

# A pragmatic randomised controlled trial of the cost-effectiveness of palliative therapies for patients with inoperable oesophageal cancer

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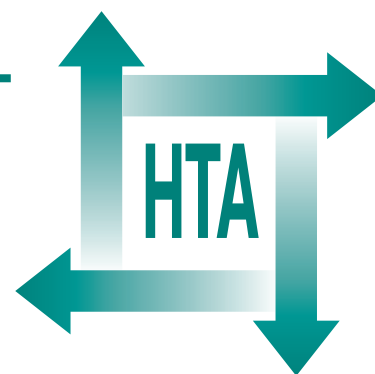
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## Executive summary

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## Executive summary

### Background

Inoperable oesophageal cancer is a devastating diagnosis. Without treatment, swallowing deteriorates with dramatic effects on quality of life. There is no evidence for using one dysphagia-relieving palliative treatment over another. Self-expanding metal stents (SEMS) may be most effective, but are expensive and the NHS burden of palliation is escalating. A prospective, randomised controlled trial (RCT) is essential for informed, cost-effective treatment choice.

### Objectives

The primary objective of this study was to compare whether treatment with SEMS is more cost-effective than treatment with conventional modalities in patients with inoperable oesophageal cancer.

The secondary objectives were also included as part of the study. The first was to determine whether metal stents provide a better quality of swallowing, require fewer follow-up interventions and provide a greater number of quality-adjusted life-years. The second was to determine quality of life effects associated with all treatment and health outcomes.

### Methods

#### Design

A multicentre pragmatic RCT with health economic analysis.

#### Setting

Seven NHS hospitals were selected to represent a cross-section of UK hospitals in terms of facilities and staffing.

#### Subjects

All patients attending the centres with oesophageal cancer deemed unsuitable for surgery were assessed for inclusion in the main trial; 217 patients were randomised. A health state utilities substudy was also performed in 71 patients who had previously received curative surgery for oesophageal cancer.

### Interventions

Eligible patients were randomised to one of four treatment groups within two study arms. Assessments were performed by research nurses at enrolment, 1 week following treatment and thereafter at 6-weekly intervals until death, with prospective data collection on complications and survival. Structured interviews to elicit patient preferences to health states and treatments were performed in a substudy, using one of two randomly assigned techniques.

### Main outcome measures

The main outcome measures were: dysphagia grade at 6 weeks; quality of life at 6 weeks; survival; resources consumed from randomisation to death; and quality-adjusted life-years.

### Results

It was found that there was no difference in cost or effectiveness between SEMS and non-SEMS therapies. It was also found that the 18-mm SEMS had equal effectiveness to, but less associated pain than, 24-mm SEMS. Rigid intubation was associated with a worse quality of swallowing and increased late morbidity. Bipolar electrocoagulation and ethanol-induced tumour necrosis were found to be poor in primary palliation. A survival advantage for non-stent therapies was evident, but with a significant delay to treatment. The length of hospital stay accounts for the majority of the cost to the NHS. Patients were found also to have distinct individual treatment preferences.

### Conclusions

It was concluded that rigid tubes and 24-mm SEMS should no longer be recommended. Similarly, bipolar electrocoagulation and ethanol-induced tumour necrosis should not be used for primary palliation.

### Implications for healthcare

It is suggested that the choice in palliation should be between non-stent and 18-mm SEMS treatments, and that non-stent therapies should be made more

available and accessible to reduce delay. A multidisciplinary team approach to palliation may be appropriate, with consideration also being given to length of stay in order to reduce the NHS burden of palliation, with due regard to quality of life and costs.

### **Recommendations for further research**

A randomised controlled clinical trial of 18-mm SEMS versus non-stent therapies considering survival and quality of life end-points would be valuable. An audit of palliative patient admissions is also suggested in order to determine the reasons and need for inpatient

hospital care, with a view to implementing cycle-associated change to reduce inpatient stay. Delay in palliative radiotherapy treatment should also be studied, with a view to implementing cycle-associated change to reduce waiting time.

### **Publication**

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