Long term outcome and cost-effectiveness of stenting versus balloon angioplasty for acute myocardial infarction


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
Two forms of primary angioplasty for patients requiring treatment for acute myocardial infarction (MI) were examined. These were angioplasty with balloon alone and angioplasty with stents.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with acute MI presenting within 6 hours after symptoms onset, or between 6 and 24 hours if they had persistent symptoms with evidence of ongoing ischaemia, and with the infarct-related vessel considered suitable for stenting. Patients with small and diffusely diseased infarct-related vessels, and those presenting conditions that would make follow-up unlikely, were excluded.

Setting
The setting was a hospital. The economic study was conducted at the Department of Cardiology, Isala Klinieken, Hospital de Weezenlanden in The Netherlands.

Dates to which data relate
The effectiveness and resource use data were gathered from June 1995 to March 1997. No price year was reported.

Source of effectiveness data
The effectiveness evidence was derived from a single study, the main details of which had been published by the same authors (see Other Publications of Related Interest).

Link between effectiveness and cost data
The costing was performed retrospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were conducted in the preliminary phase of the study. These indicated that an overall sample of 211 patients (105 in each group) would have been required to detect statistically significant differences in terms of the primary health outcomes, with a power of 90% at the 5% significance level. An initial sample of 532 patients was admitted to the study institution. Of these, 452 patients underwent angioplasty, but 225 were subsequently excluded as
they did not meet the trial inclusion criteria. Thus, the final sample enrolled in the study comprised 227 patients. One hundred and twelve patients underwent primary stenting, while 115 underwent balloon angioplasty. In the primary stenting group, the mean age was 59 (+/- 11) years, 83% were men, and 13% had prior infarction. In the balloon angioplasty group, the mean age was 57 (+/- 11) years, 85% were men, and 13% had prior infarction. The excluded patients were generally comparable with those who were enrolled in the study. The exception was multi-vessel disease, which was more frequent among the excluded patients.

**Study design**
This was a randomised controlled trial, which was conducted in a single centre. The method of randomisation was not reported. The two cardiologists reviewing all events were blinded to patient allocation to the study groups. The patients were followed for two years and no patients were lost to follow-up.

**Analysis of effectiveness**
The clinical study was analysed on an intention to treat basis, as all of the patients enrolled in the study were taken into account in the effectiveness analysis. The primary health outcomes used in the analysis were several cumulative clinical outcomes after one year, such as death, nonfatal reinfarction, the combined death/reinfarction, need for myocardial revascularisation of the target vessel, and cumulative cardiac event-free survivor rate. Cumulative cardiac event-free survivor rate was estimated using the Kaplan-Meier method.

MI was defined as electrocardiographic signs of infarction combined with an increase in serum creatine kinase of greater than 200 U/L and creatine kinase MB isoenzyme fraction/total creatine of at least 10%. Revascularisation was defined as angioplasty or bypass surgery performed because of restenosis of the target lesion after an indication sustained by symptoms, and electrocardiogram or scintigraphy evidence of ischaemia at rest or during exercise. The rate of restenosis at 6 months (at least 50% diameter stenosis of the target lesion detected on a follow-up angiogram) was also assessed as a secondary outcome. The study groups were shown to be comparable at baseline in terms of demographics and clinical conditions.

**Effectiveness results**
The rate of death was 3% in the stent group and 3% in the balloon group, (p=1.0).

The rate of nonfatal reinfarction was 1% in the stent group and 9% in the balloon group, (p=0.01).

The combined death/reinfarction rate was 4% in the stent group and 11% in the balloon group, (p=0.04).

The need for myocardial revascularisation of the target vessel was 13% in the stent group and 34% in the balloon group, (p=0.0003).

Cumulative cardiac event-free survivor rate was 84% in the stent group and 62% in the balloon group, (p=0.0002).

The rate of restenosis at 6 months was 12% in the stent group and 34% in the balloon group, (p<0.001).

**Clinical conclusions**
The effectiveness analysis showed that stent angioplasty was associated with significantly better clinical outcomes than balloon angioplasty.

**Measure of benefits used in the economic analysis**
The benefit measure in the economic analysis was event-free survival. It was derived from the effectiveness analysis using the Kaplan-Meier approach.

**Direct costs**
Discounting was not conducted since the costs were incurred during 2 years. The unit costs were reported separately from the quantities of resources. The health services included in the economic evaluation were in-hospital and follow-up services, such as percutaneous transluminal coronary angioplasty (PTCA) procedure, stent, intra-aortic balloon pumping, angiography, coronary artery bypass graft, repeat PTCA, coronary or intensive care unit stay, and ward stay. The follow-up visits included also echo, stress test, and radionuclide ejection fraction. The resource use for follow-up was limited to cardiac hospitalisations, cardiac outpatient visits and diagnostic tests. The cost/resource boundary adopted was not explicitly reported, but appears to have been that of the hospital. The source of the cost data was not reported. The quantities of resources used were estimated through telephone interviews with the general practitioner of each patient, 24 months after the intervention. The patients also reported resource use, which was confirmed from hospital discharge summaries. The price year was not reported.

**Statistical analysis of costs**
Statistical analyses of the costs were conducted to test for the statistical significance of the results. Both parametric (Student's t-test) and non-parametric (Mann-Whitney U-test) tests were performed. It was assumed that the costs approached a bivariate distribution. Uncertainty was tested using confidence ellipses.

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

**Currency**
Dutch guilders (Dfl).

**Sensitivity analysis**
Sensitivity analyses were not performed.

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

**Cost results**
The per patient costs during initial hospitalisation were Dfl 21,484 in the stent group and Dfl 18,625 in the balloon group, (p=0.0001).

The per patient costs during follow-up were Dfl 9,939 in the stent group and Dfl 14,308 in the balloon group, (p=0.028).

The total per patient costs were Dfl 31,423 in the stent group and Dfl 32,933 in the balloon group, (p=0.83).

**Synthesis of costs and benefits**
Average and incremental cost-effectiveness ratios were calculated to combine the costs and benefits of the two angioplasty treatments.

The average cost per event-free survival was Dfl 37,408 in the stent group and Dfl 53,117 in the balloon group, (p<0.001).

The incremental cost-effectiveness ratio of stent angioplasty over balloon angioplasty was Dfl -6,297 (95% confidence interval: -18,828 - +16,390).

The statistical analyses based on confidence ellipses showed that the stent procedure was likely to be dominant (both
more effective and less costly) over balloon angioplasty. Stent angioplasty was more effective and more expensive under less likely conditions, but it was never less effective.

Authors’ conclusions
Stent angioplasty was a safe approach, more cost-effective than balloon angioplasty in the treatment of patients with acute myocardial infarction (MI). The initial costs were higher for stent angioplasty, but the long-term data showed that the costs did not differ statistically in the two study groups.

CRD COMMENTARY - Selection of comparators
The authors stated that the two treatments were selected for analysis since no comparison using long-term data had been published in the relevant literature. You should decide whether they represent widely used interventions in your own setting.

Validity of estimate of measure of effectiveness
The analysis of effectiveness used a randomised clinical trial, which was appropriate for the study question. Blind assessment of the outcome was partially performed. Statistical analyses were performed to show that the study groups were comparable at baseline. The study sample appears to have been representative of the study population. However, the method of randomisation was not reported. The length of follow-up was given and no patient was lost to follow-up. Thus, the clinical study was analysed on an intention to treat basis. The authors reported the baseline characteristics of the patients who were excluded from the initial sample, and commented that such patients were similar to those who remained in the study. To reduce potential assessment bias, an independent laboratory also performed quantitative angiography. These issues tend to enhance the internal validity of the analysis.

Validity of estimate of measure of benefit
The benefit measure used in the economic analysis was disease-free survival, which was appropriately derived from the effectiveness analysis using Kaplan-Meier techniques. It represents a commonly used method in studies assessing the benefits of cardiovascular interventions.

Validity of estimate of costs
The perspective adopted in the study was not explicitly reported, but is likely to have been that of the hospital. If this is the case, all the relevant direct costs have been included in the analysis. A detailed breakdown of the costs was given. The resources were reported separately from the unit costs, but no price year was reported. This makes reflation exercises in other settings difficult. Standard statistical analyses of both the costs and the quantities were conducted. However, the source of the cost data was not explicitly reported. The authors commented that, as there were fewer readmissions in the stent group, the inclusion of the indirect costs could increase the cost-savings associated with stent angioplasty in comparison with balloon angioplasty.

Other issues
The authors stated that their findings were comparable with those from recent studies. In terms of the generalisability of the study results to other settings, no sensitivity analyses were performed. In addition, the authors commented that their data may not be valid for other centres and countries. Thus, the external validity of the analysis was low. The study enrolled patients undergoing emergency angioplasty and this was reflected in the conclusions of the analysis. The authors discussed some limitations of their analysis. They presented their results and methods in a clear and informative manner.

Implications of the study
The authors recommend the adoption of stent angioplasty in the population of patients similar to those included in their analysis. However, they also highlight the fact that the routine performance of coronary stenting depends on two main
issues. First, the potential benefits of platelet glycoprotein IIb/IIIa receptor antagonists and the result of heparin coated stents. Second, the definition of a specific sub-group of patients who could benefit from stent angioplasty. The authors state that their ongoing trial is trying to assess whether favourable results may be obtained in patients with smaller and diffusely diseased infarct-related vessels.

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None stated.

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Other publications of related interest

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