A cost-effectiveness analysis of biliary anastomosis with or without T-tube after orthotopic liver transplantation


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 use of choledochocholedochostomy performed with and without a T-tube in the course of an orthotopic liver transplant (OLT).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients who were undergoing an OLT. Patients under 18 years old, who had received a primary Roux-en-Y choledochojejunostomy, or who had undergone hepatic re-transplantation were excluded.

Setting
The setting was a hospital. The economic study was undertaken at the University of California Los Angeles Medical Center, USA.

Dates to which data relate
The effectiveness and resource use data related to the time between 1 January 1998 and 31 December 1998. The price year was not reported.

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

Link between effectiveness and cost data
The resource use data were obtained retrospectively from the same sample as the clinical effectiveness data.

Study sample
The study undertook a review of medical records to establish the clinical effectiveness of the two interventions under consideration. Patients were included in the study if their OLT was performed during the study period. No power calculations to determine the power of the study were reported.

Of the 216 OLTs performed during the study period, a total of 147 patients were included in the study. Of these, 76 received a bile duct reconstruction with a T-tube and 71 received a bile duct reconstruction without a T-tube. The
reasons for exclusion are likely to have been those reported as exclusion criteria in the study population. However, a detailed description of the patients excluded from the study and the reasons for their exclusion were not presented. The paper reported patient demographics, the cause of underlying liver disease and the patient's status on the transplant register, but it did not consider whether this indicated that the patient sample was representative of the total patient population. The mean age was 51.8 years (standard deviation, SD=11.7) in the T-tube group and 52.9 years (SD=12.3) in the without T-tube group. There were 43 (T-tube) and 39 males (no T-tube) in the two groups, respectively.

**Study design**
This was a single-centre, retrospective cohort study. It does not appear to have had a set follow-up period. However, the mean length of follow-up was 15 months (SD=11.7) in the T-tube group and 17.8 months (SD=7.9) in the without T-tube group. The paper did not report whether any patients were lost to follow-up. There was no blinding in this study, either at the point of treatment or in the retrospective review.

**Analysis of effectiveness**
The paper stated that all data were analysed on an intention to treat basis and data were presented for all study participants. The clinical effectiveness was assessed on the basis of the following:

- the length of hospital stay after transplantation;
- hospital readmission rates and length of stay;
- the development of biliary complications (biliary leakage and biliary strictures); and
- mortality in the 30 days after transplantation.

There was no statistical difference between the two groups in terms of the mean age, gender, underlying cause of liver disease and the patient's status on the transplant register. Consequently, no adjustment was made for potentially confounding factors.

**Effectiveness results**
The mean hospital stay after transplantation was 31.1 days (SD=27.9) for patients in the T-tube group and 18.8 days (SD=15.5) for those in the without T-tube group, (p=0.001).

The mean number of hospital readmissions was also lower in the group where a T-tube was not used, 1.8 days (SD=2.3) versus 3.1 days (SD=2.6), (p=0.002).

Biliary complications were higher in the T-tube group (32.9%) than in the without T-tube group (15.5%), (p=0.01). In particular, bile leakage occurred in 22.7% of the patients when a T-tube was used, compared with 7.0% of the patients when a T-tube was not used, (p=0.004).

There were 7 (9.2%) deaths amongst patients who received biliary reconstruction with a T-tube versus 8 (11.3%) deaths amongst those where a T-tube was not used. However, there were no deaths directly attributable to biliary complications.

Non statistically significant differences in the rate of biliary strictures and the length of hospital stay resulting from complications were also found between the two patient groups.

**Clinical conclusions**
Choledochocholedochostomy without a T-tube resulted in fewer biliary complications than choledochocholedochostomy with a T-tube, leading to significantly lower lengths of stay in the hospital.
Measure of benefits used in the economic analysis
No summary measure of benefit was used in the economic evaluation. A cost-consequences analysis was therefore performed.

Direct costs
The unit costs and the resource quantities were reported for the diagnostic, therapeutic and radiological procedures related to biliary reconstruction. The paper stated that the total cost figures reported include professional fees. However, there was no breakdown of the unit costs and quantities for this item. Data relating to the quantities of resources used were obtained from a historical review of the patients’ medical notes, while the price data were obtained from the University of California Los Angeles. The prices were converted to costs using a ratio of 0.53. No rationale for using this ratio was reported. The costs of re-transplantation were taken from a published study (see Other Publications of Related Interest). No discounting was undertaken and, on balance, this was appropriate since the mean length of follow-up was less than two years. The price year was not stated.

Statistical analysis of costs
Statistical tests were performed to estimate the significance in cost differences. The total costs were presented as means with SDs.

Indirect Costs
No indirect costs were included.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was performed.

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

Cost results
The mean total cost was $13,022 (SD=35,726) for patients with a T-tube compared to $7,291 (SD=20,184) for patients who were operated on without a T-tube. These costs represented the costs of treatment for the full duration of postoperative follow-up. They also included the costs related to complications following surgery. However, the difference in total costs between the two groups did not reach statistical significance, (p=0.235).

Synthesis of costs and benefits
The costs and benefits were not combined.

Authors’ conclusions
Choledochocholedochostomy without a T-tube resulted in fewer biliary complications and was less costly than choledochocholedochostomy with a T-tube.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. Choledochocholedochostomy with a T-tube represented usual
practice for biliary reconstruction in the USA. You should consider how this compares with usual practice in your own setting before applying the results of this study.

Validity of estimate of measure of effectiveness
The clinical study design provided an appropriate method for obtaining the clinical effectiveness data. However, the authors acknowledged the limitations of retrospective studies and the scope for differences in the patients’ characteristics to influence the results in non-randomised studies. They also added that, given the large number of patients included in the study and the similarity in severity and type of liver disease, the study design is not likely to have introduced substantial bias into the results. The authors also performed appropriate statistical analyses to compare the patients’ characteristics at baseline. A randomised controlled trial, however, would have provided more robust evidence on the clinical effectiveness of the two interventions. The paper did not provide any information on the degree to which the patient sample was representative of the study population.

Validity of estimate of measure of benefit
The study did not derive a summary measure of health benefit. Consequently, a cost-consequences study was undertaken.

Validity of estimate of costs
The perspective adopted in the study was not explicitly reported, although it appears to have been undertaken from the perspective of the healthcare provider or purchaser. The study only included those costs that were directly related to biliary reconstruction. It is possible that costs relating to the original liver transplant were excluded because they were common to both interventions. However, this was not stated and it was unclear whether the use of a T-tube altered the cost of transplantation. The lack of any sensitivity analysis limits the generalisability. Reporting the units consumed for some resources assists the reproducibility of the study, although this approach was only taken for some resources included in the total costs and there was no reporting of the unit costs for some items. Future reflation exercises will be severely limited by the absence of a clear price year. The prices were converted to costs, but no justification was given for the ratio used. Appropriate statistical analyses were performed to estimate the significance in cost differences.

Other issues
The authors compared their findings with similar published studies and reported the results of these investigations in detail. However, the lack of sensitivity analyses reduced the applicability of the study results to other settings. The authors’ conclusions accurately reflected the results of the study. The authors acknowledged some limitations in the study design, as described earlier.

Implications of the study
The authors stated that a large multicentre randomised trial is needed to provide further evidence on the clinical and cost-effectiveness of the two interventions under investigation.

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Bibliographic details

Other publications of related interest

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Subject indexing assigned by NLM

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