Direct coronary stenting without predilation

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
Direct stenting without predilation in selected lesions in patients who underwent stent implantation.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients who underwent stent implantation and who were suitable candidates for direct stenting without predilation. The suitable candidates for direct stenting were expected to meet the following criteria: (1) vessel equal or greater than 2.5 mm in diameter; (2) absence of severe coronary calcifications; (3) absence of significant angulation (bend >45 degree); and (4) absence of occlusions and bifurcation lesions.

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

Dates to which data relate
Effectiveness and resource use data corresponded to patients who underwent stent implantation between February and June 1998. The price year was 1997.

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

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

Study sample
Power calculations were not used to determine the sample size. After having reviewed all cases of stent implantation in the study period (585 patients, 806 lesions), 185 (32%) of these patients were retrospectively selected as candidates for direct stent implantation without predilation. By operator preference, direct coronary stent implantation was actually attempted in 123 (21%) of the 585 patients. These 123 patients comprised the study sample. The study sample was divided into 2 study groups: group 1 had 69 patients with a mean (SD) age of 61 (12) years who underwent single-vessel stenting without predilation; and group 2 had 46 patients with a mean (SD) age of 62 (10) years who underwent single-vessel traditional stenting (with predilation).
Study design
This was a retrospective cohort study, carried out in a single centre. The duration of the follow-up was 1 month after operation (by telephone contact to the patients or the referring physicians). Loss to follow-up was not reported. In all patients, indications for stenting were elective, in that the operator elected to use stenting before starting the procedure. The study comparisons excluded all patients with multi-vessel disease who were traditionally less suitable for direct stenting. Two senior PTCA (percutaneous transluminal coronary angioplasty) operators independently reviewed coronary angiograms to identify suitable candidates for direct stenting without predilation.

Analysis of effectiveness
The analysis was based on treatment completers only. The health outcome measures were; success rate, residual stenosis and minimal lumen diameter after stent deployment, the presence of residual dissection, procedure time, radiation exposure time, contrast dye used, and any in-hospital major adverse cardiac event (MACE) (i.e., death, Q and non-Q wave myocardial infarction, coronary artery bypass graft surgery or PTCA). Comparison of the study groups in terms of baseline characteristics showed that they were different with respect to hypertension and diabetes mellitus (more frequent in the group without predilation).

Effectiveness results
The effectiveness results were as follows:

Direct stenting was successful in 118 patients (96%).

Direct stenting was successful in all 69 patients of the intervention group (procedural success of 100%); no additional stent and/or balloon was necessary.

Angiographic success was achieved in all patients in the two groups.

Residual stenosis and minimal lumen diameter after stent deployment were not statistically different between the two groups.

No residual dissection was present in the two groups.

The mean (SD) procedure time was 45 (21) min in the intervention group and 64 (46) min in the comparator group (p<0.05);

radiation exposure time was 12 (9) min in the intervention group and 16 (10) min in the comparator group (p<0.05);

contrast dye used, 183 (96) ml in the intervention group and 255 (110) in the comparator group (p<0.05).

No acute or subacute complications occurred in either of the two study groups one month after the procedure.

Clinical conclusions
The main finding that emerges from this single-centre study is that direct coronary stenting without predilation is a feasible and safe therapeutic approach.

Measure of benefits used in the economic analysis
No summary benefit measure was identified in the economic analysis, and only separate clinical outcomes were reported.

Direct costs
Costs were not discounted due to the short time frame of the cost analysis. Most quantities were reported separately.
from the costs. Some cost items were reported separately. Cost analysis covered the procedure cost, (accounting for angioplasty balloons and devices) and cardiac catheterisation and laboratory costs (including additional equipment costs, room costs, and personal costs). The perspective adopted in the cost analysis was not reported. The resource utilisation for the procedure costs was recorded for each procedure, while the catheterisation costs were estimated on the basis of an average cost per procedure adjusted for actual procedure duration. The cost data for each item of the procedure cost was based on the manufacturer's charges to the hospital. The cost data for the catheterisation costs were obtained from the study institution. The price year was 1997.

**Statistical analysis of costs**
Student's t test was used to compare the study groups in terms of costs.

**Indirect Costs**
Not considered.

**Currency**
Euro. The conversion rate was Euro 1 = US$0.93.

**Sensitivity analysis**
No sensitivity analysis was conducted.

**Estimated benefits used in the economic analysis**
Not applicable. The reader is referred to the effectiveness results reported above.

**Cost results**
The mean (SD) total cost per patient was Euro 1,305 (363) in the intervention group versus Euro 2,210 (803) in the comparator group, (p<0.05).

**Synthesis of costs and benefits**
Costs and benefits were not combined since the use of direct stenting without predilation appears to be the dominant strategy.

**Authors’ conclusions**
Direct stenting without predilation in selected lesions seems to be a safe and successful procedure that provides a way to contain cost and to shorten radiation exposure time.

**CRD COMMENTARY - Selection of comparators**
A justification was given for the choice of the comparator (direct stenting with predilation) which was the traditional practice in the context in question at the time of the study. You, as a database user, should consider which health technology is used widely in your own setting.

**Validity of estimate of measure of effectiveness**
The internal validity of the effectiveness results cannot be guaranteed due to the retrospective nature of the study design and the subjective nature of the criteria used to select patients suitable for primary stenting, which makes the study prone to intrinsic bias (as acknowledged by the authors). Furthermore, no power calculations were performed to justify the sample size. It was noted that operator preference may have acted as a confounding variable in this study since the
direct stent implantation without predilation was deemed to be more demanding than the conventional procedure, and more experience was perceived to be required with this new method. The study groups were comparable in terms of baseline demographic and clinical characteristics, except for hypertension and diabetes mellitus, which were more frequent in the intervention group. It was further noted that the study had no cases of incomplete balloon and stent expansion in a calcified lesion (as a potential limitation of the direct stenting approach), because of exclusion of lesions with severe calcification and the study sample being quite small. It was acknowledged that the possibility of the smaller lumen cross-sectional area in the direct stenting compared to the conventional method (as another potential limitation of the new approach) was not investigated in this study due to the fact that no intravascular ultrasound evaluation was systematically performed. The degree to which the study sample was representative of the study population cannot be assured as the authors noted that the criteria used for selecting patients suitable for primary stenting were subjective.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit and, as such, the study was a cost-consequences analysis. The main benefit may be proxied through shorter exposure time to radiation through the intervention.

Validity of estimate of costs
The validity of the cost results may have been enhanced by the following positive features of the cost analysis: most quantities were reported separately from the costs; adequate details of methods of cost estimation were given; the price year was reported; and statistical analyses were performed on most resource consumption and cost data. However, the following limitations may have adversely affected the validity of the cost results: the perspective adopted in the cost analysis was not specified; the effects of alternative procedures on indirect costs were not addressed; and cost results may not be generalisable outside the study setting.

Other issues
The authors’ conclusions may need to be treated with some caution due to the inherent limitations of the study design. Regarding the issue of generalisability to other settings or countries, it should be noted that cost effectiveness data are difficult to verify in the absence of sensitivity analysis. Some comparisons, however, were made with other studies. The representativeness of the study sample of the study population was, in part, addressed by acknowledging that the criteria used for selecting patients suitable for primary stenting were subjective.

Implications of the study
Other studies are needed to verify the impact of direct stenting on restenosis rates and long-term clinical outcomes.

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None stated.

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