Balloon angioplasty versus bypass grafting in the era of coronary stenting

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 either percutaneous transluminal coronary angioplasty plus stenting (PTCA+S) or coronary artery bypass grafting (CABG) as vascularisation processes for patients with multivessel coronary artery disease (MVCAD).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with MVCAD (as defined by the Canadian Cardiovascular Society), unstable angina pectoris class IV, or silent ischaemia, who were eligible for PTCA+S or CABG, and had at least two lesions and de novo lesions.

Patients were excluded if they had undergone PTCA+S or CABG, had comorbid non-cardiac disease likely to limit long-term prognosis, overt congestive heart failure, congenital heart disease, or acute or chronic renal failure. Also excluded were patients with a need for comorbid major surgery, those who had suffered a transmural myocardial infarction (MI) in the week before the intervention, and those with a history of stroke.

Setting
The setting was a hospital. The economic study was performed in Jerusalem, Israel.

Dates to which data relate
The effectiveness and cost data related to 1997 to 1998. The price year was 1999.

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

Link between effectiveness and cost data
The costing was performed prospectively on the same sample population as that used for the effectiveness analysis.

Study sample
No power calculations to assure a certain power were performed in the planning phase of the study. Patients who were eligible for the ARTS study, but who refused randomisation, were considered for the analysis. The patients chose the method of revascularisation. The final study sample comprised 96 patients, 50 underwent PTCA+S and 46 underwent
CABG. The authors did not report evidence that the study sample was representative of the study population.

**Study design**
This was a single-centred, prospective cohort study. The duration of follow-up was 6 months. The authors reported some losses to follow-up, but not the exact number. The outcome assessment does not appear to have been blinded, but the authors stated that two cardiologists assessed the study findings.

**Analysis of effectiveness**
The effectiveness results were analysed on the basis of treatment completers only. The primary health outcomes used for both the PTCA+S and CABG groups were:

- the number (and percentage) of patients that accomplished complete revascularisation;
- the number (and percentage) of patients that experienced major and minor complications during hospitalisation;
- the number (and percentage) of patients that experienced major and minor complications at 1 and 6 months' follow-up.

The functional capacity (as assessed by the Canadian Cardiovascular Society criteria) and quality of life of the patients, at 1 and 6 months after the intervention, were also assessed. Quality of life was assessed in terms of mobility, self-care, usual activity, pain/discomfort, anxiety/depression and general health, using the same questionnaire as that used in the ARTS study. In addition, the incidence of complications between diabetic and non-diabetic patients was compared, as 52% of PTCA+S patients and 48% of CABG patients were diabetic.

The PTCA+S and CABG groups were shown to be non significantly different in age, gender, the number of lesions per patient and risk factors for heart disease (prior MI, diabetes mellitus, hypertension, smoking, hyperlipidaemia, family history and body mass index). There were significant differences between the groups in terms of the person who chose the intervention (either the patients or their families, or the referring physician).

**Effectiveness results**
During hospitalisation, more CABG patients experienced complications than PTCA patients. Five (11%) versus 0 experienced pericarditis, (p=0.053), 10 (21%) versus 1 (2%) experienced arrhythmia, (p=0.007), and 7 (15.2%) versus 0 experienced pulmonary complications. The incidence of minor complications was 14% in the PTCA+S group versus 46% in the CABG group, (p<0.01).

In general, complications at 1 month were not significantly different between the PTCA and CABG patients. Eleven CABG patients (25%) reported minor complications compared with only 1 PTCA patient (2%), (p=0.05). PTCA patients showed significantly better results for quality of life in terms of usual activity, (p=0.001), pain/discomfort, (p=0.04), and general health dimensions, (p<0.001). However, CABG patients showed better results in terms of the self-care dimension, (p<0.001).

After 6 months, 19 PTCA patients (40%) versus 4 CABG patients (9%) required recatheterisation, (p=0.001). Seventeen PTCA patients (36%) versus 3 CABG patients (7%) required revascularisation, (p=0.002), of which 6 PTCA patients (13%) and 0 CABG patients underwent CABG as the revascularisation method, (p<0.0001). When general health was assessed after 6 months, the PTCA patients had a significantly higher score (80 +/- 14) than the CABG patients (71 +/- 18), (p=0.008).

The incidence of complications was higher among diabetic patients than non-diabetic patients, but the differences were not statistically significant.

**Clinical conclusions**
Patients in the PTCA+S group experienced fewer complications during hospitalisation, although the major complications were not significantly different between PTCA+S and CABG patients at 1 and 6 months after the...
intervention. Recatheterisation and revascularisation procedures were more common among PTCA patients than CABG patients, although their general health score was significantly better after 6 months.

**Measure of benefits used in the economic analysis**
No summary measure of health benefit was considered in the economic analysis. The study was therefore categorised as a cost-consequences analysis.

**Direct costs**
The resource quantities and the costs were not reported separately. The direct costs considered in the economic analysis appear to have been those of the hospital. These were for diagnostic catheterisation, balloon angioplasty (with or without stenting), bypass grafting, and hospitalisation for primary revascularisations. Diagnostic-related group data from the Ministry of Health (1999) were the source for the cost estimation. Therefore, the costs seem to have been estimated from actual data. Discounting was not performed, but was irrelevant since the period considered at analysis was shorter than 2 years. The price year was 1999. The authors reported the average costs per patient.

**Statistical analysis of costs**
No statistical analyses of the costs were reported.

**Indirect Costs**
No indirect costs were reported in the economic analysis.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analyses of the costs were reported.

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

**Cost results**
The average cost per patient was $8,390 in the PTCA+S group and $14,242 in the CABG group.

**Synthesis of costs and benefits**
Not applicable because a cost-consequences analysis was undertaken.

**Authors' conclusions**
Percutaneous transluminal coronary angioplasty plus stenting (PTCA+S) and coronary artery bypass grafting (CABG) have similar short-term major complications for multivessel coronary artery disease (MVCAD) patients. However, while the quality of life was higher and the costs lower among PTCA-S patients, the rate of repeat revascularisation was higher.

**CRD COMMENTARY - Selection of comparators**
PTCA+S and CABG are interventions commonly used and compared for the treatment of patients with MVCAD. You
must decide which is the health technology most used in your own setting.

**Validity of estimate of measure of effectiveness**
The design of the study appears to have been appropriate, as one of the objectives of the study was to compare the effectiveness of the interventions among those patients eligible for the ARTS study who refused randomisation. However, this design is more subject to bias than a randomised controlled trial. Although the authors stated that the study sample could be considered representative of patients with MVCAD, they did not provide evidence in support of this contention. Moreover, only patients from a single hospital were considered at analysis. The patient groups were, however, shown to be comparable at analysis in terms of the main risk factors related to MVCAD. The lack of significance for some of the effectiveness comparisons may have been due to the small sample size of the study, above all for the sub-group analysis. The authors stated that the follow-up period was relatively short, although, as they stated, the main complications are known to occur during the early period after the intervention.

**Validity of estimate of measure of benefit**
No summary measure of benefit was used in the economic analysis. The study was therefore categorised as a cost-consequences analysis.

**Validity of estimate of costs**
The resource quantities and the costs were not reported separately. The reporting of the costs was very brief, and it could not be stated whether all the costs relevant to the perspective adopted (i.e. the hospital) were included. Also, it appears that only the costs related to the primary revascularisation procedures have been considered, and not those of repeat revascularisation. Statistical or sensitivity analyses of the costs were not performed. These factors introduce uncertainty into the reliability of the cost results. The price year was reported. Discounting was not performed, which was appropriate given that the period considered at analysis was shorter than 2 years.

**Other issues**
The authors made appropriate comparisons of their study findings with those from other studies, both in terms of comparisons between PTCA+S and CABG effectiveness and comparisons of the effectiveness results between diabetic and nondiabetic patients. The issue of the generalisability of the results to other settings was not addressed. The study considered MVCAD patients and this was reflected in the authors’ conclusions.

**Implications of the study**
The authors recommended that future research should reassess the study findings in order to keep abreast of recent advances in interventional cardiology.

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**Other publications of related interest**

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