The role of acute wall recoil and late restenosis: results of the OCBAS trial (Optimal Coronary Balloon Angioplasty with Provisional Stenting versus Primary Stent)

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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 provisional stenting (PS) after a successful percutaneous transluminal coronary angioplasty (PTCA) for those patients experiencing early luminal deterioration, in order to reduce the likelihood of restenosis. Early luminal deterioration was defined as a loss in the minimal lumen diameter (MLD) and/or a greater than 10% increase in the diameter stenosis severity 30 minutes after successful PTCA.

Type of intervention
Treatment and secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with symptomatic coronary artery disease who underwent successful PTCA. Patients with symptomatic coronary artery disease undergoing successful PTCA were considered at analysis. To be included in the effectiveness analysis, the patients had to have a successful PTCA with good immediate result. This was defined as a residual diameter stenosis of less than 30% and no major dissections, as determined by on-line quantitative coronary angiography. Patients were excluded if they presented the following:

- lesions longer than 20 mm,
- lesions in coronary artery bypass grafts,
- vessels with unsuitable anatomy for stenting (reference diameter less than 2.5 mm, diffuse disease, severe left main stenosis, severe vessel tortuosity), and
- lesions with acute complications or suboptimal results after PTCA.

Setting
The setting was a hospital. The number of centres in which the study was carried out was not reported, although the centres appear to have been located in Argentina.

Dates to which data relate
The dates to which the effectiveness and cost data related were not given. The price year was not reported.

Source of effectiveness data
The effectiveness data were derived from a single study.
Link between effectiveness and cost data
The costing did not appear to have been undertaken on the same patient sample as that used in the effectiveness study. The authors reported that the costing was estimated on the basis of the average costs of the centres participating in the single study.

Study sample
The sample size was not determined in the planning phase of the study to assure a certain power. From a total of 953 PTCA interventions, 206 patients met the inclusion criteria. Eighty-six (41.7%) of these were excluded because of suboptimal PTCA results or acute complications. A total of 120 patients presented a good immediate PTCA result (58.3%). The study sample finally consisted of 116 patients, 57 were randomised to stent and 59 to optimal PTCA. Four patients refused to participate. The authors provided no evidence that the initial study sample was representative of the study population.

Study design
The study was a randomised controlled trial. It was reported that the study was multi-centred, but the number of centres participating in the effectiveness analysis was not reported. The authors did not provide information about the randomisation method, although additional information may have been published elsewhere (Rodriguez et al., see Other Publications of Related Interest). The period of follow-up was one year. No loss to follow-up was reported.

Analysis of effectiveness
The basis of the analysis of effectiveness was intention to treat. All the patients included in the study were accounted for in the analysis.

The primary health outcomes assessed for both strategies were the reference luminal diameter, the pre- and post-PTCA MLD, the acute gain, the MLD at follow-up, the late loss, the net gain, and the percentage stenosis pre-PTCA, post-PTCA and at 6 months’ follow-up. The authors also reported the number and percentage of patients in each group who underwent follow-up angiogram, the average time when the follow-up angiogram was performed, and the angiographic restenosis rates. This was in addition to the number (and percentage) of patients in each group who died, and the number of patients (and percentage) with non-Q-wave myocardial infarction, target vessel revascularisation or coronary artery bypass graft. Finally, the number (and percentage) of patients who experienced event-free survival (no experience of any clinical event, including procedural and hospital events) was reported.

Angiographic restenosis was defined as at least 50% stenosis of the index artery at follow-up, as determined by quantitative coronary angiography.

The groups were shown to be comparable in terms of their age, gender and clinical characteristics. The clinical characteristics included angina (unstable/stable), acute myocardial infarction, prior infarction, diabetes mellitus, left anterior descending artery, left circumflex artery, right coronary artery, lesions morphology (A, B1, B2, C) and follow-up angiogram.

Effectiveness results
Eight patients (13.5%) from the optimal PTCA group received stent due to the presence of early loss, as detected by a repeat coronary angiogram 30 minutes after successful PTCA.

Post-PTCA MLD was significantly greater in the ES group (2.7 +/- 0.59 mm) than in the PS group (2.2 +/- 0.49 mm), (p<0.0001).

The acute gain was also significantly larger in the ES group (1.90 mm) than in PS group (1.50 mm), (p<0.03).

The late loss was significantly larger for ES patients (0.63 +/- 0.59 mm) than for PS patients (0.26 +/- 0.44 mm), (p<0.001).
The post-PTCA percentage diameter stenosis was significantly lower in the ES group (12.8 +/- 9) than in the PS group (22.1 +/- 11), (p<0.0001).

The follow-up angiogram was performed at 7.6 (+/- 0.4) months. In total, 112 patients (96.6%) had follow-up angiogram. Of these, 56 (98.2%) were in the ES group and 56 (94.9%) in the PS group.

There were no statistically significant differences between ES and PS for the rest of the health outcomes assessed in the effectiveness analysis. The results for these outcomes were as follows:

- the angiographic restenosis rate was 19.2% for ES and 16.1% for PS, (p=0.9);
- the reference diameter was 3.1 (+/- 0.56) mm for ES and 2.81 (+/- 0.55 mm) for PS;
- the pre-PTCA MLD was 0.80 (+/- 0.46) mm for ES and 0.70 (+/- 0.46 mm) mm for PS;
- the MLD at follow-up was 2.1 (+/- 0.9) mm for ES and 1.94 (+/- 0.68) mm for PS;
- the net gain was 1.32 (+/- 0.33) mm for ES and 1.24 (+/- 0.29) mm for PS;
- stenosis prior to PTCA was 73.06% (+/- 13) for ES and 74.07% (+/- 15) for PS;
- stenosis at 6-months' follow-up was 29.4% (+/- 2.1) for ES and 30.3% (+/- 2.1) for PS.

One person died in the PS group (1.6%), compared with none in the ES group.

One patient in the PS group presented non-Q-wave myocardial infarction. None of the ES patients experienced this event.

Ten ES patients (17.5%) and 8 PS patients (13.5%) had repeated target vessel revascularisation.

The number of patients undergoing coronary artery bypass graft was higher in the ES group (4 patients, 6.7%) than in the PS group (2 patients, 1.7%). This difference was not statistically significant.

In total, 80.8% of the ES patients and 83.1% of the PS patients experienced event-free survival.

Clinical conclusions
Patients in the ES group presented a greater acute gain than those in the PS group, and a better post-PTCA stenosis rate. However, they also experienced a greater late loss, leading to similar angiographic restenosis rates during the follow-up. Procedural and hospital events such as death, target vessel revascularisation and freedom from clinical events at one year of follow-up were similar in both groups.

Measure of benefits used in the economic analysis
A cost-consequences analysis was performed. Therefore, no summary measure of benefit was used in the economic analysis. See the 'Effectiveness Results' section.

Direct costs
Only some of the resource quantities were reported separately from the costs. The direct costs considered in the analysis were those of the health service. These included procedural, hospital and follow-up costs for both treatment strategies. The authors reported that the PTCA costs included non-complicated procedural and hospital costs, while the costs of stent included hospital charges, physician fees and the cost of hospital stay. The costs of emergency or elective coronary artery bypass graft, surgical vascular repair and the associated costs for hospital stay were also considered. The costs were estimated using the average costs for the interventions in the participant centres. Discounting was not performed since the time period considered was less than two years. The authors reported the overall costs. The price year was not
Statistical analysis of costs
A statistical analysis compared the overall costs for both procedures (ES and PS).

Indirect Costs
No indirect costs were reported.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was reported.

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

Cost results
The in-hospital costs for ES were significantly higher than for PS ($502,740 versus $331,480; p <0.03). After considering both hospital and follow-up costs, the costs for ES were significantly higher than those for PS ($591,740 versus $398,480; p <0.02).

Synthesis of costs and benefits
Not applicable due to the cost-consequences approach.

Authors’ conclusions
The use of percutaneous transluminal coronary angioplasty (PTCA) with the limited use of provisional stenting (PS) to treat angioplasty complications or suboptimal results may be highly cost-effective when compared with elective stenting (ES). This is because, in comparison with ES, PS presents similar angiographic restenosis rates, target vessel revascularisation and freedom from major clinical events at one year of follow-up, but the costs are significantly smaller.

CRD COMMENTARY - Selection of comparators
No explicit justification was given for the comparator chosen, although ES appears to have been chosen because it was the current practice in the authors' setting. 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 and should limit the influence of bias and confounding. However, the authors did not state the randomisation method used to allocate the patients to the study groups. The study sample was not shown to be representative of the study population. However, the authors stated that the study was multi-centred, which may have increased the likelihood that the sample represented the study population. The patient groups were shown to be comparable at analysis. The sample size was small, which may have contributed to the lack of statistically significant differences in the effectiveness results between the groups. The power used for the statistical analysis was not reported, although it may have been 95%.
Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The analysis was therefore categorised as a cost-consequences study and the commentary on ‘Validity of estimate of measure of effectiveness’ should be referred to.

Validity of estimate of costs
Not all of the resource quantities were reported separately from the costs, and no statistical analysis of the quantities was performed. Moreover, the dates to which the cost data related and the price year were not given. These facts introduce uncertainty into the reliability of the conclusions and could hinder reflation exercises to other settings. It was unclear whether all the costs relevant to the perspective adopted were included in the analysis. First, the authors did not explicitly report the perspective adopted and it was unclear from the paper. The perspective could have been either that of the hospital or of the health service. Second, the costs of the drugs given to the patients before the PTCA intervention and during the follow-up period did not seem to have been included in the analysis, even though they were not the same for the strategies compared. Discounting was not undertaken, although this was appropriate given the study period (less than two years).

Other issues
The authors made appropriate comparisons of their findings with those from other studies. However, they did not address the issue of the generalisability to other settings. The authors’ conclusions reflected the scope of the analysis.

Implications of the study
The results of this study seem to favour the use of PS after PTCA. This is because the effectiveness results were similar in the follow-up period, with some of the effectiveness health outcomes favouring its use, and the costs were lower than for ES. However, a degree of caution is necessary because of the limitations reported in terms of the reporting of the costs and the small sample size considered at analysis.

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