Post-shunt resource consumption favors small-diameter prosthetic H-graft portacaval shunt over TIPS for patients with poor hepatic reserve

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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 8-mm prosthetic H-graft portacaval shunts (HGPCS) was investigated. The intervention was compared with the transjugular intrahepatic portasystemic shunt (TIPS).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with advanced cirrhosis and severe hepatic dysfunction (i.e. Child's Class C), who had bled from oesophageal or gastric varices or portal gastropathy, and had failed nonoperative therapy (e.g. endoscopic sclerotherapy or banding). Patients were not considered for the trial if the portal vein (PV) was thrombosed, or their chances of surviving shunting were thought to be hopeless due to ill health. Patients were also excluded if they were felt not to be a candidate for either of the two interventions, for example, patients with profound cardiorespiratory impairment. In addition, patients who had undergone multiple complex abdominal operations may not have been considered because of their poor candidacy for abdominal surgery.

Setting
The setting was secondary care. The economic study was carried out at the Department of Surgery, University of South Florida, Tampa, USA.

Dates to which data relate
The patients were randomised to undergo either treatment from 1993 to 1999. The dates to which the prices related were not reported.

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

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

Study sample
A sample size does not seem to have been determined in the planning phase of the study. No power calculations were
performed retrospectively. It was not explicitly stated, but the sample appeared to be unselected. By protocol, each patient underwent pre-shunt colour flow Doppler ultrasound imaging to document PV patency. If there were questions about the patency of the PV or the quality of the portal blood flow, visceral angiography with portal vein runoff was undertaken. PV patency was documented in 62 patients. These patients were then randomised to undergo TIPS (n=29) or 8-mm prosthetic HGPCS (n=33). In the TIPS group, 72% were males and the mean age was 56 (+/- 12.8) years. In the HGPCS group, 79% were males and the mean age was 54 (+/- 12.8) years.

Study design
This was an RCT that was carried out in a single centre. The patients were randomised to undergo TIPS or 8-mm prosthetic HGPCS, in pairs, to allow for sequential analysis by pair differences. The investigators in the trial were blinded as to which shunt was next to be assigned. The duration of follow-up ranged from 3 to 9 years. The median follow up was 6 years and 1 month after TIPS, and 6 years and 2 months after HGPCS. After TIPS, one patient underwent liver transplantation at 7 months from shunting. The follow-up for this patient ended at that point.

Analysis of effectiveness
For 3-year survival, the analysis of the clinical study was conducted on an intention to treat basis. However, for other aspects of the study, such as post-shunt PV pressures and portal vein inferior vena cava (PV-IVC) pressure gradients, the basis of the analysis (intention to treat or treatment completers only) was unclear.

The primary health outcomes used in the analysis were:

- shunt failure;
- post-shunt PV pressures and PV-IVC pressure gradients;
- the resolution or improvement of ascites;
- survival at time intervals up to 3 years (including and excluding patients dying within 30 days of shunting); and
- the occurrence of shunt failure with follow-up as long as 9 years.

Shunt failure was defined prospectively as an inability to complete the shunt, irreversible shunt occlusion, major variceal re-bleeding, liver transplantation, or death.

The patients undergoing TIPS or HGPCS were very similar. The patients were, on average, of similar ages and of a similar gender distribution. Of the patients undergoing TIPS, a few more had alcoholic cirrhosis and a few less had cirrhosis due to viral hepatitis or unknown causes. Ascites were more common in patients undergoing HGPCS. In all, the authors concluded that nothing of note discriminated the groups of patients undergoing either of the shunts.

Effectiveness results
TIPS could not be completed in 2 patients. Otherwise both shunts significantly reduced PV pressures and PV-IVC pressure gradients.

For patients undergoing TIPS, post-shunt PV pressures were 28 (+/- 7.4) mmHg and PV-IVC pressure gradients were 8 (+/- 4.3) mmHg. Both were significantly lower than pre-shunt values, (p<0.01).

For patients undergoing HGPCS, post-shunt PV pressures were 22 (+/- 6.6) mmHg and PV-IVC pressure gradients were 5 (+/- 2.7) mmHg. Both were significantly lower than after TIPS.

Major re-bleeding reoccurred in 6 patients after TIPS and in 4 patients after 8-mm HGPCS.

Overall, the patients undergoing HGPCS received fewer units of packed red blood cells than those undergoing TIPS, 0.1 (+/- 1.4) units versus 1.3 (+/- 2.7) units, (p=0.05).
By 30 days after shunting, ascites had resolved or improved in 72% of patients with ascites before TIPS and in 90% of patients with ascites before HGPCS. With long-term follow-up, ascites was noted in 2 patients with ascites preceding TIPS and in 2 patients with ascites preceding HGPCS.

Six (21%) of the patients died within 30 days of undergoing TIPS versus 7 (21%) of those undergoing HGPCS. No significant differences in survival were noted at 3, 6 and 12 months, and at 2 and 3 years after shunting. At 3 years after shunting, 58% of patients who underwent HGPCS and 55% of those who underwent TIPS were still alive.

With follow-up as long as 9 years, shunt failure occurred in 24 (83%) of patients undergoing TIPS and in 24 (73%) of those undergoing HGPCS.

Clinical conclusions
TIPS offered no quantifiable benefits in comparison with 8-mm prosthetic HGPCS.

Measure of benefits used in the economic analysis
No summary benefit measure was used in the economic analysis. In effect, a cost-consequences analysis was conducted.

Direct costs
The resource use and the costs were reported separately only for some categories of costs. The costs of the health service were included in the analysis. These were for packed red blood cells consumed, hospital days, days in the intensive care unit, and hospital and professional fees. The cost of care per day of survival was determined by dividing the cost of care for each patient by the duration of survival or follow-up. The authors did not report the sources from which the unit costs were derived. Discounting seems to have been relevant, as some costs were incurred during more than two years. However, the authors did not discount the costs. The study reported the mean cost of care per patient, and the median cost per day of survival. The dates to which the price data referred were not reported.

Statistical analysis of costs
The costs were presented with their means and standard deviations. Resource use and costs were treated stochastically. Statistical significance was tested using Student's t-test (significance level of p<0.05).

Indirect Costs
The indirect costs were not included.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analyses were performed.

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

Cost results
Following discharge, the cost of care after HGPCS was less, although not statistically different, than after TIPS. The cost of care was $24,623 (+/- 55,662) after HGPCS versus $33,840 (+/- 59,026) after TIPS.
The median cost of care per day of survival after shunting was less after HGPCS than after TIPS, $39.41 versus $43.91. This difference was also not significant.

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

**Authors' conclusions**
The transjugular intrahepatic portasystemic shunt (TIPS) offered no quantifiable benefits when compared with the 8-mm prosthetic H-graft portacaval shunt (HGPCS). TIPS was also associated with higher resource consumption.

**CRD COMMENTARY - Selection of comparators**
A justification was given for using TIPS as the comparator. TIPS was considered a commonly employed treatment option for patients with bleeding varices, portal hypertension and cirrhosis. You should decide if this is a widely used health technology in your own setting.

**Validity of estimate of measure of effectiveness**
The basis of the analysis was an RCT, which was appropriate for the study question. The study sample was representative of the study population. In some instances, it was unclear whether the analysis of effectiveness was conducted on an intention to treat basis or on treatment completers only. Further, even if the median follow-up was approximately 6 months for both groups, the authors reported occurrences of shunt failure with follow-up as long as 9 years. This was inappropriate, as at least half of these patients were never followed up for so long. However, appropriate statistical tests of significance were performed.

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of health benefit. In effect, a cost-consequences analysis was conducted.

**Validity of estimate of costs**
Even though the perspective adopted was not explicitly stated, it would appear to have been that of the health service. All the relevant costs for this perspective, and the relevant costs for each category of cost, seem to have been included. Only some costs were reported separately from the quantities, which will limit the generalisability of the authors’ findings. The resource use quantities were derived from the study. Statistical tests of significance were appropriately performed. The authors did not report the sources of the unit costs. Hence, it is unclear whether they were derived from suitable sources, or were based on authors' assumptions. Statistical analyses of mean total costs and median costs per survival day were appropriately performed to test for statistical significance between the two groups. The costs were incurred during more than two years, but they were left undiscounted. Further, the dates to which the prices related were not reported, thus hampering any reflation exercises.

**Other issues**
The authors did not compare their findings with those from other studies. This would appear to have been justified, as their study seems to be the only RCT to compare both interventions. The issue of generalisability to other settings was not addressed. The authors do not appear to have presented their results selectively and their conclusions reflected the scope of the analysis. The authors did not report any further limitations of their study.

**Implications of the study**
From their results, the authors reported that there is little to recommend the use of TIPS in patients with significant dysfunction, varices, portal hypertension and cirrhosis. The authors only recommended the use of TIPS for those patients with such conditions who are awaiting imminent transplantation, and those with contraindications for an
abdominal operation.

**Source of funding**
None stated.

**Bibliographic details**

**PubMedID**
12796578

**DOI**
10.1097/01.SLA.0000072102.38993.05

**Other publications of related interest**

Zervos EE, Rosemurgy AS. Small-diameter portacaval shunt vs. transjugular intrahepatic portosystemic shunt for portal hypertension. Advances in Surgery 1997;31:105-25.


**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Adult; Aged; Blood Vessel Prosthesis Implantation; Decompression, Surgical; Erythrocyte Transfusion /statistics & numerical data; Esophageal and Gastric Varices /surgery; Female; Gastrointestinal Hemorrhage /surgery; Humans; Length of Stay; Male; Middle Aged; Portacaval Shunt, Surgical; Portasystemic Shunt, Transjugular Intrahepatic; Postoperative Period; Prospective Studies

**AccessionNumber**
22003001369

**Date bibliographic record published**
31/07/2004

**Date abstract record published**
31/07/2004