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Cost effectiveness of clinically appropriate decisions on alternative treatments for angina pectoris: prospective observational study

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ABSTRACT

Objective To assess whether revascularisation that is considered to be clinically appropriate is also cost effective.

Design Prospective observational study comparing cost effectiveness of coronary artery bypass grafting, percutaneous coronary intervention, or medical management within groups of patients rated as appropriate for revascularisation.

Setting Three tertiary care centres in London.

Participants Consecutive, unselected patients rated as clinically appropriate (using a nine member Delphi panel) to receive coronary artery bypass grafting only (n=815); percutaneous coronary intervention only (n=385); or both revascularisation procedures (n=520).

Main outcome measure Cost per quality adjusted life year gained over six year follow-up, calculated with a National Health Service cost perspective and discounted at 3.5%/year.

Results Coronary artery bypass grafting cost £22 000 (€33 000; $43 000) per quality adjusted life year gained compared with percutaneous coronary intervention among patients appropriate for coronary artery bypass grafting only (59% probability of being cost effective at a cost effectiveness threshold of £30 000 per quality adjusted life year) and £19 000 per quality adjusted life year gained compared with medical management among those appropriate for both types of revascularisation (probability of being cost effective 63%). In none of the three appropriateness groups was percutaneous coronary intervention cost effective at a threshold of £30 000 per quality adjusted life year. Among patients rated appropriate for percutaneous coronary intervention only, the cost per quality adjusted life year gained for percutaneous coronary intervention compared with medical management was £47 000, exceeding usual cost effectiveness thresholds; in these patients, medical management was most likely to be cost effective (probability 54%).

Conclusions Among patients judged clinically appropriate for coronary revascularisation, coronary artery bypass grafting seemed cost effective but percutaneous coronary intervention did not. Cost effectiveness analysis based on observational data suggests that the clinical benefit of percutaneous coronary intervention may not be sufficient to justify its cost.

INTRODUCTION

Guidelines based on clinical appropriateness criteria are widely used to inform decisions about practice but are insufficient grounds for allocating healthcare resources. Although consensus exists that cost effectiveness analysis is needed to maximise the health gains achieved from a limited budget, how closely formally measured clinical appropriateness accords with cost effectiveness is not known. No three way randomised comparisons of the cost effectiveness of medical management, percutaneous management, and coronary artery bypass grafting exist.[1] We studied three management strategies for coronary disease: coronary artery bypass grafting, percutaneous management, and medical management.

METHODS

The appropriateness of coronary revascularisation (ACRE) cohort consists of consecutive patients, recruited without exclusion criteria, who had coronary angiography between 15 April 1996 and 14 April 1997 at three hospitals of one National Health Service trust in London.[2] We identified 4121 patients and followed them for six years. Most patients had chronic coronary disease at baseline. This economic evaluation focuses on the subgroup of 1740 patients rated as appropriate to have bypass surgery, percutaneous management, or both.

A nine member expert panel rated separately the clinical appropriateness of bypass surgery and percutaneous management in hypothetical patients for 985 specific clinical indications.[3] Appropriateness ratings were assigned to ACRE participants on the basis of their clinical characteristics at the time of angiography to identify patients who would benefit from revascularisation.

We adopted the cost perspective of the NHS and included the costs of bypass surgery, percutaneous management and angiography procedures, drugs, admissions for chest pain, general practitioner visits, outpatient appointments, and visits to the emergency department.

We ascertained acute non-fatal myocardial infarction through the NHS-wide clearing service.[4] Patients completed the EQ-5D health related quality of life instrument, from which we derived utility scores.[5 6] Utilities represent quality weights for the calculation of quality adjusted survival; 1 corresponds to the highest degree of quality of life, and 0 is equivalent to dead. We calculated an estimate of quality adjusted survival for each patient by weighting their survival according to their quality of life.

Statistical methods

We analysed patients in three groups on the basis of their being rated clinically appropriate for bypass surgery only, for both procedures, or for percutaneous management only. Within the three groups, we compared those who had bypass surgery, those who had percutaneous management, and those who had neither type of revascularisation (medical management). We used regression analyses to estimate the effect of actual management, by appropriateness category, on cost effectiveness, presence of angina, and mortality at six years' follow-up. We adjusted analyses for potential confounders. We analysed cost effectiveness by using seemingly unrelated regression,[7] a multivariate regression technique that accounts for the potential correlation between costs and quality adjusted survival.

We calculated the incremental cost effectiveness ratio comparing two management strategies, which represents the cost per quality adjusted life year gained by moving to a more costly, more effective method of management.We derived cost effectiveness acceptability curves showing the probability that each treatment is cost effective at a threshold of £30 000 (€45 000; $58 000) per quality adjusted life year.[8]

RESULTS

Baseline characteristics

Of the 1720 patients in the economic analysis, 815 (47%) were rated as appropriate for bypass surgery only, 520 (30%) were rated as appropriate for both procedures, and 385 (22%) were rated as appropriate for

Effectiveness and economic measures by appropriateness category and actual management. Values are mean (SD) unless stated otherwise

	Appropriate for CABG only (n=815)			Appropriate for both (n=520)			Appropriate for PCI only (n=385)		
	Received CABG (n=408)	Received PCI (n=54)	Received MM (n=353)	Received CABG (n=149)	Received PCI (n=173)	Received MM (n=198)	Received CABG (n=45)	Received PCI (n=137)	Received MM (n=203)
Utility at baseline*	(n=281) 0.54 (0.23)	(n=35) 0.48 (0.22)	(n=262) 0.60 (0.22)	(n=94) 0.45 (0.22)	(n=120) 0.50 (0.22)	(n=145) 0.54 (0.22)	(n=33) 0.56 (0.24)	(n=96) 0.57 (0.23)	(n=148) 0.61 (0.21)
Utility at 6 years*	(n=264) 0.69 (0.29)	(n=35) 0.61 (0.36)	(n=219) 0.67 (0.31)	(n=100) 0.66 (0.31)	(n=108) 0.65 (0.30)	(n=131) 0.61 (0.30)	(n=28) 0.69 (0.28)	(n=100) 0.65 (0.29)	(n=129) 0.66 (0.29)
Life years†:	4.95 (1.47)	4.95 (1.57)	4.94 (1.32)	5.14 (1.19)	5.07 (1.27)	5.08 (1.14)	5.07 (1.15)	5.31 (0.95)	5.20 (0.95)
Adjusted MD (95% CI)	0‡	0.03 (−0.32 to 0.39)	−0.03 (−0.21 to 0.15)	0‡	−0.17 (−0.45 to 0.11)	−0.09 (−0.36 to 0.17)	−0.13 (−0.55 to 0.29)	0‡	0.06 (−0.21 to 0.33)
QALYs†:	(n=317) 3.29 (1.55)	(n=40) 3.01 (1.54)	(n=293) 3.02 (1.53)	(n=114) 3.13 (1.37)	(n=127) 2.93 (1.65)	(n=164) 2.83 (1.39)	(n=40) 3.08 (1.59)	(n=111) 3.31 (1.47)	(n=161) 3.15 (1.43)
Adjusted MD (95% CI)	0‡	−0.15 (−0.51 to 0.20)	−0.40 (−0.58 to −0.22)	0‡	−0.24 (−0.52 to 0.04)	−0.39 (−0.70 to −0.09)	−0.07 (−0.50 to 0.37)	0‡	−0.06 (−0.36 to 0.24)
Total cost (£)†:	16 980 (7879)	13 875 (7815)	10 850 (7220)	17 859 (6940)	14 007 (10 453)	10 690 (7888)	16 541 (5571)	11 493 (6468)	8775 (7364)
Adjusted MD (95% CI)	0‡	−3230(−5417 to −1044)	−5870 (−6961 to −4779)	0‡	−3820 (−5510 to −2130)	−7255 (−8875 to −5636)	4947 (2359 to 7534)	0‡	−2847 (−4510 to −1184)
ICERs (£ per QALY) (from adjusted values)	22 000 (*v* PCI)	11 000 (*v* MM)	–	19 000 (*v* MM)	ED	–	D	47 000 (*v* MM)	–

CABG=coronary artery bypass graft; PCI=percutaneous coronary intervention; D=dominated; ED=ruled out by extended dominance; ICER=incremental cost effectiveness ratio (cost per QALY gained calculated in comparison with next relevant, less costly alternative); MD=mean difference; MM=medical management; QALY=quality adjusted life year.
*Includes values from prediction model as well as observed utility (for six year values only).
†Discounted at rate of 3.5% a year.
‡Reference category.
Adjustments are for age, sex, ethnic group, Canadian Cardiovascular Society score, left ventricular function, previous stroke, myocardial infarction, previous CABG, previous PCI, diabetes, diffuse disease, diseased vessels, heart failure, and Parsonnet score; adjusted analysis of QALYs and total cost are from seemingly unrelated regression and include an additional adjustment for baseline utility; for all analyses missing data have been imputed by multiple imputation; results are a summary of those from five imputation datasets.

percutaneous management only. The severity of angina was similar across the three appropriateness groups.

Clinical outcomes

Over the six year follow-up, 44% (335/754) of patients initially treated with medical management and 26% (93/364) of those initially treated with percutaneous management went on to have additional revascularisation procedures; of those who initially had bypass surgery, further revascularisation was needed for only 4% (25/602) of patients. Angina was present in 55% of patients at six years. Among patients rated as appropriate for bypass surgery, adjusted analyses showed a significantly raised odds of angina for those who had percutaneous management or medical management compared with those who had bypass surgery (see bmj.com). Overall, 16% (277/1720) of patients died during follow-up. Adjusted analyses in the group appropriate for bypass surgery showed a raised risk of death for those who had medical management compared with bypass surgery or percutaneous management.

Costs

In year one, the costs of medical management were 9-12% of bypass surgery costs and those for percutaneous management were 43-50% of bypass surgery costs. By year six, these ratios rose to 43-50% for medical management and 78-82% for percutaneous management, primarily owing to the need for additional revascularisation procedures. The average unadjusted costs of each initial treatment strategy were, at baseline, £12 500 for bypass surgery, £5800 for percutaneous management, and £1400 for medical management; these rose to £16 200, £12 100, and £9200 at six years. The adjusted analysis made little difference to the estimated cost differences (table).

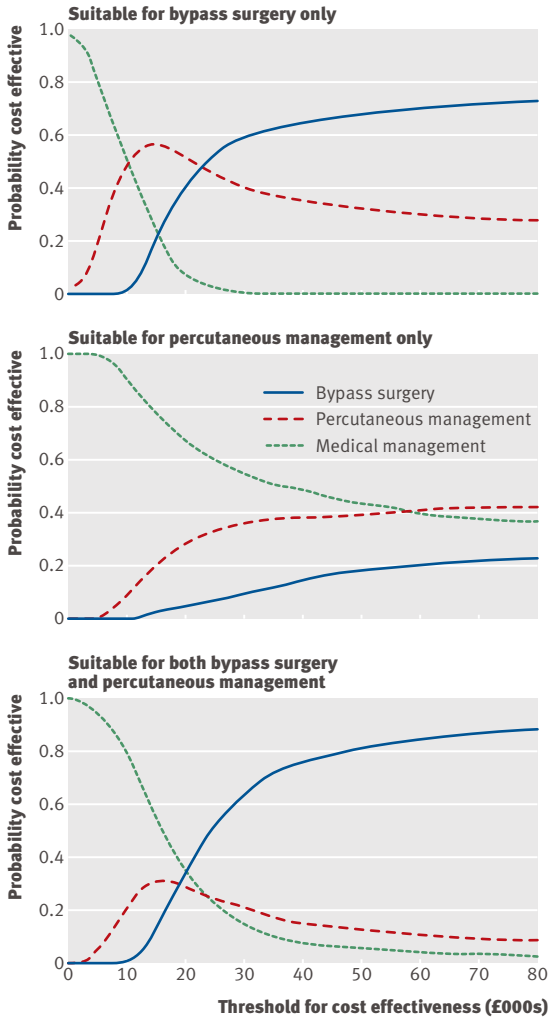
Cost effectiveness

Average predicted baseline utility was 0.55, considerably lower than the United Kingdom population norm of 0.80 for people aged 55 to 64.[9] The average utility score among those alive at six years improved to 0.65. Adjusted analyses by appropriateness category showed no significant differences in discounted mean survival duration across treatment groups. For the groups rated appropriate for bypass surgery only or percutaneous management only, the clinically appropriate treatment had the highest mean quality adjusted life years. In the group rated appropriate for either type of revascularisation, bypass surgery had the highest mean quality adjusted life years.

Among patients rated as appropriate for bypass surgery only, the incremental analysis showed that percutaneous management had an incremental cost effectiveness ratio of £11 000 per quality adjusted life year compared with medical management and bypass surgery had an incremental cost effectiveness ratio of £22 000 per quality adjusted life year compared with percutaneous management (table). Thus bypass surgery is the most cost effective procedure for patients rated as appropriate for bypass surgery. The probability that bypass surgery is the most cost effective treatment strategy was 59% at a willingness to pay of £30 000 per quality adjusted life year, compared with 40% for percutaneous management (figure).

In patients rated as appropriate for both procedures, either medical management or bypass surgery was a more cost effective option than percutaneous management (figure). The incremental cost effectiveness ratio for bypass surgery compared with medical management was estimated as £19 000 per quality adjusted life year (table). The probability that bypass surgery, percutaneous management, and medical management are the most cost effective forms of management was estimated at 63%, 22%, and 15% respectively (figure).

Among patients appropriate for percutaneous management only, percutaneous management was less costly and more effective than bypass surgery and had an estimated incremental cost effectiveness ratio of £47 000 per quality adjusted life year compared with medical management (table). Medical management is therefore the most cost effective treatment strategy in patients rated as appropriate for percutaneous management. The probability that percutaneous management is most cost effective was estimated at 36%, compared with 54% for medical management (figure).



Cost effectiveness acceptability curves

WHAT IS ALREADY KNOWN ON THIS TOPIC

Guidelines based solely on clinical appropriateness are widely used to inform decisions about practice; whether care based on appropriateness criteria is also cost effective is unknown

No three way randomised comparisons of the cost effectiveness of medical management, percutaneous coronary intervention, and coronary artery bypass grafting have been done

Evidence of cost effectiveness in "real world," routine practice settings is also lacking

WHAT THIS STUDY ADDS

Coronary artery bypass grafting seems both clinically beneficial and cost effective for patients judged clinically appropriate for revascularisation

The clinical benefit of percutaneous coronary intervention, however, does not seem to be sufficient to justify its additional cost

DISCUSSION

Among consecutive patients, the analysis suggests that bypass surgery within 12 months was cost effective in relation to a standard UK threshold but that percutaneous management was not. These findings challenge clinical practice and healthcare policy, which has evolved on a basis of evidence of effectiveness from clinical trials, largely in isolation from considerations of cost effectiveness.

Strengths and limitations

We defined clinical appropriateness by using an explicit method that has been shown to be reliable and prognostically valid.[2 10] We used an expert panel to provide an independent measure of appropriateness, before recruitment of patients. More than 90% of unselected consecutive patients were matched to an appropriateness rating, allowing our results to represent a real world view of cost effectiveness.[11] The case fatality we observed in this population was comparable to that seen in large, less selected, primary care populations.[12] We have shown that clinical appropriateness ratings in a broad unselected population accord with evidence of clinical effectiveness from trials.

We were able to make comparisons between three alternative management strategies that may never be simultaneously investigated in cost effectiveness analysis alongside randomised trials. This is both a strength and limitation. Patients who go on to receive bypass surgery may have been destined to have better outcomes than those who do not, and the results may therefore be "confounded by indication." A second limitation of our analysis is that we do not know whether percutaneous management judged clinically appropriate according to the most recent criteria remains not cost effective. Although this awaits empirical testing, several lines of evidence indicate that this may be the case.

Association of clinical appropriateness with better outcomes

Patients who had bypass surgery were least likely to have angina present at six years. The treatment rated as clinically appropriate corresponds with the greatest number of quality adjusted life years, although this result was statistically significant only for the comparison of medical management with clinically appropriate bypass surgery. Throughout the six year follow-up of this unselected patient group, quality of life remained lower than expected from age specific population norms.

Cost effectiveness of interventions

Our analysis indicates that clinically appropriate percutaneous management within 12 months was not cost effective. We do not find this result surprising: the high costs of percutaneous management and the need for subsequent procedures,[13-15] absence of mortality benefit,[16] and absence of a marked gain in quality of life have all been reported in trials.

Bypass surgery within 12 months was the most cost effective strategy among patients rated as appropriate to have bypass surgery if the maximum incremental cost effectiveness ratio the NHS is willing to accept is around £30 000 per quality adjusted life year. We found that the relative cost differences between bypass surgery and percutaneous management reduced over the follow-up period, but the absolute difference remained significant at six years. Medical management is consistently the least costly form of management. Future work could extend the cost effectiveness model over a lifetime horizon, in which interventions with large "up-front" costs, such as bypass surgery, may seem more cost effective.

Conclusion

This cost effectiveness analysis in a real world setting offers a challenge to physicians, providers, and payers to show that the management of coronary disease currently offered, however clinically beneficial, is also cost effective. This was the case for bypass surgery within 12 months, but not for percutaneous management, for which the additional benefit was too small to justify the additional cost over the consistently less costly strategy of medical management.

SCG and JAB contributed equally to this paper.

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BMJ UPDATES

Intensive cessation programme reduces mortality in smokers with heart disease

Research question

Can an intensive smoking cessation programme reduce morbidity and mortality among inpatients with heart disease?

Answer

Yes

Why did the authors do the study?

We already know that intensive programmes can help high risk smokers to quit. These authors wanted to find out if these programmes also had a measurable impact on patients' health and survival.

What did they do?

209 inpatients took part in a randomised controlled trial. All had been admitted to a single US coronary care unit with acute coronary syndrome or decompensated heart failure, and all were current smokers who had smoked every day for at least five years. Just before the patients were discharged, the authors gave them all 30 minutes of advice about how to stop smoking and two self help guides. In addition, 109 were enrolled in a smoking cessation programme. The rest had usual care. Participants enrolled in the programme met a trained counsellor for an hour a week for at least three months after discharge. Participants who relapsed could opt for further sessions. Three quarters (75%) also had some kind of pharmacotherapy—mostly nicotine replacement therapy, either alone (28%) or combined with bupropion (40%).

The authors interviewed each participant regularly for two years. At each visit they corroborated self reported smoking habits by measuring the concentration of carbon monoxide in expired air. They also recorded all cardiovascular events, hospitalisations, and deaths. The authors used intention to treat analysis to compare the intervention and control groups at regular intervals during the study and at the end.

What did they find?

Participants enrolled in the smoking cessation programme were significantly more likely to quit and significantly more likely to quit for good than participants who had usual care. Two years after randomisation, 33% (36/109) of the intervention group had been continuously abstinent compared with only 9% (9/100) of controls ($P<0.0001$). The difference was evident by three months and persisted throughout the study.

The participants enrolled in the programme were also less likely than controls to be readmitted to hospital (25/109 (23%) *v* 41/100 (41%), relative risk reduction 44% (95% CI 16% to 63%)), and more likely to survive for at least two years (all cause mortality 3/109 (3%) *v* 12/100 (12%), relative risk reduction 77% (27% to 93%)). The authors estimate their programme would save one extra life for every 11 patients treated.

What does it mean?

Three months of intensive counselling with the option of free pharmacotherapy helped these high risk smokers to quit, kept them out of hospital, and improved their chances of long term survival compared with usual care. But the results can't be generalised to outpatients or to anyone without significant cardiovascular disease. Shorter, less intensive programmes or those that don't give away free drugs and nicotine replacement therapy are unlikely to work as well.

The authors say theirs is the first study to show that these kind of programmes can save the lives of patients with heart disease. The clinical benefits look similar to those provided by established drug treatments such as β blockers, statins, and antiplatelet agents.

Mohiuddin et al. Intensive smoking cessation intervention reduces mortality in high-risk smokers with cardiovascular disease. *Chest* 2007;131:446-52

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