Long-term patency rates, complications and cost-effectiveness of polytetrafluoroethylene (PTFE) grafts for haemodialysis access: a prospective study that compares Impra versus Gore-tex grafts


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
Two types of polytetrafluoroethylene (PTFE) grafts used for chronic haemodialysis access were compared in patients with end-stage renal disease. The two types of PTFE grafts evaluated were Gore-tex (W L Gore and Associates, Flagstaff, AZ) and Impra (C R Bard Inc., Tempe, AZ).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The population comprised patients with end-stage renal disease undergoing chronic haemodialysis. The mean age was 64.1 years for those receiving a Gore-tex graft, and 63.2 years for those receiving an Impra graft. No further study inclusion or exclusion criteria were reported.

Setting
The setting was tertiary care. The economic study was carried out in Illinois, USA.

Dates to which data relate
The effectiveness evidence was collected between November 1993 and September 1996. The resource data were collected during the same period. The authors did not report the price year.

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

Link between effectiveness and cost data
The effectiveness and cost data were collected from the same sample of patients.

Study sample
The authors did not report the use of power calculations to determine the sample size. The method of sample selection was not described. All of the patients had end-stage renal disease requiring haemodialysis. Thus, the sample appears to have been appropriate for the study. A total of 190 PTFE grafts were implanted in 168 patients. There were 100 Gore-tex grafts and 90 Impra grafts.
Study design
The study was a single-centre, non-randomised controlled trial. The grafts were not selected in a randomised fashion, instead the selection was conducted prospectively in an alternating manner. The mean duration of follow-up was 13 months (range: 1 - 34). No patients were lost to follow-up. There was no blinding method for the assessment of the outcomes.

Analysis of effectiveness
The study was analysed on an intention to treat basis. The primary effectiveness outcome was graft patency. Primary patency was defined by the first episode of thrombosis. Secondary patency was defined as the time until the graft was abandoned.

The two groups of patients were comparable in terms of their age, gender, race, graft position, graft size and risk factors (hypertension, smoking, diabetes, coronary artery disease).

Effectiveness results
The Gore-tex grafts had a primary patency of 52% at one year and 38% at two years. No significant differences were observed with the Impra grafts, which had a primary patency of 47% at one year and 37% at two years.

The Gore-tex grafts had a secondary patency of 96% at one year and 78% at two years. Again, no significant differences were observed with the Impra grafts, which had a secondary patency of 87% at both one and two years.

Clinical conclusions
The authors concluded that there was no difference between the Gore-tex and Impra grafts in terms of the primary or secondary patency at two years.

Modelling
A life-table analysis was used to calculate the survival rates for the grafts.

Measure of benefits used in the economic analysis
A summary measure of benefit was not used in the economic analysis. The authors assumed that all outcomes were equivalent, and hence reported a cost-minimisation analysis.

Direct costs
The resource quantities and costs were not reported separately. The costs to the hospital were included in the analysis. The analysis included the cost of the graft itself, implanting the graft, and maintaining graft patency (including thrombectomy and thromectomy plus revision). The physician's charges were not included in the cost data. The authors did not report the source of the unit cost data. It was unclear whether the costs or charges were used. Discounting was not performed. The study reported average costs. The authors did not state the price year.

Statistical analysis of costs
The costs were analysed using Student's t-tests.

Indirect Costs
The indirect costs were not reported as they were irrelevant to the perspective of the study.
Currency
US dollars ($). No currency conversion rates were reported.

Sensitivity analysis
A sensitivity analysis was not reported.

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

Cost results
The mean total hospital cost for graft implantation was $3,033 for a Gore-tex graft and $3,418 for an Impra graft. There was no significant difference between the two costs, (p <0.34).

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

Authors' conclusions
The authors concluded that there was no statistical difference in cost between the Gore-tex and Impra grafts. In addition, either graft can be used for haemodialysis access, with similar outcomes expected for at least two years following implantation.

CRD COMMENTARY - Selection of comparators
The comparators were justified on the grounds that Gore-tex and Impra grafts are used widely in the USA. You should decide if these are widely used health technologies in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a non-randomised study comparing the two types of grafts, which was inappropriate for the study question. It would have been more appropriate to have conducted a randomised controlled trial. The study sample was representative of the study population, and the patient groups were shown to be comparable at analysis. Appropriate statistical analyses were undertaken to take account of potential biases. However, the study did not report a power calculation to determine the sample size. The lack of statistical difference may, therefore, have been due to an inadequate sample size rather than equivalence between the two groups.

Validity of estimate of measure of benefit
The analysis of benefits was based upon the therapeutic equivalence of the treatment alternatives. The economic analysis only therefore included the costs. It was unclear, however, whether the two groups were equivalent given the lack of power calculations to estimate the sample size. In addition, the study did not assess all the potential measures of health gain. In particular, the study did not assess the benefits of each graft from the patient’s, rather than the clinical, perspective. This would have allowed some valuation of the impact of complications arising from the grafts.

Validity of estimate of costs
The analysis included all the categories of cost relevant to the perspective adopted. However, for each category of cost, it was not possible to determine whether all the relevant costs were included in the analysis. The study did not include the indirect costs, but this was unlikely to have affected the authors’ conclusions. The costs and quantities were not reported separately. A sensitivity analysis of resources was not performed, which will limit the generalisability of the results.
The unit costs were taken from the authors’ setting, but it was unclear whether the prices or charges were used. If charges were used, this would affect the generalisability of the results. The costs were analysed statistically, and were reported to have not been statistically different. It was unclear, however, whether the two groups were actually equivalent in terms of the costs, given the lack of power calculations to estimate the sample size. A sensitivity analysis of the costs was not performed. Although, in some instances the costs were incurred over a 34-month period, discounting was not undertaken. The authors did not report the price year.

Other issues
The authors made appropriate comparisons of their findings with those from other studies. The issue of generalisability to other settings was not addressed due to the lack of a sensitivity analysis. The authors did not present their results selectively. The study considered patients with end-stage renal disease requiring haemodialysis and this was reflected in the authors’ conclusions. The authors did not report any limitations to their study.

Implications of the study
The authors suggested that either graft can be used for haemodialysis access, with similar outcomes expected for at least two years following implantation.

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