VIEWPOINT

PCI or CABG: which patients and at what cost?

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Major changes in the management of symptomatic obstructive coronary artery disease have been seen in the past 10 years with a substantial shift towards percutaneous coronary intervention (PCI). In the UK in 2005, for example, 73 000 PCIs were performed compared with 22 000 isolated coronary artery bypass grafting (CABG) procedures.[1] Recently, there has been much debate about which of these two revascularisation options is ''better'' as measured by clinical outcome and overall cost effectiveness. This editorial will attempt to redress the balance on the use of PCI versus medical treatment in stable angina and its use in multivessel disease.

PCI VS MEDICAL TREATMENT IN STABLE CORONARY ARTERY DISEASE

Some have interpreted the recently published COURAGE trial,[2] which randomised (*after* coronary angiography) 2287 patients with positive non-invasive tests to either optimal medical treatment (OMT) or PCI, as indicating that OMT is equivalent to PCI for stable coronary artery disease and suggested that PCI is an overcostly, overused procedure. The 4.6-year composite of death/non-fatal myocardial infarction was 19.0% for PCI with OMT and 18.5% for OMT alone ($p = 0.62$). The relevance of this study to UK practice is doubtful since angioplasty in the UK is generally reserved for patients who have continuing symptoms despite OMT, although clearly there are patients who undergo PCI where there is clear evidence on objective non-invasive testing of silent ischaemia and a significant lesion in the same territory.

It has never been the interventionist's claim that PCI has an impact on mortality. Given that patients with left main stem disease and important left ventricular dysfunction (the very patients who may benefit prognostically from revascularisation) were excluded from this trial it seems highly likely that a similar trial comparing CABG with OMT would also show no difference. It is important to note that >40% of patients had little or no angina at trial entry. At follow-up 32.6% of the OMT group and 21.1% of the PCI group required a subsequent revascularisation (presumably for angina despite OMT). Given that <3% of the PCI group received a drug-eluting stent (DES), this difference would probably have been greater if patients had received contemporary PCI when initially randomised. One might also reasonably assume that the majority of patients undergoing PCI in the OMT group were from the 56% who initially had ''important'' (Canadian Cardiovascular Society (CCS) II or III) angina when randomised. Given this, one message of the trial is that most patients with significant angina at presentation will require PCI within 5 years because symptoms are not controlled by OMT. This, in addition to the fact that 50% of PCIs in the UK are performed in patients with unstable coronary syndromes, suggests that COURAGE may not be relevant to UK PCI practice.

PCI VS CABG FOR THE TREATMENT OF CORONARY ARTERY DISEASE: ARE THERE MORTALITY DIFFERENCES?

In a recent editorial in the *BMJ* the ''headline'' comment from Professor Taggart[3] was ''surgery is effective on clinical and economic grounds, but stenting does not appear to be a cost effective procedure''. Consequently the *Times* reported on 24 March 2007, ''thousands of patients with heart disease may be being denied their best chance of long-term survival''. Three main publications were quoted[4–6] in this and a previous, similar editorial to support the case of ''proven mortality advantage'' of CABG over PCI in multivessel disease. They are all registry data with no randomised clinical trials being used to support the argument.

The first registry reported was that by Hannan *et al*,[4] who compared 3-year survival outcomes of patients receiving CABG and PCI from two New York State databases, and showed an apparent advantage favouring surgery. Why only a small proportion of patients treated in New York State during this period (37 212 reported of 75 217 CABGs performed and 22 102 reported of 137 798 PCIs performed) were included in this analysis is worrying and unclear. The demographic data for the two cohorts were very different with p values of <0.01 for most comparators, and although these appear to disadvantage the surgical cohort, many of the differences are small (ejection fraction 53% vs 50%) or would appear not to have a major impact on mortality (peripheral vascular disease). Previous myocardial infarction was ''significantly'' higher in the stent group. Furthermore, preprocedural assessment is always more rigorous before CABG. In any event whether any statistical correction can take account of such differences is questionable. The unadjusted hazard ratios show no difference in outcome, irrespective of two- or three-vessel disease or involvement of the left anterior descending artery; the significant differences only appearing once the ratios were ''adjusted'' to attempt to equalise differences between groups.

Such differences in patient cohorts make subsequent comparisons non-robust and highly questionable. Similar criticism can be directed towards Brener *et al*,[5] who apparently showed a similar

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Abbreviations: AMI, acute myocardial infarction; BMS, bare metal stents; CABG, coronary artery bypass grafting; DES, drug-eluting stent; OMT, optimal medical treatment; PCI, percutaneous coronary intervention

benefit for surgery, this time using propensity analyses. Even the authors acknowledge that although ''propensity analyses are powerful they are inherently limited by the number and accuracy of the variable evaluated. There have been substantial changes in the management of PCI since this cohort was analysed''. Since differences between their registry populations were again so large, we are highly sceptical that any statistical test could take account of these, and the two groups (of 800 PCIs and 5000 CABGs) could be considered different and non-comparable. It is worrying if statistical manipulation of data is needed and the results then drive clinical practice.

Finally, a meta-analysis by Hoffman *et al*[6] was quoted, which suggests a survival benefit favouring surgery in patients with multivessel disease at 5 and 8 years (but no difference at 1 and 3 years) and must also be questioned. Patency of grafts falls over time (the graft failure rate was 46% at 18 months in the control group undergoing angiography in PREVENT IV[7]) and thus makes the contention of increased benefit of surgery over time counterintuitive. Worse still, 10 of the 13 trials included in the meta-analysis were in the pre-stent (balloon angioplasty) era.

On the other hand, there are data to support mortality equivalence for PCI and CABG in multivessel disease. Three randomised trials compared stenting with surgery,[8–10] which showed no mortality or acute myocardial infarction (AMI) difference in the groups at 1 year (indeed there was a worse outcome for the surgical patients in ERACI II[8]). The ARTS I study, which randomised patients to bare metal stents (BMS) or CABG, has now reported 92% survival for BMS and 92.4% for CABG at 5.5 years.[9] These outcome data are supported by 5-year data from the recently published MASS II trial[10] (which showed no significant difference in the hard end points of death or AMI in the CABG and PCI groups: death relative risk (RR) CABG/PCI 1.08, 95% CI 0.64 to 1.83, $p = 0.85$; AMI, RR = 0.37, 95% CI 0.13 to 1.07, $p = 0.085$) and a meta-analysis of all three DES trials at 1 year by Mercado *et al*,[11] showing mortality of 3% for PCI and 2.8% for CABG. Those who say that these trials favour PCI, because higher-risk patients were excluded, should consider the similarity in the demography and extent of disease in both groups in these analyses. The ERACI III[12] and ARTS II[13] DES trials show comparable mortality and AMI rates to those for BMS at 12 months. All this information supports the similarity in mortality between the techniques (with or without DES) in randomised trials with up to 5-years' follow-up.

An important randomised study (the SYNTAX trial), comparing left main/multivessel DES with CABG, has recently completed recruitment and should report in 2008.[14] To date the trial has not been stopped by the Independent Data and Safety Monitoring Board, suggesting no major differences in adverse events, including mortality. We believe this trial will shed appropriate scientific light on the morbidity and mortality in patients with severe coronary artery disease.

Cost effectiveness of PCI vs CABG

In a recent edition of the *BMJ* a further series of three papers were published[15–17] with an accompanying editorial,[3] which again purported to show the superiority of surgery over angioplasty and additionally that this was more cost effective.

The paper by Griffin *et al*[15] is somewhat difficult to understand, appearing not to be about real patients who had an actual procedure but of a nine-member consensus panel who rated the clinical ''appropriateness'' of surgery or stenting in hypothetical patients in 1996–7. Importantly (and contrary to the accompanying editorial and inappropriate media speculation), there was no reported difference in mortality between PCI and CABG. In patients thought only suitable for surgical management, it was medical management rather than PCI that was associated with increased mortality. The quoted difference in quality of life favouring surgery is presumably driven by the need for repeat PCI, which would be dramatically reduced in the current DES era.

The other two papers published on minimally invasive surgery to the left anterior descending artery were interesting but unfortunately flawed also. The first was a meta-analysis of a number of small trials and registries[16] and apparently shows a clinical advantage of surgery. Only six of the 12 trials are randomised studies. The apparent superiority of CABG was driven exclusively by need for repeat revascularisation (again these studies were from the pre-DES era). Long-term myocardial infarction or mortality, once again, was not statistically different and indeed the trend was in favour of PCI.

The paper on cost efficacy comparing minimally invasive surgery with PCI[17] also merits comment. We interpret this paper as showing that the cost-efficacy data do not favour CABG at any level. We are surprised at the inflated figure of £6317.07 for single-vessel stenting. These procedures would increasingly be performed as ''day cases'' in most interventional units. For information about cost efficacy over the reported short/medium term, we would point the reader to appropriate randomised trials that track patient level data over time, such as that by Weintraub *et al*.[18] Studies like this have very consistent findings: PCI is cheaper for the in-hospital phase and up to the 1- or 2-year follow-up. Any CABG advantage shown by reduction in angina symptoms (and hence improvement of quality of life) cannot be justified on the basis of cost.

SUMMARY

Clinical practice should in the main be driven by randomised trials and in their absence registry data should be viewed critically. The SYNTAX trial will be the most relevant trial to modern practice and will report in 2008. Using flawed historical registry data to suggest a mortality advantage of CABG is unacceptable and untrue. The randomised clinical trials clearly indicate that there is no mortality benefit between the two techniques. The previous published and statistically manipulated registry data and the recent papers in the *BMJ* add little useful information to the debate.

Angioplasty is generally offered in the UK to patients with angina resistant to OMT and is for the vast majority of patients, a simple, effective, patient-friendly and cost-effective strategy requiring a maximum of one overnight stay and negligible morbidity. For patients with complex (previously presumed) ''surgical disease'' the jury must remain out until trials such as SYNTAX report. Maybe PCI will be effective in these patients also; to date there is no robust evidence to show otherwise. We agree with Professor Taggart and others that in the meantime patients with complex disease should be discussed at multidisciplinary team meetings including non-interventional cardiologists. Angioplasty will remain the dominant mode of revascularisation in the UK because of sound clinical trial data.

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IMAGES IN CARDIOLOGY

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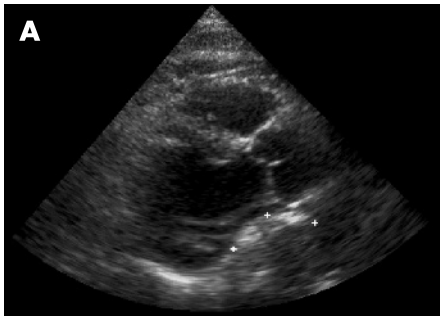
Severe haemodynamic compromise due to left atrial compression by oesophageal haematoma

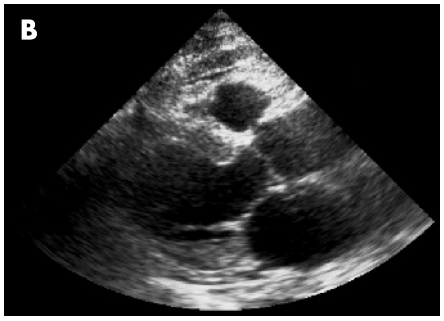
A 70-year-old man was transferred after thrombolysis for an acute inferior myocardial infarction. Soon after thrombolysis, he developed haematemesis. Upon arrival, vomiting had stopped. Owing to persisting chest pain, we proceeded to rescue angioplasty. The mid right coronary artery was occluded. Balloon angioplasty was initially performed. Considering the thrombotic burden and impending vessel re-occlusion, intracoronary abciximab was given (0.25 mg/kg). Because of a large coronary aneurysm, a covered stent was implanted and the final result was excellent.

Soon after percutaneous coronary intervention (PCI), the patient redeveloped upper gastrointestinal bleeding, leading to haemodynamic compromise requiring vasopressor infusion. Protamin was given and all antiplatelet agents were stopped. Several transfusions, with fresh frozen plasma and platelet transfusions were given. Urgent gastroscopy showed that the bleeding originated from the oesophagus.

An echocardiogram disclosed a collapsed left atrium (panel A). A thoracic CT scan confirmed the presence of an important intraparietal oesophageal haematoma. Upon intensive medical treatment, the condition of the patient gradually improved and control echocardiography showed full expansion of the left atrium with complete disappearance of the haematoma (panel B).



Panel A Echocardiography: parasternal long axis view with complete left atrial collapse. Oesophageal haematoma borders are delineated.



Panel B Complete resolution of the left atrial compression with full re-expansion of the left atrium.

Gastrointestinal bleeding is a common complication of thrombolysis. Oesophageal tumours, dilatation, achalasia and haematoma as well as hiatal hernia or localised tamponade causing left atrial compression have been previously reported. To the best of our knowledge, this is the first case of oesophageal haematoma showing near-complete compression of the left atrium after thrombolysis and administration of glycoproteins IIb–IIIa receptor inhibitors for rescue PCI and then, full restoration of the left atrium size upon haematoma resolution.

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