Cost-effectiveness of the unrestricted use of sirolimus-eluting stents vs bare metal stents at 1 and 2-year follow-up: results from the RESEARCH Registry

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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 study considered the use of sirolimus-eluting stents (SES) for the treatment of coronary artery stenosis. The comparator was the use of bare metal stents (BMS).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients undergoing stent implantation for coronary artery stenosis.

Setting
The setting was inpatient care in a tertiary hospital. The economic study was carried out in Rotterdam, the Netherlands.

Dates to which data relate
The clinical effectiveness and resource use data referred to the period from November 2001 to October 2004. No single price year was identified.

Link between effectiveness and cost data
The resource use and cost data were collected from the same patient sample that provided the clinical effectiveness information.

Study sample
All patients who underwent stenting at the study hospital during the study period were included in the study sample. No exclusions were reported. The study sample consisted of 958 patients, of whom 450 were in the BMS group and 508 in the SES group. No sample size or power calculations were reported in the paper.

Study design
This was a comparative study with a historical control. Data on the patients were collected for 2 years. No loss to follow-up was reported.

Analysis of effectiveness
The health outcomes reported in this paper were death or myocardial infarction (combined) and re-intervention rates. The two patient groups were generally well matched in terms of their baseline characteristics, except where the patient had previously had a myocardial infarction (higher in the BMS group). Analysis was performed on an intention to treat basis. The full clinical effectiveness results are reported elsewhere (Ong et al. 2006, see ‘Other Publications Of Related Interest’ below for bibliographic details).

**Effectiveness results**
The cumulative incidence of revascularisation was 14.7% in the BMS group compared with 6.4% in the SES group, (p<0.001).

The combined mortality or myocardial infarction rates were similar in both groups.

**Clinical conclusions**
SES reduced the rate of revascularisation in comparison with BMS.

**Measure of benefits used in the economic analysis**
The measure of health benefit used was the number of revascularisations avoided. These data were taken from the clinical effectiveness study.

**Direct costs**
The direct costs of the tertiary hospital were identified in the study. The costs of inpatient stay in secondary hospitals, where stable patients were released, were not included. The costs of interventions, drugs and inpatient stays were identified. Resource use was collected prospectively from the same patient sample that provided the clinical effectiveness evidence. The unit cost of hospital stay was estimated using information from the study hospital. The sources of the other unit costs were not reported. No discounting appears to have been applied to costs incurred in the second year after index treatment. No single price year was reported.

**Statistical analysis of costs**
The differences in costs between the two treatment groups were compared using t-tests.

**Indirect Costs**
No productivity costs were included in this analysis.

**Currency**
Euros (EUR).

**Sensitivity analysis**
Uncertainty around the cost and health benefit data was examined using bootstrapping techniques. Bootstrapping was run 1,000 times and provided 95% confidence intervals (CIs).

**Estimated benefits used in the economic analysis**
The number of revascularisations avoided was not stated clearly in the paper.

**Cost results**
The total costs after 2 years were EUR 10,911 in the SES group compared with EUR 9,042 in the BMS group, (p value
Synthesis of costs and benefits
The incremental cost-effectiveness at 2 years for SES compared with BMS was EUR 22,627 per revascularisation avoided (95% CI: 10,737 to 65,978).

Authors' conclusions
The use of sirolimus-eluting stents (SES) resulted in fewer revascularisations but was not cost-effective in comparison with bare metal stents (BMS).

CRD COMMENTARY - Selection of comparators
This study compared the use of SES with BMS for the treatment of coronary artery stenosis. This comparator was chosen as it represented previous usual practice in the authors' setting. You should consider how these options compare with usual practice in your own setting before applying the results of this study.

Validity of estimate of measure of effectiveness
The clinical effectiveness study was taken from a comparative study with a historical control. This study design has a number of inherent limitations, such as a lack of internal validity. However, whilst the authors noted that a number of randomised controlled trials had been undertaken to assess the clinical effectiveness of the two types of stents, they indicated that they wanted to identify the impact of a change in practice in their own setting. No sample size or power calculations were reported in the study, so it is not clear whether the study findings were due to the different stents or to chance. The authors did not consider whether their patient sample was representative of the wider patient population undergoing revascularisation.

Validity of estimate of measure of benefit
The number of revascularisations avoided was the summary measure of health benefit used. It was taken directly from the analysis of the clinical effectiveness data. No rationale for this choice of health benefit was included in the paper. It was unclear whether this measure would capture the full health benefits of the intervention.

Validity of estimate of costs
The aim of the study was to identify the costs of the tertiary hospital. The costs evaluated were appropriate for this perspective, but one should be aware that inpatient and other costs associated with secondary hospitals would have to be taken into account for a health service perspective. The authors examined the impact of uncertainty around the cost data using bootstrapping techniques. A comprehensive breakdown of resource use was given in the paper. These factors enhance the generalisability of the study findings. However, few unit costs were reported and, although costs were incurred during 2 years, no discounting was undertaken. These factors limit the generalisability of the study findings. No clear price year was reported and the cost data appear to have been taken from more than one year. This will prevent any future reflation exercises.

Other issues
The authors did not present all the results of their study in this paper (as they are reported elsewhere). However, this makes it difficult to clearly identify the clinical effectiveness data. Their conclusion reflected the scope of the analysis. The authors compared their findings with other similar studies and commented on the differences found.

Implications of the study
The authors did not make any recommendations for changes in practice or for further research.
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None stated.

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Other publications of related interest
Because readers are likely to encounter and assess individual publications, NHS EED abstracts reflect the original publication as it is written, as a stand-alone paper. Where NHS EED abstractors are able to identify positively that a publication is significantly linked to or informed by other publications, these will be referenced in the text of the abstract and their bibliographic details recorded here for information.


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Subject indexing assigned by NLM

MeSH
Coronary Restenosis /economics /therapy; Cost-Benefit Analysis; Female; Follow-Up Studies; Humans; Immunosuppressive Agents /administration & dosage /economics; Male; Middle Aged; Randomized Controlled Trials as Topic; Sirolimus /administration & dosage /economics; Stents /economics; Treatment Outcome

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