Efficacy of plastic tube stents without side holes for middle and lower biliary strictures

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
Patients with unresectable malignant biliary obstruction received one of three kinds of biliary stent. These were plastic tube stents with side holes (PS), plastic tube stents without side holes (PWOS) (including double-layer stents), and expandable metallic stents (EMS).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with unresectable malignant biliary obstruction being treated by insertion of a biliary stent.

Setting
The setting was secondary care (hospital). The economic study was carried out in Japan.

Dates to which data relate
The dates for the effectiveness evidence were 1984-2001. No dates for resource evidence were given. No price year was given.

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

Link between effectiveness and cost data
Costing was carried out retrospectively on the same group of patients as that used in the effectiveness analysis.

Study sample
No power calculations were reported. There was no sample selection: all patients who met the criteria of the study were included. Initially 150 patients were enrolled in the study. Exclusion of patients because of early death (within 30 days after the introduction of the stent) or insufficient data (this was not fully explained in the paper) meant that data were analysed for 130 patients out of the original 150. There were 64 patients in the PS group, 28 in the PWOS group and 38 in the EMS group.
Study design
This was a multi-centred, non-randomised trial with concurrent controls carried out in 4 Japanese hospitals.

Analysis of effectiveness
The analysis was based on patients who survived for 30 days after stent placement. The health outcomes used in the analysis were whether or not the stent was effective at drainage, the mean patency period and the cumulative patency rate measured over time. Effective drainage was defined as follows:

in cases where the serum bilirubin values were more than 5mg/dL before stenting, there was a reduction after stenting to less than 5mg/mL within 2 weeks;

in cases where the serum bilirubin was less than 5mg/dL before stenting, this level was maintained at less than 5mg/dL for 2 weeks.

The stent patency period was defined as the time period between the day of stent placement to the day of stent occlusion, replacement because of cholangitis or jaundice or the patient’s death.

The patients were not comparable at baseline: PS and PWOS were inserted for primary biliary drainage whereas EMS were inserted as a secondary measure after primary biliary drainage. The mean age in the PS group at 64 years (+/- 9.5 years), was significantly lower (the text of the article states higher), (p<0.05) than in the PWOS (72.2 +/- 12.8 years) and EMS (71.3 +/- 11.4 years) groups. No statistical tests were reported on the other patient characteristics but the male/female ratio was much lower (18:20) for the EMS group than for the PS, (39:25), and PWOS (17:11) groups.

Effectiveness results
The drainage efficacy rate for PS group was 81.3%, for the PWOS group 85.7% and for the EMS group 94.7%, (p=0.29 for EMS being better than the other two groups).

The mean patency period was 81.2 (+/- 11.2) days for the PS group, 155.8 (+/- 33.0) days for the PWOS group and 153.3 (+/- 17.3) days for the EMS group.

The cumulative patency rates for PS were:

- 70% at 50 days,
- 41% at 100 days, and
- 30% at 200 days.

For PWOS patency rates were

- 91% at 50 days,
- 85% at 100 days, and
- 51% at 200 days.

For EMS patency rates were:

- 94% at 50 days,
- 81% at 100 days, and
- 66% at 200 days.

The cumulative patency rate of the PWOS and EMS groups was higher than that for PS, (p<0.05).
When the cumulative patency rates were broken down according to the location of stricture, the rates for middle and lower strictures were similar to the overall result, but the patency rates for upper biliary tract strictures were as follows:

- **PS**, patency rate of 77% at 50 days, 54% at 100 days and 43% at 200 days;
- **PWOS**, patency rate of 100% at 50 days, 100% at 100 days, and 0% at 200 days; and
- **EMS**, patency rate of 100% at 50 days, 85.7% at 100 days, 85.7% at 200 days.

For patients with pancreatic cancer the patency rates were as follows:

- **PS**, 63% at 50 days, 49% at 100 days, and 37% at 200 days;
- **PWOS**, 85% at 50 days, 85% at 100 days, and 71% at 200 days; and
- **EMS**, 94% at 50 days, 72% at 100 days, and 60% at 200 days.

The rates for PWOS and EMS were significantly higher, \( p<0.05 \), than the rate for PS.

**Clinical conclusions**

The statistically significant results showed that EMS had the best drainage efficacy, and PWOS and EMS had the longest cumulative patency period overall for lower biliary tract strictures and cancer of the pancreas. For upper biliary tract strictures EMS had the longest cumulative patency period.

**Measure of benefits used in the economic analysis**

The measure of benefits used in the economic analysis was the mean patency period, which was taken directly from the effectiveness results.

**Direct costs**

The prices and quantities of the stents were analysed separately. The following costs were included: the price of the stent, the cost of inserting the stent and the cost of endoscopic retrograde cholangiopancreatographic examination. The two latter costs were taken as the same for all the stents. The prices were based on actual data. No price year was given, and no allowance was made for changing prices during the period of study. Appropriately, as the costs were incurred over a period of less than 2 years, no discounting took place.

**Statistical analysis of costs**

No statistical analysis of costs was carried out.

**Indirect Costs**

No indirect costs were included.

**Currency**

US dollars ($) converted from Japanese Yen (Y) at a rate of $1.00 = Y120.

**Sensitivity analysis**

No sensitivity analysis was carried out.

**Estimated benefits used in the economic analysis**
The mean patency period for PS was 81.2 days, for PWOS was 155.8 days and for EMS was 153.3 days.

Cost results
The cost of PS was $83.00 + $631.00, of PWOS was $83.00 + $631.00 and of EMS was $2,500.00 + $631.00. ($631.00 was the cost of the cholangiopancreatographic examination, which was common to all stent insertions).

Synthesis of costs and benefits
The cost per patency day was $8.80 for PS, $4.60 for PWOS and $20.40 for EMS.

Authors' conclusions
Allowing for the fact that EMS was inserted for secondary drainage and the PS and PWOS were mainly used for primary drainage, PWOS and EMS were superior to PS for middle and lower biliary obstruction. EMS was best for upper biliary obstruction. Overall drainage was best for EMS. The higher relative cost of the EMS contributed to the fact that it had the highest cost per day. The authors concluded that PWOS is the best choice of stent. They used two kinds of PWOS. One was a double layer stent with an inner surface smoother than the usual tube stent, but they could not perceive any significant difference in the efficacy between the two kinds of PWOS.

CRD COMMENTARY - Selection of comparators
The authors justified the choice of comparators, plastic stents with and without holes, and expandable metal stents, on the grounds that there is no clear first choice as to the type of stent to be used in biliary drainage. However, the comparators used may not have been valid in terms of addressing the question posed by this study.

Validity of estimate of measure of effectiveness
The study design was inadequate to answer the question of which kind of stent should be used, as the authors acknowledged that the metal stent (EMS) can only be used for secondary drainage. Therefore, the authors should have only considered patients requiring secondary drainage if they were considering the use of EMS. The study sample should have consisted of either patients only requiring primary drainage or those only requiring secondary drainage. There was no sample selection, because all patients requiring stents for biliary drainage were recruited for the study. However, the authors excluded patients who died within 30 days of having the stent and patients for whom there was inadequate information. The exclusion of these patients could have biased the results.

The authors described patient characteristics but did not report statistical tests to show that they were equal. They showed that the mean age in the PS group was lower than in the other two groups, but in the text the age was reported to be higher. No allowance was made for this age difference. The main flaw of the study design is that it was not a randomised controlled trial: it is unclear how the decision on which kind of stent a patient should receive was made, thus leaving the study open to bias and confounding.

Validity of estimate of measure of benefit
The authors used the mean patency period as a measure of benefit, taken directly from the measures of effectiveness. The choice of this benefit measure, as opposed to a utility-based measure such as quality-adjusted life years, will limit the comparability of the results to results from other studies in different areas.

Validity of estimate of costs
Insufficient cost information was provided. Very little information was given about how the costs were calculated and no information was given about the dates during which the costs were gathered. Due to a lack of reporting the reproducibility of the study in other settings will be seriously hindered.
Other issues
The authors compared their work with that of other authors in terms of the effectiveness results but not in terms of the cost information. The authors did not address uncertainty in the data and hence the generalisability of the results is limited.

Implications of the study
The authors concluded that PWOS are the best kind of stent on grounds of cost and effectiveness. However, they acknowledged some of the limitations of their work including the fact that it was a retrospective nonrandomised study. The authors reported that they are currently carrying out a prospective randomised study. For the other weaknesses in the study please see above.

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