (Higgins 2011c).

Assessment of reporting biases

If the authors are able to include sufficient data (10 studies or more), they will assess reporting bias among the studies using the funnel plot as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011d). If asymmetry is present, the authors will explore possible causes including publication bias, risk of bias, outcome reporting bias and true heterogeneity.

Data synthesis

The authors will use RevMan 5.1 to combine outcomes when it is possible (RevMan 2011). The authors will use a fixed-effect model unless substantial heterogeneity (a value of I^2 over 50%) is observed, in which case they will use a random-effects model.

Subgroup analysis and investigation of heterogeneity

If the authors are able to include sufficient data (10 studies or more) and identify substantial heterogeneity (a value of I^2 over 50%) they plan to conduct the following subgroup analyses:

1. treatment length (studies of up to seven days treatment and studies of longer duration);
2. age (newborn, infants and pre-school children);
3. treatment setting (inpatient and outpatient)
4. angle of the head-down tilt (30° to 45° head down tilt and 15° to 20° head down tilt);
5. association with other chest physiotherapy techniques (vibration, percussion, inhalation therapy, breathing exercises and instrumental techniques).

Sensitivity analysis

If the authors are able to include sufficient data, sensitivity analysis will be performed in order to explore the influence on the results of the following factors:

1. trial quality (RCTs with poor methodology);
2. trial size (stratify by sample size);
3. allocation concealment (high risk of bias versus low risk of bias);
4. assessor blinding (high risk of bias versus low risk of bias).

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* *Indicates the major publication for the study*

CONTRIBUTIONS OF AUTHORS

Diana Freitas: developed and advised on the protocol. Completed the first draft of the protocol. Made an intellectual contribution to the protocol. Approved the final version of the protocol prior to submission.

Fernando Dias: completed the first draft of the protocol. Made an intellectual contribution to the protocol. Approved the final version of the protocol prior to submission.

Gardenia Ferreira: contributed with clinical expertise. Approved the final version of the protocol prior to submission.

Cibele Ribeiro: completed the first draft of the protocol. Made an intellectual contribution to the protocol. Approved the final version of the protocol prior to submission.

Ricardo Guerra: contributed with methodological expertise. Approved the final version of the protocol prior to submission.

Karla Mendonça: developed and co-ordinated the protocol. Completed part of the first draft of the protocol. Made an intellectual contribution to the protocol and approved the final version prior to submission.

DECLARATIONS OF INTEREST

None known.