Outcomes of non-cardiac surgery after coronary bypass surgery or coronary angioplasty in the Bypass Angioplasty Revascularization Investigation (BARI)


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
Two revascularisation procedures in patients with coronary disease were examined in the study: coronary angioplasty versus coronary bypass surgery.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population consisted of patients with two- or three-vessel coronary artery disease, eligible for both angioplasty and bypass surgery. Patients had either severe angina pectoris, objective evidence of severe myocardial ischemia, or both. Patients older than 80 years of age, who had undergone prior coronary angioplasty or bypass surgery, and those who had primary congenital, valvular, or myocardial disease or had single-vessel or main coronary artery disease were excluded.

Setting
The setting was hospital. The economic study was conducted in seven centres in US.

Dates to which data relate
Data on effectiveness and resource use were gathered from August 1988 to August 1997. The price year was 1995.

Source of effectiveness data
The effectiveness evidence came from a single study.

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

Study sample
No power calculations were reported. The method of sample selection was not stated. First, 934 patients (representing a subgroup of the BARI study sample) were initially randomized between the intervention group who underwent angioplasty and the control group who underwent surgery. The study sample, however, included only those out of the 934 who subsequently had noncardiac surgery. The sample size was therefore 501 with a mean age of 63.8 (+/- 8.6) years (69% men; 24% current smokers) with 251 (mean age: 64.5 +/- 8.7 years; 69% men) in the intervention group.
and 250 (mean age: 63.1 +/- 8.5 years; 70% men) in the control group. Four hundred and thirty three patients (mean age: 59.8 +/- 9.9 years; 74% men; 32% current smokers) did not undergo noncardiac surgery interventions.

Study design
This was a randomised controlled trial, carried out in seven centres. The method of randomisation was not reported but fuller details may be available in other reports of the BARI trial and its associated studies (see Other publications of related interest, below). The authors stated that patients were stratified by initial randomised treatment assignment (surgery or angioplasty), presence or absence of preoperative angina, and type of noncardiac surgery performed. Analysis was conducted on all those who underwent noncardiac surgery. Patients were followed for an average of 7.8 (+/- 0.9) years and follow-up assessment was performed through contacts with the patients at three-month intervals. There was no loss to follow-up for those who underwent noncardiac surgery. Perioperative cardiac events were assessed through standardised diagnostic criteria, by trial investigators blinded to treatment assignment.

Analysis of effectiveness
The main analysis of the clinical study was based on intention to treat. The primary health outcomes assessed in the effectiveness study were rate of perioperative cardiac events by risk level of the procedure in the overall study sample; and rates of cardiac events, such as death and nonfatal myocardial infarction for first cardiac procedure between the study groups. A multivariate model was performed to adjust for baseline characteristics (age, sex, diabetes, smoking, heart failure, three-vessel disease, and abnormal left ventricular function). The effect of cross-overs and the impact of recurrent angina were also assessed. The study sample (those who underwent noncardiac surgery) were older and more likely to have a prior myocardial infarction or abnormal ventricular function than patients who did not undergo noncardiac surgery. However, similar proportions of surgery-assigned and angioplasty-assigned patients underwent noncardiac surgery during follow-up. The study groups were generally comparable at baseline, but patients in the angioplasty group were significantly more likely to have abnormal left ventricular function and a significantly shorter interval between the most recent coronary revascularisation and the noncardiac surgery.

Effectiveness results
In the overall study sample of 501 patients undergoing noncardiac surgery procedures (comparison 1), the overall rate of perioperative cardiac events was 1.4% (15 episodes out of 1,049 procedures performed).

The event rate was 2.3% (95% CI: 1.0% - 4.4%) (8 episodes out of 352 procedures) in high-risk procedures, 1.0% (95% CI: 0.4% - 2.1%) (7 episodes out of 697) in low-risk procedures, and 1% (1/151) in skin and miscellaneous low-risk procedures.

The differences in event rate between the procedures at different risk levels were not statistically significant.

To compare the study groups, the rate of cardiac events was 1.6% in both the surgery and the angioplasty groups, and the rates of both death and nonfatal myocardial infarction were 0.8% in both groups.

The multivariate analysis showed that there was no statistically significant difference in the risk of noncardiac surgery between angioplasty and surgery groups (OR: 1.4; 95% CI: 0.3 - 6.1; p=0.64).

Twenty-three patients (9%) patients assigned to the surgery group had at least a subsequent angioplasty before the first noncardiac procedure, while 73 patients (29%) assigned to the angioplasty group had coronary bypass surgery.

The impact of both cross-overs and recurrent angina was not relevant.

The multivariate model showed that age was the most significant predictor of perioperative cardiac events (OR: 1.3 per year; 95% CI: 1.1 - 1.5; p=0.002), followed by years since last coronary revascularisation (OR: 1.3 per year; 95% CI: 0.96 - 1.9).

Clinical conclusions
The effectiveness analysis showed that the rate of cardiac events was very low and comparable with both angioplasty and coronary surgery. Thus the two interventions were considered similar in terms of clinical outcome measures.

Measure of benefits used in the economic analysis
The effectiveness study showed that the two revascularisation procedures were similarly effective in preventing major cardiac events, thus the result was that the study, in effect, became a cost-minimisation analysis.

Direct costs
No discounting appears to have been conducted although costs were incurred over a period of time much greater than two years. Unit costs were not reported separately from the quantities of resources used. The economic analysis estimated only the costs related to length of hospitalisation. The cost/resource boundary adopted in the analysis was that of the hospital. Resource use was estimated over the period August 1988 to August 1997 from hospital billing data. Charges were used as the source of cost data and a charge-to-cost ratio specific to the study hospitals was used to assess the true costs of the hospital stay. The price year was 1995.

Statistical analysis of costs
Costs were reported as means and standard deviations and standard statistical analyses were performed to test for statistical significance of differences in total costs.

Indirect Costs
Indirect costs were not included.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analyses were performed.

Estimated benefits used in the economic analysis
Please refer to the effectiveness results reported earlier.

Cost results
The length of hospital stay was 6.3 (+/- 6.7) days in the surgery group and 6.2 (+/- 6.8) days in the angioplasty group, (p=0.47).

Total hospitalisation costs were $8,920 (+/- 11,511) in the surgery group and $7,785 (+/- 7,643) in the angioplasty group, (p=0.33).

Synthesis of costs and benefits
Not relevant as a cost-minimisation analysis was conducted.

Authors' conclusions
The authors concluded that the rates of myocardial infarction and death were low and similar in the two study groups, as were length of hospitalisation and overall costs. Thus coronary angioplasty and coronary bypass surgery were comparable in selected patients with coronary disease.
CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparators was clear. Coronary angioplasty and coronary bypass surgery represented two common revascularisation procedures for patients with coronary disease. However, the authors stated that there is a further recent alternative of angioplasty using coronary stents which did not feature in this study. You, as a user of this database, should decide whether they are widely used approaches in your own setting.

Validity of estimate of measure of effectiveness
The method of sample selection was not reported. The analysis of effectiveness was based on a randomised controlled trial, which was appropriate for the study question. Randomisation was stratified, but the actual method used to allocate patients to study groups was not reported in this study but may be reported in other related publications. The authors stated that the efficacy of initial randomisation may have been broken by the subsequent selection of patients for noncardiac surgery. However, the effect may have been minimal as there was no significant difference in the risk of cardiac events between the groups. The assessment of outcomes was partially blinded. The study sample was representative of the study population. Study groups were not perfectly comparable at baseline: the authors commented that although patients undergoing both procedures were generally comparable, the whole group considered in the analysis was statistically different from those patients who did not undergo any noncardiac surgery. Power calculations were not reported and the authors noted that the initial study sample may have been too small to detect statistically significant differences between the groups. Some statistical analyses were performed to take into account potential confounding factors.

Validity of estimate of measure of benefit
No summary benefit measure was used in the economic analysis and no statistically significant differences were found in any of the clinical outcomes used in the effectiveness study. The analysis was therefore categorised as a cost-minimisation study (see validity of effectiveness comments above).

Validity of estimate of costs
There was limited cost analysis but this was likely to have been driven by the specific study question. The analysis of costs was presumably conducted from the perspective of the hospital. Only hospitalisation costs were included in the analysis. For a full economic evaluation of the two interventions, a consideration of the costs of surgery and related future surgical costs at least would have been required. Unit costs and the quantities of resources used were not reported separately and a detailed breakdown of costs was not given. The price year was reported, thus making reflation exercises in other settings easy. A charge-to-cost ratio was used to convert charges into real costs. The source of cost data was reported. Standard statistical analyses of costs were performed, but no sensitivity analyses were conducted. As costs were incurred over a long time horizon, discounting was relevant, but was not carried out. The values of standard deviation of total hospitalisation costs were quite high, perhaps reflecting a skewed distribution of costs among the patients included in the analysis.

Other issues
The authors compared their findings with those from previously published studies and commented on the factors that led to better perioperative outcomes than those reported in the literature. The issue of the generalisability of the study results to other settings was not addressed and no sensitivity analyses were performed, thus the external validity of the analysis was low. The authors stressed that their findings should be limited to the population of patients included in the study and that their results may not be used for the management of patients at high risk for coronary disease or who have clinical evidence of coronary disease, and who have not undergone coronary angiography. Similarly, the study did not provide any information about the risk of medically treated patients.

Implications of the study
The study suggests that coronary revascularisation, performed using either angioplasty or surgery, is successful in reducing the risk of myocardial infarction and death among patients with multivessel coronary disease. However, this
conclusion should be interpreted with caution due to the potential limitation of the present study.

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**Other publications of related interest**


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