Systematic review: endoluminal therapy for gastro-oesophageal reflux disease: evidence from clinical trials
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CRD summary
The review assessed evidence on the effect of endoscopic therapies for gastro-oesophageal reflux disease and concluded that there were not enough scientific and clinical data on safety, efficacy and durability to support use of the therapies in routine clinical practice. Methodological flaws in the review meant the authors' cautious conclusions may not be reliable.

Authors' objectives
To review the evidence on the effect of endoscopic therapies for gastro-oesophageal reflux disease (GORD).

Searching
MEDLINE (from 1966 to May 2007) and The Cochrane Library were searched for articles published in English; search terms were reported. Identified articles, abstracts, congress books, personal archives and pharmaceutical industry and FDA web pages were searched for further studies.

Study selection
Retrospective and prospective studies of endoscopic therapies in patients with gastro-oesophageal reflux disease were eligible for inclusion. Case series of fewer than 10 patients, studies of children and studies with a follow-up of less than three months were excluded. Interventions used in included studies were bulking methods or injection of synthetic substances, suturing and plication procedures, and high-frequency thermal coagulation procedures through the delivery of radiofrequency energy. The primary endpoint in most studies was the reduction of the use of proton pump inhibitors by more than 50%.

The authors stated neither how studies were selected for the review nor how many reviewers performed the selection.

Assessment of study quality
The authors did not state that they assessed validity.

Data extraction
Two reviewers independently extracted data.

Methods of synthesis
A narrative synthesis was undertaken, with studies grouped by type of intervention.

Results of the review
The authors reported that 43 studies were included in the review, although 46 studies were presented in the results section.

Radiofrequency energy: Fifteen trials, 14 were non-randomised, open-label, pre-post studies and one was blinded and sham-controlled. Sample sizes ranged from 18 to 118 participants. Follow-up periods ranged from three to 48 months. Significant improvement in the median heartburn score, GORD score, satisfaction, mental SF-36 and physical SF-36 were found in most studies. The most common side effects were fever, odynophagia, mucosal injury and gastroparesis. Proton pump inhibitor use was the primary endpoint in half the studies and 43% to 87% of patients discontinued usage.

Implant methods: Eight trials, one sham-controlled and the rest pre-post studies. Sample sizes ranged from 15 to 144 participants. Follow-up periods ranged from six to 24 months. The proportion of patients off proton pump inhibitors at the end of follow-up ranged from 53% to 80%. Significant improvements in symptoms, quality of life and heartburn scores were found. The most common side effects were chest pain, dysphagia, fever and pneumonitis.
Suturing and plication devices: There appeared to be 23 trials, all single-group except for one randomised and sham-controlled and two open-label and non-randomised. Where stated, sample sizes ranged from 15 to 85 participants and follow up periods ranged from three to 24 months. Symptomatic improvement was found in most studies, but median oesophageal acid exposure did not always show a significant difference. Studies with follow-ups of up to 24 months showed the efficacy of suturing devices decreased over time. The most common side effects were fever, abdominal pain, pharyngitis and sore throat.

All three types of treatment could lead to mild and severe complications (such as perforation and abscess), some of which resulted in death.

Authors' conclusions
Subgroups of patients experienced improvement or resolution of typical gastro-oesophageal reflux disease symptoms, decreased proton pump inhibitor use and improvement of quality of life. These optimistic results were not sustained over the longer follow-up periods.

CRD commentary
The review addressed a clear question and was supported by appropriate inclusion criteria. Only two databases were searched for articles published in English; some relevant studies may have been missed, although searches for unpublished studies were made. Two reviewers independently extracted data, but no details were provided on methods used for selecting studies, so the possibility of reviewer error and bias could not be ruled out. The authors did not conduct a quality assessment of the studies (although most trials had no comparator group), so it was difficult to assess the reliability of the evidence. Study details were not always tabulated, which resulted in little information being provided (in the text only) for several studies of suturing devices. It was difficult to ascertain how many studies met the inclusion criteria. The authors' cautious conclusions appeared to reflect the limited evidence presented, but the presence of flaws in review methodology and reporting mean the conclusions may not be reliable.

Implications of the review for practice and research
Practice: The authors stated that there were not enough scientific and clinical data on safety, efficacy and durability to support use of endoluminal therapies for gastro-oesophageal reflux disease in routine clinical practice.

Research: The authors stated that it should be feasible to perform large multi-centre sham-controlled studies that should follow consensus guidelines after standardising the inclusion and exclusion criteria. An adequate number of patients should be enrolled and a standard approach used to locate the gastro-oesophageal junction. Validate reflux questionnaires should be used, rather than visual analogue scales.

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