Aortoiliac stent deployment versus surgical reconstruction: analysis of outcome 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
Stent deployment or direct surgical reconstruction for the treatment of severe aortoiliac occlusive disease.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients who had severe aortoiliac occlusive disease and who were candidates for either aortoiliac stent deployment or direct surgical reconstruction.

Setting
Hospital. The study was carried out at Loma Linda University Medical Centre, California, USA.

Dates to which data relate
Effectiveness, resource use and cost data were collected from 1 March 1992 to 31 May 1996. The price year was not reported.

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

Link between effectiveness and cost data
The costing was undertaken on the same patient sample as that used in the effectiveness analysis and was carried out prospectively alongside the effectiveness analysis.

Study sample
The study sample looked at 184 patients who received treatment for severe aortoiliac occlusive disease. 65 patients were not analysed for the following reasons: a category 1 lesion was treated (37 patients), the patient was considered to be a prohibitive surgical risk (8 patients), or an extra-anatomic bypass graft had been placed (20 patients). No power calculations were reported. 65 surgically fit patients (79 symptomatic limbs) with category 2, 3, or 4 iliac artery lesions had stent deployment and 54 patients (103 symptomatic limbs) had surgical reconstruction.

Study design
The study was a retrospective cohort carried out at a single centre. No patients were lost to follow-up. Mean patient follow-up was 22 months (range: 1-67 months).

Analysis of effectiveness
The analysis of the clinical study was based on intention to treat. The primary health outcomes studied included complications, homodynamic improvement, clinical improvement, patient survival, primary patency rate, predictors of bypass graft or stent thrombosis, and hospital length of stay. There was no significant difference between the groups with regard to demographic features or presenting symptoms (all p-values > 0.07). In the surgery group, significantly more category 4 lesions were treated, and more often the atherosclerotic disease involved the common and external iliac arteries. More patients in the stent group had single vessel tibial artery runoff (p=0.00) and more patients in the surgery group had three-vessel tibial artery runoff (p=0.03).

Effectiveness results
Incidence of procedure-related complications was similar (p=0.3) between the groups. More systemic complications occurred in the surgery group (15 versus 2, RR=5.5, p<0.01), and more vascular complications were experienced in the stent group (16 versus 3, RR=12, p<0.002).

Early homodynamic improvement, as evidenced by a significant change in ankle brachial index of the treated extremity, was noted following either procedure (mean increase, 0.4 mm Hg, p=0).

Clinical improvement, as evidenced by no symptoms and a palpable graft or femoral pulse distal to the treated iliac artery, was noted in 89% of limbs at latest follow-up.

Cumulative patient survival was not significantly different between groups (p=0.97).

Cumulative primary patency rate of bypass grafts was significantly better than stented iliac arteries at 18 months (93% versus 77%), 30 months (93% versus 68%), and 42 months (93% versus 68%), (p=0.002).

Risk factors identified by univariate analysis to be significant predictors of bypass graft or stent thrombosis included stent deployment (RR=3.7, p=0.03), female gender (RR=5.0, p=0.005), ipsilateral superficial femoral artery (SFA) occlusion (RR=3.8, p=0.01), procedure-related vascular complication (RR=6.3, p=0.002), and hypercholesterolemia (RR=4.1, p=0.01).

Multivariate logistic regression analysis identified procedure-related vascular complication (RR=9.7, p=0.002), ipsilateral SFA occlusion (RR=5.6, p=0.01), female gender (RR=4.6, p=0.03), and hypercholesterolemia (RR=5.0, p=0.02) as independent predictors of bypass graft or stent thrombosis.

Within the stent group, there was a significant linear relationship between category of treated iliac artery and ultimate risk of stented iliac artery thrombosis (p=0.01).

Cumulative primary patency of stented iliac artery occlusions was worse than stented iliac artery stenoses (p=0.0004).

A significant difference was noted in mean length of hospital stay between the groups (10 days for surgery versus 2 days for stent deployment, p=0.02)

Clinical conclusions
Treatment of severe aortoiliac occlusive disease by surgical reconstruction or stent deployment has a similar complication rate. Cumulative primary patency rate of bypass grafts is superior to stents.

Modelling
Univariate and multivariate logistic regressions were undertaken to determine the factors that independently predicted bypass graft or stent thrombosis.
Measure of benefits used in the economic analysis
No summary benefit measure was used. The following outcomes were used as measures of benefit: incidence and type of complications, primary patency rate, and predictors of bypass graft or stent thrombosis.

Direct costs
Direct costs were not discounted given the short time frame of the study (less than 1 year). Quantities and costs were not reported separately. Direct costs included costs related to the surgical or interventional radiologic procedure in addition to overheads allocated to the treating department. These costs included all labour and supplies related to delivery of the procedure and expenses of cost centres that were administrative or ancillary in nature, as well as expenses such as utilities. The quantity/cost boundary adopted was that of the hospital. The estimation of quantities and costs was based on actual data. Cost estimates were collected from Loma Linda University Medical Centre. Professional fees were based on current Medicare reimbursement in the local region. The price year was not reported.

Statistical analysis of costs
Not reported.

Indirect Costs
Not included.

Currency
US dollars ($).

Sensitivity analysis
Not reported.

Estimated benefits used in the economic analysis
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Cost results
Mean total hospital cost between the two groups was essentially the same per limb treated ($10,585 for surgical reconstruction versus $9,161 for stent deployment, p=0.24).

Synthesis of costs and benefits
Costs and benefits were not combined into a cost-effectiveness ratio.

**Authors’ conclusions**
Treatment of severe aortoiliac occlusive disease by surgical reconstruction or stent deployment has a similar complication rate. However, cumulative primary patency rate of bypass grafts is superior to stents. Mean hospital cost per limb treated is essentially equal. Therefore, surgical revascularisation has greater value.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparator was clear. You, as a user of the database, should verify whether these health technologies are relevant to your setting.

**Validity of estimate of measure of benefit**
Relevant measures of benefit were used although the study had a relatively small sample size. The analysis may be subject to selection bias because the decision for treatment was based on joint consultation between vascular surgeons and interventional radiology staff. It was not clear how the groups could be compared when most bypass grafts encompassed both limbs, whereas most primary stents treated only one.

**Validity of estimate of costs**
Only direct costs were included. Indirect costs related to lost productivity were not considered. Continued quality improvements in terms of post-operative recovery time and early discharge are likely to decrease hospital costs. Costs for management of late complications of surgery were not included. In order to be inclusive, the cost of any vascular treatment may need to be calculated over 2 or 3 years. Costs were derived from a local source, and are unlikely to be generalisable to other settings as no sensitivity analysis was performed on costs. The authors reported costs on the basis of cost per limb rather than cost per patient. This method of calculation may tend to skew cost data in favour of bypass grafts rather than angioplasty.

**Other issues**
Comparisons with other relevant studies were not made and the generalisability of the results to other settings or countries was not discussed. However, the authors do not appear to have presented their results selectively. The study enrolled patients with severe aortoiliac occlusive disease and this was reflected in the authors’ conclusions.

**Implications of the study**
The gold standard for cost-effective treatment of severe aortoiliac occlusive disease remains direct surgical reconstruction. Future studies should compare direct surgical, indirect surgical, and non-operative endovascular treatment strategies.

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