Tratamiento paliativo del cáncer avanzado de esofago. Estudio comparativo: protesis metalica autoexpansible y tubo gastrico isoperistaltico [Palliative treatment of advanced esophageal cancer. Comparative study: auto-expandable metal stent and isoperistaltic esophagogastric bypass]  
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Record Status  
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology  
Two palliative treatments for patients with advanced oesophageal cancer were compared. The treatments were auto-expandable metal stent and isoperistaltic oesophagogastric bypass.

Type of intervention  
Palliative care.

Economic study type  
Cost-effectiveness analysis.

Study population  
The study population comprised patients with advanced oesophageal cancer, in particular TNM stage III or IV SCCE. Patients were excluded if they had neurologic difficulty in swallowing, broncho-oesophageal or tracheo-oesophageal fistula, prior radiotherapy or brachytherapy, or there was a lack of clinical conditions for surgery.

Setting  
The setting was a hospital. The centres in which the study was carried out were not reported, but the economic study was conducted in Brazil.

Dates to which data relate  
The effectiveness evidence and resource use data were gathered during 1996 to 1999. No price year was reported.

Source of effectiveness data  
The effectiveness data were derived from a single study.

Link between effectiveness and cost data  
The costing was performed prospectively on the same patient sample as that used in the effectiveness analysis.

Study sample  
An overall sample of 40 patients with advanced oesophageal cancer participated in the analysis. There were 20 patients in the surgical group and 20 patients in the endoscopic group. The mean age was 55 (+/- 9) years (range: 36 - 69) in the surgical group and 61 (+/- 11) years (range: 39 - 79) in the endoscopic group. The method used to select the sample was not reported. Power calculations to determine the sample size were not performed. No patient was excluded from the...
initial sample.

**Study design**
This was a randomised controlled trial. The method of randomisation, and the number of sites in which it was carried out, were not reported. The patients were followed up by monthly assessments until death or June 2000. No loss to follow-up was reported.

**Analysis of effectiveness**
The basis for the clinical analysis appears to have been intention to treat. The primary health outcomes were:

the length of hospitalisation;

dysphagia, measured on a scale of 0 (absent) to 4 (total aphagia);

quality of life, measured through the Karnofsky index,

survival, assessed using the Kaplan-Meier method; and

the frequency of complications.

The study groups were comparable at baseline in terms of their demographics, clinical characteristics and lifestyle, such as smoker status.

**Effectiveness results**
The mean length of hospitalisation was 18 (+/- 9) days (median: 15.5; range: 9 - 40) in the surgical group and 5 (+/- 6) days (median: 3; range: 1 - 25) in the endoscopic group, (p<0.001).

Before treatment, the dysphagia scores were 2.5 (+/- 1.2) (median: 3) in the surgical group and 3.3 (+/- 0.9) (median: 4) in the endoscopic group.

At 30 days postoperatively, the dysphagia scores were 1.4 (+/- 1) (median: 2) in the surgical group and 1.2 (+/- 0.8) (median: 1) in the endoscopic group.

At 120 days postoperatively, the dysphagia scores were 1.1 (+/- 0.9) (median: 1) in the surgical group and 1.7 (+/- 0.5) (median: 2) in the endoscopic group.

Within each group, but not between the groups, the improvement was statistically significant.

The Karnofsky index was statistically different across the study groups before the intervention, but the difference disappeared in the postoperative period.

The mean survival was 253.5 (+/- 36.5) days in the surgical group and 225.3 (+/- 49.9) days in the endoscopic group. This difference was not statistically significant.

The frequency of complications was high in both groups and was not statistically different.

**Clinical conclusions**
The effectiveness analysis showed that the two interventions were generally similar in terms of quality of life, survival and improvements in dysphagia. However, the surgical treatment resulted in a significantly longer hospitalisation than the endoscopic procedure.
Measure of benefits used in the economic analysis
The health outcomes were left disaggregated. A cost-consequences analysis was therefore carried out.

Direct costs
The economic analysis included two categories of costs, those related to hospitalisation and those of the procedure itself. The unit costs were not reported. The cost/resource boundary adopted in the analysis appears to have been that of the hospital. The source of the cost data was not stated. The resources were estimated using actual data derived from the trial and measured from 1996 to 1999. Discounting was irrelevant since the costs for each patient were incurred over less than one year, due to the short patient survival. No price year was reported.

Statistical analysis of costs
Statistical analyses of the total costs were performed to test for statistical significance of the results. Standard tests were used.

Indirect Costs
The indirect costs were not included.

Currency
Brazilian reais (R$).

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The mean procedural costs were R$ 3,652.86 (+/- 61.28) (median: 3,626.11) in the surgical group and R$ 3,954.36 (+/- 840.69) (median: 3,762.71) in the endoscopic group, (p<0.001).

The mean hospitalisation costs were R$ 5,477.68 (+/- 2,485.23) (median: 4,280.90) in the surgical group and R$ 663.89 (+/- 1,281.34) (median: 292.25) in the endoscopic group, (p<0.001).

The overall treatment costs were R$ 9,380.91 (+/- 2,720.56) (median: 8,069.77; range: 6,030.57 - 15,360.30) in the surgical group and R$ 5,236.48 (+/- 1,889.97) (median: 4,269.55; range: 3,928.96 - 9,470.82) in the endoscopic group, (p<0.001).

Synthesis of costs and benefits
Irrelevant as a cost-consequences analysis was performed.

Authors' conclusions
Both of the interventions were effective in terms of quality of life, reduction of dysphagia, frequency of complications and survival. However, shorter length of hospitalisation and fewer costs were observed with auto-expandable metal stent than with isoperistaltic oesophagogastroduodenal bypass.
CRD COMMENTARY - Selection of comparators
The authors justified their choice of the comparators. Both represented widely used palliative procedures for the treatment of patients with advanced SCCE. You should decide whether they are currently implemented in your own setting.

Validity of estimate of measure of effectiveness
The internal validity of the analysis was ensured by the design of the study, which used a randomised controlled trial and was appropriate for the study question. However, the method of randomisation was not reported. The study sample appears to have been representative of the study population. The authors stated that the study groups were comparable at baseline, but statistically significant differences were reported in the scores of the quality of life index in the preoperative period. The main threat to the internal validity of the analysis was the lack of power calculations and the small sample size.

Validity of estimate of measure of benefit
The health outcomes were left disaggregated and no summary benefit measure was considered. Thus, a cost-consequences analysis was performed. However, as survival and quality of life were assessed, the use of a summary benefit measure such as quality-adjusted life-years would have been useful.

Validity of estimate of costs
The economic evaluation included the costs of the procedure and hospitalisation. This appears to have been relevant from the perspective of the hospital, and was presumably adopted in the analysis. The unit costs and the source of the cost data were not reported. Statistical analyses were carried out to assess the statistical significance of the estimated costs. However, no price year was given, thus making reflation exercise to other settings difficult.

Other issues
The authors compared their findings with those from other studies. The generalisability of the study results to other settings and contexts is low, as sensitivity analyses were not performed and the unit costs were not reported. The study enrolled a sample of patients with advanced SCCE, and this was reflected in the conclusions of the analysis.

Implications of the study
The authors note that the choice of the most convenient procedure for patients with SCCE may be crucial in developing counties, due to the scarcity of resources and the fact that patients are hospitalised when the stage of the disease is already advanced. Thus, the endoscopic procedure based on auto-expandable metal stent should be the treatment of choice for this patient population.

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