Randomized clinical trial comparing self-expanding metallic stents with plastic endoprostheses in the palliation of oesophageal cancer

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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
The use of self-expanding metallic stents and plastic endoprostheses for the palliation of oesophageal cancer.

Type of intervention
Palliative care.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients aged over 35 years who were suffering from dysphagia, due to a malignant tumour arising from the oesophagus (including the gastro-oesophageal junction), that was either inoperable or the patient was unsuitable for surgical resection because of poor general health or advanced age. Patients without histological evidence of a tumour, a tracheo-oesophageal fistula, or a tumour within 3 cm of the upper oesophageal sphincter, were excluded.

Setting
The setting was a hospital. The economic study was conducted in two acute hospitals in Glasgow, UK.

Dates to which data relate
The dates during which the data were collected were not reported. No price year was indicated.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

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

Study sample
Power calculations were not performed because there was a lack of appropriate clinical data. The study was designed to provide information for future studies. A research nurse assessed the eligibility of patients at the two study hospitals. From an initial sample of 76 patients, 50 patients were included in the study, 25 in each group. The mean age of the patients in the plastic prosthesis group was 72.3 (+/- 13) years and the duration of symptoms was 4.1 (+/- 2.9) months. In the metallic stent group, the mean age was 72.9 (+/- 10) years and the duration of the symptoms was 5.7 (+/- 3.7) months.
Study design
This was a randomised controlled trial, which was conducted in two acute hospitals in Glasgow, UK. Randomisation was performed using a computer-generated number sequence in sealed envelopes. An assessor who was not involved in any step of the study oversaw the list generation. After one month, all the patients underwent plain radiography, as carried out by two independent radiologists. Any discrepancies were resolved by one of the authors. The patients were followed before treatment and then monthly at home until death. No loss to follow-up was reported.

Analysis of effectiveness
The clinical study was analysed on an intention to treat basis. The primary health outcomes were dysphagia, complications, re-interventions, procedural and 30-day mortality, survival and quality of life. Dysphagia was measured on a 5-point scale, ranging from 0 (able to eat a normal diet) to 4 (complete dysphagia). Survival was assessed using the Kaplan-Meier approach. Quality of life was estimated before the intervention and afterwards at monthly intervals, using the European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30 questionnaire plus an oesophageal cancer-specific module. Two main dimensions were estimated in the quality of life assessment, a functional status (high score corresponding to favourable conditions) and a symptom scale (low scores corresponding to good symptoms). When patients had died prior to the monthly assessment, the mean score was calculated by assigning the lowest possible functional score (0) and the highest symptom score (100). The study groups were shown to be comparable at baseline, but more patients in the metallic treatment group had metastatic spread than those in the plastic treatment group.

Effectiveness results
Two patients in the plastic treatment group died before placement, while another was switched to the metallic stent treatment because the plastic prosthesis failed.

All the metallic stents were placed successfully.

In terms of complications, pain was observed in 14 patients in the plastic prosthesis group and in 11 patients in the metallic stent group. Aspiration/reflux was observed in 3 patients in the plastic treatment group and 4 patients in the metallic stent group.

One patient in the metallic stent group suffered from stent migration, haemorrhage and perforation.

No procedure-related mortality was reported.

Five patients in the plastic prosthesis group and 6 in the metallic stent group died within 30 days.

Dysphagia improved in all patients after the intervention, with the improvements continuing at the one-month assessment (13 patients in the plastic prosthesis group and 14 patients in the metallic stent group showed improvements). After 2 months, 5 patients in the plastic prosthesis group and 14 patients in the metallic stent group showed improvements in comparison with baseline estimations. No statistically significant difference was found between the two groups, although there was a trend towards metallic stents being more effective than plastic prostheses.

Eight patients (26 episodes) in the plastic prosthesis group and 10 patients (23 episodes) in the metallic stent group required further interventions.

Median survival was 62 days (range: 0 - 431) in the plastic prosthesis group and 107 days (range: 4 - 462) in the metallic stent group.

The estimated relative hazard ratio was 0.66 (95% confidence interval, CI: 0.37 - 1.16).

The quality of life scores were not statistically different between the study groups. However, there was a trend in favour of metallic stents for specific dimensions such as emotional function, insomnia and symptom of dry mouth.
Clinical conclusions
The effectiveness analysis showed that both treatments were effective in terms of primary clinical outcomes and quality of life issues.

Measure of benefits used in the economic analysis
The number of days survived was used as the benefit measure in the economic analysis. This was estimated in the effectiveness study.

Direct costs
Discounting was irrelevant due to the short time horizon of the study. The unit costs were not reported separately from the quantities of resources. The health service costs included in the economic evaluation were for prostheses or metallic stents, other equipment, drugs, staff, time in endoscopy, radiology or theatre, and screening. The costs of hospital stays unrelated to prosthesis placement were not included in the analysis. The cost/resource boundary adopted was that of the health service. The quantities of resources were estimated using data derived from the effectiveness study. The unit costs were derived from distinct sources. For example, the manufacturer’s list price was used for disposable equipment and drug prices, while local prices were used for staff, operating theatre and overhead costs. Routine data were used for the remaining services. The costs were estimated by attaching the unit costs at 1997 to 1999 prices. An explicit price year was not reported.

Statistical analysis of costs
Standard statistical analyses of the costs were conducted.

Indirect Costs
The indirect costs were not included in the analysis.

Currency
UK pounds sterling (€).

Sensitivity analysis
A sensitivity analysis was conducted to assess the impact of variation in the costs on the estimated results of the analysis. The average national costs were used in place of the costs used in the base-case.

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

Cost results
The mean per patient costs of the initial intervention were 295.74 (+/- 41.53) in the plastic prosthesis group and 982.96 (+/- 7.04) in the metallic stent group. The difference was 687.20 (95% CI: 600.51 - 773.90).

The cumulative mean costs were higher in the metallic stent group than in the plastic prosthesis group. However, the difference was only statistically significant for the initial weeks following placement. The cost differences were not statistically significant after 4 weeks.

Synthesis of costs and benefits
An average cost-effectiveness ratio was calculated to combine the costs and benefits of the interventions.
The crude mean cost per day survived was 60.40 (+/- 16.32) in the plastic stent group and 85.58 (+/- 22.83) in the metallic stent group. The cost difference, 25.18 (95% CI: -31.25 - 81.60) did not reach statistical significance.

The inclusion of hospital stay costs increased the costs in both groups, but the cost differences continued to be insignificant.

The use of average national costs in the analysis did not have a strong impact on the estimated costs.

**Authors' conclusions**
The clinical outcomes were similar between the patients treated with metallic stents and plastic prostheses. The initial costs were higher in the metallic stent group, but this difference was not statistically significant after the fourth week of treatment. However, the authors noted that there was a trend towards better quality of life and survival among patients treated with metallic stents.

**CRD COMMENTARY - Selection of comparators**
The authors stated that the plastic prosthesis represented a standard approach for palliative treatment of dysphagia derived from oesophageal cancer, while self-expanding metallic stents were a more recent procedure. You should decide whether both treatments are widely used interventions in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis of the effectiveness used a randomised controlled trial, which was appropriate for the study question. The methods of randomisation and sample selection were reported. The study sample appears to have been representative of the study population. The study groups were comparable at baseline. The basis of the effectiveness analysis was intention to treat, and the length of follow-up was clearly reported. However, the authors acknowledged that the sample size was somewhat small, and no power calculations were performed because of a lack of published data on the most appropriate sample size.

**Validity of estimate of measure of benefit**
Survival was used as the benefit measure in the economic analysis. It appears to be a common measure in the case of patients suffering from cancer. However, as quality of life was estimated, the use of quality-adjusted life-years would have been interesting.

**Validity of estimate of costs**
The analysis of costs was conducted from the perspective of the health system. It appears that all the relevant categories of costs related to the two interventions have been included in the study. Statistical analyses of the costs were conducted and the use of different cost estimates was tested in the sensitivity analysis. However, the unit costs were not reported separately from the quantities of resources and no price year was explicitly reported. These factors limit the external validity of the cost analysis.

**Other issues**
The authors compared their findings with those from other studies. They stated that their study represented the second largest randomised clinical trial published in the literature. However, the issue of the generalisability of the study results to other settings was not addressed.

**Implications of the study**
Both metallic stents and plastic prostheses were effective in improving survival and quality of life, at similar costs, although metallic stents were initially more expensive. The authors suggested that a multi-centre randomised trial, involving at least 300 patients, should be carried out to assess the costs and clinical outcomes of metallic stents in
comparison with plastic prostheses.

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