A new system for rapid large-caliber percutaneous transhepatic drainage in patients with obstructive jaundice: a prospective randomized trial


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
A new system for rapid large-caliber percutaneous transhepatic biliary drainage (PTBD) in patients with obstructive jaundice.

Type of intervention
Diagnosis and treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population was consecutive male or female patients undergoing percutaneous drainage for biliary diseases.

Setting
The study setting was a hospital. The economic study was carried out in Germany.

Dates to which data relate
Effectiveness data, resource use, and cost data were collected over a 19-month period although the specific dates for this were not specified.

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

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

Study sample
Of the 60 patients included, 29 were assigned to the new method and 31 to conventional dilation. Patients were included if they had successful placement of a 10-Fr pigtail catheter into the right or left hepatic system, which passed into the duodenum/small bowel, and if subsequent dilation to larger-diameter percutaneous catheters was felt to be necessary. Patients who were too ill for the dilation procedure to be continued and who were sent home with the 10-Fr catheter in place, and patients, in whom a stricture could not be passed with the drain, were not included. No power calculations were reported.
Study design
The study was a prospective, randomised clinical trial carried out at a single centre. No patients were lost to follow-up. Patients were followed-up for one month after randomisation.

Analysis of effectiveness
Three patients crossed over to the new method group. Three strategies were used for the analysis: omitting the three cross-over patients, analysis per protocol, and analysis based on intention to treat. The primary health outcomes used included premedication, duration of the procedure, fluoroscopy time, number and type of accessories used, ease of the procedure, success rates, adverse events, and patient tolerance. There were no significant differences between the two groups in terms of clinical data or biliary pathology.

Effectiveness results
The technical success rates were 97% in the new method group and 90% in the conventional dilation group.

The clinical efficacy of PTBD was similar in the two groups: regression of manifest jaundice in 90% in the new method group and in 83% in the conventional dilation group.

The rates of major complications (4/29 in the new method group and 5/31 in the conventional dilation group) and patient tolerance were also similar.

No significant differences were seen in the amount of premedication or the requirement for pain medication after PTCD, although the patients' assessments favoured the new method. However, the new procedure led to a significant reduction in the cumulative procedure duration (20.1 minutes versus 30.1 minutes), mean number of sessions (1.1 versus 1.7), and mean number of hospital days (2.0 versus 5.5).

The 30-day follow-up showed that patients' symptoms did not differ significantly between the two groups.

Clinical conclusions
The new system for rapid establishment of large-caliber PTBD maintains clinical efficacy.

Measure of benefits used in the economic analysis
Given that clinical effectiveness results were equal between the groups, a cost minimisation analysis was carried out.

Direct costs
Direct costs were not discounted because the time horizon was less than one year. Quantities and costs were reported separately. Direct costs included the costs of PTCD sessions, hospital days, pain medication, antibiotics, premedication, and further materials. The quantity/cost boundary adopted was that of the hospital. The estimation of quantities and costs was based on actual data. Costs and quantities were obtained from hospital records. The price year was not reported.

Statistical analysis of costs
The null hypothesis of no difference in median cost values of groups was tested using the Mann-Whitney U-test.

Indirect Costs
Indirect costs were not included.

Currency
German Marks (DM).

**Sensitivity analysis**
A sensitivity analysis was not conducted.

**Estimated benefits used in the economic analysis**
As no summary benefit measure was used in the economic analysis the reader is referred to the effectiveness results reported above.

**Cost results**
Mean costs were DM2,581 in the new method group, DM5,813 in the conventional dilation group, and DM10,252 in the cross-over group.

**Synthesis of costs and benefits**
The new method of PTCD was a dominant strategy: it was cheaper than classical dilation but maintained equivalent success and complication rates.

**Authors' conclusions**
The new system for rapid establishment of large-caliber PTBD offers significant advantages in terms of saving hospital resources and also maintains clinical efficacy.

**CRD COMMENTARY - Selection of comparators**
A justification was given for the comparators used, namely conventional dilation. You, as a user of the database, should decide if these health technologies are relevant to your setting.

**Validity of estimate of measure of effectiveness**
The analysis was based on a randomised controlled trial, which was appropriate for the study question. The study sample was representative of the study population. Patient groups were shown to be comparable at analysis. The analysis of effectiveness was handled credibly and included both treatment completers and intention to treat analyses, as well as cross-over patients. For these reasons it is reasonable to anticipate good validity for the effectiveness results.

**Validity of estimate of measure of benefit**
The analysis of benefits was based on the therapeutic equivalence of treatment alternatives. The economic analysis was therefore a cost-minimisation analysis, which was appropriate.

**Validity of estimate of costs**
Good features of the cost analysis were that all relevant direct cost categories were included, and quantities and costs were reported separately. However, the price year was not reported, it was unclear whether charges had been used to proxy costs and no sensitivity analyses were conducted on costs, although appropriate statistical analyses were conducted with significant findings in favour of the new approach. Some of these limitations tend to hinder the generalisability of the results.

**Other issues**
The authors made appropriate comparisons of their findings with those from other studies, but did not address the issue of generalisability to other settings. The authors do not appear to have presented their results selectively. The study
considered patients undergoing percutaneous drainage for biliary diseases and this was reflected in the authors’ conclusions.

**Implications of the study**
The findings of the present study show that the new system for rapid establishment of large-caliber PTBD offers significant advantages in terms of saving hospital resources and also maintains clinical efficacy. Further studies will need to evaluate the best and safest approach for achieving adequate and rapid percutaneous biliary drainage.

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