A randomized trial of thermal ablative therapy versus expandable metal stents in the palliative treatment of patients with esophageal carcinoma

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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
Expandable metal stent insertion was compared with thermal tumour ablation (TTA) in the palliation of dysphagia in advanced oesophageal cancer. The stents used were Ultraflex, Streker, a 12-mm diameter balloon Bluemax (Meditech/Boston Scientific), or a covered stent (Wallstent). TTA was applied with an Nd:YAG (Fibrelase) or argon diode (Diomed) laser, or occasionally by argon plasma coagulation (APC 300 ERBE).

Type of intervention
Palliative care.

Economic study type
Cost-effectiveness analysis; cost-utility analysis.

Study population
The study population comprised patients referred for palliative treatment of dysphagia caused by inoperable oesophageal or gastroesophageal cancer. Patients were excluded from the study if their predicted life expectancy was very short, if they were unsuitable for stenting because of the proximity of the pharynx, or if they were confused or unable to cooperate with completing the quality of life questionnaires.

Setting
The setting was tertiary care. The location of the economic study was not stated.

Dates to which data relate
The years during which the effectiveness data, resource use and prices were collected were not reported.

Source of effectiveness data
The evidence for the final outcomes was derived from a single study.

Link between effectiveness and cost data
The link between the effectiveness and cost data was not stated. The costs were obtained from the Western General Hospitals Trust, Scotland. It is likely that the effectiveness data were gathered from the same location. The costings were based on charges made by the Trust to fund holding general practitioners.

Study sample
A power calculation established that, to show a 1-point improvement in dysphagia score, a minimum of 28 patients would be needed in each group. This would give 80% power at a p-value of less than 0.05. Patients who were eligible
and consented to enter the study were randomly assigned to one of the two groups. Sixty-five patients were recruited, of which 31 were assigned to the stent arm and 34 to the TTA arm. Nine patients (14% of the total sample) who were still alive at one month failed to complete the health-related quality of life (HRQoL) questionnaires. Four of these patients received TTA therapy and five were treated with a stent. Thus, the losses to follow-up were 12% (TTA group) and 16% (stent group), respectively. In addition, 3 patients (10%) in the stent group did not complete dysphagia scores at one month.

**Study design**
The study was a randomised controlled trial. The number of centres participating in the study was not stated. The participants were randomised in blocks of 6. There was no indication of blinding. All of the patients were followed until death, although 3 TTA patients and 1 stent patient were still alive when the analysis was performed.

**Analysis of effectiveness**
The basis of the analysis was intention to treat. The primary health outcomes were survival, relief of dysphagia and quality of life. At the start of the trial, the groups were shown to be comparable in terms of median age, gender, median dysphagia score and tumour characteristics.

**Effectiveness results**
Survival in the TTA group was 125 days (range: 17 - 546). This was significantly greater than the 68 days (range: 8 - 602) in the stent group, (p<0.05). The mortality rate after TTA was lower than that after stent insertion, with an odds ratio of 0.6.

The median change in dysphagia score after one month was zero for both groups. A comparison of paired data at baseline and 1 month, and again at 2 and 3 months, was not significant for either group.

The HRQoL scores were analysed at one month and only for patients alive at this time.

The Hospital Anxiety and Depression questionnaire showed an increase in rates of depression for both groups. However, the rate of anxiety increased in the stent group and decreased in the TTA group.

The Short Form 36 showed that both groups experienced the same impaired (compared with the general public) quality of life at baseline. One month later, the TTA group results remained stable whereas the stent group experienced significantly poorer physical and emotional functioning, (p<0.05).

The EORTC-QLQ-C30 results also showed that the groups were similar at baseline and that the TTA group maintained their scores one month later. However, the stent group reported poorer emotional functioning.

One month later, there was no significant difference for either group in the dysphagia, deglutition or eating scores.

**Clinical conclusions**
Patients in the TTA group lived longer and maintained their HRQoL. As well as living for a shorter time, patients in the stent group experienced deterioration in their HRQoL. Functional palliation of dysphagia was not achieved in either group.

**Measure of benefits used in the economic analysis**
The authors did not derive a summary measure of benefit. In effect, a cost-consequences analysis was performed.

**Direct costs**
Only the direct costs of the hospital were included in the analysis. The costs reported were for hospital stay, therapy and the total cost. It was unclear whether the resource use data were captured alongside the trial or obtained from...
medical records. The hospital stay costs were obtained from a Hospital Trust and were based on charges made to fund holding general practitioners. For stent treatment, the cost comprised a basic cost of a radiograph session plus the cost of the stent. For TTA therapy, the estimated cost included the basic cost of an upper endoscopy plus the cost of the wave guides. The resource quantities and the costs were not reported separately. The study reported the median resource use for each patient group and the mean costs. The price year was not reported. Discounting was not relevant since the longest survival time at analysis was 602 days.

Statistical analysis of costs
The cost data were deterministic. No statistical analysis of the costs was reported.

Indirect Costs
The indirect costs were not included.

Currency
UK pounds sterling ( ).

Sensitivity analysis
No sensitivity analysis was undertaken.

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

Cost results
For the stent group, the total mean cost was 3,378 (standard deviation, SD=8.7). Of this, 2,278 (SD=10.6) was for hospital stay and 1,100 (SD=5.7) was for therapy.

For the TTA group, the total mean cost was 6,235 (SD=13.4). Of this, 4,202 (SD=23.3) was for hospital stay and 2,031 (SD=3.3) was for therapy.

Twenty-five adverse events were observed. It would appear that the only cost ramification of these that was included was the impact on length of hospital stay and the need to administer a further procedure.

Synthesis of costs and benefits
Not applicable.

Authors' conclusions
Neither therapy provided satisfactory palliation of dysphagia. However, patients who underwent thermal tumour ablation (TTA) had a longer average survival and maintained their health-related quality of life (HRQoL) scores. In comparison, the stent group showed a deterioration in their HRQoL scores. The cost of TTA was nearly double that of stent therapy, owing to the need for repeated overnight hospitalisation of patients receiving ablative therapy.

CRD COMMENTARY - Selection of comparators
Although no explicit justification was given for the choice of the two technologies used, it would appear to represent current practice in the authors' setting. You should decide if the technologies represent current practice in your own setting.
Validity of estimate of measure of effectiveness
The analysis was based on a randomised controlled study, which was appropriate for the study question. The method of sample selection ensured that the study sample was representative of the study population. The patient groups were shown to be comparable at baseline. Appropriate statistical analyses were undertaken to take potential biases and confounding factors into consideration.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The analysis was, in effect, as a cost-consequences study.

Validity of estimate of costs
The authors did not state the perspective from which the costs were estimated. Only ‘top down’ hospital costs were used, rather than costs derived from the patients’ actual resource use. This obscured costing information, for example, when adverse effects of treatment necessitated specialist (and considerably more expensive) care such as that found in an intensive care unit. Consequently, the precision of the cost results was unclear. The unit costs and the resource quantities were not reported separately, thus limiting the generalisability of the findings.

No statistical analyses of the quantities or prices were performed. In addition, there was no exploration of the effect of variation and uncertainty in pricing in the analysis. Charges were used to proxy prices. The price year was not reported, which will make future comparisons with other studies difficult.

Other issues
The authors made appropriate comparisons of their findings with those from other studies. However, the issue of the generalisability to other settings was not addressed. The authors do not appear to have presented their results selectively. The study considered a number of elderly and frail patients with advanced disease, and this was reflected in the authors’ conclusions.

The authors noted that the difference in survival time between the two groups could be due to the treatment, or may have occurred by chance due to the small sample size. The authors suggested the need to confirm the finding in a larger study. The cost of TTA was inflated because of the need to stay in hospital overnight for non-medical reasons. Performing ablation on an outpatient basis could reduce the cost. Finally, the difficulty in collecting complete and accurate HRQoL data in an ill and elderly sample, owing to overburdening, was noted.

Implications of the study
This study highlighted the difficulties of palliation in advanced oesophageal cancer. The authors noted the need to have the capability to administer both stent and TTA technologies, as each is indicated in different clinical conditions. They also noted the need to include quality of life, as well as dysphagia assessment, in future studies since the relationship between the two is unclear.

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