Practice patterns and outcomes of percutaneous coronary interventions in the United States: 1995 to 1997


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 percutaneous coronary interventions (PCIs), such as coronary stents, anticoagulants (heparin, enoxaparin, and warfarin), and antiplatelet agents (abciximab and ticlopidine), was examined.

Type of intervention
Treatment and secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients requiring PCIs.

Setting
The 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 gathered from October 1995 to October 1997. The price year was not reported.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was carried out retrospectively on the same sample of patients as that used in the effectiveness study.

Study sample
Power calculations to determine the sample size were not carried out. However, the sample of patients included in the study was large. A single group of patients was identified from the review of clinical charts retrieved from the proprietary HCIA Sachs Clinical Pathways database from October 1995 to October 1997. The database included data from 94 acute care, non-federal hospitals. The patients were identified from those undergoing a PCI based on the presence of a hospital discharge procedure code referring to single or multi-vessel coronary angioplasty or atherectomy, with or without thrombolysis. A sample of 37,088 patients was considered in the analysis. The mean age was 62.4 years. There were 66.4% men and 84.4% of the patients underwent single vessel angioplasty without thrombolysis. Over 40% of the patients had diagnoses of acute myocardial infarction, angina, or hypertension.
Study design
This was a historical case series study. The length of follow-up of the patients in the study was not reported. To ensure that the data used were representative of the entire US population, demographic data were compared with the 1996 National Hospital Discharge Survey (NHDS). The NHDS is based on official statistical data on inpatients discharged from non-federal hospital, and it represents 467,210 discharged across the USA.

Analysis of effectiveness
All of the patients included in the initial study sample were accounted for in the effectiveness analysis. The outcomes considered in the study were patterns of medication use for stents, enoxaparin, warfarin, abciximab, ticlopidine and heparin dosage. Also considered were changes in in-hospital outcomes, such as ischaemic events and bleeding requiring transfusion, and average length of stay (both from admission to intervention and from intervention to discharge). The ischaemic events considered were hospital death, urgent coronary artery bypass graft (CABG) and in-hospital repeat PCI. In addition, the rate of ischaemic events was evaluated in the sub-groups of patients with or without stent placement or abciximab therapy, as these factors could represent confounding factors. The data were analysed in 6-month intervals.

Effectiveness results
Four 6-month intervals were considered. These were October 1995 to March 1996 (n=17,063) (O5-M6), April to September 1996 (n=8,939) (A6-S6), October 1996 to March 1997 (n=6,761) (O6-M7), and April to October 1997 (n=4,325) (A7-O7). The utilisation patterns were:

- for stents, 32% (O5-M6), 44.6% (A6-S6), 47.6% (O6-M7) and 57.5% (A6-O7), (p<0.001);
- for enoxaparin, 2.6% (O5-M6), 6.3% (A6-S6), 5.9% (O6-M7) and 5.3% (A7-O7), (p<0.001);
- for warfarin, 28.5% (O5-M6), 14.8% (A6-S6), 10.9% (O6-M7) and 6.8% (A7-O7), (p<0.001);
- for abciximab, 5.4% (O5-M6), 14% (A6-S6), 21% (O6-M7) and 21% (A7-O7), (p<0.001);
- for ticlopidine, 33.9% (O5-M6), 59.1% (A6-S6), 68.5% (O6-M7) and 75.9% (A7-O7), (p<0.001); and
- for heparin dosage, 101,812 IU (O5-M6), 88,003 IU (A6-S6), 86,003 IU (O6-M7) and 76,533 IU (A7-O7), (p<0.001).

The changes in in-hospital outcomes in the four time intervals were:

- for hospital deaths, 1.9% (O5-M6), 1.8% (A6-S6), 1.4% (O6-M7) and 1.6% (A7-O7), (p non significant);
- for urgent CABG, 3.4% (O5-M6), 3% (A6-S6), 2.6% (O6-M7) and 2.1% (A7-O7), (p<0.001);
- for in-hospital repeat PCIs, 7% (O5-M6), 5.3% (A6-S6), 3% (O6-M7) and 2.8% (A7-O7), (p<0.001); and
- for bleeding requiring transfusion, 7.7% (O5-M6), 6.5% (A6-S6), 6.7% (O6-M7) and 5.5% (A7-O7), (p<0.001).

The average length of stay was 5.2 days (O5-M6), 4.7 days (A6-S6), 4.1 days (O6-M7) and 3.8 days (A7-O7), (p<0.001);

the average length from admission to intervention was 2.6 days (O5-M6), 2.4 days (A6-S6), 2.2 days (O6-M7) and 2.2 days (A7-O7); and

the average length from intervention to discharge was 2.6 days (O5-M6), 2.3 days (A6-S6), 1.9 days (O6-M7) and 1.6 days (A7-O7).

In the sub-groups of patients with and without stents:
the rate of death was 1.3% versus 2%, (p < 0.001),
the rate of CABG was 1.8% versus 3.8%, (p < 0.001), and
the rate of repeat PCI was 6.1% versus 4.8%, (p < 0.001).

In the sub-groups of patients with and without abciximab therapy:
the rate of death was 2.3% versus 1.7%, (p non significant),
the rate of CABG was 2.8% versus 3%, (p non significant), and
the rate of repeat PCI was 5.5% versus 5.4%, (p non significant).

Clinical conclusions
The effectiveness analysis showed that acute events decreased over time as treatment patterns switched to a more frequent use of stents and/or abciximab.

Measure of benefits used in the economic analysis
No summary benefit measure was used. Therefore, the study was classified as a cost-consequences analysis.

Direct costs
Discounting was not relevant since the costs were not incurred during more than two years. The unit costs were not presented separately from the quantities of resources used. A breakdown of the costs included in the economic evaluation was not provided and only hospital costs were considered. The cost/resource boundary of the study was that of the third-party payer. The estimation of both resource use and cost data came from the HCIA Sachs Clinical Pathways database from October 1995 to October 1997. Charges were converted into costs using the cost-to-charge ratio derived from Medicare reports, accounting for regional variations and teaching status. The costs of patients who did not experience adverse events were calculated. Also calculated were the costs of patients who experienced a combination of bleeding, need for urgent CABG, and need for repeat intervention. The price year was not reported.

Statistical analysis of costs
Statistical tests were carried out to test the statistical significance of the difference in the average total costs. The impact of some variables on the total estimated costs was estimated through multivariate regression analyses. The variables considered were age, gender, race, diabetes, renal failure, acute myocardial infarction, unstable angina, single- versus multi-vessel procedure, hospital type, geographic region, and the use of stents and abciximab.

Indirect Costs
The indirect costs were not included in the economic analysis.

Currency
US dollars ($).

Sensitivity analysis
Sensitivity analyses were not performed.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.
Cost results
The average total costs were $12,124 in October 1995 to March 1996 (n=17,063), $11,894 in April to September 1996 (n=8,939), $11,273 in October 1996 to March 1997 (n=6,761), and $10,685 in April to October 1997 (n=4,325). The reduction in costs was statistically significant, (p<0.001).

The average total cost was:
- $10,290 for patients who did not experience any complication (n=31,828),
- $22,074 for those who experienced bleeding (n=1,897),
- $14,957 for those with repeat PCI (n=1,731),
- $27,833 for those who experienced repeat PCI and bleeding (n=322),
- $27,380 for those who experienced urgent CABG (n=432), and
- $35,588 for those who experienced urgent CABG and bleeding (n=662).

The multivariate analysis showed that urgent CABG and bleeding requiring transfusion were the two largest contributors to total costs. The additional cost was $13,832 (+/- 486) for CABG and $10,226 (+/- 300) for bleeding requiring transfusion.

Other relevant contributors to the additional costs were renal failure, abciximab use, acute myocardial infarction, stent use and same-admission repeat PCI. Cost-savings were observed with the status of teaching hospital.

Synthesis of costs and benefits
The costs and benefits were not combined because the study was classified as a cost-consequences analysis.

Authors’ conclusions
The use of stents and abciximab increased dramatically among patients undergoing percutaneous coronary intervention (PCIs). Heparin dosage and bleeding decreased, but bleeding remained the most common complication. This pattern was associated with a decrease in the rate of acute events such as deaths, need for repeat PCI and coronary artery bypass graft (CABG), and length of stay.

CRD COMMENTARY - Selection of comparators
The comparators were chosen on the basis of the procedures and treatments that patients undergoing PCI usually receive, that is, antiplatelets, anticoagulants and coronary stents. Therefore, standard practice patterns were considered. You should decide whether they represent valid interventions in your own setting.

Validity of estimate of measure of effectiveness
The analysis of the effectiveness used a historical case series study, which was based on a descriptive design and provided a picture of disease and treatment patterns. These studies were useful to raise a question rather than to confirm a hypothesis of relationship between exposure and disease. Another factor was the lack of an appropriate comparison group. These represented the main limitations to the internal validity of the effectiveness study. Clearly, the use of an observational or intervention study based on a prospective design would have been more appropriate. The patient demographics were reported but details on the follow-up were not.

Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted.
Validity of estimate of costs
The authors stated explicitly the perspective adopted in the study, but a breakdown of the costs was not provided. However, as the resource use data came from a nationally representative database, it is likely that all the relevant categories of costs were included in the analysis. The price year was not reported. It could have been relevant since the costs were estimated over a 2-year period. The cost estimates came from a large sample of hospitals, and thus reflected costs across the USA. Statistical tests were conducted to identify those factors that had a significant impact on the total costs. The true costs were estimated using a charge-to-cost ratio.

Other issues
The authors compared their findings with those from other studies. They did not address the issue of the generalisability of the study results to other settings. Sensitivity analyses were not carried out and the external validity of the study was low. The authors noted some limitations of their analysis. These were mainly related to the use of a registry that did not consider the rate of procedures performed beyond the initial hospitalisation. This affected both the costs and effectiveness. Finally, the event rates were not adjusted by disease severity, which may strongly affect the final outcomes.

Implications of the study
The study results suggested that the use of coronary stents and abciximab may lead to a reduction in the rate of acute events and total hospital costs. However, this conclusion should be interpreted with caution due to the limitations of the effectiveness analysis.

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