Management of occluded biliary Wallstents

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
Insertion of another Wallstent, plastic stent, or mechanical cleaning in the treatment of patients with biliary Wallstent occlusions.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with biliary Wallstent occlusions.

Setting
Hospital. The economic study was carried out in New England, USA.

Dates to which data relate
No dates were reported.

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

Link between effectiveness and cost data
No comprehensive costing was performed since it was reported that "the cost for all treatment strategies differed only with respect to equipment price."

Study sample
Power calculations were not used to determine the sample size. The study sample consisted of 38 patients with 44 Wallstent occlusions. Another Wallstent, plastic stent, or mechanical cleaning were performed in 19, 20, and 5 cases, respectively.

Study design
This was a retrospective cohort study, conducted in six centres. The median duration of the follow-up for the whole study patients was 231 (range: 30 - 1095) days. The median duration of the follow-up for the insertion of another Wallstent, plastic stent, and mechanical cleaning were 75 (range: 14 - 353) days, 128 (range: 7 - 370) days, and 176
(range: 9 - 278) days, respectively. The data for one patient with Wallstent occlusion were missing.

**Analysis of effectiveness**
The principle (intention to treat or treatment completers only) was not explicitly specified. The clinical outcome measures were bilirubin concentration, complications, cumulative stent patency, and patient survival (measured using the Kaplan-Meier technique). The main cause of Wallstent occlusions and correlation between the patency of the first Wallstent and the period of patency of subsequent treatments were investigated.

**Effectiveness results**
Treatment of the occlusions resulted in a bilirubin decrease from 6.0 (range: 0.5 - 34.3) to 2.1 (range: 0.2 - 27.7) mg/100 ml, (p<0.05). No significant complications were observed during the study follow-up for any of the treatment methods. The patients had a median duration of second stent patency of:

Wallstent, 75 (95% CI: 43 - 107) days;
Plastic stent, 90 (96% CI: 71 - 109) days;
Cleaning, 34 (95% CI: 30 - 38) days, (NS).

The corresponding values for median survival were 70 (95% CI: 22 - 118) days, 98 (95% CI: 54 - 142) days, and 34 (95% CI: 30 - 380) days, (NS), respectively.

It was reported that tumour ingrowth was the main cause of Wallstent occlusions in 64% of cases. A positive correlation (r=0.63, p=0.04) was observed between the patency of the first Wallstent and the period of patency of subsequent treatment of the occlusion by another Wallstent, plastic stent, or mechanical cleaning.

**Clinical conclusions**
The authors found no significant differences in the duration of patency or survival after managing Wallstent occlusions by any of the three methods under investigation. All methods of treatment investigated seemed to be equally effective.

**Measure of benefits used in the economic analysis**
The mean number of prevented endoscopic retrograde cholangiopancreatography (ERCPs) per patient was regarded as the main benefit measure.

**Direct costs**
Costs were not discounted due to the short time frame of the cost analysis. Quantities were not reported separately from the costs. Cost analysis covered only the cost due to the equipment price since it was reported that "the cost for all treatment strategies differed only with respect to equipment price." The perspective adopted in the cost analysis was not explicitly specified. The sources of cost data were not specified. The date of the price data was not given.

**Indirect Costs**
Not considered.

**Currency**
US dollars ($). A conversion to UK pounds sterling () was carried out.

**Sensitivity analysis**
No sensitivity analysis was performed.

**Estimated benefits used in the economic analysis**
The mean number of ERCPs for patients was 1.31 for those receiving another Wallstent, 1.44 for plastic stents, and 1.4 for mechanical cleaning.

**Cost results**
The cost of inserting another Wallstent was $995 (622) compared to $83 (52) for a plastic stent, and $115 (72) for mechanical cleaning.

**Synthesis of costs and benefits**
The incremental cost-effectiveness ratio for the insertion of another Wallstent relative to plastic stent was $7,015 (4,384) per prevented ERCP. The corresponding values for the insertion of another Wallstent relative to mechanical cleaning, and plastic stent relative to mechanical cleaning were $9,778 (6,111), and $880 (500) per prevented ERCP.

**Authors' conclusions**
Although all three methods were equally effective in managing an occluded Wallstent, the most cost-effective method appears to be plastic stent insertion.

**CRD COMMENTARY - Selection of comparators**
No specific health technology was regarded as the comparator. You, as a database user, should consider which health technology is widely used in your own setting.

**Validity of estimate of measure of benefit**
As acknowledged by the authors, the internal validity of the estimates of measures of effectiveness and benefit may be weakened by the lack of a prospective randomised design.

**Validity of estimate of costs**
Resource utilisation was not reported separately from the costs and insufficient details were provided of the methods of cost estimation. The cost results may not be generalisable outside the authors' setting.

**Other issues**
In view of the lack of randomisation, sensitivity analysis, and statistical analysis of the costs, the results need to be treated with some caution, as acknowledged by the authors. No dates were specified with regard to the collection of effectiveness and cost data.

**Implications of the study**
The authors recommended a prospective randomised stratified study to confirm the results of this study.

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