Natural course of inoperable esophageal cancer treated with metallic expandable stents:
quality of life and cost-effectiveness analysis

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
Stent placement was compared with laser therapy in the palliative treatment of inoperable oesophageal cancers. The metallic stents were inserted endoscopically and were highly flexible, knitted and self-expanding (Ultraflex Esophageal Prostheses; Microvasive, Natick). Endoscopic laser therapy was administered with Nd-Yag or Diomed laser with a light energy per session between 1,200 and 17,000 Joules (mean 4,500).

Type of intervention
Palliative care.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised adults suffering from inoperable primary oesophageal carcinoma. Patients with either squamous cell carcinomas or adenocarcinoma were enrolled in the study. Patients were included if the site of obstruction was in the upper, middle or lower oesophagus, or involved the gastroesophageal junction. Patients with broncho-oesophageal fistulas were also eligible. The patients were aged from 53 to 102 years.

Setting
The setting was tertiary care. Although not directly stated, the economic study appears to have been carried out at Saint Savvas' Cancer Hospital in Athens and the University Hospital, Heraklion, Crete, Greece.

Dates to which data relate
The effectiveness and resource use data were collected from May 1997 to December 2002 for patients undergoing stent placement, and from September 1996 to March 1999 for patients who received laser therapy. With the exception of equipment costs, which used 2000 prices, the price year was not reported. The paper was accepted for publication in 2004.

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 unclear. The costing was based on prices established from a database of health care costs in Greece.
Study sample
No power calculation was reported. The unselected sample was formed from consecutive patients who met the inclusion criteria during the study period. The authors did not justify the choice of the patient sample. Seventy-eight patients who underwent stent placement were included in the intervention group. For the comparative study, 27 patients who received laser therapy were included.

Study design
The authors described the design as a “retrospective analysis”. More precisely, it was a comparative study with an historical control. For the study to be retrospective, it would have been necessary to collect the quality of life data for before and after the intervention at a later date and it was unclear whether this was the case.

The number of study centres was unspecified. From the author list, it is possible that two centres were involved. The authors reported that patient follow-up continued until death. In the stent group, 8 patients (10%) were lost to follow-up at 1 month due to death or critical illness. None of the patients in the laser therapy group were lost to follow-up at 1 month. The authors did not report if the psychiatrist who performed the quality of life assessments was blinded to which treatment the patient had received.

Analysis of effectiveness
The analysis of effectiveness was based only on those patients for whom complete data were available.

For the comparative study, the primary health outcomes were survival time and quality of life. Length of hospital stay and complications of treatment were also reported. Quality of life was assessed on the basis of the QLQ-C30 questionnaire proposed by the European organisation for research and treatment of cancer (see Other Publications of Related Interest).

Other outcomes reported in the evaluation of the efficacy and safety of the metallic stent were dysphagia before and after stenting, side effects of the procedure, the ability to tolerate a solid or semisolid diet, and changes in body weight. Dysphagia was assessed using a modified version of the scoring system described in Mellow et al. 1985 (see ‘Other Publications of Related Interest’ below for bibliographic details).

The demographic and diagnostic features of the two groups were described. Although they appear to have been similar, they were not analysed for comparability.

Effectiveness results
The median overall survival time for the stent group was 18 weeks (95% confidence interval, CI: 16 - 20). The mean survival time for the laser therapy group was 17 weeks (95% CI: 15 - 19). A comparison of baseline quality of life scores with those at 1 and 2 months showed improvement in 96% and 75% of stent patients versus 71% and 54% of laser therapy patients.

The mean length of hospital stay was 3.2 (+/- 1) day for the stent group and, 13.4 (+/- 1) day for the laser therapy group. No complications of treatment were observed in the stent group, but two complications (including one fatality) were observed in the laser therapy group.

Other effectiveness results were reported for the stent group only.

There was a significant improvement in the mean dysphagia score, (p=0.04), from 2.91 (+/- 0.36) before stenting to 1.17 after stenting.

Further dysphagia due to impaction was successfully treated endoscopically, while tumour overgrowth was treated with a second stent.

Broncho-oesophageal fistulas were effectively sealed in all instances.
One patient experienced side effects of chest pain, fever, and leukocytosis after the procedure, but responded to antibiotics, and one case of stent migration was observed.

All of the patients were able to tolerate a solid or semi-solid diet 48 hours after stent insertion. With the exception of 8 patients with advanced malignant disease, all patients gained weight.

**Clinical conclusions**
The authors concluded that stenting is a safe and effective palliative treatment for dysphagia in inoperable oesophageal cancer. It results in a greater improvement in patient quality of life than other palliative therapies. However, this improvement only lasts for a few weeks.

**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**
Resource use was not reported separately and it was unclear how much detail was incorporated in the costing. Only the direct costs to the hospital were included in the analysis. Four cost categories were reported. The staff costs included the time of the physician, technician, nurse and, assistant personnel. The cost of the materials included stents, drugs, contrast liquids, films and, liquids for film processing. The equipment cost was calculated on an hourly basis for endoscopic equipment, lasers, Savary dilators and radiological equipment. The housing and overhead costs were based on floor area, and incorporated the services of overhead departments and length of hospital stay. The costs were developed from a database of health care costs in Greece and the current price of Ultraflex oesophageal stents. Discounting was relevant, as the cost data were collected over a 5- to 6-year period, but was not conducted. The average costs were reported. The price year was not reported, except for equipment costs which used 2000 prices.

**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**
Euros (Euro).

**Sensitivity analysis**
No sensitivity analysis of the costs was undertaken.

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

**Cost results**
For the stent group, the overall cost per patient was Euro 3,103. This comprised Euro 37 for salaries, Euro 452 for hospitalisation, Euro 2,504 for consumables, and Euro 110 for housing, overheads and equipment.

For the laser therapy group, the overall cost per patient was Euro 2,947. This comprised Euro 99 for salaries, Euro 1,893 for hospitalisation, Euro 482 for consumables, and Euro 473 for housing, overheads and equipment.
The cost of palliative treatment was estimated to be Euro156 less per patient receiving laser therapy.

The cost of adverse effects was not addressed in the study.

### Synthesis of costs and benefits
Not applicable.

### Authors’ conclusions
The cost per patient was similar for both procedures.

### CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used. Laser therapy and stenting are the most commonly used palliative therapies for managing obstruction or stenosis in inoperable oesophageal cancer. You should decide if laser therapy represents a widely used palliative therapy for these patients in your own setting.

### Validity of estimate of measure of effectiveness
The analysis was based on a comparative study with an historical control, which was associated with some limitations given the study question. In particular, collecting data for the two therapies in two different time periods introduces the risk of confounding due to, for example, changes in the patient population, or advances in diagnostic or treatment methods. The study referred to patients with inoperable oesophageal cancer, but the authors did not discuss whether their sample was representative of patients with this disease. In addition, the two patient groups were not shown to be comparable at analysis. However, the sample did include patients with different tumour aetiologies and locations, and patients with fistulas. The authors reported that follow-up was until patient death, in which case it would have been useful to have presented the survival range in addition to the confidence intervals. No power calculation was reported, so it is not possible to ascertain whether the results obtained were due to the intervention or to chance.

### Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. In effect, a cost-consequences analysis was performed.

### Validity of estimate of costs
The authors did not state the study perspective, but the cost analysis appears to have been performed from the perspective of a hospital. The costs and the quantities were not reported separately, which will limit the reproducibility of the study in other settings. It was unclear how much detail of resource use was incorporated in the costing. No statistical analysis of the quantities was performed. Kaplan-Meier techniques were used to estimate survival for stent patients for the 18 months following treatment. Since the authors reported that patients were followed up until patient death, it was unclear why this was necessary. The authors did not report either any measures of variance or the results of any statistical analysis of the costs. Although the costs were incurred over a 5- to 6-year period, discounting was not conducted. With the exception of one category, the price year was not reported.

### Other issues
The authors made appropriate comparisons of their findings with those from other studies. They did not directly address the issue of the generalisability of the results to other settings. The authors do not appear to have presented their results selectively, although they did not always report the results from the statistical tests performed. The study enrolled patients with a range of tumour aetiologies and locations and this was reflected in the authors’ conclusions. The authors did not report any limitations to their study.
Implications of the study
The results of this study suggested that palliation of symptoms is improved by stent placement, but that survival rates are no different than when laser therapy is administered. The authors recommended that further research be undertaken to establish whether the use of stents improves survival in this patient group.

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None stated.

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Other publications of related interest


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