Costs and effects of combining stenting and abciximab (ReoPro) in daily practice
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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 combination of abciximab (GP IIb/IIIa receptor blocker) and stent implantation for the treatment of patients undergoing percutaneous transluminal coronary angioplasty (PTCA), was examined.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients receiving PTCA. Specific inclusion and exclusion criteria were not reported.

Setting
The setting was a hospital. The economic study was conducted in The Netherlands.

Dates to which data relate
The effectiveness and resource use data were gathered from June 1995 to June 1999. No price year was reported.

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 sample of patients as that used in the effectiveness study.

Study sample
Power calculations to determine the sample size do not appear to have been performed. A sample of 184 consecutive patients admitted into a regional hospital, who were administered abciximab and who were subsequently transported to one of two specialised centres to receive PTCA, were enrolled into the study from 1995 to 1999. There were 83 patients in the non-stented group and 101 in the stented group. The mean age in the non-stented group was 63.5 (+/- 2.4) years and 68.7% were men. The mean age in the stented group was 62.8 (+/- 2.4) years and 80.2% were men.

Study design
This was a prospective cohort study, which was carried out in two centres in the Netherlands. The physicians allocated the patients to the study groups. However, there was no discussion of a rationale for this allocation. At one and 6
months after the procedure, the patients revisited the regional hospital for a clinical check-up including an electrocardiogram. No loss to follow-up was reported. The method of outcome evaluation (for example, the use of a questionnaire) was not reported.

### Analysis of effectiveness

All patients included in the initial sample were taken into account when estimating the effectiveness. The primary health outcomes evaluated in the analysis were two composite end points. One was death or myocardial infarction (MI). The other was death, MI or any revascularisation procedure (major adverse cardiac events, MACE). The rates of coronary artery bypass grafting (CABG) and re-PTCA/re-stent were also reported. The study groups were generally comparable at baseline, but those in the stented group tended more often to be male, (p=0.09). Age, gender, Braunwald score, prior PTCA, restenosis, prior CABG and prior MI were identified as confounders. Statistically adjusted odds ratios (ORs) were also calculated.

### Effectiveness results

The rates of death were 1.2% in the non-stented group and 0% in the stented group.

The rates of MIs were 2.4% (non-stented) and 1% (stented). The OR was 0.41 (0.03 - 4.5) and the adjusted OR was 0.30 (0.02 - 4.4).

The rates of re-PTCA/re-stent were 9.6% (non-stented) and 5% (stented). The OR was 0.49 (0.15 - 1.6) and the adjusted OR was 0.73 (0.19 - 2.7).

The rates of CABG were 6% (non-stented) and 2% (stented). The OR was 0.32 (0.06 - 1.7) and the adjusted OR was 0.48 (0.06 - 4).

The rates of death or MI were 3.6% (non-stented) and 1% (stented). The OR was 0.27 (0.03 - 2.6) and the adjusted OR was 0.20 (0.01 - 2.8).

The rates of MACE were 16.9% (non-stented) and 6.9% (stented). The OR was 0.37 (0.14 - 0.96) and the adjusted OR was 0.56 (0.19 - 1.7). The difference in MACE was statistically significant, (p=0.04), but did not reach statistical significance when adjusted estimates were calculated. These results were similar to those observed in the EPISTENT study.

### Clinical conclusions

The effectiveness analysis showed that the risk of MACE was reduced among patients receiving both the abciximab and stenting procedure, compared with those receiving only abciximab.

### Measure of benefits used in the economic analysis

The health outcomes were left disaggregated and no summary benefit measure was used. A cost-consequences analysis was therefore conducted.

### Direct costs

Discounting was not performed since the costs were incurred in a short time period. The unit costs were reported separately from the quantities of resources used. The health services included in the economic analysis were for the initial procedure, abciximab, additional stents, hospital stay, revascularisation and CABG. The cost/resource boundary adopted in the study seems to have been the health service. Resource use was estimated using actual data derived from the effectiveness study, while the unit costs were derived from a published study (Serruys et al., see Other Publications of Related Interest). The price year was not reported.
Statistical analysis of costs
Statistical analyses of the costs were not conducted.

Indirect Costs
The indirect costs were not included.

Currency
Euros (Euro).

Sensitivity analysis
The authors stated that sensitivity analyses were conducted to evaluate the impact of differences in baseline characteristics on the estimated outcome measures. However, these appear to have been statistical adjustments rather than proper sensitivity analyses.

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

Cost results
The average costs per patient were Euro 7,908 in the non-stented group and Euro 7,844 in the stented group. The estimated costs were similar to those observed in the EPISTENT study.

Synthesis of costs and benefits
Not relevant as a cost-consequences analysis was conducted.

Authors' conclusions
The study confirmed the results of published studies, namely, that the combination of abciximab and stenting may be effective among patients undergoing percutaneous transluminal coronary angioplasty (PTCA) without increasing the costs, not only under the strict patient selection conditions in the clinical trial, but also among patients evaluated in the setting of everyday clinical practice. Although, in the adjusted analysis, the difference in the risk of major cardiac adverse events (MACE) was no longer statistically significant, the authors commented that such a change was due to the small sample size.

CRD COMMENTARY - Selection of comparators
The combination of abciximab and stenting was compared with abciximab alone because the aim of the study was to evaluate the additional value of stenting. You should decide whether abciximab without stenting represents a widely used approach in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness analysis used a prospective cohort study, which was appropriate for the study question. Consecutive patients were selected so there was unlikely to have been any sampling bias, yet it is hard to tell if the study sample was representative of the study population. No power calculations were conducted to evaluate whether or not the sample size was sufficient to detect statistically significant differences in the outcome measures between the groups. Selection bias may well have been a problem since physicians allocated the patients to the intervention and no rationale was discussed for this. The period during which the clinical data were collected was reported, as well the length of follow-up. However, the methods of outcome assessment were not mentioned. No patients were lost to follow-up. There were no highly, statistically significant baseline differences between the groups. However, the statistical significance of the
difference in MACE fell after adjusting for baseline factors. There could have been further confounding as a result of selection bias.

**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 explicitly reported. Thus, it was unclear whether all the relevant categories of costs had been included. The unit costs were reported separately from the quantities of resources used, but no price year was given. This makes reflation exercises in other settings difficult. The source of cost data, a published study, was reported. Resource use was estimated using data collected prospectively alongside the effectiveness study. The costs were treated deterministically and no sensitivity analyses were performed.

**Other issues**
The authors made detailed comparisons of their findings with a published study and also reported the results of other studies. The authors did not address the issue of the generalisability of the results to other settings and did not perform sensitivity analyses. Thus, the external validity of the analysis was low. The study enrolled unselected patients undergoing PTCA and this was reflected in the conclusions of the study. The authors noted some limitations of their study, which have already been highlighted.

**Implications of the study**
The study suggests that stenting may have potential additional value in patients receiving abciximab before PTCA, at no extra cost, in comparison with abciximab alone. However, the authors admitted that their study was based on a small sample of patients and the issue of the beneficial effect of abciximab and stenting should be further addressed.

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None stated.

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**Other publications of related interest**


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