Endovascular versus surgical treatment for thrombosed hemodialysis grafts: a prospective, randomized study
Dougherty M J, Calligaro K D, Schindler N, Raviola C A, Ntoso A

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
Thrombolytic therapy with urokinase using the pulse-spray technique (ENDO), with adjunctive percutaneous transluminal angioplasty as indicated for patients with thrombosed dialysis grafts.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with thrombosed dialysis grafts. The exclusion criteria included contrast allergy, urokinase allergy, bleeding diatheses, graft infection, history of significant gastrointestinal haemorrhage, any prior cerebral or ocular haemorrhage, major surgery within the preceding 3 months, or ipsilateral dialysis access surgery within the preceding 4 weeks.

Setting
Hospital. The economic study was carried out in the USA.

Dates to which data relate
Effectiveness and resource use data corresponded to patients enrolled between 15 November 1994 and 15 August 1998. The price year was not given.

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

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

Study sample
Power calculations were not used to determine the sample size. The study sample consisted of 80 patients randomly assigned either to the ENDO group (n=39, mean (SD) age of 59.2 (15.4) years) or to the control group (n=41, mean (SD) age of 67.9 (15.1) years). 4 eligible patients refused to participate in the randomisation process.

Study design
This was a randomised controlled study, carried out in a single centre. The median duration of the follow-up was 24 months. Loss to follow-up was not reported (except for 11 who crossed-over to the SURG group and two who required adjunctive percutaneous transluminal angioplasty). All the grafts were upper extremity expanded polytetrafluoroethylene grafts. All the procedures were performed in an endovascular operating suite with fistulography. Inadequate information was given regarding the randomisation procedure.

**Analysis of effectiveness**

The principle used in the analysis of effectiveness was both intention to treat and treatment completers. The health outcomes were procedure time, procedure-related complications, cumulative primary and assisted primary patency, time to graft rethrombosis, and the number of cross-over patients. The patency outcomes were calculated using the Kaplan Meier life-table method. With the exception of age, the study groups were comparable in terms of preoperative features.

**Effectiveness results**

The average procedure time was 99 minutes in the SURG group versus 113 minutes in the ENDO group, \( p=0.12 \). There were no procedure-related complications which required treatment in either group. At a median follow-up time of 24 months, there was no difference in primary or assisted primary patency between groups, which averaged 6 (SURG) and 7 (ENDO) months, (NS). Eleven patients in the ENDO group crossed over to surgical revision as compared with two patients in the SURG group who required adjunctive percutaneous transluminal angioplasty, \( p=0.005 \). The analysis per protocol had similar findings in terms of patency rate.

**Clinical conclusions**

The authors concluded that although long-term success is limited with both approaches, the patency rates for patients who undergo treatment with endovascular therapy are comparable with the rates for those who undergo surgical treatment.

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

No summary benefit measure was identified in the economic analysis, and only separate clinical outcomes were reported.

**Direct costs**

Costs were not discounted due to the short time frame of the cost analysis. Some quantities were reported separately from the costs Cost items were not reported separately. Cost analysis covered the procedure-related costs (including complications) which included operating room time and supply costs but excluded professional fees. The perspective adopted in the cost analysis was not explicitly specified and the price year was not given.

**Statistical analysis of costs**

Student's t test appears to have been used to compare the groups in terms of costs.

**Indirect Costs**

Not included.

**Currency**

US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was performed.

**Estimated benefits used in the economic analysis**
Not applicable.

**Cost results**
The mean cost for the ENDO group was $2,945 versus $1,512 in the SURG group, (p<0.001). After exclusion of cross-over patients from the analysis, the corresponding values were $2,663 and $1,538, (p<0.001).

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

**Authors' conclusions**
Although thrombolytic therapy combined with endovascular treatment can extend the life of dialysis grafts with results similar to surgical revision, there is a high rate of technical failure necessitating surgery and a substantially higher cost for thrombolysis.

**CRD COMMENTARY - Selection of comparators**
A justification was given implicitly for the choice of the comparator (the surgical treatment) which was the traditional treatment in the context in question. You, as a database user, should consider whether this is a widely used health technology in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness results are likely to be internally valid given the randomised nature of the study design, and the intention to treat analysis conducted. However, no power calculations were performed to assess the adequacy of the sample size to detect differences between the two study groups. The study groups were found to be comparable in terms of preoperative features, except for age (the SURG group being older, p=0.013). The patient sample appears to have been representative of the study population. It was noted that the high cross-over rate in this study for the ENDO group (11 of 39; 28.2%), although similar to technical failure rates in other reports, may reflect the surgeon's cognisance of procedure time as a factor under analysis and the protocol-established limits on urokinase amounts.

**Validity of estimate of measure of benefit**
The authors did not derive a measure of health benefit. The study may therefore be regarded as a cost-consequences analysis.

**Validity of estimate of costs**
Some quantities were reported separately from the costs and adequate details of the methods of cost estimation were given. It is not clear whether the cost analysis was based on charge data or on true costs. Neither the price year nor the perspective adopted in the cost analysis were reported. The effects of different procedures on indirect costs (productivity loss) were not addressed. Cost results may not be generalisable to other settings or countries.

**Other issues**
The authors' conclusions appear to be justified given uncertainties in the data. The issue of generalisability to other settings or countries was not addressed, although appropriate comparisons were made with other studies. The degree to which the study sample was representative of the study population was not discussed. Selection of a summary benefit measure in order to perform an incremental cost-effectiveness analysis may have helped in the objective assessment.
of the superiority of one procedure over the other.

**Implications of the study**
Although endovascular treatment avoids a small incision, it currently does not offer superior results, and it costs more. The authors' current practice is to reserve endovascular treatment for situations in which operative exposure may be unusually difficult or morbid, such as treatment high in the axilla in obese patients or in the setting of unhealed wounds. However, given the poor long-term results with both surgical and endovascular treatment for dialysis graft thrombosis, more diligent efforts should be made at early construction of autogenous fistula to avoid the need for prosthetic grafts when possible.

**Source of funding**
None stated.

**Bibliographic details**

**PubMedID**
10587385

**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Adult; Aged; Aged, 80 and over; Angioplasty, Balloon /economics; Arteriovenous Fistula /economics; Cost-Benefit Analysis; Female; Graft Occlusion, Vascular /economics /surgery; Humans; Male; Middle Aged; Renal Dialysis /economics; Reoperation; Thrombectomy /economics; Thrombolytic Therapy /economics; Treatment Outcome; Urokinase-Type Plasminogen Activator /administration & dosage /economics

**AccessionNumber**
2200000024

**Date bibliographic record published**
30/11/2000

**Date abstract record published**
30/11/2000