Clinical outcome of the use of enteral stents for palliation of patients with malignant upper GI obstruction

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 health intervention studied was endoscopic deployment of enteral stents for patients with malignant gastrointestinal (GI) obstruction who were not fit for surgery.

Type of intervention
Palliative care.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients undergoing palliative enteral stent placement. Patients with oesophageal malignancy were excluded.

Setting
The setting was hospital. The economic study was carried out at the Endoscopy Center, Brigham and Women's Hospital, Boston, Massachusetts, USA.

Dates to which data relate
Data on effectiveness and resource use were gathered from October 1994 to October 1999. No price year was reported.

Source of effectiveness data
A single study was used as the source of the effectiveness evidence.

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

Study sample
Power calculations were not performed. All patients undergoing palliative enteral stent placement (excluding oesophageal malignancy) at the study centre during the studied period were enrolled. A total sample of 29 patients (mean age: 67.7 years; age range: 33 - 87 years; 45% men) underwent 31 stent deployment procedures.

A sub-sample of 12 patients (with advanced pancreatic cancer) undergoing stent deployment was then selected and compared with 15 other patients (with the same diagnosis of advanced pancreatic cancer) who underwent palliative surgical gastrojejunostomy between October 1994 and August 1999.
Study design
This was an observational study with a historical control group carried out in a single centre (the Endoscopy Centre, Brigham and Women's Hospital, Boston, Massachusetts, USA). Patients were followed after the intervention, but the actual length of follow-up was not reported.

Analysis of effectiveness
All patients included in the study were accounted for in the analysis. The primary health outcomes were technical success rate (satisfactory deployment and positioning of a stent) and positive clinical outcome (a relative improvement in the retention of food or flow of luminal materials), which were estimated only for patients who underwent stent placement to determine the safety of the intervention; survival, length of hospitalisation, number of patients undergoing the procedure on an outpatient basis, and number of procedures requiring hospitalisation. Comparability of study groups was not demonstrated.

Effectiveness results
The effectiveness results were as follows:

Technical success was reached in 29 of the 31 procedures performed (93.5%) and a positive clinical outcome was reached in 25 procedures (80.6%).

Median survival was 94 days in the stent subgroup and 92 days in the surgery group, (p>0.05).

Median length of hospitalisation was 4 days in the stent subgroup and 14 days in the surgery group, (p<0.005).

The number of patients undergoing the procedure on an outpatient basis was 5 (41.7%) in the stent subgroup and 15 in the surgery group (100%).

The number of procedures requiring hospitalisation was 7 (58.3%) in the stent subgroup and 15 (100%) in the surgery group.

Clinical conclusions
The authors stated that enteral stent deployment proved to be a safe technique which resulted in more effective outcomes than palliative surgery.

Measure of benefits used in the economic analysis
Health outcomes were left disaggregated and no summary benefit measure was used, therefore a cost-consequences analysis was carried out.

Direct costs
Discounting was not carried out since costs per patients were incurred over a short period of time. Unit costs and resource quantities were not reported. The cost/resource boundary adopted appears to have been that of the hospital. The cost items included in the study and the source of cost and quantity data were not reported. Quantities of resources were gathered from April 1996 to October 1999. No price year was reported.

Statistical analysis of costs
Statistical analyses of costs were carried out.

Indirect Costs
Indirect costs were not included.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analyses were conducted.

**Estimated benefits used in the economic analysis**
See effectiveness results above.

**Cost results**
The median charges incurred were $9,921 (range: $2,439 - $48,889) for enteral stent deployment and $28,173 (range: $2,439 - $139,146) for palliative surgery, (p<0.005).

**Synthesis of costs and benefits**
Not relevant.

**Authors' conclusions**
The authors concluded that endoscopic enteral stent placement was a safe technique, associated with very high success rates and lower hospitalisation and costs in comparison with standard palliative surgery.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparator was clear. Palliative surgery was selected as it represented the standard intervention for the patients in the study. You, as a user of this database, should assess whether it represents a widely used health intervention in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis of effectiveness was based on an observational design, which is prone to selection and other biases. Power calculations were not performed and the sample size was very small. In addition, comparability of study groups at baseline was not demonstrated and statistical analyses were not carried out to take into account potential bias and confounding factors. Also, the length of follow-up was not reported. These issues tend to limit the internal validity of the analysis.

**Validity of estimate of measure of benefit**
No benefit measure was used in the economic analysis and, hence a cost-consequences analysis was carried out. It would have been interesting had the authors assessed the impact of the interventions on patient's health, although the difference in median survival (the main outcome) did not reach statistical significance. Again, this could have been due to lack of power.

**Validity of estimate of costs**
The analysis of costs appears to have been conducted from the perspective of the hospital. However, very few details of cost items and sources of cost data were reported. Moreover, wide ranges of total costs were observed. Hospital charges rather than costs were used and this could have resulted in an overestimation of the opportunity costs of the interventions.
Other issues
The authors made some comparisons of their findings with those from other studies. The issue of the generalisability of the study results to other settings was not addressed and sensitivity analyses were not carried out, thus the external validity of the study is low. Patients undergoing a palliative treatment, but excluding those with malignant oesophageal disease, were enrolled in the study, and this was reflected in the authors’ conclusions. The conclusions of the study should be interpreted in the light of the limitations reported above.

Implications of the study
The main implication of the study was the adoption of endoscopic enteral stent placement for the palliative treatment of patients with malignant upper gastrointestinal obstruction. The authors suggested that further research should be based on prospective studies.

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