Medical care costs and quality of life after randomization to coronary angioplasty or coronary bypass surgery

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
Coronary angioplasty and coronary bypass surgery in the revascularization process of coronary heart disease.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population consisted of patients with objective evidence of myocardial ischemia severe enough to warrant coronary revascularization, stenosis of 50% or more in two or more coronary vessels, technical suitability for both angioplasty and bypass surgery, and no prior coronary revascularization procedure. Just over 70% of the population were males, and the mean age was 63.6 years for the angioplasty group and 62.4 for the bypass surgery group.

Setting
Secondary care. The study was carried out in 7 clinical sites in the USA.

Dates to which data relate
Resource, effectiveness and cost data were gathered throughout the 5 year period of the study which began in 1988. The price year was 1995.

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

Link between effectiveness and cost data
The effectiveness and cost data were derived from the same study population. The costing was conducted prospectively.

Study sample
The study sample consisted of 952 adults which formed a sub-sample of a larger randomized trial consisting of 1829 patients. Of the sample, 934 agreed to participate (98% of the original figure). The sample was randomly divided into two groups: the angioplasty group containing 465 subjects and the bypass surgery group containing 469 subjects. The two groups were closely matched in terms of their clinical and health history characteristics. Power calculations were not used in determining the sample size.
Study design
Randomized controlled trial. The trial was conducted over seven sites and the average length of follow-up was 5.5 years. No loss to follow up was reported among the surviving populations but the results indicated that 14% of the angioplasty group and 11% of the bypass surgery group died during the trial.

Analysis of effectiveness
The trial was based on intention to treat. The effectiveness of the two treatments was measured in terms of functional status, quality of life, life-years gained and employment status. Instruments used to determine effectiveness were: The Duke Activity Status Index, which provided a functional status score and the RAND Mental Health Inventory, which assesses anxiety, depression and positive affect. Questionnaires were also used to determine employment status every three months throughout the trial.

Effectiveness results
The angioplasty group had a higher mortality rate ((P=0.54), significantly more second or subsequent revascularizations (P<0.001), and significantly more angina after one year (P=0.001) and three years (P=0.01) of follow-up. Functional status of all patients increased by 5.7 units (P<0.001) after one year. The functional status of patients in the bypass group was significantly greater than angioplasty after one year (7.0 vs 4.4 units, P=0.02), two years (5.5 vs 3 units, P=0.02), and 3 years (5.6 vs 3.2 units, P=0.04) of follow-up, but the difference was not significant after four (4.3 vs 2.6 units, P=0.17) or five (3.6 vs 2.0 units, P=0.26) years. Emotional health improved by a mean of 1.8 units (P<0.001) after one year and there was no statistical difference between the groups throughout the follow-up. The proportion of patients who initially worked and continued to work either full or part time declined to 83% after six months, to 73% after one year, to 57% after 3 years, and to 45% after 5 years, with no statistical difference between the groups. The patients in the angioplasty group returned to work significantly earlier than those in the bypass group (median = 6 vs 11 weeks, P<0.001). After returning to work the hours spent on the job did not differ significantly between the groups.

Clinical conclusions
In patients with multivesSEL coronary disease, bypass surgery was associated with better functional status for the first three years than coronary angioplasty, after the initial morbidity caused by the procedure has subsided. In other aspects the quality of life was equivalent for both methods.

Measure of benefits used in the economic analysis
The measure of benefit used in the economic analysis was life-years gained.

Direct costs
Direct costs included the initial medical costs of revascularization by either bypass surgery of angioplasty, plus hospitalization and medication costs incurred over the period of follow-up. Costs were discounted at 3%. Prices were determined by each hospital's Medicare cost report. When data on charges were unavailable the 1995 Medicare reimbursement for the diagnosis-related group (DRG) specific to the patient's diagnosis was used. Physicians' charges were obtained from the participating hospitals, and Medicare rates of reimbursement to physicians were assigned to office visits. Costs for cardiac medications were calculated on the basis of the average wholesale prices in the 1995 Red Book. Costs were calculated over the period of follow-up of approximately five years and converted to 1995 prices.

Statistical analysis of costs
Statistical analyses of costs were conducted using the Wilcoxon rank-sum test. The time course of the accumulation of costs during the follow-up period was described using the life-table method. Variability in cost was assessed by means of a permutation test and base-line predictors of costs were assessed by linear regression, with the logarithm of the
four-year cumulative cost used as the dependent variable.

Currency
US dollars ($)

Sensitivity analysis
Sensitivity analysis was not carried out.

Estimated benefits used in the economic analysis
The estimated benefit for all patients with either 2 or 3 diseased vessels in the bypass surgery group was 4.4 years gained, and 4.3 years in the angioplasty group. For patients without diabetes mellitus the life-years gain was 4.4 for both groups, and for those with diabetes mellitus the gain was 4.3 for surgery and 3.8 for angioplasty. For nondiabetics the gain was 4.4 years for both groups and for diabetics the gain for 2-vessel disease was 4.4 and 4.0, and for 3-vessel disease 4.3 and 3.5 for surgery and angioplasty respectively.

Cost results
The initial mean cost of angioplasty was 65% that of surgery ($21,113 vs $32,347, P<0.001). However, the total cost per patient for the coronary bypass group over the study period was $56,225 and for the angioplasty group the total cost was $58,889 (P=0.047). The five year cost of angioplasty was significantly lower than that of surgery among patients with 2-vessel disease at $52,930 vs $58,498 (P<0.05) but not among patients with 3-vessel disease ($60,918 vs $59,430). Both sets of figures were discounted by 3%.

Synthesis of costs and benefits
The measure of final outcome was cost per life-year gained. After five years of follow-up, coronary bypass surgery had an overall cost-effectiveness ratio of $26,117 per year of life added, but unacceptable ratios of $100,000 or more per life year added could not be excluded (P=0.13).

Authors' conclusions
The authors concluded that, on average, functional status was improved more with bypass surgery than with angioplasty in the first three years, while in other respects the quality of life experienced by both groups of patients was equivalent. The initial mean cost of revascularization by angioplasty was $11,234 lower than that of bypass surgery, which generated a saving of 35%. However, because of higher subsequent costs for hospitalization and medication amongst the angioplasty group, the savings reduced to $2,664 at the five year point. For patients with 2-vessel disease, angioplasty has a significant cost-advantage over bypass surgery but costs are similar for patients with 3-vessel disease. The authors stated that their findings both confirmed and extended the findings of other similar studies comparing the two treatments, but argued that their findings were more valid as they were conducted over a longer period of follow-up.

CRD Commentary
The study was comprehensive in terms of its methods, analysis and reporting and added to the findings of other studies which had previously conducted comparative analyses of angioplasty and bypass surgery.

The authors employed a wide range of outcomes to determine the benefits and effectiveness of each treatment over a five year period including functional status, quality of life, employment status and life years gained. However, in calculating the cost-effectiveness ratio the authors used only one factor, namely life-years. This study would therefore have benefitted from the generation of one summary measure such as the QALY or HYE which could have captured and utilized all the factors considered in determining the effectiveness of each treatment regime.
The authors further acknowledged that the estimates of cost-effectiveness in the study were relatively imprecise due to the considerable variation in long-term costs among patients and the relatively small difference in mortality five years after initial treatment. They therefore need to be treated with caution.

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