Balloon angioplasty for arteriovenous graft stenosis

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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 surgical thrombectomy followed by angioplasty (SBA) or thrombolysis followed by angioplasty (TBA) in haemodialysis patients who had suffered an arteriovenous graft (AVG) thrombosis.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised haemodialysis patients who suffered thromboses in 6-mm polytetrafluoroethylene straight or loop bridge AVGs. Patients who underwent lysis or thrombectomy without angiographically documented outflow stenosis, and patients who failed lysis or thrombectomy, were excluded from the study.

Setting
The practice setting was an institution. The economic analysis was carried out in Buffalo, NY, USA.

Dates to which data relate
The effectiveness data were collected between February 1996 and February 1999. The dates for the resources used and for the charges were not reported.

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

Link between effectiveness and cost data
Both the cost and the effectiveness data were obtained retrospectively from the medical records. It was unclear whether the costing was undertaken on the same patient sample as that used in the effectiveness study.

Study sample
Power calculations were performed retrospectively, on the basis of the sample size. All haemodialysis patients who suffered AVG thromboses and who had received either SBA or TBA during the study period were analysed. There was no evidence that the initial sample study was appropriate for the clinical study question. A total of 105 AVG thromboses occurred in 63 patients. The mean age of the patients was 62.2 years and 35 were women. SBAs were performed in 48 of the patients, while TBAs were performed in 55, all of them without complications. There were two missed cases of AVG thrombosis, which may have been related to the exclusion criteria reported for the study.
population. The authors did not provide any detail of these missed cases.

**Study design**
This was a retrospective cohort study that used the medical records of a single institution. The method used to allocate the patients to each group depended on the decision of the nephrologists. Therefore, there was no randomised pre-assignment to either group. The authors did not state the duration of follow-up for each group, and they did not report the loss to follow-up.

**Analysis of effectiveness**
The clinical study was analysed on the basis of treatment completers only. Two cases of AVG thrombosis were not accounted for in the analysis, but the authors did not mention them.

The primary health outcomes used in the analysis were:

the primary patency rates at 1, 2 and 3 months after SBA and TBA;

the mean graft survival for SBA and TBA; and

the combined secondary patency rates (after performing repeat angioplasty) at 1, 3 and 5 months, including both procedures in each rate.

A life-table analysis was performed to evaluate the graft patency. The survival curves were compared using the Wilcoxon test (significance level: p<0.05).

The authors did not report evidence that the groups were comparable at analysis.

**Effectiveness results**
The primary patency rate for SBA was significantly longer than that for TBA, (p<0.025). The results were presented graphically.

The mean graft survival after SBA was 31 days, as opposed to 10 days for TBA.

The secondary patency rates were longer than the primary patency rates in the short-term. However, less than 5% of these grafts were patent at 5 months.

There was stated to have been no statistically significant difference in the secondary patency rates between both procedures.

It was stated that multiple attempts at TBA showed patency intervals that were uniformly poor.

**Clinical conclusions**
Although patients who underwent primary SBA maintained a viable graft longer than those treated with TBA, the mean patency rate was short for both procedures. Secondary angioplasty resulted in better short-term patency, but with very poor patency after 5 months. Additional TBA after multiple graft failures seemed to present the worst patency rates.

**Measure of benefits used in the economic analysis**
No summary of health benefit was used in the economic analysis. Therefore, a cost-consequences analysis was performed.

**Direct costs**
The resource quantities and the costs were not reported separately. The direct costs reported were for the total hospital and physician charges, and reimbursement for each procedure. Discounting was not carried out, but this was irrelevant as the costs were incurred over less than 2 years. The cost data were obtained from records, i.e. they were obtained from actual data. The price year was not reported.

**Statistical analysis of costs**
No statistical analysis of the costs was reported.

**Indirect Costs**
The indirect costs were not reported.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was reported.

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

**Cost results**
Medicare reimbursement for both treatments was $1,638 for TBA and $1,670 for SBA.

**Synthesis of costs and benefits**
Not applicable due to the cost-consequences approach adopted.

**Authors’ conclusions**
The authors concluded that the poor patency rates and high costs of thrombectomy followed by angioplasty (SBA) and thrombolysis followed by angioplasty (TBA) did not justify their routine use. Therefore, they should not be routinely used for salvage of thrombosed arteriovenous grafts (AVGs) with outflow stenosis. Repeated procedures for TBA should be abandoned.

**CRD COMMENTARY - Selection of comparators**
The health technologies compared were justified on the grounds that surgical thrombectomy and thrombolytic therapy are the two most frequently used methods for graft salvage.

**Validity of estimate of measure of effectiveness**
The analysis used a retrospective cohort study. It is possible that the patients were assigned to either group according to some specific characteristics. Consequently, the fact that the nephrologists referred patients to either group may have been a confounding factor that biased the results of the effectiveness analysis. Also, the study sample was not shown to be representative of the study population. Moreover, the patient groups were not shown to be comparable at analysis. No appropriate statistical analyses were undertaken to take account of the potential bias.

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of health benefit.

**Validity of estimate of costs**
The perspective from which the study was conducted was not specified clearly, but it appears to have been that of the institution. Only Medicare reimbursement for the procedure was considered in the costing. The consideration of charges limited the conclusions of the study, since charges do not show the breakdown to resources used and unit costs. The unit costs and the resource quantities were not reported separately. In addition, it was not stated specifically what charges were included for each one of the procedures. The reliability of the results is uncertain as no statistical analysis of the quantities was performed. It was unclear whether the charges were obtained from the records corresponding to the analysed setting. The method of calculating the charges per procedure was not reported and the price year was not given. These facts tend to weaken the generalisability of the results and hinder reflation exercises to other settings.

**Other issues**
The authors made appropriate comparisons of their findings with those from other studies. However, the issue of generalisability to other settings was not addressed. The authors' conclusions reflected the scope of the analysis. The authors did not report any limitations of their study. The cost and effectiveness results were reported selectively, thus reducing transparency.

**Implications of the study**
The findings of the study suggest that SBA and TBA lead to poor graft patency and high costs. The authors recommend that other modalities of graft salvage, such as new access creation or surgical thrombectomy in conjunction with either patching or bypassing the outflow stenosis, should be considered. They also highlight the need for further evaluation, in order to identify the most cost-effective and technically successful approach to be used.

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None stated.

**Bibliographic details**

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**Other publications of related interest**


Lumsden AB, MacDonald MJ, Kikeri D, et al. Prophylactic balloon angioplasty fails to prolong the patency of

**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
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