In-hospital costs of self-expanding nitinol stent implantation versus balloon angioplasty in the femoropopliteal artery (The VascuCoil Trial)

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 placement was compared with percutaneous transluminal angioplasty (PTA) in patients with peripheral arterial disease (PAD).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patient candidates for PTA, with symptomatic leg ischaemia, requiring treatment of the superficial femoral/popliteal vessel with an occluded lesion length \( \leq 12 \) cm and located proximal to the bifurcation of the tibial artery.

Setting
The setting was secondary care. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness and resource use data were collected between May 1997 and December 1999. The costs were expressed in 2002 prices.

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

Link between effectiveness and cost data
The resource use data were collected prospectively for the same sample as that used for the effectiveness data.

Study sample
The authors referred to the study of Ansel et al. (2002) for detailed information on the study sample (see 'Other Publications of Related Interest' below for bibliographic details). The final sample size comprised 266 patients randomised to intracoil stent implantation (n=135) and PTA alone (n=131). The mean age was 66.8 (+/- 10.6) years in the intracoil stent group and 68.1 (+/- 10.2) years in the PTA group. Approximately, two thirds of the patients in both groups were men (67.4% versus 63.4%). The proportion of patients with occlusive PAD was 22.7% in the intracoil stent group and 16.8% in the PTA group.
Study design
The study was a randomised controlled trial that was conducted in multiple centres. The patients seem to have been followed for 9 months after the intervention. Twenty centres took part in the study. No loss to follow-up was reported. The reader is referred to Ansel et al. 2002 for more information on the study design.

Analysis of effectiveness
The primary health outcome was a composite end point defined as death within 30 days, peri-procedural Q wave myocardial infarction, or clinically driven target lesion revascularisation within 9 months. The secondary health outcomes were other complications such as amputation, major bleeding complications, abrupt closure, renal failure and major vascular complications. The investigators conducted an intention to treat analysis. The two treatment groups had similar baseline demographic, clinical and angiographic characteristics.

Effectiveness results
There were no significant differences in the primary health outcome (16.3% versus 16.0%; p=0.949) or in the incidence of any other complications between the intracoil stent and the PTA groups.

The effectiveness results were presented in full in the main clinical paper (Ansel et al. 2002).

Clinical conclusions
The results of the trial suggested similar outcomes between the intracoil stent and the PTA groups.

Measure of benefits used in the economic analysis
As the effectiveness results suggested that both techniques had similar outcomes, the analysis should be considered a cost-minimisation analysis.

Direct costs
The direct costs related to health care were included in the analysis. All the cost categories relevant to the perspective adopted seem to have been included. In-hospital, vascular and cardiac catheterisation laboratory (including overhead and depreciation), staff and other hospital costs were identified as important resources categories for the economic evaluation. Detailed information was provided on how each category was derived and computed. Investigators used well-known bottom-up and top-down techniques to derive the appropriate costs. Hospital charges and cost-to-charge ratios were used to derive ancillary costs. The costs and resource use were reported separately. The hospital unit costs were taken from the finance department at the participating centres. The unit costs were obtained from sources such as the Medicare Fee Schedule (staff costs) and the manufacturer's sales price (stent costs). All costs were expressed in 2002 prices. Discounting was not needed as the time horizon was 9 months.

Statistical analysis of costs
The costs were treated stochastically, i.e. measures of uncertainty were associated with the point estimates. A non-parametric Wilcoxon sum-rank test was used to compare resource use and costs between the two groups. The analysis was conducted on an intention to treat basis.

Indirect Costs
The indirect costs were not included in the analysis.

Currency
US dollars ($).
Sensitivity analysis
As sample data were available, the sensitivity analysis was handled through hypothesis testing. No further sensitivity analysis was described in the text.

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

Cost results
The total mean (+/- standard deviation) costs were $8,435 (+/- 2,664) in the intracoil stent group and $4,980 (+/- 2,808) in the PTA group, (p<0.01).

The incremental costs, which were approximately $3,500, favoured the PTA arm.

The cost-difference was mainly due to the initial procedural costs ($5,484 +/- 1,910 for intracoil stent versus $2,367 +/- 1,061 for PTA). The hospital length of stay and the ancillary hospital costs were similar in the two groups.

Synthesis of costs and benefits
The costs and effects were not combined, as the authors conducted a cost-minimisation study.

Authors’ conclusions
The non significant difference in outcome between the two groups at 9 months' follow-up, and the higher initial costs of the intracoil stent, suggested that for patients with moderately long stenoses of the femoropopliteal artery, percutaneous transluminal angioplasty (PTA) is preferred on economic grounds to routine stent implantation.

CRD COMMENTARY - Selection of comparators
The selection of the comparators was clear and justified on clinical grounds. The optimal strategy for femoropopliteal arterial disease is uncertain and the standard practice of PTA must be compared with new alternatives such as intracoil stent placement. The comparator seems to have represented current practice in the authors’ settings. You should consider whether the comparator represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The measure of primary health outcome was defined as death within 30 days, peri-procedural Q wave myocardial infarction, or clinically driven target lesion revascularisation within 9 months. This would seem to be a widely used outcome in the area. The study appears to have been a well-conducted randomised controlled trial. The study sample, although relatively small, provided some evidence on this controversial topic. The analysis of effectiveness was based on intention to treat. However, the number lost to follow-up was no described. The patient groups were shown to be comparable at baseline. The authors referred to the main clinical paper for a complete presentation of the effectiveness results (Ansel et al. 2002) and the reader is strongly recommended to study this reference.

Validity of estimate of measure of benefit
As both techniques showed similar outcomes between the groups, the analysis was considered to be a cost-minimisation analysis. Please see the comments in the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs
All the categories relevant to direct health care cost perspective were included in the analysis. However, the authors did not mention whether readmissions for related events were also considered. The investigators argued that the higher
costs of stent placement are unlikely to be offset by follow-up costs, as both groups showed similar outcomes. Therefore, it is unlikely that the omission would have changed the results of this study. For some resource use categories the authors used charges to proxy costs. Resource and costs were reported separately, as suggested by standard guidelines for reporting economic evaluations. The sources of the unit costs were clear. Discounting was not an issue as the time horizon was 9 months. The price year was reported, which will aid any future inflation exercises.

Other issues
The authors made appropriate comparisons of their results with other studies. They also acknowledged that the generalisability of the results to other self-expanding stent designs is unknown, and that the sample size was small. The authors presented the results in a clear and understandable fashion.

Implications of the study
The results of this study suggested that for patients with moderately long stenoses of the femoropopliteal artery, a strategy of initial PTA is preferred on economic grounds to routine stent implantation. However, further research is needed to better define the short- and long-term costs associated with alternative stent designs and novel therapeutic alternatives.

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Other publications of related interest


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MeSH
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AccessionNumber