Coronary angioplasty versus medical therapy for angina: health service costs based on the second Randomised Intervention Treatment of Angina (RITA-2) 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
Percutaneous transluminal coronary angioplasty (PTCA) was compared with an initial strategy of conservative medical therapy.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population included patients with arteriographically proven coronary artery disease. This appears to have been the target population. Patients were recruited if their cardiologist thought that either medical therapy or PTCA treatment were acceptable forms of treatment. Patients were excluded if they had prior myocardial revascularisation, had left main stem disease, had haemodynamically significant valve disease, or a life-threatening non-cardiac disease that was likely to have an impact on survival.

Setting
The setting was secondary care, in the UK and Ireland. The economic study was carried out in the UK.

Dates to which data relate
The cost information was collected from data obtained in 1998 to 1999. The effectiveness data were collected from the RITA-2 trial, which started recruitment in 1992. The end date of the trial was unclear, but it appears to have been around 1998-99. The patients were followed-up over a 3-year period.

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

Link between effectiveness and cost data
The costing was carried out prospectively and appears to have been undertaken on the same patient sample as that used in the effectiveness study.

Study sample
Full details of the design of the RITA-2 trial were provided associated publication (see Other Publications of Related Interest). This paper did not state whether the sample size was determined in the planning stage of the study. The study
did not provide details of the sample selection. No patients appear to have refused to participate in the study, nor did any appear to have been excluded from the study. There were 504 patients randomised to receive PTCA and 514 randomised to receive medical therapy.

**Study design**

This was a randomised controlled trial. The study was multi-centred, involving 20 centres. The methods of randomisation were not reported in this study. Follow-up was for 3 years, with data being collected after 3 months, 6 months and then annually.

For patients in the PTCA group, there was 100% data completeness for the randomised treatment, 99% for subsequent events, 98% for days in hospital, 98% for outpatient and general practitioner (GP) visits and 98% for anti-anginal medication.

For patients in the medical therapy group, there was 100% data completeness for the randomised treatment, 99% for subsequent events, 97% for days in hospital, 97% for outpatient and GP visits, and 99% for anti-anginal medication.

**Analysis of effectiveness**

The primary health outcomes used were the number of deaths and the number of myocardial infarctions. Other outcomes recorded were the number of subsequent procedures and the number of days on anti-anginal medication. It was unclear whether the basis of the analysis was intention to treat or treatment completers only. It would appear that the groups were comparable at analysis.

**Effectiveness results**

After 3 years there had been 14 deaths in the PTCA group and 9 in the medical therapy group, and 7.3% of patients in the PTCA group reached the end point (defined as death or myocardial infarction) versus 4.1% in the medical therapy group, (p=0.025).

After 1 year, 17% of patients in the PTCA group had Grade 2 angina or worse, compared with 27.4% in the medical group (difference of 10.4%; p<0.001). By year 3, 19.5% of patients in the PTCA group had Grade 2 angina or worse, compared with 21.5% in the medical group, (difference of 2.0%).

Of the patients randomised to PTCA, 93% received PTCA.

Of the patients initially randomised to medical therapy, 18.1% underwent a subsequent coronary arteriogram, 19.8% underwent a subsequent PTCA, and 7.2% underwent a subsequent coronary artery bypass graft (CABG).

Of the patients initially randomised to PTCA, 25.9% underwent a subsequent coronary arteriogram, 12.3% underwent a subsequent PTCA, and 7.4% underwent a subsequent CABG.

There was higher use of anti-anginal medication (beta-blockers, long-acting nitrates and calcium antagonists) in patients initially randomised to medical therapy. On average, a higher number of inpatient days was used in the PTCA group. Outpatient visits were similar in the two groups.

**Clinical conclusions**

In patients with coronary artery disease considered suitable for either PTCA or medical care, early intervention with PTCA was associated with greater symptomatic improvement, especially in patients with more severe angina. There was a small excess hazard associated with PTCA, owing to procedure-related complications.

**Measure of benefits used in the economic analysis**

The authors did not derive a summary measure of health benefit. In effect, a cost-consequences analysis was performed.
Direct costs
The direct costs of the health service provider were included in the study. The costs from five centres (two in Greater London, one in the Midlands and two in Northern England) were included. These were for the coronary arteriograms, PTCA and CABG. These covered the unit costs of the medical and nursing staff, the standard procedure-related drugs and anaesthetics, equipment, consumables and relevant overheads. The hospitals provided details concerning the acquisition costs of guide wires, guiding catheters, balloons and stents. They also provided the average cost per day in a general cardiac ward, coronary care unit and intensive therapy unit, which included all relevant overheads and staff costs. Hospitals provided costs of outpatient visits for cardiac reasons.

In the base case, the hospital costs were taken to be the average of the five hospitals. The costs of GP and district nurse contact were based on published estimates. Drug costs were included and were obtained from the British National Formulary. In order that the drug costing was nationally representative, details of the pricing and prescribing data were used alongside the trial data. This was obtained from the Prescription Pricing Authority (PPA). PPA data and trial data were combined to give a cost per mg for each drug. The resource use and quantities were not reported separately. Discounting was undertaken at a rate of 6%. The price year appears to have been 1998-99.

Statistical analysis of costs
Descriptive statistics, in the form of mean values and ranges, were provided.

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

Currency
UK pounds (£).

Sensitivity analysis
A sub-group analysis was undertaken. The mean costs per patient were increased with severity for both groups.

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

Cost results
The procedure cost was 1,761 for the PTCA group and 0 for the medical group. The hospital stay costs were 1,032 for the PTCA group and 0 for the medical group. This gave a total cost of 2,793 for the PTCA group and 0 for the medical group (difference +2,793, 95% confidence interval, CI: 2,625 - 2,995).

The cost of a subsequent PTCA was 269 for the PTCA group and 421 for the medical group. A subsequent CABG cost 337 (PTCA group) and 315 (medical group), respectively, and a subsequent coronary angiogram cost 236 (PTCA group) and 145 (medical group). This gave a total cost of 842 for the PTCA group and 881 for the medical group (difference -38, 95% CI: -282 - +165).

The cost of days in a general ward subsequent to randomised treatment was 728 for the PTCA group and 759 for the medical group. The costs of days in the intensive therapy unit were 133 (PTCA group) and 201 (medical group), respectively, while the costs of days in the cardiac care unit were 702 (PTCA group) and 574 (medical group). The total cost of the days in hospital was 1,564 for the PTCA group and 1,534 for the medical group (difference +30, 95% CI: -418 - +463).

The costs of the outpatient visits were 241 for the PTCA group and 230 for the medical group (difference +11, 95%
The costs of the all-cardiac medication were 639 for the PTCA group and 732 for the medical group (difference -93, 95% CI: -164 - -15).

The costs of the community-based resources were 213 for the PTCA group and 231 for the medical group (difference -18, 95% CI: -41 - +1).

The total costs were 6,299 for the PTCA group and 3,613 for the medical group (difference +2,685, 95% CI: 2,074 - 3,322).

When the costs were left undiscounted, the mean total cost-difference was reduced from 2,685 to 2,680. The mean differential cost was reduced to 2,674 if the cost of inpatient stays and outpatient visits for non-cardiac reasons were excluded. Using the specific unit costs for each hospital gave an average unit cost of 6,298 for the PTCA group and 3,613 for the medical therapy group.

**Synthesis of costs and benefits**
The costs and benefits were not synthesised.

**Authors' conclusions**
The cost of an initial strategy of percutaneous transluminal coronary angioplasty (PTCA) exceeded that of a strategy of medical therapy by 74% over 3 years. The authors therefore suggested that, compared with medical therapy, PTCA had a greater likelihood of being cost-effective in patient sub-groups with more severe symptoms, assuming differential rates of death and myocardial infarction do not change with symptom severity.

**CRD COMMENTARY - Selection of comparators**
A justification was given for the choice of the comparator. The authors considered that, given that there are few published studies that compare PTCA and medical therapy, a study comparing the two would help inform decisions. You should decide if this is a widely used health technology in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis was based on a randomised controlled trial, which was appropriate for the study question. The study sample was representative of the study population. The patient groups were shown to have been comparable at analysis.

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of health benefit and the analysis was, in effect, a cost-consequences study. The reader is therefore referred to the comments in the 'Validity of estimate of measure of benefit' field (above). To allow for meaningful comparison in other disease areas, quality-adjusted life-years should have been used as the measure of health benefit.

**Validity of estimate of costs**
All the categories of cost relevant to the perspective adopted were included in the analysis. The costs and the quantities were not reported separately. A statistical analysis of the quantities and prices was performed.

**Other issues**
The authors made appropriate comparisons of their findings with those from other studies. The issue of generalisability to other settings was addressed. The authors do not appear to have presented their results selectively. The authors’ conclusions were based on the study sample (patients who their cardiologist believed to be acceptable for both medical
therapy or PTCA) and the conclusions were therefore applied to this group.

The authors reported a number of further limitations to their study. First, since the RITA-2 trial was conducted, the number of coronary stents used in the PTCA procedure has increased. The stent rate in RITA-2 was 9.3% in randomised PTCA and 21.9% in non-randomised PTCA, which reflected practice in 1991-96. This is compared to a UK average stent rate of about 70% in 1998. If a higher rate of stents had been used in the RITA-2 trial, there might have been lower rates of repeat PTCA or CABG in patients who were randomised to PTCA. The effect this would have had on the costs is difficult to determine. Second, there might have been difference in the data collection methods used between the centres, which might have affected the generalisability of the results to different settings.

**Implications of the study**
The authors recommended that a full cost-effectiveness analysis be carried out to determine the overall value for money of the two strategies.

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**Other publications of related interest**

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