Cost-effectiveness of coronary stenting in acute myocardial infarction: results from the stent primary angioplasty in myocardial infarction (Stent-PAMI) 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
The use of coronary stenting versus primary balloon angioplasty (PTCA) in acute myocardial infarction (AMI).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis/Cost-utility analysis.

Study population
The study population comprised patients with AMI undergoing direct angioplasty using either coronary stenting or PTCA. Patients presenting within 12 hours of AMI were referred for emergency coronary angiography. If angiography demonstrated the coronary anatomy was suitable for either PTCA or stent implantation, the patient was eligible for randomisation.

Setting
The setting was secondary care. The economic study was conducted in 35 hospitals across the United States.

Dates to which data relate
The effectiveness and resource use data were collected between December 1996 and November 1997. The price year was 1998.

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

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

Study sample
Nine hundred patients with AMI were randomised to undergo PTCA (n=448) or coronary stenting (n=452). The baseline characteristics were reported to allow comparison with the study population. The characteristics reported included age, gender, percentage with diabetes, percentage current smokers, percentage with prior MI, infarct-related vessel, percentage with multi-vessel disease, and percentage ejection fraction. For patients assigned to PTCA, crossover to stenting was discouraged unless it was necessary to treat a severe dissection or an unacceptable PTCA result (greater than 50% residual stenosis) was obtained. Any procedures judged by a clinical events committee to be not clinically
driven were excluded from the economic analysis. Power calculations related to the sample size were not reported in this paper.

**Study design**
This was a randomised, prospective study (Stent-PAMI trial) conducted in 35 US hospitals. The duration of the follow-up was 1 year. Stenting was performed in 98% of the stent group and bailout stenting was required in 15% of the PTCA group. An independent clinical research committee, blinded to treatment assignment, reviewed all major outcomes.

**Analysis of effectiveness**
The effectiveness was analysed on an intention to treat basis. The main health outcomes used in the analysis were death, nonfatal MI, repeat revascularisation (any, percutaneous coronary intervention or coronary artery bypass graft), diagnostic catheterisation, bleeding complications, and hospital admissions during the follow-up period. These were expressed as percentages. With the exception of age, the treatment groups were shown to be well matched at analysis in terms of their characteristics. On average, the patients in the stent group were 2 years older than those in the PTCA group (61 years, versus 59 years, p=0.05).

**Effectiveness results**
The initial results for the stent versus PTCA group were:

- for death, 1.8 versus 0.9%, (p=0.39);
- for nonfatal MI, 0.2 versus 1%, (p=0.25);
- for repeat revascularisation, 5.1 versus 6.3% for any, (p=0.45), 4.6 versus 5.8% for percutaneous coronary intervention, (p=0.46), and 0.4 versus 0.5% for coronary artery bypass graft, (p=0.69);
- for diagnostic catheterisation, 4.4 versus 6.5%, (p=0.19); and
- for bleeding complication, 6.2 versus 7.1%, (p=0.58).

Follow-up repeat hospitalisation was required for 24.3% of the patients in the stent group and for 31% in the PTCA group, (p=0.03)

Repeat revascularisation was required for 13.1% of the patients in the stent group and for 22.5% in the PTCA group, (p<0.001).

**Clinical conclusions**
At the 1-year follow-up, there was a trend towards higher mortality among those patients randomised to stenting, compared with conventional PTCA, although the repeat procedures were statistically significantly lower in the stent group.

**Modelling**
The life expectancy for MI survivors, conditional on surviving the first year after AMI, was estimated using the Coronary Heart Disease Policy Model. A regression model was used to assign utility weights for every patient. Also, for those admissions for which billing information was missing, the nonprocedural costs were calculated using a linear regression model that was developed using admissions for which complete billing information were available.

**Methods used to derive estimates of effectiveness**
Life expectancy for MI survivors, conditional on surviving the first year after MI, was estimated using the Coronary Heart Disease Policy Model.
Estimates of effectiveness and key assumptions
Life expectancy for MI survivors was estimated as 10.43 years (8.24 discounted years) for a typical 60-year old stent patient. The authors assumed that there would be no differences in the annual costs, utilities, or mortality rates beyond the 1-year follow-up period.

Measure of benefits used in the economic analysis
The measures of benefits were the repeat revascularisations avoided and the quality-adjusted life-years (QALYs). Quality of life was determined using the EuroQol health status instrument. This was administered to 771 patients at 1, 6 and 12 months after randomisation.

Direct costs
The direct hospital costs were considered by using data from the authors' setting, hospital room costs, nursing costs, ancillary costs and physician costs. The authors' setting provided data on the cardiac catheterisation laboratory costs, the cost of the heparin-coated stent, disposable equipment, non-physician personnel, overheads, depreciation, and the Medicare billing schedules. The resource quantities and the unit costs were reported separately. The resource quantities underwent a separate statistical analysis. For those admissions for which billing information was missing, the nonprocedural costs were calculated using a linear regression model that was developed using admissions for which complete billing information was available. The costs were not discounted due to the short duration of the study. All costs were converted to 1998 dollars on the basis of the medical care component of the consumer price index.

Statistical analysis of costs
The costs were compared using the Wilcoxon rank-sum test. The uncertainty in the sensitivity analysis was estimated using a bootstrapping technique with 1,000 samples.

Indirect Costs
The indirect costs were not considered.

Currency
US dollars ($).

Sensitivity analysis
A sensitivity analysis was performed in which the authors projected the long-term survival for the two treatment groups on the basis of the observed mortality in the trial. Also, a sensitivity analysis was performed to account for the economic impact of technological advances since the Stent-PAMI trial was originally conducted.

Estimated benefits used in the economic analysis
Follow-up repeat revascularisation was required for 13.1% of the patients in the stent group and for 22.5% in the PTCA group, (p<0.001). Serial utility assessment during the 1-year follow-up period demonstrated a difference of 0.015 QALYs in favour of the stent group, 0.85 (+/-0.18) versus 0.83 (+/- 0.19), (p=0.27).

Cost results
Compared with PTCA, stenting increased procedural costs by approximately $2,000 per patient. The procedural costs were $6,538 (+/-1,778) in the stent group and $4,561 (+/-1,598) in the PTCA group, (p<0.001). While the follow-up costs were significantly lower with stenting ($3,613 +/-7,743) than with PTCA ($4,592 +/- 8,198), (p=0.03), the overall 1-year costs remained higher by approximately $1,000 per patient. These were $20,571 (+/-10,693) for stenting versus 19,595 (+/-10,990) for PTCA, (p=0.02).
Synthesis of costs and benefits

The cost-effectiveness ratio for stenting, compared with PTCA, was $10,550 per repeat revascularisation avoided. This improved to $3,753 per repeat revascularisation avoided when the new technical advances were considered in the analysis. Assuming no difference in survival or utility beyond 1 year, the base-case incremental cost-utility ratio was $65,066 per QALY for stenting compared with PTCA. With updated cost assumptions, this decreased to $22,067 (64.4% of the samples less than $50,000). The cost-utility ratio for primary stenting was less than $50,000 per QALY gained only if stenting did not increase the 1-year mortality by more than 0.3% when compared with PTCA. Projecting on the basis of 1-year values, angioplasty was dominant in 85.8% of samples with base-case costs and in 64.1% of those with updated costs.

Authors' conclusions

"Primary stenting for acute myocardial infarction (AMI) increased 1-year medical care costs when compared with primary balloon angioplasty (PTCA). The overall cost-effectiveness of primary stenting depends on the societal value attributed to avoidance of symptomatic restenosis, as well as on the relative mortality rates of primary PTCA and stenting.”

CRD COMMENTARY - Selection of comparators

The reason for the choice of the comparators, PTCA versus stent, was clear. Both treatment alternatives for AMI were used in the authors' setting. You should consider if the same applies to your own setting.

Validity of estimate of measure of effectiveness

The analysis used a prospective, randomised, multi-centre trial, which was appropriate for the study question. The study sample seems to have been representative of the study population. Also, the baseline characteristics were given in detail to allow comparisons with the study population. Power calculations were not reported. Extensive statistical analyses were conducted on the effectiveness data. The authors also identified limitations of their study. For example, there was no blinding of the patients and clinicians, although this was justified by having to allow for bailout stenting. Also, any uncertainty regarding differences in mortality was handled appropriately by the sensitivity analysis.

Validity of estimate of measure of benefit

The measures of benefit were repeat revascularisations avoided and QALYs. Both were valid measures of benefit, with utility values being measured prospectively within the trial.

Validity of estimate of costs

All the categories of costs relevant to the perspective adopted were included in the analysis. The resource quantities and the unit costs were presented separately. The costs were not discounted due to the short duration of the study, although this could have been used in the extrapolation. Extensive statistical analyses were conducted on the costs. The authors also justified their use of appropriate bootstrapping techniques in the sensitivity analysis.

Other issues

The results were reported fully, and appropriate comparisons were made with other studies. The issue of generalisability was partly addressed through the sensitivity analysis. The conclusions were stated appropriately in relation to the study population.

Overall, this study seems to have been conducted appropriately and reported transparently. Any caveats have been reported in this commentary.

Implications of the study
The authors state that further studies are needed to better define the long-term mortality rates. Also, to investigate the clinical and economic value of pharmacological adjuncts to stenting for AMI.

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