Cost-effective analysis of primary infarct-artery stenting versus optimal primary angioplasty (the Florence Randomized Elective Stenting in Acute Coronary Occlusions (FRESCO) 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
Use of primary stenting in patients with acute myocardial coronary angioplasty (AMI).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study included patients with AMI, who were eligible for primary PTCA. Criteria for enrollment included: chest pain, persisting for longer than 30 minutes, associated with ST segment elevation of at least 0.1 mV in two or more contiguous electrocardiographic (ECG) leads; and admission within 6 hours of symptom onset, as well as admission between 6 and 24 hours if there was evidence of continuing ischaemia. Patients with cardiogenic shock were included. The exclusion criteria included previous administration of fibrinolytic treatment and inability to provide informed consent. Angiographic criteria for exclusion from PTCA included stenosis of the IRA of less than 70%, and inability to identify the IRA. After performing optimal primary PTCA, the only criterion for exclusion from randomisation was a reference vessel diameter less than 2.5 mm.

Setting
Hospital. The economic analysis was carried out in Italy.

Dates to which data relate
Effectiveness and resource use data corresponded to those patients eligible for primary PTCA between January 1996 and March 1997. The price year was not explicitly specified.

Source of effectiveness data
The evidence for the final outcomes was based on a single study.

Link between effectiveness and cost data
Costing was prospectively conducted on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were used to determine the sample size with the assumptions of 30% of the occurrence of the
primary end-point in the conventional PTCA group and 10% in the stent group. To test for an absolute reduction of 20% with p value of 0.05 and a power of 80%, 59 patients were required in each study group; with accounting for other adverse events not included in the primary end-point and withdrawal, it was expected that at least 75 patients/group would be available for analysis. A total of 223 patients eligible for PTCA were enrolled, of whom 220 patients (99%) had successful primary angioplasty. A total of 70 patients with a mean (SD) age of 64 (11) years were not randomised to either study group because of an initial suboptimal acute angiographic result or a reference vessel diameter less than 2.5 mm. After successful primary PTCA, 150 patients were randomly assigned to elective stenting (the stent group, n=75) with a mean age of 62 (12) years or no further intervention (the PTCA group, n=75) with a mean (SD) age of 61 (12) years.

Study design
The randomised, controlled trial (the Florence Randomized Elective Stenting in Acute Coronary Occlusions (FRESCO) trial), appears to have been carried out in a single centre. The duration of the follow-up was for 1 year after the operations. In terms of follow-up, it was reported that one-month angiographic follow-up data were available for 143 (97%) of 147 randomised patients eligible for follow-up (99% in the PTCA group and 96% in the stent group, p=0.33); at 6 months, angiographic follow-up data were available for 95% of the eligible patients in the PTCA group and 94% of eligible patients in the stent group, (p=0.905); the corresponding information for 1-year follow-up was not reported. Randomisation was performed by means of sealed envelopes. Coronary angiography was required for all patients at 48 to 72 hours, at 1 month and at 6 months after the procedure. Information about mortality, morbidity, and functional status was gathered during visits to the outpatient clinic and by telephone interview with referring physicians.

Analysis of effectiveness
The principle used in the analysis of effectiveness was intention to treat. The primary end-point of the trial was a composite end point, defined as death, reinfarction or repeat target vessel revascularisation as a consequence of target vessel failure. The secondary end-point was angiographic evidence of restenosis or reocclusion. Kaplan-Meier survival curves were used to characterise the timing of the primary study end point during the follow-up period. Multivariate analysis using a logistic regression model was performed to identify correlates of recurrent ischaemia. Between the randomised groups, more patients with an anterior AMI were assigned to the stent group than to the PTCA, but the two groups were well matched with respect to other clinical and angiographic characteristics. There were significant differences between non-randomised and randomised patients; the former had a greater incidence of anterior AMI, cardiogenic shock, severe left ventricular dysfunction and multivessel disease.

Effectiveness results
At 6 months, the incidence of the primary end point was 9% in the stent group and 28% in the PTCA group, (p=0.003); the incidence of restenosis or reocclusion was 17% in the stent group and 43% in the PTCA group, (p=0.001).

Multivariate analysis showed that the only independent predictor of freedom from recurrent ischaemia was stenting of the IRA (odds ratio 0.304; 95% CI: 0.110 - 0.839; p=0.021).

The 1-year clinical outcome in terms of adverse events was 13% in the stent group versus 35% in the PTCA group, (p=0.002).

Clinical conclusions
Primary stenting of the IRA, compared with optimal primary angioplasty, resulted in a lower rate of major adverse events related to recurrent ischaemia and a lower rate of angiographically detected restenosis or reocclusion of the IRA.

Measure of benefits used in the economic analysis
Event-free survival was used as a measure of benefit. Events included death, myocardial infarction, repeat percutaneous procedure, coronary surgery, and cerebrovascular accident.
Direct costs
Costs were not discounted due to the short time frame of the cost analysis. Quantities were reported separately from the costs. Cost items were reported separately. Cost analysis covered the costs of hospital stay, percutaneous coronary procedures, coronary surgery, peripheral vascular percutaneous procedures or surgery and pharmacologic treatment. The perspective adopted in the cost analysis was not explicitly specified, but appears to have been that of the hospital. The unit fixed costs, which included professional charges and were adjusted for the increased costs of procedures during the night or the weekend, were calculated based on the information provided by the study institution. Variable costs of the procedures included the costs of all disposable devices and stents. Drug costs were based on the average treatment costs of different drugs according to their prices during the study period. The price year was not explicitly specified.

Statistical analysis of costs
A statistical analysis using Student's t test was performed on the cost data.

Indirect Costs
Indirect costs were not included.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was conducted.

Estimated benefits used in the economic analysis
The 1-year event-free survival rate was 87% in the stent group versus 65% in the PTCA group, (p=0.002).

Cost results
The mean (SD) total cost per patient was $10,217 ($4,547) in the PTCA group versus $10,422 ($2,626) in the stent group, (p=0.735).

Synthesis of costs and benefits
The average cost per event-free survivor over the 12-month period was $15,638 in the PTCA group versus $12,026 in the stent group. In terms of the additional cost of elective stenting procedure compared with optimal PTCA with no further intervention, the incremental cost-effectiveness ratio per additional event-free survivor was $962.

Authors’ conclusions
Despite the uncertainty with regard to effectiveness and cost definition and subsequent measurement, the lower average cost-effectiveness ratio in stent patients compared with optimal PTCA patients, and the very small incremental cost-effectiveness ratio per additional event-free survivor, support the use of primary stenting in patients with AMI.

CRD COMMENTARY - Selection of comparators
The strategy of performing primary PTCA with no further intervention, as the conventional procedure in the context in question, was regarded as the comparator. You, as a database user, should consider whether this is a widely used health technology in your own setting.
Validity of estimate of measure of effectiveness
The internal validity of the effectiveness results is likely to be high given the randomised nature of the study design, the power calculations performed, the fact that the effectiveness analysis was based on intention to treat, and the multivariate analysis performed to identify the predictors of the recurrent ischaemia. The two groups were well matched with respect to other clinical and angiographic characteristics, except that more patients with an anterior AMI were assigned to the stent group than to the PTCA. The study sample appears to have been representative of the study population.

Validity of estimate of measure of benefit
The estimate of the summary benefit measure was directly derived from the effectiveness study. The choice of the measure was implicitly justified. Other benefit measures such as quality-adjusted life-years gained could be used in future studies to take into account the subjective assessment of the patients.

Validity of estimate of costs
The following features enhanced the validity of the cost results: quantities were reported separately from the costs; the cost breakdown was reported; the perspective adopted in the cost analysis was clear; statistical analysis was performed on some resource use and cost data. However, the price year and the conversion rate from the Italian currency to US dollars were not reported; it is not entirely clear whether the unit costs were calculated based on charges or true costs; the effects of alternative procedures on indirect costs were not addressed. This tends to limit the generalisability of the cost results

Other issues
The authors' conclusions appear to be justified given uncertainties in the data, as acknowledged by the authors. Regarding the issue of generalisability of the trial results, it was reported that after the conclusion of the FRESCO trial, the applicability of the trial results was verified in a series of 190 consecutive non-selected patients with AMI, and included a high percentage of high-risk patients (19% over 75 years, 11% cardiogenic shock). Comparisons with other studies were not made. The degree to which the study sample was representative of the study population was addressed in the authors' comments by mentioning that, to assess correctly the efficacy of stenting, the study protocol used no exclusion criterion other than a reference diameter of less than 2.5 mm, rendering the cohort more representative of the entire population of patients with AMI. The authors also noted that in the FRESCO trial, patients were randomised only after an optimal PTCA result was achieved, because they took for granted the benefit of stenting in patients with a suboptimal or a poor angiographic result after PTCA.

Implications of the study
The results appear to strongly support the use of primary stenting in patients with AMI.

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Other publications of related interest
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