



Title	A Pragmatic Randomized Controlled Trial of the Cost Effectiveness of Palliative Therapies for Patients with Inoperable Esophageal Cancer
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Aim

To compare whether treatment with self-expanding metal stents (SEMS) is more cost effective than treatment with conventional modalities (non-SEMS) in patients with inoperable esophageal cancer.

Conclusions and results

This study demonstrated no overall differences in effectiveness or cost effectiveness between SEMS and non-SEMS therapies. Insertion of an 18 mm diameter SEMS led to equal effectiveness as with insertion of a 24 mm diameter SEMS. Rigid stents were associated with a significantly worse quality of swallowing following treatment and higher late morbidity than other therapies. BICAP and Ethanol Tumor Necrosis treatments were associated with poor outcomes for primary palliation. A survival advantage was demonstrated in patients receiving non-stent therapies, but these treatments were associated with significant treatment delays. No cost differences were found between therapies, with the highest contributor to cost of palliation being the length of inpatient stay. Patients demonstrated distinct but individual treatment preferences.

Recommendations

Despite underpowering, this study suggested that rigid stents and 24 mm diameter SEMS offer no advantages to either non-stent therapies or an 18 mm diameter SEMS; they should no longer be recommended for primary palliation. Subgroup analysis suggested that BICAP and Ethanol Tumor Necrosis treatments were unsuitable for primary palliation.

Methods

A multicenter, pragmatic, randomized controlled trial with health economic analysis. All patients with esophageal cancer who were deemed unsuitable for surgery in any 1 of 7 NHS hospitals were assessed for inclusion. The centers were chosen to represent a cross-section of UK hospitals in terms of facilities and staffing. Eligible patients were randomized to 1 of 4 treatment groups

within 2 study arms. Research nurses assessed patients on enrollment, 1 week following treatment, and thereafter at 6 weekly intervals until death. Structured interviews to elicit patient preferences to health states and treatments were performed in a substudy to the main trial, using 1 of 2 randomly assigned techniques.

Further research/reviews required

- 1) A randomized controlled clinical trial of an 18 mm SEMS versus non-stent therapies with survival and quality of life endpoints.
- 2) An audit of palliative patient admissions to hospital to determine the reasons and need for inpatient care, with a view to implementation of cycle-associated change to reduce inpatient stay and thereby costs.
- 3) Audit of delays from diagnosis to palliative radiotherapy treatment with a view to implementation of cycle-associated change to reduce these delays.