Iliac occlusions: stenting or crossover grafting? An examination of patency and cost

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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
Angioplasty using iliac stenting versus femorofemoral crossover graft for iliac artery occlusions.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients presenting to the hospital with iliac occlusion. The mean age was 67.9 years for crossover group and 61.9 years for stent group, the male female ratio was 2.52 for crossover and 1.55 for stent. The majority of patients had short-distance intermittent claudication (121), the remainder had ischemic rest pain (10) and ulcers (7). Fourteen patients were diabetic. Half of the occlusions involved the common iliac artery, with half of these also involving the external iliac artery; the remainder were confined to the external iliac artery. Patients with iliac stenosis alone were not included in this study.

Setting
The setting was secondary care, namely the departments of Surgery and Radiology, Royal Berkshire Hospital, a district hospital in Reading. The economic study was conducted in the UK.

Dates to which data relate
Effectiveness data were collected between January 1993 and December 1997. The year to which costs related was not stated and the price year was not stated.

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

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

Study sample
138 patients presenting to the hospital with iliac occlusion were considered, of whom 87 underwent crossover graft and 51 underwent stent. Power calculations related to the sample size were not reported. The patients were not randomised to the treatment groups or stratified according to the run-off vessel status. In the beginning, femorofemoral crossover grafting was the treatment of choice, but in time stenting increased in popularity, so more patients were stented.
Baseline characteristics (age and sex) were reported to allow comparisons with the study population.

**Study design**
This was a single-centre, prospective, non-randomised observational trial with concurrent controls. Duration of follow-up was 4 years. No losses to follow-up were reported.

**Analysis of effectiveness**
The analysis of effectiveness was based on intention to treat. The main health outcome used in the analysis was procedure patency assessed in all patients 2 months after the procedure and at intervals during the following years. Analysis of patency in each group was performed using Kaplan Meyer analysis. The success rate of the procedure, in terms of successful stenting or bypass, as well as complication rates was also considered. Groups were shown to be comparable at analysis in terms of mean age (67.9 years for crossover group/61.9 years for stent), with 10.5 standard deviation (SD) for the crossover graft group and 10.1 SD for the stent group.

**Effectiveness results**
Intention to treat patency following stent insertion at 6 months was 52%, compared to 100% patency after crossover grafting, (p<0.0001).

Stented arteries suffered a rapid fall in patency over the first 6 months to 78% (secondary) declining to 68% at 4 years.

In 13 cases, it was impossible to place the stent successfully.

In a further 10 stented patients, major complications occurred which were mainly thromboembolic.

15 patients underwent crossover grafting after failure to insert a stent or after stent occlusion.

No major complications occurred following crossover grafting.

**Clinical conclusions**
With only one graft occlusion at 24 months, crossover grafting appears to be a durable procedure.

**Modelling**
Analysis of patency in each group was performed using Kaplan Meyer analysis.

**Measure of benefits used in the economic analysis**
The authors did not provide a summary measure of benefits, and, as such, a cost-consequences analysis was conducted.

**Direct costs**
Direct hospital costs were considered in the analysis, namely:

- device costs, including insertion devices, packs, sterile drapes, drugs and contrast;
- theatre and angiogram suite cost, hourly rate including all staff costs and anaesthetic/recovery time; and
- cost of overnight stay.

Although not explicitly stated, it appears that costs related to the authors’ institution. For some cost components, quantities and costs were presented separately; such as mean duration of the procedure and theatre and angiogram suite costs, length of stay and overnight stay costs. Whilst the main determinant of cost, length of stay, was reported as...
median, the costs were based on the arithmetic mean of the costs incurred by each patient. Costs were not discounted. The costs of pre-intervention radiology and of outpatient follow-up were not included in the analysis, since they were the same for both groups. The price year was not stated.

Statistical analysis of costs
Statistical analysis was performed using the Breslow-Gehan-Wilcoxon test with StatView (SAS Inc).

Indirect Costs
Indirect costs were not considered.

Currency
UK pounds sterling (€).

Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
As no summary benefit measure was used, the reader is referred to the effectiveness results reported above.

Cost results
The calculated total mean cost for crossover graft was 3,072 versus 1,912 for stent (S.E.M. 201 versus 215).

The mean additional cost of those patients sustaining complications after stenting was 2,481 (S.E.M 191).

The cost advantage of stenting is lost when 48% of stents are occluded, which in this study happened within six months of the procedure.

Synthesis of costs and benefits
Costs and benefits were not combined due to the cost-consequences approach adopted in the analysis.

Authors’ conclusions
The authors stated that they recommend stenting for those patients with limited life expectancy, while patients who are younger and fitter should be offered femorofemoral crossover grafting. The also stated that their study demonstrates clearly that stenting is not as cost-effective as femorofemoral crossover grafting in unilateral iliac artery disease.

CRD COMMENTARY - Selection of comparators
The reason for the choice of iliac stent versus femorofemoral crossover graft was clear, as both angioplasty procedures were used in the authors' setting. You, as a database user, should consider if the same applies to your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a single-centre, prospective, non-randomised observational trial with concurrent controls. The lack of randomisation raises questions as to the appropriateness of the study design for the study question. The study sample seemed to be representative of the study population, with some baseline characteristics presented such as mean age, but no power calculations were reported as having been used in determining the sample size. Patient groups were shown to be comparable in their baseline characteristics; age was presented as mean with standard deviation.
Appropriate statistical analyses were conducted on the effectiveness data.

**Validity of estimate of measure of benefit**
The authors did not derive a measure of health benefit. The analysis was therefore categorised as cost-consequences only.

**Validity of estimate of costs**
All categories of costs relevant to the perspective adopted were included in the analysis, except for costs of pre-intervention radiology and of outpatient follow-up, since these were the same for both groups. For some cost components, quantities and costs were presented separately; such as mean duration of the procedure, theatre and angiogram suite costs, length of stay and overnight stay costs. Costs were not discounted. The price year was not stated.

**Other issues**
Extensive comparisons were conducted with relevant studies dealing with the same topic. The issue of generalisability of the results to other settings was not addressed. The authors do not appear to have presented their results selectively.

**Implications of the study**
The authors stated that further research is needed to enable identification of those patients who are most likely to maintain long-term patency after stenting.

**Source of funding**
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