Expandable metal stents for inoperable oesophageal cancer

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Authors' objectives
To assess the effectiveness and cost-effectiveness of self-expanding metal stents (SEMs) compared with semi-rigid plastic tubes in patients with inoperable oesophageal cancer.

Searching
MEDLINE, EMBASE Cancerlit, the Cochrane Controlled Trials Register and the National Research Register were searched from 1980, or inception, to 2002; the search terms were given and no language restrictions were employed. In addition, conference abstracts were searched, experts were contacted and citations were checked.

Study selection

Study designs of evaluations included in the review
Randomised controlled trials and pseudo-randomised trials were eligible for inclusion in the review.

Specific interventions included in the review
SEMs compared with plastic tubes were eligible for inclusion. The included studies used five different types of SEMs and four different comparators.

Participants included in the review
Patients with inoperable oesophageal cancer were eligible for inclusion. Two studies in the review included a few patients with mediastinal malignancies producing external compression of the oesophagus, while three included patients with cardial cancers.

Outcomes assessed in the review
All outcomes were eligible for inclusion. The outcomes included in the review were: technical success, relief of dysphagia, dysphagia recurrence, device migration, food impaction, procedural complications (including life-threatening ones), procedure-related mortality, duration of hospital stay, quality of life and survival.

How were decisions on the relevance of primary studies made?
Two independent reviewers made decisions on the relevance of primary studies.

Assessment of study quality
Validity was assessed using a checklist based on the Jadad scale which assessed the following: randomisation, allocation concealment, blinding of the patients and outcome assessors, comparability of follow-up, reporting of loss to follow-up, use of an intention-to-treat analysis, reporting of the results, and type of outcome assessors. Two independent reviewers made judgements of validity.

Data extraction
Two independent reviewers extracted the data. The relative risks (RRs) were calculated for binary outcomes.

Methods of synthesis

How were the studies combined?
The studies were combined in meta-analyses for several outcomes, with a narrative synthesis undertaken where meta-analysis was not possible.

How were differences between studies investigated?
Differences between the studies in patient population, SEM and comparator employed, and study quality were discussed in a narrative synthesis. Where a meta-analysis was used to combine the studies, a chi-squared test for statistical heterogeneity was employed.

**Results of the review**

Six studies with a total of 277 patients were included in the review.

Technical success: 5 studies were pooled in a meta-analysis. There was no significant difference between SEMs and plastic tubes (RR 1.03, 95% confidence interval, CI: 0.98, 1.07; result in favour of SEMs).

Relief of dysphagia: one study showed significantly greater improvement in dysphagia with SEMs at 1 week (P=0.04), but not at 6 weeks.

Dysphagia recurrence: 6 studies were pooled in a meta-analysis. There was no significant difference between SEMs and plastic tubes (RR 0.91, 95% CI: 0.67, 1.22; result in favour of SEMs).

Device migration: 4 studies were pooled in a meta-analysis. There was no significant difference between SEMs and plastic tubes (RR 0.48, 95% CI: 0.22, 1.05; result in favour of SEMs).

Food impaction: 6 studies were pooled in a meta-analysis. There was no significant difference between SEMs and plastic tubes (RR 0.64, 95% CI: 0.30, 1.35; result in favour of SEMs).

Life-threatening procedural complications: 6 studies were pooled in a meta-analysis. There was a significantly lower risk of perforation or haemorrhage among patients randomised to SEMs than to plastic tubes (RR 0.40, 95% CI: 0.19, 0.81).

Procedure-related mortality: 4 studies were pooled in a meta-analysis. There was a significantly lower risk of death among patients randomised to SEMs than to plastic tubes (RR 0.22, 95% CI: 0.07, 0.75).

Duration of hospital stay: 4 studies reported the duration of hospital stay, which was shorter for patients in the SEMs group in all studies; this difference was significant in 2 studies.

Quality of life: 3 studies reported quality of life or general health status outcomes. There was no significant difference between the groups in any study.

Survival: 5 studies were pooled in a meta-analysis. There was no significant difference in 30-day mortality between patients randomised to SEMs and plastic tubes (RR 0.72, 95% CI: 0.45, 1.16; result in favour of SEMs).

**Cost information**

Yes. Inserting covered SEMs cost £2,220 and uncovered SEMs £1,970, compared with £1,610 for plastic tubes. Compared with plastic tubes, the mean cost per life-year saved was £7,630 for covered SEMs and £7,920 for uncovered SEMs, and the costs per 1-point improvement in dysphagia score were £880 and £1,430, respectively.

**Authors’ conclusions**

There was fair evidence that SEMs are superior to plastic stents.

**CRD commentary**

The review question and the inclusion criteria were clear and the search was extensive. The lack of language restrictions and the attempts to locate unpublished studies mean that bias is unlikely to have been introduced into the review, although publication bias was not assessed. The authors used appropriate methods to minimise bias and error in the study selection, validity assessment and data extraction processes, and the use of meta-analyses was appropriate. The authors’ conclusions are likely to be reliable.
Implications of the review for practice and research

Practice: The authors stated that it is possible that substantially improved outcomes could result if less oesophageal dilation was employed during the insertion of plastic tubes. They also stated that the ease of insertion of SEMs could result in greater clinical and economic benefits in everyday practice than was observed in clinical trials.

Research: The authors did not state any implications for future research.

Funding

The review was conducted by people funded by the NHS.

Bibliographic details


Original Paper URL


Indexing Status

Subject indexing assigned by CRD

MeSH

Esophageal Neoplasms /therapy; Stents

AccessionNumber

12004008032

Date bibliographic record published

28/02/2006

Date abstract record published

28/02/2006

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.