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Myocardial Revascularization: Surgery or Stenting?

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ABSTRACT

There is current debate regarding the relative merits and roles of surgical revascularization and percutaneous revascularization for patients with obstructive coronary artery disease. This article reviews the current literature relating to this subject.

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INTRODUCTION

Since the introduction of coronary artery bypass grafting (CABG) in 1967, and percutaneous transluminal coronary angioplasty (PTCA) 10 years later, several major clinical trials have compared the two therapeutic strategies, including the Bypass Angioplasty Revascularization Investigation (BARI) and the Coronary Angioplasty versus Bypass Revascularization Investigation (CABRI) trials.^{1,2} The 7-year outcome data of the BARI trial (involving 1,829 patients) demonstrated that CABG carried a significant survival benefit over PTCA, and this was particularly pronounced in diabetic patients.¹ In addition, nearly 60% of the patients treated with PTCA had to undergo repeat revascularization procedures, and half of them relied on CABG as a subsequent therapy.¹ Nevertheless, the past decade has witnessed a rapid progression of PTCA technology; in particular, the development of intracoronary stents. Drug-eluting stents (DES), especially, appear to have impacted significantly on the daily practice of treating patients with coronary artery disease.³ These advances and their immediate clinical application provide a good example of how technology may shift the paradigm of medicine. As a consequence of this, it is believed by many that the role of surgical revascularization needs to be redefined, despite its success over the past 4 decades. To clarify this important issue, we appraised the available evidence comparing CABG and percutaneous coronary intervention (PCI) in the modern era of stenting.

CABG VS BARE-METAL STENTS

The endothelial response to injury during PCI may result in extensive proliferation of smooth muscle cells and extracellular matrix around the angioplasty site, leading to neointimal hyperplasia and restenosis, which in turn may result in recurrent angina and necessitate repeat revascularization.^{4–6} Various measures have been proposed to limit this process, such as directional atherectomy, rotabators, or lasers. However, clinical results following these interventions have been largely disappointing as they may cause further damage to the vessel and lead to more severe neointimal hyperplasia.^{7–10} The use of stents following PTCA has been suggested as a method of improving the long-term outcome of PCI by reducing the incidence of restenosis and the need for repeat revascularization.

Several randomized controlled trials have been conducted to compare CABG and PCI with stenting. The Arterial Revascularization Therapies Study (ARTS) is one of the largest, and it evaluated the clinical outcomes of 1,205 patients over a 5-year period.¹¹ Although the 5-year mortality rate of the PCI group (8.0%) was comparable to that of the CABG group (7.6%), the need for repeat revascularization was significantly more frequent in the former group (30.3% vs 8.8%).¹¹ In terms of symptomatic relief, angina persisted in 21.2% of patients after PCI, compared to a significantly lower incidence of 15.5% in the CABG group.¹¹ Similar findings have been reported by other investigators. The

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Argentine randomized trial of PCI vs CABG (ERACI-II, $n = 450$, with a 5-year follow-up) and the Medicine, Angioplasty or Surgery Study (MASS-II, $n = 611$, with 1-year follow-up) both revealed significantly higher rates of repeat revascularization in patients receiving PCI, despite similar mortality to CABG in these selected patients.^{12,13} Among all the major trials comparing stenting and surgery, the Stent or Surgery (SoS) trial was the one to report differences in mid-term (as opposed to early) survival. The trial involved 988 patients with multivessel disease from 11 European countries and Canada.¹⁴ In contrast to previous studies, a significant and more than 2-fold increase in death in the PCI group was found at 2-year follow-up (5% in the PCI group vs 2% in the CABG group).¹⁴

Although randomized controlled trials are considered to represent the highest level of evidence, helping to determine the place of therapeutic interventions, registry data and meta-analyses are also pivotal in reflecting the true efficacy of various treatments in the “real world”, involving the full spectrum of patients. In a meta-analysis comparing CABG to PTCA with (4 studies), or without (9 studies) stents in 7,964 patients, Hoffman and colleagues¹⁵ found a 1.9% absolute survival advantage favoring CABG over PTCA at 5 years, although the significance may not be maintained at 8 years. In patients with multivessel disease, CABG provided significant survival advantages at both 5 and 8 years. Patients randomized to PTCA had more repeat revascularizations at all time points; and with stents, this risk difference was still 15% at 3 years.¹⁵ In addition, patients treated with CABG also had a significantly lower risk of recurrent angina than those receiving PTCA, with a risk difference of 10% at 3 years.¹⁵

A recent propensity analysis involving 6,033 consecutive patients over a 5-year period at the Cleveland Clinic (86% of them received CABG) indicated that in those patients with multivessel coronary artery disease and many high-risk characteristics, CABG was associated with better survival than PCI with stenting after adjustment for risk profiles.¹⁶ In fact, it was found that PCI with stenting was associated with a more than 2-fold increase in death (hazard ratio 2.3, $p < 0.0001$), and this difference was observed across all categories of propensity.¹⁶ In 2,319 diabetic patients, a higher mortality rate was observed in the PCI group and the most significant difference occurred among insulin-treated diabetics in whom the adjusted hazard ratio reached 2.6 (95% confidence interval: 1.7–3.9) in the PCI group.¹⁶

Treatment options for diabetic patients with a bare-metal stent (BMS) have always been of concern in clinical practice, as up to one third of patients receiving PCI

or CABG suffer from diabetes, as recorded in various registry data. The BARI trial showed a sustained survival benefit of more than 20% in patients treated with CABG at 7 years, adding strong evidence that CABG should be the preferred method of revascularization in diabetic patients.¹ The ARTS trial also attempted to address this issue in a subgroup analysis of 211 diabetic patients; diabetic patients in the PCI group had a higher (though statistically not significant) 5-year mortality (13.5%) than those treated with CABG (8.3%), and a significantly higher repeat revascularization rate than would be expected considering the results of previous trials.¹¹ Moreover, comparisons of diabetic and non-diabetic patients in this trial revealed that those with diabetes were more likely to die when treated with PCI rather than CABG.¹¹ This finding was echoed by the ERACI-II trial.¹² A meta-analysis by Hoffman and colleagues¹⁵ confirmed a significant survival benefit for CABG over PCI at 4 years, but not at 6.5 years, in diabetic patients. Another meta-analysis by Mercado and colleagues¹⁷ suggested higher (though statistically not significant) 1-year mortality in diabetic patients after stenting. More recently, the report of the New York cardiac registries, which included 37,212 patients undergoing CABG and 22,102 having PCI with stenting from 1997 to 2000, confirmed that risk-adjusted survival rates in the PCI group were significantly lower, whereas the repeat revascularization rate was significantly higher than that in the CABG group at 3 years.¹⁸ In particular, the adjusted hazard ratio for the risk of death after CABG relative to PCI was 0.64 (95% confidence interval: 0.56–0.74) for patients with triple-vessel disease.¹⁸ Although without risk-stratification, Mack and colleagues¹⁹ recorded lower mortality after PCI; the proportion of multivessel disease was greater in the CABG group in their database. It is noteworthy that the risk-adjusted survival benefit of CABG over stenting has been repeatedly demonstrated not only in North America but also in Europe.^{15,16,18,20}

The Angina With Extremely Serious Operative Mortality (AWESOME) trial was conducted to compare PCI and CABG in 454 patients with refractory myocardial ischemia and one or more risk factors for an adverse surgical outcome.²¹ These risk factors included prior open-heart surgery, age > 70 years, left ventricular ejection fraction < 35%, myocardial infarction within 7 days, or pre-revascularization use of an intra-aortic balloon pump. A variable proportion of patients received stenting in the PCI group (26% in 1995 rising to 88% in 1999/2000). Although survival rates in the CABG (79%) and PCI (80%) groups were not significantly different at 36 months, the need for subsequent repeat revascularization was higher in the PCI group.²¹ The Stenting vs Internal Mammary Artery (SIMA) study compared CABG with stenting in 123 patients with proximal, isolated, de

novo left anterior descending coronary artery disease.²² Although 2-year mortality was not significantly different in this particular study, a significantly higher incidence of repeat revascularization was documented in the stent group. In contrast, the event-free survival rate in the ARTS trial was significantly higher after CABG than after PCI for patients with triple-vessel disease.¹¹ It was acknowledged that in the ARTS trial, patients with left ventricular dysfunction, a left main lesion, or concomitant hepatic or renal diseases were excluded.¹¹ These criteria have provided a framework that may magnify the apparent efficacy of PCI. As an example to put this in context, in the New York cardiac surgery registry, up to 24% of patients receiving CABG had an ejection fraction < 40%; these patients are often excluded in controlled trials, yet they are known to have a survival advantage with surgical revascularization.¹⁸ Excluding such patients may unfairly reduce the potential survival benefits for surgery and introduce a bias in favor of PCI. Hence, it must be recognized that patients in clinical trials do not necessarily accurately represent those in the “real world”.

CABG VS DRUG-ELUTING STENTS

Although BMS implantation has significantly reduced the incidence of repeat revascularization following PCI, the rate of restenosis remains high and comparable to CABG. It was not until the emergence of drug-eluting stents (DES) that a true reduction in the restenosis rate following percutaneous intervention was reported, marking a new era in PCI development. However, to date there are no published data from randomized trials comparing DES with CABG. We may gain a better insight by looking into trials comparing DES and BMS.

SIROLIMUS-ELUTING STENTS

The RAVEL study was the first randomized double-blind trial that compared the Cypher sirolimus-coated eluting stent (SES) with a BMS in 238 patients with relatively simple, single de novo coronary lesions.²³ Encouraging results were reported, with an angiographic restenosis rate of 0% in the SES group and 26% in the BMS group at 6 months. The 4-year results of the study also revealed sustained and significant reductions in major adverse cardiac events and repeat target lesion revascularization in the DES group. While the RAVEL trial was criticized for the simple nature of the lesions treated, the larger sirolimus-coated stent had been developed and a subsequent clinical trial (SIRIUS) involving 1,058 patients with longer coronary lesions was instigated.²⁴ The 3-year follow-up data showed a significant reduction in target lesion revascularization and angiographic stenosis in the SES group. The NEW-SIRIUS study, which comprised Canadian and European data involving 452 patients, also showed significant reductions in major adverse cardiac events at 9 months in the SES group.^{25,26} Other trials

in more complicated coronary lesions have also shown positive results. These include the Sirolimus-Eluting vs Uncoated Stents for Prevention of Restenosis in Small Coronary Arteries (SES-SMART) trial on small coronary vessels, and the Stenting of Coronary Arteries in Non-Stress/Benestent Disease (SCANDSTENT) trial on bifurcation, ostial, angulated, and occlusive lesions.^{27,28}

PACLITAXEL-ELUTING STENTS

Recently, large clinical series, such as TAXUS-IV ($n = 1,314$) and TAXUS-V ($n = 1,156$), have investigated the Taxus slow-release stent for longer coronary lesions in smaller coronary vessels.^{29,30} Significant reductions in target lesion revascularization for up to 2 years in the TAXUS-IV trial and 1 year in the TAXUS-V trial have been reported. The TAXUS-VI ($n = 446$) study also demonstrated a lower repeat revascularization rate following the use of the TAXUS moderate-release stent compared to the BMS.³¹ More recent studies suggest, however, that there are serious concerns aside from restenosis or repeat intervention following DES implantation, which may occur at a higher rate than usually thought. For instance, several groups of investigators have observed the development of subacute or late stent thrombosis.^{32–35} Such complications could lead to fatal myocardial infarction even a few years after DES implantation.³⁵

DISCUSSION

With the encouraging results from various trials comparing DES and BMS, it is believed that the new technology of DES has the potential to further decrease the morbidity and repeat revascularization rate after PCI. However, many of these trials involved relatively simple coronary lesions. Even the SES-SMART, SCANDSTENT, and TAXUS-V trials did not truly represent the un-selected patient population routinely presenting for CABG. Moreover, the longest follow-up period in these studies was only 4 years. There have been concerns over the long-term efficacy of DES, and some authors have postulated that DES might merely be delaying rather than reducing restenosis, since there may be stent dilapidation following total elution of the drug. Thus it would be unwise to extrapolate data comparing DES and BMS and apply the findings to a comparison of DES with CABG. Ongoing clinical trials, such as the Synergy between PCI with TAXUS and Cardiac Surgery (SYNTAX) trial, are primarily designed to compare the 1-year outcomes of PCI with the TAXUS stent and CABG in patients with triple-vessel and/or left main coronary artery disease.³⁶ This study aims to recruit over 4,250 patients at 90 centers in Europe and the United States. Attempting to reflect the “real world”, the study includes not only the randomized arms but also the 2 ineligible registries and a “preference registry”

(refusal of treatment allocation). It will address some important issues on the relative roles of DES and CABG in the treatment of patients with complex coronary artery disease, the short- and long-term cost-effectiveness, as well as quality of life. With respect to the previous data of the CABG arm of the ARTS trial, an ARTS II trial was started in 2003 at 45–50 centers across Europe to assess the “non-inferiority” of SES implantation.^{11,37} However, based on the patient population enrolled in ARTS I, the ARTS II trial has been limited to include 1/3 of patients with 3-vessel disease vs 2/3 with 2-vessel disease.³⁷ Another Future Revascularization Evaluation in patients with Diabetes Mellitus: Optimal Management of Multivessel Disease (FREEDOM) trial was also carried out to compare 5-year mortality in diabetic patients treated with either DES or CABG.³⁸ Obviously, more large-scale prospective studies will be needed to elucidate and define the accurate role of the currently available treatment strategies in patients with ischemic heart disease.

Coronary artery bypass grafting has stood the test of time for 4 decades with excellent success as measured by a variety of clinical outcome markers, and patency rates of the left internal mammary artery grafted to the left anterior descending coronary artery are consistently over 90% at 10 years. No similar claim can currently be made for any catheter-based intervention. The longest trial of BMS has not reached 10-year follow-up. Moreover, as far as patient survival is concerned, no solid evidence from previous trials comparing BMS and CABG supported the superiority of PCI over CABG. Registry data with much larger patient numbers have also unequivocally indicated survival benefits for patients treated with CABG rather than PCI. A recent report involving 14,493 BARI-like patients with multivessel coronary disease once again confirmed the significant survival advantage of CABG over PCI in a 7-year period (1994–2001; mean follow-up, 3.6 years).³⁹ It is noteworthy that such therapeutic benefit was mainly driven by the superior survival after CABG in patients with 3-vessel disease.³⁹ On the contrary, the 30-day mortality in the SHOCK trial (302 patients with cardiogenic shock after acute myocardial infarction for emergency revascularization) was similar between the CABG (57.4%) and PCI (55.6%) groups, although in the former group there was a much greater prevalence of diabetes, 3-vessel, and left main disease.⁴⁰ It must be acknowledged that while PCI has been changing, advances in many aspects of the CABG technique have been remarkable. As a result, CABG has been consistently regarded as the “gold standard” for treatment of coronary disease worldwide.⁴¹

It has been well recognized that CABG provides better protection against repeat revascularization than PCI with stenting. The high rate of repeat revascularization following PCI should not be overlooked. Although the use of stents has substantially reduced this, the figure still remains high (30.3% in the ARTS trial and 28.4% in the ERACI-II trial at 5 years). Indeed, in these two studies, a significant percentage of patients (34.7% in ARTS and 29.6% in ERACI-II) treated with PCI eventually required subsequent revascularization with CABG, a fact disguising to some extent ‘real’ differences in reported survival rates as the trial was conducted and analyzed on an intention-to-treat principle. This high rate of repeat revascularization with the need to resort to CABG therefore questions the applicability of the survival data because up to 10.5% and 8.6% of all PCI patients eventually required CABG.^{11,12} Perhaps more important than restenosis is the issue of the completeness of revascularization potentially achieved by the two treatment options.^{39–42} By placing grafts distal to the diseased coronary segment, CABG deals not only with the immediate culprit lesion but with future lesions, whereas PCI only addresses the existing lesions.⁴² For this reason, surgery has been considered to carry an intrinsic advantage that makes it superior to PCI, irrespective of the type of stent used.

Last, but not least, every patient deserves to make their own decision regarding treatment, based on updated evidence and a balance of clinical opinion. This, by definition, would require multi-disciplinary input into this important process.^{41,42} Only with unprejudiced interpretation of published literature and information disclosure can we provide holistic and comprehensive care to patients with coronary artery disease.

Over the past decade, the techniques and outcomes of both CABG and PCI have substantially advanced. Nevertheless, as a majority of the previous clinical trials comparing these two therapeutic strategies have been limited to selected patient populations, optimal treatment modalities for high-risk patients with complex coronary lesions and multiple comorbidities remain undetermined. Although the rapid growth of the PCI industry and the consequent decline in the caseload for CABG has generated much speculation about the future role of each type of intervention, so far no valid data exist to indicate that PCI plus DES could replace CABG entirely. Fortunately, such an opinion is largely shared by both surgeons and cardiologists.^{41–44} While eager to gain scientific knowledge from some on-going important clinical trials, we must bear in mind that the patient with complex coronary disease demands safe and cost-effective treatment that provides good long-term quality of life. Therefore, the choice of myocardial revascularization

for an individual patient should not be based simply on the anatomical findings. Each patient should be advised by a multidisciplinary team that can present in the most balanced way the advantages and limitations of PCI and CABG.

APPENDIX

Following submission of this manuscript, there have been some recent randomized and observational studies have documented a consistent and disturbing small increase in the absolute risk for late stent-related thrombotic events with DES. Compared DES (47% sirolimus-eluting, 53% paclitaxel-eluting) with BMS using data from 14 randomized trials (involving 6,675 patients), it was found that when stent thromboses occurred more than 30 days after implantation they tended to appear much later with DES than with BMS.⁴⁵ In particular, the thrombosis incidence was significantly greater with DES than with BMS more than 6 months and 1 year after implantation.⁴⁵ In another single-center observational study, 746 patients who had received 6 months of clopidogrel maintenance therapy during a 6-month randomized DES-versus-BMS trial were followed for an additional 12 months after clopidogrel discontinuation.⁴⁶ The incidence of cardiac death or myocardial infarction after discontinuation of clopidogrel was significantly higher with DES than with BMS (4.9% vs 1.3%), even after adjustment for potential confounders.⁴⁶ Thrombosis-related events occurred at a median of 116 days after discontinuation of clopidogrel, accounted for 25% of late events, and tended to occur more often with DES than with BMS.⁴⁶ Therefore, experts from five major professional societies recently recommend dual antiplatelet therapy for 12 months after DES implantation in patients who are not at high risk for bleeding.⁴⁷ This duration exceeds that recommended in manufacturer instructions.

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