A randomized trial comparing transjugular intrahepatic portosystemic stent-shunt with variceal band ligation in the prevention of rebleeding from esophageal varices


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
Using transjugular intrahepatic portosystemic stent-shunt (TIPSS) or variceal band ligation (VBL) in the secondary prophylaxis of esophageal variceal hemorrhage in patients with cirrhosis.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
Patients aged 18-75 years with cirrhosis presenting with the first episode of esophageal variceal hemorrhage.

Setting
Hospital. The economic study was carried out in Edinburgh, UK.

Dates to which data relate
The effectiveness and resources use data were collected between May 1993 and December 1995. The price year was not stated.

Source of effectiveness data
The evidence for the final outcomes was derived from a single study.

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

Study sample
A power calculation determined the sample size. The required sample size to detect a 25% difference in the rate of rebleeding between the two health technologies with alpha and beta values of 0.05 and 0.20 in a one-tailed test was 27 patients in each group. A total of 108 patients were assigned to the study centre. The application of inclusion criteria allowed 58 patients to be enrolled into the study. 27 patients were randomly allocated to the VBL group and 31 to the TIPSS group. 3 patients (2.8%) refused to participate in the study and 44 patients (41.9%) were excluded from the study.
Study design
The study was a randomised controlled trial. The TIPSS group had an average follow-up of 15.7 (+/-10.2) months and the VBL group was 16.8 months (+/-10.9).

Analysis of effectiveness
The analysis of the clinical study was based on intention to treat. The health outcomes were measured by the rate of rebleeding, mortality rate, the rate of complications such as encephalopathy, sepsis, and shunt insufficiency. The groups were shown to be comparable in age, sex and prognostic features.

Effectiveness results
The TIPPS group had a significantly lower rate of rebleeding than the VBL group (9.8% versus 51.9%, p<0.0006). The mortality rate in the TIPPS group was 42.2% and in the VBL group was 36.9% (this was not significant). The encephalopathy rates before TIPPS and before VBL were 25.8%, and 33.3%, respectively. The encephalopathy rates after TIPPS and after VBL were 35.5%, and 11.1%, respectively. The rate of sepsis in the TIPPS group and VBL group was 9.7% and 14.7%, respectively. The study revealed no significant differences between the groups in terms of complications such as encephalopathy and sepsis. The shunt insufficiency rate was 31.1%.

Clinical conclusions
The study revealed that TIPPS was more effective than VBL for the secondary prophylaxis of esophageal variceal hemorrhage in patients with cirrhosis.

Measure of benefits used in the economic analysis
No single measure of benefit was produced in the economic evaluation.

Direct costs
The costs were not discounted. Quantities and costs were reported separately. The average direct cost were divided into procedure costs and the costs of hospital treatment. The procedure costs were further subclassified as the costs of TIPPS, VRL, portography, angioplasty, parallel stent, and reducing stent. The costs of hospital treatment were divided into the costs of intensive therapy unit, high-dependency unit, and ward treatment. The direct costs to the National Heath Service (NHS) were considered in the analysis. The estimation of the quantities was based on the actual data. The costs of in-patient and out-patient care were obtained from an NHS institution. Costs omitted included the establishment costs, hardware costs, radiology or endoscopy time, and the costs of training personnel. The dates for price data were not specified.

Indirect Costs
Not calculated.

Currency
UK pounds Sterling (£). The conversion rate was 1= US$1.6.

Sensitivity analysis
Not carried out.

Estimated benefits used in the economic analysis
Not applicable.
Cost results
The average total cost was 7,059 for the TIPPS group and 8,432 for the VBL group, therefore the TIPPS group incurred 1,373 ($2,200) less in costs than the VBL group.

Synthesis of costs and benefits
A synthesis was not carried out by the authors as TIPPS was the dominant strategy.

Authors' conclusions
The results of this study show that TIPPS is superior to VBL for the secondary prophylaxis of esophageal variceal hemorrhage in patients with cirrhosis.

CRD COMMENTARY - Selection of comparators
The reason for the selection of the comparator is clear. You should consider whether this is a widely used health technology in your own setting.

Validity of estimate of measure of benefit
The estimate of the measures of benefits used in the study is likely to be internally valid.

Validity of estimate of costs
The resource quantities were reported separately from the prices. As the authors noted, some items of the costs were omitted from the analysis.

Other issues
The authors pointed out that the results of cost analysis may not be generalised to other settings. The lack of sensitivity analysis and statistical analysis of costs may have further weakened the power of the study to generalise the results to other settings.

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