The impact of acute coronary syndrome on clinical, economic, and cardiac-specific health status after coronary artery bypass surgery versus stent-assisted percutaneous coronary intervention: 1-year results from the Stent or Surgery (SoS) trial


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 artery bypass grafting (CABG) and stent-assisted percutaneous coronary intervention (PCI) in the treatment of angina. Both revascularisation procedures were evaluated in patients with and without acute coronary syndrome (ACS). ACS referred to a spectrum of acute severe cardiac disorders that included unstable angina, non ST-segment elevation myocardial infarction (MI) and ST elevation MI.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised symptomatic patients with typical angina pectoris and multi-vessel disease who were eligible for both CABG and PCI.

Setting
The setting was a hospital. The economic study was carried out in the UK.

Dates to which data relate
The effectiveness and resource use data were gathered from November 1996 to December 1999. The price year was 2000.

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

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

Study sample
There was limited information on the design and sample characteristics of the patients included in the trial since the study had already been published. Overall, 988 patients were recruited. There were 488 patients in the PCI group and 500 patients in the CABG group. There were 242 patients with ACS (116 received PCI and 126 received CABG) and 746 patients without ACS (372 received PCI and 374 received CABG). The mean age was 61.9 (+/- 9.5) years in ACS
PCI patients, 62.6 (+/- 9.4 years) in ACS CABG patients, 61.1 (+/- 9.1) years in non-ACS PCI patients, and 61.2 (+/- 9.5) years in non-ACS CABG patients. The proportion of women was 28.5% in ACS PCI patients, 24.6% in ACS CABG patients, 61.1% in non-ACS PCI patients, and 61.2% in non-ACS CABG patients.

**Study design**

This was an open-label, prospective, randomised clinical trial that was carried out in 53 centres in Europe and Canada. The length of follow-up was one year. Since some patients were lost to follow-up, the impact of missing data was analysed using a multiple imputation approach. This showed that missing data did not affect the conclusions of the effectiveness analysis. Thus, only non-imputed data were used.

**Analysis of effectiveness**

The analysis of the clinical study appears to have been restricted to patients with complete follow-up data. The primary outcome measures used were:

- Procedural factors (such as number of stents, cross lamp time),
- In-hospital outcomes (deaths, MI, bleeding, cerebrovascular accidents, repeat revascularisations, length of index and post-procedure stay),
- 1-year clinical outcomes (deaths, Q-wave MI, deaths or Q-wave MI, bleeding, cerebrovascular accidents and repeat revascularisations), and
- Cardiac-related health status.

Health status was assessed using the Seattle Angina Questionnaire (SAQ), a 19-item self-administered, well-validated questionnaire quantifying five clinically-relevant domains of cardiac-related health status. The three most relevant dimensions of care, (i.e. physical limitation, angina frequency and quality of life) were considered.

The study groups were well matched at baseline in terms of their clinical and demographic characteristics. However, ACS patients were significantly more likely to be women and current smokers, to have a history of prior MI, and to present with heart failure and Class III/IV angina. In contrast, patients without ACS were significantly more likely to have a family history of cardiovascular disease, a history of hyperlipidaemia, and to have been smokers. A multi-regression analysis was carried out to evaluate the comparative improvement from baseline to 6 and 12 months.

**Effectiveness results**

In the PCI group, the mean number of stents implanted was 2.8 in patients with ACS and 2.5 in patients without ACS, (p=0.03). There was a trend towards more patients with ACS having stents implanted (99.1% versus 94.9%; p=0.057). No statistically significant differences in the duration of the PCI procedure and the use of abciximab were observed between patients with and without ACS.

In the CABG group, the cross clamp time was 45.5 minutes in patients with ACS and 39.6 minutes in patients without ACS, (p=0.001). There was a trend towards longer overall CABG procedure time (3.55 versus 3.43 hours) and bypass time (1.26 versus 1.19 hours) in patients with ACS versus patients without ACS.

In patients with ACS, most in-hospital outcomes were similar between groups. The exceptions were index hospital stay (8.6 days in the PCI group and 15.2 days in the CABG group; p<0.001), post-procedure stay in the intensive care unit (0.1 days in the PCI group and 1.4 days in the CABG group; p<0.001), and post-procedure stay in the general ward (1.8 days in the PCI group and 4.7 days in the CABG group; p<0.001).

In the non-ACS group, the rate of repeat revascularisation procedures was significantly higher in the PCI group than in the CABG group (2.7% versus 0.5%; p=0.02). Other outcomes were generally comparable between the groups. The exceptions were index hospital stay (4.5 days in the PCI group and 11.2 days in the CABG group; p<0.001), post-procedure stay in the intensive care unit (0.1 days in the PCI group and 0.9 days in the CABG group; p<0.001), post-
procedure stay in the high-dependency unit (0.1 days in the PCI group and 0.5 days in the CABG group; p<0.001), and post-procedure stay in the general ward (0.9 days in the PCI group and 3.2 days in the CABG group; p<0.001).

In the ACS group, among 1-year clinical outcomes, only the rate of repeat revascularisations was different between groups (15.5% in the PCI group and 7.1% in the CABG group; p=0.04). In the non-ACS group, several 1-year clinical outcomes were significantly different between the groups. These included the rates of death (2.4% versus 0.5%; p=0.03) and the rates of repeat revascularisations (18% versus 3.2%).

Cardiac-related health status improved over the 1-year treatment period in both groups after controlling for ACS and other covariates. In patients without ACS, CABG patients had significantly greater improvement in the three SAQ domains than did PCI patients at both 6 and 12 months. In patients with ACS, CABG patients showed significantly greater improvement in SAQ scores for angina frequency at 6 months, whereas the improvement was similar between treatment arms for all three domains at 12 months.

Clinical conclusions
The effectiveness analysis showed that CABG led to fewer repeat revascularisation procedures in comparison with PCI in patients with and without ACS. Other clinical outcomes were similar between the groups. Both procedures were associated with a significant improvement in cardiac-related health status at 6 and 12 months after intervention. However, in patients without ACS, CABG was more effective in relieving angina, increasing physical functioning and improving quality of life. In the ACS group, there was a non significant slight trend towards an advantage of CABG over PCI, although the relative difference tended to be smaller.

Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used in the economic evaluation. In effect, a cost-consequences analysis was carried out.

Direct costs
The perspective adopted in the study was not stated, but only hospital costs were included in the analysis. A breakdown of the cost items was not provided. The unit costs and the quantities of resources used were not reported, although length of hospital stay and post-procedure stay were provided together with the clinical outcomes. Resource use was estimated alongside the clinical trial, while the costs were derived from publicly available British unit costs. Discounting was not relevant since the costs were incurred during a 1-year time horizon. The costs were presented in 2000 values using the Hospital and Community Health Service price index.

Statistical analysis of costs
Owing to the non-normal distribution of the costs, bootstrapping (5,000 samples) was used.

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

Currency
UK pounds sterling (€).

Sensitivity analysis
Sensitivity analyses were not performed.

Estimated benefits used in the economic analysis
Cost results
In the sub-group of ACS patients, the 1-year total costs were 8,014 with PCI and 10,080 with CABG. The difference was 2,066 (95% confidence interval, CI: -690 - 3,487).

In the sub-group of non-ACS patients, the 1-year total costs were 5,760 with PCI and 8,509 with CABG. The difference was 2,749 (95% CI: 1,890 - 3,409).

Synthesis of costs and benefits
A synthesis of the costs and benefits was not relevant since a cost-consequences analysis was carried out.

Authors' conclusions
Patients without acute coronary syndromes (ACS) might achieve better clinical outcomes with coronary artery bypass grafting (CABG) in comparison with percutaneous coronary intervention (PCI), although such benefits were achieved at higher hospital costs. In patients with ACS, the clinical and economic outcomes were quite similar, although fewer repeat revascularisation procedures were observed in CABG patients.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparators was clear. CABG and PCI are the two most commonly used revascularisation procedures for the treatment of angina. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness evidence came from a published clinical trial, which was appropriate for the study question. The randomised multi-centre design of the trial and baseline comparability of the study groups enhance the internal validity of the analysis. Although the methods used to deal with the loss to follow-up were reported, there was limited information on other aspects of the trial as it had already been published. The authors noted that the small sample size of patients with ACS might have reduced the power to detect statistically significant differences in the outcome measures. Further, the open-label design might have introduced some bias.

Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted. Please refer to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs
There was little detail on the cost analysis. A breakdown of the cost items was not reported, and the unit costs were generally not presented separately from the quantities of resources used. This limits the possibility of replicating the study in other settings. The costs were estimated using publicly available costs but the source of the data was unclear. The cost estimates were specific to the study setting. The price year was reported, which aids reflation exercises in other time periods.

Other issues
The authors reported the results of other clinical trials and made some comparisons of their findings with those from other studies. However, the issue of the generalisability of the study results to other settings was not addressed. Sensitivity analyses were not carried out, which limits the external validity of the study. The authors stated that the use of a measure of cardiac-related health status alongside more "traditional” measures of health used in clinical trials (i.e.
mortality and MI rates) was a strength of the analysis. The study referred to patients with angina and this was reflected in the authors' conclusions.

**Implications of the study**
The study results suggested that the benefits of CABG relative to PCI tend to be greater in patients without ACS.

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**Other publications of related interest**
Stables RH. Design of the (Stent or Surgery( Trial (SoS): a randomised controlled trial to compare coronary artery bypass grafting with percutaneous transluminal coronary angioplasty and primary stent implantation in patients with multi-vessel coronary artery disease. Semin Interv Cardiol 1999;4:201-7.


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