Comparison of direct coronary stenting with and without balloon predilatation in patients with stable angina pectoris


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 direct stent implantation (DS+) versus standard stent implantation (DS-) was examined. DS+ consisted of stent deployment without predilatation, while DS- required routine predilatation of the target lesion with a balloon catheter. DS+ was performed using the second generation of Tenax stents.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients undergoing coronary angioplasty, because of stable angina due to a single de novo lesion in a coronary artery, and having no contraindications to anticoagulated or antiplatelet therapy. Patients with unstable angina or myocardial infarction in the previous two days were excluded. Specific angiographic criteria were 70% or more stenosis, lesion 15 mm or less in length and potentially spanned by a single stent, and a vessel diameter of at least 2.5 mm. Patients with an ostial lesion, a lesion at bifurcation, or a highly calcified lesion in a previously grafted vessel, were excluded. Also excluded were patients with a suspected intracoronary thrombus.

Setting
The setting was a hospital. The economic study was carried out in France.

Dates to which data relate
The effectiveness and resource use data were collected between January and September 1999. Although not explicitly reported, the price year is presumed to have been 1999.

Source of effectiveness data
The effectiveness evidence came from a single study.

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

Study sample
Power calculations to determine the sample size were not reported. In addition, there was no evidence that the initial study sample was appropriate for the study question. The method of sample selection was not reported. An overall
sample of 338 patients undergoing 355 stent implantations was enrolled in the study. There were 165 patients in the DS-group and 173 patients in the DS+ group. In the DS- group, the mean age was 64.8 (+/- 11.2) years, 26% were women and 43.6% had hypertension. In the DS+ group, the mean age was 63.2 (+/- 11.9) years, 17.9% were women and 49.1% had hypertension. It was not reported whether any patients refused to participate in the study.

**Study design**
This was a randomised controlled trial. The number of centres in which the study was carried out was not reported. Randomisation was carried out by a central agency via the Internet. The randomisation sequence was developed on a site basis in blocks of four treatment assignments. The patients were followed for an average of 8 months. The proportion of patients remaining in the study at the end of the follow-up period was 98.1% in the DS- group and 98.2% in the DS+ group.

**Analysis of effectiveness**
The basis for the analysis of the clinical study (intention to treat or treatment completers only) was not stated. The health outcomes used in the analysis were:

- the crossover rate;
- the rate of procedural success (successful stent deployment with final diameter stenosis less than 20% by quantitative analysis);
- the rate of clinical success (procedural success without a procedural or clinical event);
- angiographic characteristics such as reference diameter, diameter stenosis and minimum lumen diameter;
- a composite end point reflecting the incidence of major cardiac events (MACEs) including death, angina pectoris, myocardial infarction, congestive heart failure, repeat angioplasty, or coronary artery bypass graft surgery at follow-up assessment;
- the rate of revascularisation of the target lesion (defined as angioplasty of bypass surgery performed because of restenosis of the target lesion in association with recurrent angina, objective evidence of myocardial ischaemia, or both) at follow-up; and
- some procedural outcomes, such as maximum inflation pressure, procedural duration, quantity of contrast media, rate of additional stenting, and rate of use of GPIIb/IIa receptor inhibitor.

Statistical analyses were conducted to calculate the Kaplan-Meier event-free survival. The Cox multivariate model was used to assess the parameters representing independent predictors of adverse outcome among study treatment, stent length of 10 mm, stent diameter of 3 mm, and complex lesion type C. The study groups were shown to be comparable at baseline in terms of their age, gender, and several clinical and angiographic characteristics.

**Effectiveness results**
The rate of crossover was 13.9% in the DS+ group and 0 in the DS- group.

The rate of procedural success was 98.3% in the DS- group and 97.5% in the DS+ group (not significant).

The rate of clinical success was 97.5% in the DS- group and 98.3% in the DS+ group (not significant).

Angiographic characteristics were not statistically difference between the study groups.

At follow-up assessment, the incidence of MACEs was 11.4% in the DS- group and 5.3% in the DS+ group (not significant). The target lesion revascularisation rate was 11.4% in the DS- group and 5.3% in the DS+ group (not significant).
For procedural outcomes, the maximum inflation pressure was 11.52 (+/- 2.18) atm in the DS- group and 12.25 (+/- 2.6) atm in the DS+ group, (p=0.04). Procedural duration was 10.34 (+/- 6.30) minutes in the DS- group and 7.04 (+/- 6.52) minutes in the DS+ group, (p<0.0001). The quantity of contrast media was 156.7 (+/- 87.3) mL in the DS- group and 135.46 (+/- 85.3) mL in the DS+ group, (p<0.3; this may in fact be 0.03 as the paper interprets the difference in contrast media as significant). The remaining procedural outcomes were similar across the groups.

The results of the Kaplan-Meier event-free survival were reported graphically.

The independent predictors of adverse outcome were stent length of 10 mm (relative risk, RR=3.25, 95% confidence interval, CI: 1.36 - 7.78; p=0.008), stent diameter of 3 mm (RR=2.69, 95% CI: 1.03 - 7.06; p=0.043), and type C lesion (RR=2.83, 95% CI: 1.02 - 7.85; p=0.045). The treatment used was not an independent predictor of adverse outcome.

Clinical conclusions
The effectiveness study showed that direct stent implantation without predilatation was as safe and feasible, in terms of several outcome measures, as the standard approach consisting of balloon catheter for the predilatation of the target lesion. However, the crossover rate was quite high (almost 14%).

Measure of benefits used in the economic analysis
No summary benefit measure was used because the health outcomes were left disaggregated. A cost-consequences analysis was therefore carried out.

Direct costs
Discounting was irrelevant as the costs were incurred over 8 months. The unit costs were not reported separately from the quantities of resources and a breakdown of the costs was not reported. The health service costs included in the analysis were angioplasty balloons, devices such as stents, guiding catheters, guidewires, and contract dye. The cost/resource boundary adopted in the study was not stated, nor was the source of the cost data. Resource consumption was gathered from January to September 1999. 1999 prices were presumably used.

Statistical analysis of costs
Standard statistical analyses were conducted to test the statistical significance of differences in the total costs.

Indirect Costs
The indirect costs were not included.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analyses were performed.

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

Cost results
The total procedural costs were $1,164.6 (+/- 383.9) in the DS- group and $956.4 (+/- 352.2) in the DS+ group, (p<0.0001).
Synthesis of costs and benefits
Not relevant as a cost-consequences analysis was conducted.

Authors' conclusions
The approach of direct stent implantation using stent deployment without predilatation (DS+) proved to be a safe and effective procedure for patients undergoing coronary angioplasty because of stable angina. The costs were significantly lower than those observed in patients treated using the standard stent implantation procedure based on balloon catheter (DS-).

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. Stent implantation based on balloon catheter was selected because it represented the conventional procedure for stent deployment. You should decide whether it represents a routine procedure in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness evidence used a randomised controlled trial, which was appropriate for the study question. The method of randomisation and the length of follow-up were clearly reported. The study groups were also comparable at baseline. However, it appears that power calculations were not performed. In addition, there was no evidence that the initial study sample was large enough to detect statistically significant differences in terms of outcome measures across the study groups. The method of sample selection and the number of centres in which the study was carried out were not stated. A high crossover rate was observed in patients undergoing the new procedure for stent placement, and this should be considered when interpreting the validity of the results. The authors acknowledged that the time horizon of their analysis was fairly limited. In terms of the outcome assessment, it was noted that the systematic use of intracoronary ultrasound would have improved the evaluation of the effectiveness of the interventions. These issues may limit the internal validity of the analysis.

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

Validity of estimate of costs
The perspective adopted in the study was not stated. Therefore, it was unclear whether all the relevant categories of costs were included in the analysis. Overall, few details of the cost analysis were reported. The cost items included in the economic evaluation were reported, but the unit costs were not analysed separately from the quantities of resources used. Also, the costs were treated deterministically, with the exception of the statistical analyses carried out to test the statistical significance of differences in the total costs. No sensitivity analyses were performed and the cost estimates were fairly specific to the study setting.

Other issues
The authors stated that their findings were comparable with those from other published studies. The issue of the generalisability of the study results to other settings was not addressed and no sensitivity analyses were conducted. Thus, the external validity of the analysis is rather limited. The authors noted that patients with very calcified lesions were excluded, therefore the study results should be limited to the group of patients included in the analysis. The authors highlighted some limitations of their analysis. They also stated that the small sample size could have made it difficult to draw firm conclusions about the long-term impact of the interventions.

Implications of the study
The study suggests that, in highly selected patients, the adoption of a procedure of stent placement without predilatation may be safe and more efficient than the standard procedure based on balloon catheters. However, this result should be interpreted with caution and in the light of the limitations of the analysis, especially given the fact that long-term effects of the intervention were not evaluated.

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