Prospective randomized comparison of surgical versus endovascular management of thrombosed dialysis access grafts

Marston W A, Criado E, Jaques P F, Mauro M A, Burnham S J, Keagy B 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
Endovascular management in the salvage of thrombosed prosthetic dialysis shunts. Grafts were accessed in two places percutaneously using the cross-wire technique. Balloon angioplasty of stenotic segments was performed as needed. Stents were used only in the central venous system when a stenosis was resistant to balloon angioplasty. Patients were routinely discharged immediately after endovascular salvage unless admission was required for another reason.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study investigated patients with thrombosed prosthetic dialysis shunts. Prosthetic shunts that were evaluated within 1 week of thrombosis were included in the study and were treated within 48 hours of diagnosis. Patients with thrombosed autogenous arteriovenous fistulae were excluded from the study. Shunts previously subjected to thrombectomy or revision more than twice or, which had initially been constructed less than 6 weeks before thrombosis, were also excluded. Patients were evaluated by both vascular surgery and interventional radiology staff and were required to be satisfactory candidates for both methods of treatment (no contrast allergy, no medical exclusion from operation).

Setting
The setting was hospital. The economic analysis was carried out in the USA.

Dates to which data relate
Effectiveness and resource use data corresponded to patients treated between January 1995 and September 1995. The price year was not explicitly specified.

Source of effectiveness data
The evidence for the final outcomes was based on a single study.

Link between effectiveness and cost data
Costing was performed on a subset of the patient sample used in the effectiveness analysis and appears to have been conducted retrospectively.
**Study sample**
Power calculations were not used to determine the sample size. The study sample consisted of a total of 115 patients who were randomly assigned to either the surgical group (n=56) with a mean (SD) age of 55.5 (6.4) years or the endovascular group (n=59) with a mean (SD) age of 56.2 (7.8) years. A total of 8 cases of shunt thrombosis were excluded in accordance with the study exclusion criteria. In the surgical group, salvage was attempted with thrombectomy alone in 22% and with thrombectomy plus graft revision in 78%. In the endovascular group, graft function was restored with mechanical (82%) or thrombolytic (18%) graft thrombectomy followed by percutaneous angioplasty.

**Study design**
The study took the form of a randomised, controlled trial, carried out in a single centre. The duration of the follow-up appears to have been one year. Regarding the proportion of patients who were lost to follow-up, it was reported that 92% of patients were followed-up for at least 6 months or until graft thrombosis. Patients who agreed to participate were randomised to receive either surgical salvage in the operating room or endovascular salvage in the interventional radiology suite. The authors attempted to treat all patients rapidly enough to eliminate the need for temporary central venous catheters. All patients were followed-up through monthly contact with their dialysis centre and review of dialysis flow rates and pressures. If recurrent thrombosis occurred, the patients were re-entered into the study if they satisfied the study exclusion criteria.

**Analysis of effectiveness**
The principle used in the analysis of effectiveness was intention to treat. The clinical outcomes were initial success rate in restoring graft function, primary graft patency rate after salvage, proportion of grafts remained functional at 6 and 12-month intervals, and complications. Subgroup analyses were performed on a subset of patients with venous anastomotic stenosis (VAS) compared with those with long-segment venous outflow stenosis or occlusion (LSS/occlusion). Graft failure was defined as recurrent thrombosis or increased dialysis pressures that prevented effective dialysis. Graft infection that required graft removal and a new access site was also considered a failure. The two study groups were comparable in terms of age, sex, and underlying clinical characteristics.

**Effectiveness results**
In 83% of the surgical group, and in 72% of the endovascular group, graft function was immediately restored, (non significant).

The post-operative graft function rate was significantly better in the surgical group, (p<0.05).

Thirty-six percent of grafts managed surgically remained functional at 6 months and 25% at 12 months.

In the endovascular group, 11% were functional at 6 months and 9% by 12 months.

Patients with long-segment venous outflow stenosis or occlusion had a significantly worse patency rate than those with venous anastomotic stenosis, (p<0.05).

Only three complications were noted in the study series, two in the surgical group and one in the endovascular group.

**Clinical conclusions**
The data demonstrate that the primary rate after graft salvage was significantly better in the surgical group than in the endovascular group.

**Measure of benefits used in the economic analysis**
No summary benefit measure was identified in the economic analysis, and only individual clinical outcomes were reported.
Direct costs
Costs were not discounted due to the short time frame of the cost analysis. A few items of resource use quantities were reported separately from the costs. Cost breakdown was only reported in general categories of hospital and professional charges. Cost analysis covered the costs of hospital and professional services (including anaesthesiology, surgery, radiology, and others). The boundary adopted in the cost analysis was that of the billed amounts, which may not reflect the actual reimbursed amounts or cost to Medicare or other providers, or actual cost to the hospital. A subset of 15 patients was randomly selected from each study group to examine the charges associated with shunt thrombectomy. The price year was not explicitly specified.

Indirect Costs
Indirect costs were not considered.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The mean (SD) charges associated with surgical shunt salvage were $8,472 ($453) (range: $6,711 - $11,430) versus $8,006 ($979) (range: $3,104 - $11,646) with the endovascular shunt salvage.

Synthesis of costs and benefits
Costs and benefits were not combined since the surgical method appears to have been the (weakly) dominant strategy (with better effectiveness outcome and equal charges).

Authors' conclusions
The authors concluded that neither surgical nor endovascular management resulted in long-term function for the majority of shunts after thrombosis. However, surgical management resulted in significantly longer primary patency in this patient population, supporting its use as the primary method of management in most patients who develop shunt thrombosis.

CRD COMMENTARY - Selection of comparators
A justification was given for the choice of the comparator, which was deemed to be the routine technique performed 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 internal validity of the effectiveness results is likely to be high owing to the randomised nature of the study design, and the intention to treat basis for the analysis. Furthermore, the two study groups were comparable in terms of age, sex, and underlying clinical features. However, no power calculations were performed to justify the sample size adopted in the study. The study sample appears to have been representative of the study population.
Validity of estimate of measure of benefit
The authors did not derive a measure of health benefit. The analysis was therefore of cost-consequences design.

Validity of estimate of costs
The validity of the cost results cannot reasonably be assured due to the following limitations: the price year was not specified; the costing was conducted retrospectively; the cost analysis was based on charge data rather than on true costs; the resource use profile and cost components incorporated in the cost analysis were not reported, as a result it is not possible to assess whether the cost analysis was comprehensive or not; the costing was not performed on the whole study sample; statistical analysis was not performed on resource use and cost data; the effects of the alternative modalities on indirect costs (productivity loss) were not addressed; the cost results may not be generalisable outside the study setting due to the lack of sensitivity analysis.

Other issues
Overall, the study conclusion appears to be justifiable given the uncertainties in the data; and despite the weakness of the cost analysis. The issue of generalisability to other settings or countries was not addressed, but appropriate comparisons were made with other studies. No comments were made regarding the issue of the degree to which the study sample was representative of the study population.

Implications of the study
The charges associated with surgical and endovascular salvage did not differ significantly in the subset of patients evaluated. The profession must continue to look for ways to reduce the cost of maintaining haemodialysis access.

A complimentary role for surgical and endovascular management of dialysis grafts may include both, with patent but failing grafts undergoing endovascular salvage and thrombosed shunts undergoing surgical salvage, but such an approach must also be carefully tested in prospective studies to validate its efficacy.

Source of funding
None stated.

Bibliographic details

PubMedID
9308583

Other publications of related interest


Indexing Status
Subject indexing assigned by NLM

MeSH
Angioplasty, Balloon economics/methods/statistics & numerical data; Arteriovenous Shunt, Surgical adverse effects economics/statistics & numerical data; Combined Modality Therapy; Costs and Cost Analysis; Female; Graft Occlusion, Vascular therapy; Humans; Male; Middle Aged; Prospective Studies; Renal Dialysis adverse effects economics/statistics & numerical data; Stents; Thrombectomy economics/methods/statistics & numerical data; Thrombosis therapy; Time Factors; Vascular Patency

AccessionNumber
21997007042

Date bibliographic record published
31/07/2001

Date abstract record published
31/07/2001