A one-year comparison of cost and outcomes of angioplasty in stent and nonstent patients
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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 compared percutaneous transluminal coronary angioplasty (PTCA) with and without the use of stents.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised newly treated male and female patients with PTCA who were enrolled in large, self-insured plans in regions of the USA.

Setting
The study setting was secondary care. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness and resource use data were derived from medical claims from patients undergoing PTCA during 1995. The price year was not reported, but it appears to have been 1995.

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

Link between effectiveness and cost data
The costing was undertaken retrospectively on the same patient sample as that used in the effectiveness study.

Study sample
No sample size was determined in the planning phase of the study to assure a certain power. In addition, power calculations were not performed retrospectively. The study used a national medical claims database of patients enrolled in large, self-insured plans. The ICD-9 procedure codes used to identify patients were 36.01, 36.02, 36.03 and 36.05 for non-stent angioplasty, and 36.06 for stent angioplasty. Of the 1,367 patients included in the study, 22% (n=304) received a stent. The remaining 1,063 patients did not receive a stent during the index angioplasty. The mean age was 60 years for stent patients and 61 years for non-stent patients. The majority of the patients in both the stent and non-stent groups were male (73% and 72%, respectively).
Study design
This was a retrospective cohort study that used a national medical claims database of patients enrolled in large, self-insured plans covering 1.7 million lives. The patients were followed up for one year. The authors reported that to measure all events, patients were required to be in the health plan for the entire year following the angioplasty.

Analysis of effectiveness
All patients included in the study were accounted for in the analysis. The primary health outcome used was the likelihood of nonfatal restenotic outcomes (i.e. repeat PTCA, coronary artery bypass grafting and myocardial infarction). The groups were shown to be comparable in a number of baseline characteristics, including age, gender distribution, and prior year of hospital utilisation. The groups were also shown to be generally similar in terms of previous co-morbidities. The exception was history of ischaemic heart disease (IHD), which was higher in the non-stent group (45.3% of patients) than in the stent group (40.3% of patients), (p=0.0002). The non-stent group was also shown to have a higher proportion of patients with a history of calcium-channel antagonists use than those in the stent group (39.6% versus 35.2%; p=0.05). The groups were compared in univariate as well as multivariate dimensions. Logistic regression was used to control for factors that might influence restenosis. Cox proportional hazard models were also used to estimate the effect of a stent on the risk of restenosis over time.

Effectiveness results
The proportion of patients suffering a restenotic event was 16.1% (+/- 36.8) for stent patients and 20.1% (+/- 40.1) for non-stent patients, (p=0.12).

The results of the logistic regression showed that only baseline age appears to be a significant determinant of suffering a restenotic event, with the likelihood of restenosis decreasing with age by a small margin (odds ratio 0.98; p=0.01). Stent placement did not significantly affect the likelihood of restenotic events, although it had the expected negative sign suggesting a reduction of events with the use of a stent.

Clinical conclusions
The study found that restenotic events were lower for patients with stents by a non significant margin.

Measure of benefits used in the economic analysis
The authors did not derive a measure of health benefit. The analysis was therefore categorised as a cost-consequences study.

Direct costs
The direct costs of the hospital were included in the analysis. These covered the costs of index angioplasty, IHD-related inpatient costs (including PTCA), and IHD-related follow-up costs. The authors used hospital charges associated with inpatient and outpatient claims to obtain the total medical costs for each patient. Discounting was not relevant, as the costs were incurred during one year, and was appropriately not performed. The price year was not reported, but it appears to have been 1995.

Statistical analysis of costs
The mean costs in the two groups were compared in univariate as well as multivariate dimensions. A log-linear regression was used to estimate the effect of a stent on the total 1-year medical costs after controlling for other factors.

Indirect Costs
The indirect costs were not included.
Currency
US dollars ($).

Sensitivity analysis
No sensitivity analyses were performed.

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

Cost results
The total 1-year medical care cost was $49,425 (+/- 34,289) per patient in the stent group and $40,683 (+/- 31,320) per patient in the non-stent group, (p=0.0001).

The results of the log-linear regression showed that the costs were 26% higher for stent patients than for non-stent patients, (p<0.01). Amongst other factors, age, living in the Midwest, South and North-Central regions, and a history of diabetes had a significant influence on the total 1-year medical cost.

Synthesis of costs and benefits
The costs and benefits were not combined.

Authors' conclusions
Although restenotic events were lower for patients with stents by a non significant margin, follow-up costs did not offset the higher cost of the initial stent placement.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used (PTCA without the use of stents). It represented current practice in the authors' settings. You should decide if the comparator represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a retrospective cohort study. Although valid for the study question identified, this type of study design has a higher potential for confounding and bias than prospective studies such as randomised controlled trials. The study sample appears to have been representative of the study population. The groups were shown to be generally similar in terms of previous co-morbidities. The exception was history of IHD, with the non-stent group containing a higher proportion of patients with a history of IHD than the stent group. The non-stent group was also shown to contain a higher proportion of patients with a history of calcium-channel antagonist use. However, an appropriate statistical multivariate analysis was performed to take these differences into account.

Validity of estimate of measure of benefit
The authors did not derive a measure of health benefit. The analysis was therefore categorised as a cost-consequences study.

Validity of estimate of costs
All the categories of cost relevant to the perspective adopted were included in the analysis. No major costs were omitted from the analysis. The costs and the quantities were not reported separately, which will limit the generalisability and transferability of the authors' results. The costs were obtained from medical claims. An appropriate multivariate analysis of the costs was performed. Since all the costs were incurred during one year, discounting was unnecessary and
was not performed. Charges were used to proxy costs, but this does not reflect the true cost of providing the interventions under study. The price year was not explicitly reported, which will hamper any future reflation exercises.

**Other issues**
The authors reported that the magnitude of the reduction in restenotic events due to stenting was similar to comparable statistics from other clinical trials. The issue of generalisability to other settings was not assessed, although data from several regions of the USA were used. The authors do not appear to have presented their results selectively, and their conclusions reflected the scope of the analysis.

The authors reported a number of further limitations to their study. First, statistical significance to observe differences in outcomes was lacking. According to the authors this was possibly due to confounding beyond their control or a lack of power. Second, as this was a retrospective cohort study with no detailed medical charts available, it could not be verified that the clinical events resulted from restenosis in the same vessel in which the initial angioplasty was done. Third, the authors could not control for the type of inpatient drugs used. Finally, only patients who were alive for the entire 1-year post-PTCA period were included; there were no data available on patients who died or dropped out of the insurance plans.

**Implications of the study**
The study findings support (non significantly) the use of stents but at a higher overall cost. The authors reported that further studies are needed to better understand restenosis and its associated outcomes and costs.

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**Other publications of related interest**


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