Authors' objectives
To compare the effectiveness of medical and surgical treatment of chronic gastro-oesophageal reflux (GORD).

Searching
MEDLINE was searched from 1966 to 1999 using the Cochrane Collaboration strategy for maximising the sensitivity of the search for clinical trials. The following MeSH terms and keywords were used, using both British and American spellings: 'gastro-oesophageal reflux', 'oesophagitis', 'heartburn', 'antacids', 'histamine antagonists', 'proton pump inhibitors' and 'fundoplication'. Studies published in any language were considered. The search was adapted for searching EMBASE from 1981 to 1999.

The following journals were handsearched: Gut; Gastroenterology; Scandinavian Journal of Gastroenterology; British Journal of Surgery; European Journal of Surgery; Surgery; Endoscopy; and Surgical Laparoscopy and Endoscopy. The search was supplemented by examining the references of relevant studies, tracking citations through the Science Citation Index, and by corresponding with authors and experts.

Study selection
Study designs of evaluations included in the review
Controlled trials were eligible for inclusion in the review.

Specific interventions included in the review
Comparisons of surgical and medical treatment were eligible. The medical treatments included: omeprazole or unspecified proton-pump inhibitors; symptomatic or continuous antacids, with and without ranitidine; cimetidine or unspecified histamine H2-antagonists; combinations of omeprazole and histamine H2-antagonists; and antacids or alginates, with and without histamine H2-antagonists. The surgical treatments included anti-reflux surgery, posterior gastropexy, Belsey-Mark V repair, and fundoplication. The types of fundoplication were: laparoscopic; open Nissen; Collins-Nissen; anterior fundoplication plus posterior gastropexy; Nissen-Rosetti; and Toupet. One study also included a placebo control and another a 'normal' control.

Participants included in the review
Patients with objectively GORD were eligible regardless of their age or gender. The participants included in the review were described as follows: adults with chronic GORD; adults aged less than 70 years with severe GORD for at least 6 months; adults with complicated and uncomplicated GORD; adults with GORD and non-allergic asthma; and adults with Barrett's oesophagus.

Outcomes assessed in the review
The inclusion criteria were not defined in terms of the outcomes. Both objective and subjective efficacy outcomes, and side-effects, were assessed.

The objective outcomes included: time to treatment failure; gastric glandular atrophy; lower oesophageal pressure; mean DeMeester acid reflux score; grade of endoscopic oesophagitis, including histological grading; percentage of time at a pH less than 4; lower oesophageal sphincter pressure; pulmonary medication; pulmonary function tests; stenosis cured; decrease in length of Barrett's oesophagus; absence of reflux; and reflux time (acid perfusion test).

The subjective outcomes were: symptoms including heartburn, regurgitation and wheezing; freedom from respiratory symptoms; patients' satisfaction; quality of life scores; and level of disease activity.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the reviewers performed the selection.

Assessment of study quality
Validity was assessed on the basis of the following criteria: randomisation of treatment allocation; whether the treatment groups were comparable at baseline; completeness of follow-up; analysis by intention to treat; the blinding of outcome assessors; equal treatment of each study arm, apart from the intervention; and adjustment for bias in observational studies. The two authors evaluated the studies independently, and any disagreements were resolved by consensus.

Data extraction
The authors do not state how the data were extracted for the review, or how many of the reviewers performed the data extraction.

The following information were tabulated: author and country of study; sample details; interventions; age (median, mean or range); duration of follow-up; and the number of patients followed-up. The odds ratios (ORs) and 95% confidence intervals (CIs) were calculated for each outcome measure in each study, using the number of patients showing improvement. Where possible, the numbers-needed-to-treat were estimated, along with the 95% CI.

Methods of synthesis
How were the studies combined?
A narrative synthesis was undertaken.

How were differences between studies investigated?
Sensitivity analyses were conducted on the basis of alternative assumptions about the outcomes in patients lost to follow-up. The ORs were calculated: first, assuming all patients lost to follow-up still had symptoms, and then, by assuming no patients lost to follow-up still had symptoms. The quality of the included studies was discussed in the review.

Results of the review
Six randomised controlled trials (RCTs; 864 patients) and three cohort studies (534 patients) were included.

Two RCTs were reported only in abstract form and limited information was available. The studies differed considerably in their inclusion criteria, interventions, outcome measures and duration of follow-up. It was only possible to undertake a sensitivity analysis on 2 studies.

Objective outcomes (6 RCTs and 3 cohort studies).
All the studies found improved objective outcomes to be more likely after surgery. Five of the 6 RCTs reported at least one objective measure to be significantly more common in the surgical arm.

Subjective outcomes (6 RCTs and 2 cohort studies).
All but one of the studies reported better subjective outcomes after surgery than medication. The sensitivity analysis showed that patients lost to follow-up (1 RCT and 1 cohort) did not influence the conclusions that symptom relief was significantly better after surgery, compared with medical treatment.

Side-effects.
No study reported a significant difference in dysphagia between the treatment groups, but most studies lacked the statistical power to compare side-effects.
Authors' conclusions
Surgery was more consistently more effective than medical treatment in relieving symptoms and objective oesophagitis, although omeprazole can give symptom relief with adjustment of the dose.

CRD commentary
The very broad nature of the question, encompassing a wide range of medical and surgical procedures, was not really appropriate for a systematic review. The aims were stated, and the inclusion criteria were defined in terms of the participants, interventions and study design. The eligible interventions and study designs were broadly defined. The search was adequate as several relevant sources were searched and no language restrictions were applied. Details of the search strategy were given, but no details were given of the methods used to select the studies.

The validity of the included studies was assessed using defined criteria, but the utility of the two validity assessments was severely limited by the enormous clinical diversity of the studies included. In addition, the validity of the numerous measures used to assess the outcomes was not discussed. Given the small number of identified studies and their clinical diversity, a narrative synthesis was appropriate.

The grouping of the medical treatments and their comparison with all surgical procedures appeared to be of limited utility. In reporting the results, no account was taken of the effect of multiple outcomes on the level of statistical significance. The results were not discussed in relation to the quality of evidence offered.

The conclusions should be interpreted with caution due to the limitations of this review.

Implications of the review for practice and research
Practice: The authors state that with adjustment of the dose, omeprazole can be just as effective as surgery, but that surgery is superior to histamine H2-antagonists. These statements are not supported by the review's findings.

Research: The authors state that further RCTs, which compare surgery and proton-pump inhibitors with varying inclusion and exclusion criteria and different surgeons, are a priority for assessing the generalisability of these findings.

Bibliographic details

PubMedID
11034468

DOI
10.1080/110241500750008475

Indexing Status
Subject indexing assigned by NLM

MeSH
Adult; Antacids /therapeutic use; Cohort Studies; Controlled Clinical Trials as Topic; Esophagitis, Peptic /therapy; Fundoplication; Gastroesophageal Reflux /surgery /therapy; Histamine Antagonists /therapeutic use; Humans; Proton Pump Inhibitors; Randomized Controlled Trials as Topic; Treatment Outcome

AccessionNumber
12000001865

Date bibliographic record published
30/06/2002
Date abstract record published
30/06/2002

Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.