Long-term results of RITA-1 trial: clinical and cost comparisons of coronary angioplasty and coronary-artery bypass grafting


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
The use of percutaneous transluminal coronary angioplasty (PTCA) and coronary artery bypass grafting (CABG) in the treatment of patients with coronary heart disease (CHD).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised:

patients with arteriographic evidence of coronary artery disease, where myocardial revascularisation was considered appropriate on clinical grounds;

patients with stable or unstable angina, impaired left-ventricular function or recent myocardial infarction; and

patients where either treatment method was agreed to achieve equivalent revascularisation.

The study excluded patients with more than three vessels requiring treatment, prior myocardial revascularisation, left main-stem disease, haemodynamically significant valve disease, or noncardiac disease likely to limit long-term prognosis.

Setting
The setting was secondary care. The study was carried out in the United Kingdom.

Dates to which data relate
The effectiveness and resource use data were collected between November 1991 and November 1996. The price year was 1997.

Source of effectiveness data
The evidence for the final outcomes was derived from a single study.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness study.
Study sample
The study did not report any power calculations to determine the sample size. Around 43,000 patients had coronary arteriography, of whom 22,800 required myocardial revascularisation. From the 4,800 patients judged to be eligible, 1,011 were randomly assigned to either the PTCA group (n=510) or the CABG group (n=501). Seventeen of the patients assigned PTCA did not receive the treatment and 11 patients assigned CABG failed to receive the treatment. The authors estimated that the results of the study would be relevant to around 21% of patients undergoing surgical or percutaneous revascularisation procedures.

Study design
The study was a multicentre, randomised controlled trial. Sixteen centres in the UK were involved in the trial. The method of randomisation was not stated. The median duration of follow-up was 6.5 years (range: 5.0 - 8.7) and 11 (3%) patients (5 PTCA and 6 CABG) were lost to follow-up. The assessors of the patients' outcomes were blinded to the treatment assignment.

Analysis of effectiveness
The data were analysed on an intention to treat basis. The primary end point was the combined 5-year rate of death or definite nonfatal myocardial infarction. The secondary outcomes were the need for reintervention, the prevalence of angina within each group throughout the follow-up, and the results from the Treadmill exercise test. The study reported that both treatment groups were shown to be comparable in terms of their baseline characteristics, however, the data were not reported in this paper.

Effectiveness results
Thirty-nine (7.6%) patients in the PTCA group and 45 (9%) in the CABG group died during follow-up, (p=0.51).

Fifty-five (10.8%) patients in the PTCA group and 37 (7.4%) in the CABG group suffered a nonfatal myocardial infarction during follow-up, (p=0.08).

The 5-year cumulative rate of death or definitive nonfatal myocardial infarction was 14.1% in the PTCA group and 11.1% in the CABG group. The difference was not statistically significant (95% confidence interval, CI: -1.0 - 7.1).

In terms of reintervention, 26% of the patients assigned PTCA subsequently also had CABG and a further 19% required non-randomised PTCA. Nine per cent of the patients assigned CABG also had PTCA and a further 3% required a second CABG.

Among the patients assigned PTCA, the patients with multivessel disease had a higher rate of subsequent CABG (31%) than those with single-vessel disease (21%), (p=0.01).

The trial showed a substantial difference in the repeat intervention rates between the two treatment groups. Throughout follow-up, compared with the CABG group, there was a persistent excess of angina in the PTCA group. The total exercise time did not differ significantly between the two groups.

Clinical conclusions
Both strategies resulted in substantial improvement in angina, but CABG was slightly more effective, particularly in the early years of follow up. There was no significant treatment difference in deaths alone, and the mortality risk in each treatment group was fairly constant throughout follow-up. There was a persistent excess of angina in the PTCA group in comparison with the CABG group. For the treadmill exercise test, the total exercise time did not differ significantly between the treatment groups at any of the annual follow-up visits.

Measure of benefits used in the economic analysis
No measure of benefit was used in the economic analysis. In effect, a cost-consequences analysis was performed.
Direct costs
The study perspective was not stated, but the direct costs consisted of health service costs only. These included the initial procedural costs, subsequent procedural costs, other inpatient care costs and medication costs. The costs were discounted at 6% per year and were incurred during 5 years. The quantities and unit costs were not reported separately. However, unit costs were reported in an earlier report. The resource use items were recorded prospectively in the trial. The costs and resource use were estimated from actual data. The unit costs were taken from a London centre, while another centre was used to value resource use. The price year was 1997.

Statistical analysis of costs
The data were treated stochastically. Means, standard deviations (SDs) and 95% CIs were provided for each estimate. Statistical tests of significance and CIs were used, but the study did not clearly state which tests were used in the analysis of the costs.

Indirect Costs
No indirect costs were included in the analysis.

Currency
UK pounds sterling (€).

Sensitivity analysis
No sensitivity analysis was performed.

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

Cost results
The mean total 5-year cost was 8,842 (SD=7,516) in the PTCA group and 9,268 (SD=5,384) in the CABG group.

The mean total 5-year cost treatment difference (CABG minus PTCA) was 426 (95% CI: -383 - 1,235). This was not statistically significant, (p=0.30).

Synthesis of costs and benefits
The costs and benefits were not combined as a cost-consequences analysis was undertaken.

Authors’ conclusions
Percutaneous transluminal coronary angioplasty (PTCA) and coronary artery bypass grafting (CABG) led to similar long-term results of survival and avoidance of myocardial infarction, and to similar long-term health care costs. The authors also stated that the choice of approach rests on weighting the more invasive nature of CABG against the greater risk of recurrent angina and reintervention over many years after PTCA.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used. PTCA and CABG are both effective intervention strategies for patients with CHD. It was not stated if these were the only relevant alternatives. You should decide if this is a widely used health technology in your own setting.
Validity of estimate of measure of effectiveness
The analysis used a randomised controlled trial, which was appropriate for the study question because it is considered the ‘gold’ standard study design. The method of randomisation was described in an earlier report, so it is not possible, from this paper, to evaluate the potential for selection bias. The study sample was representative of around 21% of the study population and the patient groups were stated to be comparable at analysis. The data were analysed on an intention to treat basis. Appropriate statistical analyses were undertaken to compare the intervention and control groups, to demonstrate that the differences were statistically significant, and to take uncertainty in the estimates into consideration.

Validity of estimate of measure of benefit
No summary health benefit was used so, in effect, a cost-consequences analysis was performed.

Validity of estimate of costs
The study perspective was not stated, but the costs included only the health care costs related to the interventions and the follow-up of the patients. The costs and the quantities were reported separately, which will enhance the generalisability to other settings. A statistical analysis of the quantities and prices was performed. It was not reported whether a cost-to-charge mechanism was used. However, it can be inferred from the sources used that such a mechanism was not applied. Resource use was derived from actual trial data, which is helpful as it allows for the dependence between costs and outcomes. The costs were appropriately discounted at an annual rate of 6%. The price year was reported, which will aid reflation exercises.

Other issues
The authors made appropriate comparisons of their findings with those from other studies and found their results to be consistent with other clinical trials. The authors addressed the issue of generalisability to other settings by pointing out that the results of the study would be relevant to the sub-group of patients clinically and angiographically suitable for either intervention. The authors do not appear to have presented their results selectively. In addition, they reported a further limitation to their study. The latest surgical and pharmaceutical techniques were not analysed in the study, because they were not so widespread at recruitment as they were at the time of analysis.

Implications of the study
The authors stated that further trials of optimum interventional and surgical strategies are needed. Until the results of such trials are available, the authors recommend that clinical practice be based on the long-term results of RITA-1 and other trials of PTCA versus CABG.

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