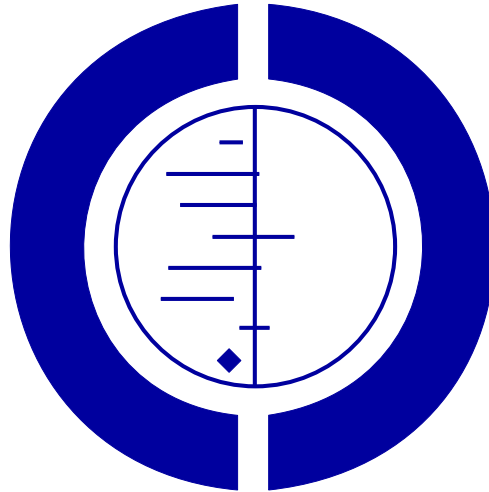


Acid reflux treatment for hoarseness (Protocol)

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TABLE OF CONTENTS

ABSTRACT	1
BACKGROUND	1
OBJECTIVES	3
CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW	3
SEARCH STRATEGY FOR IDENTIFICATION OF STUDIES	4
METHODS OF THE REVIEW	4
ACKNOWLEDGEMENTS	5
POTENTIAL CONFLICT OF INTEREST	5
SOURCES OF SUPPORT	5
REFERENCES	5
COVER SHEET	6

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:
To assess the effectiveness of antireflux therapy for adult patients with hoarseness.

BACKGROUND

Definition

Gastro-oesophageal reflux disease (often abbreviated to GERD or GORD) is defined as the retrograde flow of gastric contents into the oesophagus or above. Gastro-oesophageal reflux disease is characterised by symptoms and/or signs of mucosal injury of the oesophagus or upper aerodigestive tract secondary to this reflux. Laryngopharyngeal reflux (LPR) is gastro-oesophageal reflux disease that affects the pharynx and larynx. Not all episodes of gastro-oesophageal reflux are associated with laryngopharyngeal reflux.

Symptoms, Prevalence and Aetiology

Typical symptoms of gastro-oesophageal reflux disease include heartburn and regurgitation. The reflux episodes often occur at night in the supine (lying face up) position or if the patient bends forward (Marks 1991). In clinical practice heartburn is a daily complaint in up to 7% of the population in the US (Talley 1992). Most patients with symptoms of gastro-oesophageal reflux disease will exhibit little or no objective evidence on examination (Gaynor 1991). The complications of gastro-oesophageal reflux disease include peptic stricture, dysphagia, odynophagia, oesophagitis and Barrett's oesophagus (Johanson 2000). The aetiology of gastro-oesophageal reflux disease is not certain, but there are several factors which may contribute. These factors are delayed gastric emptying, impaired function of the lower oesophageal sphincter (Bain 1983) and incomplete oesophageal clearance (Johanson 2000). Other factors such as infection (e.g. *Helicobacter pylori*), obesity, allergy,

smoking, food intolerance and swallowing dysfunction have also been suggested (Gaynor 1991).

It is estimated that 4% to 10% of patients presenting to otorhinolaryngology clinics have reflux-related disease (Koufman 1991). This may manifest as hoarseness, dysphagia, chronic cough, post nasal drip, throat clearing or globus sensation (Koufman 2000). Signs on laryngological examination include arytenoid erythema (which can be graded), interarytenoid mucosal oedema, contact ulcers and granulomas (Gaynor 1991). Extralaryngeal symptoms include excess salivation, otalgia, hiccups, erosion of dental enamel, asthma, bronchitis and recurrent pneumonia (Gaynor 1991). Amongst these symptoms of gastro-oesophageal reflux disease, hoarseness (dysphonia) is the most common (McNally 1989).

Hoarseness is a common cause of referral to otorhinolaryngology. It is associated with anxiety as to the underlying cause, and can affect quality of life by reducing the ability to verbally communicate effectively. Underlying causes include malignancy, vocal cord palsy, cysts, polyps and nodules of the vocal cords, laryngitis and functional disorders such as muscle tension dysphonia (Carding 1997). Acute laryngitis is usually infective, whereas chronic laryngitis is often attributed to 'vocal abuse'. This encompasses a spectrum of insults including cigarette smoke, dehydration, muscular imbalance and acid reflux.

A recent study of reflux and voice disorders suggests that up to 55% of patients with hoarseness have laryngopharyngeal reflux (Koufman 2000). Patients with laryngopharyngeal reflux often differ from patients with classical gastro-oesophageal reflux disease in that heartburn and dyspepsia are absent in more than 50% (Koufman 1996; Ulualp 1999). Patients with laryngopharyngeal

reflux are more likely to experience reflux episodes in the daytime in an upright position than those with gastro-oesophageal reflux disease (Koufman 1991). Mucosal injury is thought to occur by direct contact of the laryngeal mucosa with acid, pepsin and bile. Minute amounts of acid applied experimentally in animal models causes dramatic laryngeal injury (Ludemann 1998). Direct evidence for laryngopharyngeal reflux in vivo comes from dual chamber acid monitoring, demonstrating reflux into the hypopharynx in patients with hoarseness (Katz 1990). The association between laryngopharyngeal reflux and gastro-oesophageal reflux has not been firmly established. Laryngopharyngeal reflux has been found in healthy individuals, albeit less frequently than in patients with chronic laryngitis (Shaker 1995). Not all patients with gastro-oesophageal reflux disease will develop laryngeal symptoms, although a subset is thought to have significantly greater proximal acid exposure (Jacob 1991). It has been found that 23% of patients with confirmed laryngopharyngeal reflux on pH monitoring have normal levels of acid exposure in the distal oesophagus (Ormseth 1999). Hoarseness is present in 92% of patients with reflux laryngitis (Toohill 1997).

Diagnosis

The diagnostic tests used for gastro-oesophageal reflux disease are divided into following subgroups:

- 1) Evaluation of the presence of gastro-oesophageal reflux disease:
 - a) Ambulatory 24-hour dual probe pH-metry measures of acidic reflux. Pathological reflux is defined as pH < 4 5cm or more above the lower oesophageal sphincter for > 4% of the 24-hour time period, during which the patients keep a diary of the activities during the day, e.g. eating, exercise, sleeping etc.
 - b) Oesophageal manometry measurements of the lower oesophageal sphincter (LOS) pressure, both when the oesophagus is relaxed and when it contracts, i.e. during swallowing
 - c) Oesophageal impedance measurements are useful in evaluating the volume and height of the refluxate. An advantage is that this measures non-acidic as well as acidic reflux.
 - d) Spectrophotometric measurement of bile reflux.
 - e) Barium swallow study gives a static image of the oesophageal function, while video fluoroscopy provides dynamic images of reflux.

2) Evaluation of the mucosal injury:

- a) Flexible fibre-optic oesophagoscopy to grade the oesophagitis if present. Different grading systems are available and quantify features including the circumferential extent of oesophagitis and the presence of exudate (Lundell 1999). There is inconsistency between the different classifications.
- b) Mucosal biopsy is relevant if Barrett's oesophagus (metaplasia of the epithelium) or malignancy is suspected.

The diagnostic tests used for laryngopharyngeal reflux are divided into the following subgroups:

- 1) Evaluation of the presence of laryngopharyngeal reflux:

- a) Ambulatory 24-hour dual or triple probe pH-metry. Probes are positioned at the level of the lower oesophageal sphincter and above or below the upper oesophageal sphincter. The results of this measurement are not easy to interpret because there is no consensus about pathological reflux at the level of the laryngopharynx (Nostrant 2000). The level of acidity considered to be abnormal should be less than at the lower oesophageal sphincter (i.e. pH > 4) as there may be neutralisation of acidity by saliva (Nostrant 2000), and there is a lesser ability to clear acid from the laryngopharynx compared with the lower oesophagus. In addition, there is speculation that the presence of a pharyngeal probe may precipitate reflux secondary to irritation (Mittal 1992), and loss of contact between the probe and mucosa may result in false-positive results.
- b) Barium swallow study. This study gives an image of oesophageal function at a single point in time. Since a reflux episode might occur before or after the image the method is not reliable.

2) Evaluation of the mucosal injury:

- a) Laryngoscopy (i.e. flexible, rigid or mirror, with or without stroboscopy) to demonstrate the presence of erythema, oedema, granuloma or ulcer on the vocal folds. There is confusion in the definitions used for benign laryngeal lesions, leading to considerable inter-observer variability describing laryngoscopy findings (Chau 2004). The severity of mucosal injury may be graded according to the reflux finding score (Belafsky 2001). The reflux finding score (RFS) is an 8-item clinical severity scale based on findings during fibre-optic laryngoscopy. The items included in the scale include subglottic oedema (pseudosulcus vocalis), ventricular obliteration, erythema/hyperemia, vocal fold oedema, diffuse laryngeal oedema, posterior commissure hypertrophy, granuloma/granulation tissue, and excessive endolaryngeal mucus (Lundell 1999). The reflux finding score has been shown to have high intra-observer variability. However, the clinical appearances described above are not specific for reflux laryngitis, but may also be demonstrated in patients with typical symptoms of gastro-oesophageal reflux disease and in asymptomatic, healthy volunteers (Powitzky 2003). Furthermore, there is considerable confusion in the definitions.

- 3) Objective evaluation of voice disability (including acoustic measurements of fundamental frequency, jitter, intensity with shimmer, signal to noise ratio and spectral analysis).

Management Options

The options for management of gastro-oesophageal reflux disease are non-surgical and surgical interventions.

Pharmacological treatment is the first choice. The drugs most commonly used are proton pump inhibitors (PPIs) (omeprazole, esomeprazole, lansoprazole, pantoprazole, rabeprazole). Other drugs used are H₂-receptor antagonists (cimetidine, ranitidine, nizatidine, famotidine), which inhibit gastric acid secretion. Prokinetic agents (cisapride, metoclopramide), which accelerate oesophageal clearance and increase the lower oesophageal sphincter

pressure, are rarely used due to potential side-effects, e.g. diarrhoea and ventricular arrhythmias. Antacids (including aluminium- and magnesium-containing antacids, and sodium bicarbonate) can often relieve symptoms related to gastro-oesophageal reflux disease in the lower oesophagus but may not prevent mucosal injury in the larynx. Erythromycin, a macrolide antibiotic, effective in the emptying of the stomach, is only used as an alternative when other drugs are ineffective. The medical treatment is often combined with lifestyle modification and patient education, e.g. elevation of bed head, individual-based dietary modifications, changing smoking habits and avoiding potentially harmful medications (Katz 2000).

If non-surgical treatments do not improve the patient's quality of life then surgery is considered; this group primarily consists of patients in whom the volume of liquid that refluxes is high. Surgical treatment includes both fundoplication (where the stomach is wrapped around the distal oesophagus) and non-fundoplication procedures (where other surgical techniques are employed). Fundoplication is the most commonly used surgical procedure. It may be complete (Nissen and Rossetti) or partial (Toupet, i.e. oesophagus behind the stomach, and Bore, i.e. oesophagus in front of the stomach). The surgical procedures are preferentially performed laparoscopically. Open surgery is usually undertaken only in cases where complications occur during laparoscopic procedures, or where laparoscopic surgery is contraindicated.

Pilot studies have indicated that management of reflux results in resolution of hoarseness, but the effectiveness of such treatments is not firmly established. The aim of this systematic review is to evaluate the literature with regards to this problem.

OBJECTIVES

To assess the effectiveness of antireflux therapy for adult patients with hoarseness.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

All randomised and quasi-randomised, controlled, double-blinded trials. Controlled clinical trials (trials using a control group but no adequate randomisation procedure) and quasi-randomised trials will also be identified.

Types of participants

All adult (aged 18 or over) patients with hoarseness (dysphonia). The participants should have had the symptom for at least six weeks. The participants will be included whether or not there is a definitive diagnosis of gastro-oesophageal reflux disease. All patients should have undergone laryngoscopy to exclude other

identifiable causes of hoarseness including malignancy, vocal cord paralysis and vocal cord nodules.

Types of intervention

The interventions will be divided into non-surgical and surgical.

Non-surgical treatments include:

- 1) Pharmacological treatment
 - Proton pump inhibitors (PPIs)
 - Antacids
 - H₂-receptor antagonists
 - Prokinetic agents
 - Erythromycin
- 2) Lifestyle modification and patient education

Surgical treatments include:

- 1) Fundoplication repair
 - Nissen fundoplication
 - Rossetti fundoplication
 - Toupet fundoplication (partial fundoplication)
 - Bore fundoplication (partial fundoplication)
 - Collis gastroplasty followed by fundoplication
- 2) Non-fundoplication repairs
 - Hill repair (gastropexy)
 - Belsey MK-4

The antireflux therapy will be compared with placebo or no medication where possible since the spontaneous improvement without any medication and the placebo effects have been reported as being substantial.

Types of outcome measures

The following outcomes will be assessed:

1. Primary measures

The primary reason for treating dysphonia is to improve the patient's voice quality and, in turn, their quality of life. It is therefore essential to include quality of life measures in primary outcome assessment. These are specifically designed and validated tools which measure global and disease-specific quality of life. Such outcome measurement usually involves a measurement of health-related quality of life, disease status, and disease-related functional status. For example, a patient's ability to perform normal daily activities may be reduced by their dysphonia. Questionnaires, known as instruments, are used to measure these domains. There are now many such questionnaires available that may measure general health and well being, such as the Medical Outcome Study Short Form 36 (SF 36), or measure disease-specific quality of life (VHI, VRQL).

a) Hoarseness. The proportion of patients with complete and partial resolution of symptoms will be assessed

b) Quality of Life measures (QOL)

i) Global instruments, e.g. SF-36

ii) Disease-specific instruments, e.g. Voice handicap index (VHI) (Rosen 2000), Voice related quality of life (VRQL) (Hogikyan 1999). These instruments have been validated and shown to be responsive to change following treatment for dysphonia. They measure the patient's perception of the impact of their dysphonia on quality of life, separated into emotional, physical and functional domains. However, there appears to be poor correlation between such subjective measures and voice laboratory measurements in dysphonia (Hsuing 2002).

2. Secondary measures

Our secondary measures include 'objective' findings such as laryngeal appearances and acoustic measurements due to the controversy surrounding their validity in diagnosis of symptoms.

a) Laryngeal measures

i) Visual appearance of the laryngeal mucosa, including the vocal folds

ii) Number of reflux episodes measured by pharyngeal pH-metry

b) Voice-related measures

i) Acoustic measures of continuous speech or sustained vowels

ii) Fundamental frequency with jitter

iii) Intensity with shimmer

iv) Aerodynamic measures, e.g. mean flow rate and peak flow

v) Signal to noise ratio

vi) Signal to harmonics ratio

vii) Spectral analysis (fast Fourier transform (FFT), spectrography, long-term average spectrum (LTAS), power spectrum)

Desirable time points of outcome assessment are:

short-term: 1 month; medium-term: 6 months; long-term: 1 to 5 years.

SEARCH STRATEGY FOR IDENTIFICATION OF STUDIES

See: Ear, Nose and Throat Disorders Group search strategy

An initial search will be made using the Cochrane Central Register of Controlled Trials (CENTRAL). Additional studies will be searched for using MEDLINE (1966 onwards) and EMBASE (1974 onwards), Biological Abstracts and review articles. The following search terms will be used:

1) gastro-oesophageal reflux OR gastroesophageal reflux OR gastro-oesophageal reflux OR reflux OR GORD OR GERD OR GOR OR GER OR laryngeal reflux OR pharyngeal reflux OR laryngopharyngeal reflux OR laryngo-pharyngeal reflux OR LPR

2) AND hoarseness OR dysphonia OR impaired voice function OR impaired vocal function OR posterior laryngitis OR chronic laryngitis OR reflux laryngitis

3) AND anti-reflux treatment OR anti-reflux therapy OR anti-reflux medication

For identification of randomised controlled trials (RCTs) on MEDLINE and EMBASE, including congress reports and review articles, these terms will be combined with the highly sensitive search strategy developed by the Cochrane Collaboration for identification of controlled clinical trials (CCTs).

The search will be carried out by the reviewers independently. Reference lists of identified publications will be scanned for additional trials and authors contacted if necessary. In addition, the reference lists of any previous reviews of the subject and the reviewer's own files will be scanned for relevant studies. No language restrictions will be applied. The full text articles of the retrieved trials will then be reviewed by two reviewers and the inclusion criteria applied independently. Any differences in opinion about which studies to include in the review will be resolved by discussion between the reviewers. Possible additional search terms will be discussed at two conferences where the subject will be presented.

METHODS OF THE REVIEW

Data Extraction

Data from the studies will be independently extracted by the reviewers using standardised data forms. Data will be extracted so as to allow an intention to treat (ITT) analysis. After all the data forms are filled in, all first authors of the trials to be included and possibly included will receive a copy for comments. Where data are missing, the reviewers will write to the authors of the study requesting the missing data.

The protocol will be presented at two conferences for further elucidation and discussion.

Quality Assessment

The quality of all trials will be assessed by the reviewers. Differences in opinion will be resolved by discussion. The selected studies will be assessed for the following characteristics:

- 1) The adequacy of the randomisation process and of allocation, i.e. A: adequate, B: uncertain, C: not adequate.
- 2) The potential selection bias after allocation to study group, i.e. losses to follow-up and whether analysis was by intention to treat.
- 3) Whether there was blinding of outcome assessors to the participants' study group.
- 4) Quality of outcome assessment, i.e. A: adequate.

Data Analysis

Data will be analysed by intention to treat (ITT). If data are of sufficient quality, i.e. categories A and B, they will be combined to give a summary of effect, otherwise data will not be combined. Study quality will be used in a sensitivity analysis. If the data permit, analysis will be carried out separately for different types of treatment, as well as considering non-surgical versus surgical treatment as a whole. Study outcomes are likely to be measured in a variety of ways using several categorical variables. Data may be stratified if appropriate, including whether a definitive diagnosis of reflux has been obtained or not. Statistical advice will be sought to determine the best way of presenting and summarising the data.

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POTENTIAL CONFLICT OF INTEREST

None known.

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* Indicates the major publication for the study

COVER SHEET

Title	Acid reflux treatment for hoarseness
Authors	Hopkins C, Yousaf U, Pedersen M
Contribution of author(s)	CH developed the basis of the protocol, performed a background literature search, drafted the protocol and made editorial amendments. UY performed a background literature search and helped draft the protocol. MP made editorial suggestions about the protocol, and advised in clinical aspects of the protocol.
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