Economic outcomes analysis of stenting versus percutaneous transluminal coronary angioplasty for patients with coronary artery disease in Japan

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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 use of coronary stenting and percutaneous transluminal coronary angioplasty (PTCA) in patients with coronary artery disease (CAD).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised a hypothetical cohort of patients with CAD who were treated with either stenting or PTCA. Detailed inclusion and exclusion criteria were not reported.

Setting
The setting was secondary care. The economic study was performed in Japan.

Dates to which data relate
Some of the effectiveness and resource use data were derived from studies published in 1998 and 1999. The costs were expressed in 1997 and 1998 values.

Source of effectiveness data
The effectiveness data were derived from experts' opinions and completed studies.

Modelling
A decision analytic model derived from another study (see Other Publications of Related Interest) was used to estimate the clinical effects and health care costs of coronary stenting versus PTCA. The time frame of the model was 3 years. The model included coronary artery bypass grafting (CABG) as a secondary revascularisation procedure for the treatment of adverse events.

Outcomes assessed in the review
The outcomes estimated were:

the rates of death, Q-wave myocardial infarction (MI), re-PTCA, bail-out stenting, and CABG during initial hospitalisation; and
the probabilities of interventional revascularisation, CABG, Q-wave MI, patients' sequelae, and death in the first, second and third year after the initial procedure.

**Study designs and other criteria for inclusion in the review**
Not stated.

**Sources searched to identify primary studies**
Not stated.

**Criteria used to ensure the validity of primary studies**
Not stated.

**Methods used to judge relevance and validity, and for extracting data**
Not stated.

**Number of primary studies included**
Two primary studies were included in the review.

**Methods of combining primary studies**
Not stated.

**Investigation of differences between primary studies**
Not stated.

**Results of the review**
The estimates derived from the two published studies and expert opinion are as follows.

With PTCA, the in-hospital rates were 0.4% for death, 1.3% for Q-wave MI, 2.2% for re-PTCA, 9.2% for bail-out stenting and 0% for CABG.

With stenting, the in-hospital rates were 0% for death, 0.5% for Q-wave MI, 0.7% for re-PTCA, 5.1% for bail-out stenting and 0% for CABG.

With PTCA, the probability values of interventional revascularisation were 45% in the first year, 2% in the second year and 1% in the third year. The corresponding values with stenting were 28% (year 1), 1.5% (year 2) and 1% (year 3), respectively.

With PTCA, the probability values of CABG were 4.4% in the first year, 0.5% in the second year and 0.5% in the third year. The corresponding values with stenting were 2.1% (year 1), 0.5% (year 2) and 0.5% (year 3), respectively.

With PTCA, the probability values of Q-wave MI were 6.6% in the first year, 2% in the second year and 2% in the third year. The corresponding values with stenting were 1% (year 1), 2% (year 2) and 2% (year 3), respectively.

With PTCA, the probability values of death were 4.4% in the first year, 0% in the second year and 0% in the third year. The corresponding values with stenting were 1.5% (year 1), 0% (year 2) and 0% (year 3), respectively.

**Methods used to derive estimates of effectiveness**

NHS Economic Evaluation Database (NHS EED)
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A consensus from Japanese experts from three main hospitals involving 1,095 patients (half treated with PTCA and half treated with stenting) was used to identify Japanese-specific probability estimates. These were used together with data observed in the trials.

**Estimates of effectiveness and key assumptions**
The estimates derived jointly from the literature and expert opinion are reported in the 'Results of the Review' section.

**Measure of benefits used in the economic analysis**
The summary benefit measure used in the economic analysis was the percentage of event-free survivors. This was estimated from the effectiveness data estimated from the literature and corrected by the Japanese experts. Event-free survivors were defined as patients who were free of Q-wave MI, stroke or repeat revascularisation procedure by PTCA, stent or CABG, and who had not died after the initial interventional procedure. No discounting was applied.

**Direct costs**
A 3% annual discount rate was used for the cost analysis. Most of the unit costs were presented separately from the quantities of resources used. The cost categories considered in the economic evaluation were the in-hospital costs and rehabilitation and outpatient follow-up care. The in-hospital costs covered hospitalisation, initial cardiac catheterisation (balloon catheters, stenting, intravascular ultrasound, laboratory use and personnel) and initial complications. The cost of rehabilitation and outpatient follow-up care included physician services, laboratory tests, medico-technical services, and drug treatment of adverse events.

The perspective of the Japanese health care system was used. The resource use data were estimated from published sources and interviews with experts. The unit costs were estimated mainly from three Japanese reference centres and charges from the Japanese Ministry of Health and Welfare. The drug prices were based on official pharmacy sales prices. All the costs were presented in 1997 and 1998 values.

**Statistical analysis of costs**
The estimated expenses in the two groups were compared through statistical tests of the costs. The type of test used was not reported.

**Indirect Costs**
The indirect costs were not considered.

**Currency**
Japanese yen (Y).

**Sensitivity analysis**
A one-way sensitivity analysis was carried out by varying the difference in the rate of revascularisation between PTCA and stenting (5% or 10% decrease). The type of analysis and reasons for the ranges used were not reported.

**Estimated benefits used in the economic analysis**
The in-hospital event-free survival rate was 86.9% in the PTCA group and 93.7% in the stenting group. At one year, the corresponding rates were 39.6% (PTCA) and 67.4% (stenting). Similar rates were observed thereafter.

**Cost results**
The estimated in-hospital costs per patient, excluding complication costs, were Y 1,009,295 in the PTCA group and Y
1,383,412 in the stenting group (an increase of 47%).

When the in-hospital complications were considered, the initial in-hospital costs per patient were Y 1,155,982 in the PTCA group and Y 1,455,390 in the stenting group, (p<0.001).

At one year, the overall average treatment costs per patient were Y 1,955,633 in the PTCA group and Y 1,907,960 in the stenting group. The corresponding costs after 2 years were Y 2,039,945 (PTCA) and Y 1,994,329 (stenting), respectively, and after 3 years, Y 2,117,585 (PTCA) and Y 2,070,684 (stenting). These represented small and statistically insignificant differences in favour of stenting.

The difference in the costs was statistically significant after in-hospital procedures. However, after the end of the first year, the differences in the costs in the two groups were no longer statistically significant.

Synthesis of costs and benefits
The costs and benefits were not combined because the stenting approach was more effective (higher rate of event-free survivors) than the PTCA procedure and was cost neutral (or slightly cost-saving). The sensitivity analysis revealed that a decrease of up to 10% in the re-intervention rate in the PTCA group did not affect the conclusions of the analysis.

Authors' conclusions
For patients with coronary artery disease (CAD) in Japan, the use of coronary stenting would appear to be the most appropriate approach, both because of the increased event-free survival, and the cost-effectiveness associated with the procedure.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. PTCA and coronary stenting were selected because they represent the two recommended revascularisation procedures for patients with CAD. The authors stated that CABG was not considered as a first-line procedure for CAD patients because the Japanese approach was not oriented to the use of CABG. Therefore, the choice of PTCA as the comparator reflected current practice in Japan. You should decide whether this alternative is a valid comparator in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness data were derived from published studies and experts’ opinions, which were based on their experience in 1,095 treated patients. Data were adapted to the Japanese context to reflect actual disease patterns. It was unclear whether a systematic review of the literature was performed to identify primary studies and the validity of the studies included in the review was not reported. The authors acknowledged that a randomised controlled trial would have been more appropriate for the study question. The experts' estimates were not varied in the sensitivity analysis. Thus, uncertainty remains as to the validity of the effectiveness measure.

Validity of estimate of measure of benefit
The benefit measure was derived from the effectiveness analysis and represents a disease-specific measure. This may be difficult to compare with the benefits of other health care interventions. The estimated benefits were likely to be representative of Japanese patients.

Validity of estimate of costs
The authors stated the perspective of the study and provided details of all the categories of costs considered in the analysis. The unit costs were presented separately from the resource use data and the price year was reported. Moreover, the authors used charges rather than unit cost when data were unavailable. These facts enhance the replication of the study in other settings. Statistical tests were carried out to compare the estimated costs, but no sensitivity analyses of the costs were performed. The source of the cost data was reported.
Other issues
The authors compared their results with those observed in other published studies. They found that the current analysis confirmed the superiority of stenting relative to PTCA. The authors stated that their findings reflected Japanese treatment patterns, thus caution is required when extrapolating the study results to other settings. Some limitations of the analysis, such as the use of data derived from experts’ assumptions rather than reliable clinical information, were noted.

Implications of the study
The main implication of the study is that coronary stenting should be considered as the treatment of choice for patients with CAD in Japan. However, this conclusion should be viewed in conjunction with the limitations of the present analysis.

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Other publications of related interest

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