Direct coronary stenting versus predilatation followed by stent placement

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 coronary stenting or predilatation followed by stent placement was studied.

Type of intervention

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients who underwent clinically indicated interventional revascularisation and who fulfilled the following criteria:

- had one or more native coronary lesions with a diameter reduction by quantitative coronary angiography of at least 60% in one or more multiple projections and no greater than 95% in all projections;
- had a lesion length of less than or equal to 30 mm deemed to be treatable preferably by one stent, or at most two;
- had no significant stenosis (diameter reduction of at least 60%) proximal to the lesion;
- gave written informed consent; and
- promised to undergo 6-month clinical and angiographic follow-up.

Setting
The setting was secondary care. The economic study was carried out in Clinic of Wetzlar-Braunfels, Department of Cardiology, Wetzlar, Germany.

Dates to which data relate
The effectiveness data corresponded to patients enrolled between May 1999 and January 2001. The dates relating to the resource use were not reported. The price year was not stated.

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

Link between effectiveness and cost data
The cost data were taken from the same sample as the effectiveness data, although the costs were averaged across patients.
Study sample
Power calculations were not used to determine the sample size. The inclusion criteria indicated that a well-defined group of patients participated in this study. The 335 patients enrolled in the study were randomly assigned to the two treatments, 171 to direct stenting and 164 to predilatation followed by stent placement. There was no report of patients refusing an invitation to participate in the trial. Patients were excluded from the study if they had greater than 50% unprotected left main diameter stenosis, totally occluded target vessel, presence of high calcified lesion, excessive vessel tortuosity, bifurcation or ostial stenosis. They were also excluded for angiographic presence of thrombus, saphenous vein grafts, in-stent restenosis, pretreatment other than balloon angioplasty, and an ejection fraction of less than 30%.

Study design
This was a randomised controlled trial that took place at a single centre. Eligible patients were assigned to the two different procedures using a random generator. All the patients were followed clinically for at least 6 months. The number of patients lost to follow-up was not reported.

Analysis of effectiveness
The analysis of the clinical study was conducted on an intention to treat basis. The primary end point of the study was procedural success, which was defined as normal distal vessel perfusion. The secondary end points were procedural duration and costs, radiation exposure, amount of contrast dye used, and follow-up events. The follow-up events included death, Q-wave infarction, and repeat operative or interventional revascularisation of the target lesion. There were no significant differences between the two treatment arms in terms of their baseline demographics, cardiac medications, angina class or risk.

Effectiveness results
The effectiveness results were given for both in-hospital events and for 6-month follow-up (including in-hospital events).

The study showed that the feasibility of direct stenting was 95% in the direct stenting group, with 5% requiring crossover to predilatation. Successful stent placement was performed in all patients in the predilatation group. Direct stenting was associated with less procedural duration (42.1 +/- 18.7 minutes) than the predilatation group (51.5 +/- 223.8 minutes), (p=0.004).

Direct stenting was associated with less radiation exposure time (10.3 +/- 7.7 minutes) than the predilatation group (12.5 +/- 6.4 minutes), (p=0.002). It also used a smaller amount of contrast dye, 163 (+/- 69) mL versus 197 (+/- 84) mL, (p<0.0001).

Clinical conclusions
The effectiveness study showed that, in this clearly defined group of patients, direct stenting had a lower rate of angiographic restenosis up to 6 months after the procedure. This resulted in fewer coronary reinterventions when compared with the conventional strategy of stenting with antecedent dilatation. However, the authors did not state that one intervention was more effective overall than the other. They concluded that direct stenting was comparable to predilatation in terms of effectiveness.

Measure of benefits used in the economic analysis
The procedural success rates in both groups were similar (98%), (p=0.77). The measurement of benefit was in terms of savings in procedure-related costs. As the clinical effectiveness results were reported to be equal, it would appear that a cost-minimisation analysis was conducted.
Direct costs
The mean procedure-related costs (material costs), with corresponding standard deviations, were reported. No detail was given as to how these costs were calculated. The authors stated that the material costs of the initial procedure per case were calculated and averaged for both groups. It was not stated whether or not discounting was undertaken.

Statistical analysis of costs
No statistical analysis of the costs was undertaken.

Indirect Costs
No indirect costs were included in the study.

Currency
Euros (Euro).

Sensitivity analysis
No sensitivity analysis was undertaken.

Estimated benefits used in the economic analysis
No summary measure of benefit was used in the economic analysis. The authors stated that the effectiveness of each procedure was equal and, therefore, the study became a cost-minimisation analysis.

Cost results
The material costs were Euro 845 (+/- 167) for the direct stenting group and Euro 1,064 (+/- 175) for the predilatation group. The incremental cost of the predilatation group was, therefore, Euro 219, (p<0.0001).

Synthesis of costs and benefits
Not reported. However, because the effectiveness results were reported as being equal, it was implied that the procedure exhibiting the smaller costs (i.e. direct stenting) can be considered cost-effective. This study demonstrated the safety and feasibility of direct stenting in selected patients. It resulted in a reduction in procedural costs and length, a reduction in radiation exposure, no increase in in-hospital clinical events, and a reduction in major adverse cardiac events at 6-month follow-up. The costs of direct stenting were significantly less than those associated with predilatation.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of comparators appears to have been reasonable. The two methods that were examined represented the conventional and an alternative approach to coronary stent implantation.

Validity of estimate of measure of effectiveness
The basis of the analysis was a prospective randomised controlled trial. The sample size was small, and it was unclear whether both elective and emergency cases were included in the patient sample.

The authors reported that the percentage of diabetic patients and left anterior descending artery lesions treated with predilatation tended to be higher than in the direct stenting group. They explained that this fact could have affected the restenosis rate, because diabetics and left anterior descending artery lesions are associated with a higher incidence of restenosis. Other limitations included the fact that this study only reported experiences from a single institution, a core laboratory did not assess quantitative coronary angiography, and the follow-up (which was not complete for all patients) was limited to 6 months.
Validity of estimate of benefit

No summary benefit measure was used in the economic analysis. The authors stated that the effectiveness of each procedure was equal and, therefore, the study became a cost-minimisation analysis.

Validity of estimate of costs

Figures (with confidence intervals) were given for the material costs of the two procedures. No explanation was provided as to how these figures were derived, suggesting that the generalisability of the cost findings may be severely limited. As only material costs were included in the analysis, it is possible that other important costs were omitted. The user of this database should be cautious when applying these findings for their own purpose.

Other issues

The authors made appropriate comparisons of their effectiveness findings with those from other studies, and found that their research supported previous evidence. However, the issue of generalisability to other settings was not addressed. The authors do not appear to have presented the clinical results selectively and their conclusions reflected the scope of the study.

The authors reported further limitations of their study. First, the limited follow-up period. Second, the high percentage of diabetic patients and left anterior descending artery lesions treated with predilatation compared with the percentage of such patients in the direct stenting group. Third, the data represented experience from a single institution and, finally, angiographic follow-up studies were not available in all patients.

Implications of the study

It was noted that no significant differences in effectiveness were observed, although the direct stenting group exhibited smaller costs. The authors suggested that future research should aim to establish the true long-term costs and effects of both procedures.

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