Iliac arterial occlusive disease: cost-effectiveness analysis of stent placement versus percutaneous transluminal angioplasty

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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
Using primary stent placement, percutaneous transluminal angioplasty (PTA), and PTA with selective stent placement in the treatment of patients with intermittent claudication due to an iliac arterial stenosis.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
Patients with intermittent claudication or critical ischaemia due to an iliac arterial stenosis.

Setting
Hospital. The economic study was carried out in the Netherlands.

Dates to which data relate
The effectiveness data were partly derived from a clinical trial beginning in November 1993 for a follow-up period of 2 years (mean 9.3 months). Some effectiveness data were obtained from a meta-analysis published in 1997, containing studies published after 1990 and 3 reports published between 1988 and 1992. The resource data were related to the 1993 clinical trial. The fiscal year was 1995.

Source of effectiveness data
Effectiveness data were derived from a single study, a meta-analysis, three reports and assumptions made by the authors.

Link between effectiveness and cost data
The costing was performed on the same patient sample (Dutch Iliac Stent Trial (DIST)) as that used in the clinical analysis.

Study sample
In the primary study no power calculations were reported. The primary stent group was randomly allocated 143 patients and 136 patients were randomly assigned to the group using PTA with selected stent placement.
Study design
The DIST trial was a randomised controlled trial, carried out in the Netherlands. The duration of the follow-up was up to 2 years with a mean of 9.3 months. The loss to follow up was 8% in the primary stent group and 10% in the PTA with selective stent replacement group.

Analysis of effectiveness
The principle (intention to treat or treatment completers only) used in the analysis of effectiveness was not specified. The health outcomes were patency rate, complication rate, ankle-brachial index at rest, ankle-brachial index after exercise, walking distance, and quality-of-life. The groups were shown to have comparable baseline characteristics.

Effectiveness results
The primary stent group had a 2-year cumulative patency rate of 71% versus 70% for the selective group, (p=0.09). The complication rate was 4% in the primary group versus 7% in the selective group (95% CI: -2% to 9%). The ankle-brachial index at rest, ankle-brachial index after exercise, and walking distance (metres) for the primary group changed from 0.78, 0.65, and 211m before treatment to 0.94, 0.79, and 245m, respectively, after treatment. The corresponding values for the selective group changed from 0.77, 0.63, 226m before treatment to 0.93, 0.83, 257m, respectively, after treatment. The quality of life for the primary group, measured using the standard gamble method, changed from 0.89 (SD, 0.17) before treatment to 0.91 (SD, 0.15) after treatment. The corresponding value for the selective group changed from 0.89 (SD, 0.14) before treatment to 0.92 (SD, 0.12) after treatment.

Clinical conclusions
The results of the clinical trial established the equivalent efficacy of the alternative health technologies in terms of patency rate, complication rate, clinical outcomes and quality-of-life.

Modelling
A decision model was used to evaluate the cost-effectiveness of the six strategies considered in the study.

Outcomes assessed in the review
The review assessed the following outcomes:

- annual excess mortality rate due to peripheral arterial occlusive disease for an ankle-brachial pressure index greater than 0.3 and equal or less than 0.30,
- procedural mortality rate,
- complication rate,
- proportion needing stent placement in selective placement strategy,
- initial technical success rate for stent placement for stenoses and for occlusions,
- PTA for stenoses and/or occlusions,
- long-term patency after PTA for claudication and a stenosis, including technical failures (immediate, 1 year, 2 year, 3 year, and 4 year),
- relative risk for long-term failure of patency primary versus selective stent placement and stent versus PTA and critical ischaemia versus claudication.

Study designs and other criteria for inclusion in the review
Cohort studies and three reports.

**Sources searched to identify primary studies**
Not reported.

**Criteria used to ensure the validity of primary studies**
Not reported.

**Methods used to judge relevance and validity, and for extracting data**
Not reported.

**Number of primary studies included**
The meta-analysis contained 14 studies, and three reports.

**Methods of combining primary studies**
Not reported.

**Investigation of differences between primary studies**
Not reported.

**Results of the review**
Annual excess mortality rate due to peripheral arterial occlusive disease for ankle-brachial pressure index greater than 0.30 was 0.02, and equal or less than 0.30 was 0.12. Procedural mortality rate was 0.01 (range: 0.00 - 0.03), complication rate was 0.05 (range: 0.02 - 0.07), proportion needing stent placement in selective placement strategy was 0.43 (range: 0.10 - 0.90), initial technical success rate for stent placement for stenoses was 1.0, and/or occlusions was 0.80; PTA for stenoses was 0.96, and/or occlusions was 0.80; long-term patency after PTA for claudication and a stenosis, including technical failures (immediate, 0.91, 1 year, 0.74, 2 year, 0.66, 3 year, 0.61, and 4 year, 0.58), relative risk for long-term failure of patency primary versus selective stent placement was 1.0, and stent versus PTA was 0.61 (range: 0.49 - 0.75), and critical ischaemia versus claudication was 1.54 (range: 1.12 - 2.11).

**Methods used to derive estimates of effectiveness**
Effectiveness estimates were also based on assumptions made by the authors.

**Estimates of effectiveness and key assumptions**
The mortality and complication rates were assumed to be the same for stent placement and PTA. It was assumed that patients with and without complications had the same quality of life.

**Measure of benefits used in the economic analysis**
The quality of life score for successful treatment and after failure was reported. The final benefit measure was quality-adjusted life years (QALYs).

**Direct costs**
Costs were discounted at a discount rate of 3%. Quantities were not reported separately from the costs. The cost items were reported separately. The cost analysis covered the costs of radiology department (personnel, materials, equipment,
and room), additional hospital costs (room and board and other costs, complications), and travel costs of patient. The costings for 16 procedures were performed based on a time-and-motion study and cost accounting. The source of cost data was the study hospital. The date to which the price data referred was 1995. The costs of follow-up general medical care were calculated but omitted from the analysis due to the equivalency of the considered strategies in terms of life expectancy.

**Statistical analysis of costs**
The confidence intervals for incremental costs were reported.

**Indirect Costs**
Costs were discounted at a discount rate of 3%. Quantities were not reported separately from the costs. The cost items were reported separately. The cost analysis covered the costs of time. Productivity loss costs due to morbidity were assumed to be included in the QALY estimate. Due to the majority of the patients included in the analysis being retired, the friction costs of lost opportunity were deemed negligible. 1995 price data were used.

**Currency**
Dutch guilders (Dfl). A conversion to US dollars ($) was carried out at the mean exchange rate in 1995 ($1= Dfl1.61).

**Sensitivity analysis**
One-way sensitivity analyses were performed on almost all elements of the model. Two two-way sensitivity analyses were performed on the relative risk of long-term failure after stent compared to PTA versus proportion of patients requiring stent placement after PTA, and the cost of a stent.

**Estimated benefits used in the economic analysis**
The quality of life score for successful treatment was 0.82 (0.69-0.9), and after failure was 0.70 (0.43-0.88).

The QALYs for the six strategies were:

- no revascularization, 10.30,
- PTA followed by no revascularization, 11.03,
- PTA with selective stent replacement followed by no revascularization, 11.29,
- PTA and repeated PTA, 11.36,
- PTA followed by PTA with selective stent replacement, 11.47,
- initial and repeated PTA with selective stent replacement, 11.61,
- primary stent placement followed by PTA with selective stent replacement, 11.61.

Benefits were discounted at 3%.

**Cost results**
The average (SD) total cost of primary stent placement was $3,990 (842), percutaneous transluminal angioplasty (PTA) was $2,343 (834), and PTA with selective stent placement was $3,033 (837).

The average total cost for the six strategies was:
no revascularization, $3,368

PTA followed by no revascularization, $5,868.

PTA with selective stent replacement followed by no revascularization, $6,573.

PTA and repeated PTA,$7,145,

PTA followed by PTA with selective stent replacement, $7,504,

initial and repeated PTA with selective stent replacement, $7,806

primary stent placement followed by PTA with selective stent replacement), $8,763.

Synthesis of costs and benefits
An incremental cost-utility ratio was calculated as a synthesis of costs and benefits. PTA with selective stent replacement followed by no revascularization had a ratio of $4,073 per QALY gained. The corresponding value for the initial and repeated PTA with selective stent replacement was $4,519. The rest of the strategies were dominated. The sensitivity analysis established the robustness of the results to change in the baseline values.

Authors' conclusions
PTA with selective stent placement is a cost-effective treatment strategy compared with primary stent replacement or PTA alone in the treatment of intermittent claudication caused by an iliac arterial stenosis.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator is clear.

Validity of estimate of measure of benefit
The estimates of benefit were obtained from a randomised study and a review of the literature, however the latter seems not to have been systematic.

Validity of estimate of costs
Resource utilisation was not reported separately from the costs. Adequate details of methods of cost estimation were given. As acknowledged by the authors, the cost analysis was not comprehensive.

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