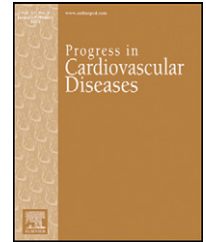


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Is There Still a Survival Advantage to Bypass Surgery Over Percutaneous Intervention in the Modern Era?

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ABSTRACT

The method of revascularization for multi-vessel coronary artery disease (MVD) has traditionally been coronary artery bypass grafting (CABG), however, due to recent advances in the field of percutaneous coronary intervention (PCI), this latter technique has gained in popularity and its role in guidelines has been promoted.

This review aims to address the current data available for the treatment of patients with complex coronary disease, including the specific disease subset in those with diabetes mellitus, focusing on the importance of risk stratification and review by the 'Heart Team'. The concept of complete versus incomplete revascularization and the assessment of lesions utilizing functional techniques are discussed.

Over recent years, PCI has grown to become the most frequently performed therapeutic intervention in medicine and continues to grow. There are encouraging data that this is an effective and safe treatment option in selected patients, however, neither strategy alone can provide a solution for the entire spectrum of patients with MVD.

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Current guidelines for coronary revascularization in patients with multi-vessel coronary artery disease (MVD) state a class I indication for coronary artery bypass grafting (CABG) from both the European Society of Cardiology (ESC) (level of evidence A) and the American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions (level of evidence B).^{1,2} However, the use of percutaneous coronary intervention (PCI) in the treatment of such patients has now been promoted from previous ESC guidance, from a class IIa to a class I (level of evidence B) in those patients with MVD and a 'SYnergy between percutaneous intervention with TAXus and cardiac surgery's' (SYNTAX) score ≤ 22 .^{1,3} This is a consequence of recent advances in technology, with new generation

drug-eluting stents (DES), adjunctive assessment tools (intravascular ultrasound and fractional flow reserve/FFR) and more potent anti-platelet agents. Furthermore, individual operators have gained increasing experience in dealing with complex PCI.

However, in the case of MVD, a full risk stratification and active discussion with a multi-disciplinary 'Heart Team' are strongly recommended (class I; level of evidence C).^{1,2} It is imperative that the most appropriate revascularization modality taking into account patient baseline clinical and angiographic characteristics is chosen to provide favorable long-term outcomes for the patient.

The aim of this discussion is to assess the growing role of PCI in the modern era, for those patients with complex

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Abbreviations and Acronyms

BMS = bare metal stent

CABG = coronary artery bypass graft

CAD = coronary artery disease

DM = diabetes mellitus

EES = everolimus-eluting stent

EuroSCORE = Logistic European System for Cardiac Operative Risk Evaluation

FFR = Fractional flow reserve

MACCE = major adverse cardiovascular and cerebrovascular events

MVD = multi-vessel coronary disease

MI = myocardial infarction

OMT = optimal medical therapy

PCI = percutaneous intervention

PES = paclitaxel-eluting stent

RCT = randomized controlled trial

SYNTAX = SYNergy between percutaneous intervention with TAXus and cardiac surgery

ULMCA = unprotected left main coronary artery

coronary artery disease (CAD), in which previously CABG would have been the treatment of choice.

Current evidence

Historically, CABG has been the gold standard treatment for patients with complex MVD; in high- and medium-risk patients, there was a certain benefit of CABG compared with medical therapy in a large meta-analysis of major CABG studies.⁴ Over more recent years, PCI has been compared with surgical treatment for MVD in a number of studies, with the data indicating no difference in mortality, but conversely a higher rate of revascularization in those undergoing PCI. **Table 1** shows the mortality data from randomized trials comparing PCI with CABG. A large

$p < 0.001$). Conversely, a higher rate of stroke was reported in patients following CABG (0.6% vs. 2.2%; $p = 0.003$). Importantly, there was no difference between revascularization strategy in the occurrence of death, stroke or myocardial infarction (MI; PCI 7.6% vs. CABG 7.7%; $p = 0.98$).⁸

The five year results of this study demonstrated a persistent difference in MACCE between the groups (PCI 37.3% vs. CABG 26.9%; $p < 0.0001$) due to the increased revascularization rates with PCI (9.7% vs. 3.8%; $p < 0.0001$). Nevertheless, there were still no differences either in all-cause mortality (PCI 11.4% vs. CABG 13.9%; $p = 0.10$) or indeed stroke (PCI 2.4% vs. CABG 3.7%; $p = 0.09$).⁹

An important factor when interpreting this study is that first generation DES were used, which have now been demonstrated to be less effective than the new generation devices, which necessitate less repeat revascularization and have less episodes of stent thrombosis.^{10,11} The new generation everolimus-eluting stents (EES) have been shown to have less rates of ischemia driven target lesion revascularization in those undergoing multi-lesion stenting (3.7% vs. 7.4%; $p = 0.01$) compared with PES (used in the SYNTAX study) in pooled data of 4689 patients from the 'Clinical Evaluation of the Xience V Everolimus Eluting Coronary Stent System in the Treatment of Patients with de novo Native Coronary Artery Lesions' (SPIRIT) III and IV randomized trials.¹²

The 'Bypass Surgery Versus Everolimus Eluting Stent Implantation for Multi-Vessel Coronary Artery Disease' (BEST) study recently published randomized 880 patients with MVD to PCI with EES vs. CABG. However, when interpreting the result from the BEST trial, there are 2 important factors to be taken into account that make the study results inconclusive. First, the study was terminated early due to slow enrollment, when only 880 out of 1776 patients were enrolled reaching then only half of the planned study population, making the statistical power of the primary endpoint insufficient. Second, the primary endpoint of death, MI and target vessel revascularization at one year did not reach non-inferiority (PCI 11.0% vs. CABG 7.9%; $p = 0.32$) and therefore all the other analyses are only hypothesis generating.

However an encouraging observational registry of 18,446 propensity matched patients with MVD comparing PCI with EES with CABG was also published recently. At a mean of 2.9 years follow-up, there was no difference in the primary end point of all-cause mortality (PCI 3.1% vs. CABG 2.9%; 95% CI 0.93–1.17; $p = 0.50$), however, a higher rate of stroke in the CABG group (PCI 0.7% vs. CABG 1.0%; $p < 0.001$) was observed. As with other studies, there was a higher need for revascularization in the PCI group (PCI 7.2% vs. CABG 3.1%; $p < 0.001$).¹³

MVD and diabetes mellitus (DM)

The concurrent presence in a patient of DM leads to an increased risk of restenosis following PCI for CAD and reduced longer term survival compared with CABG in contrast to patients without DM.^{14,15} This is likely a consequence of the aggressive nature of the disease, with smaller coronary arteries affected in a diffuse manner.

pooled analysis of over 3000 patients from four randomized controlled trials (RCTs) comparing PCI utilizing bare metal stents (BMS) with CABG, established a consistently higher need for repeat revascularization with PCI to 5 years follow-up (PCI 29.0% vs. 7.9%; hazard ratio [HR] 0.23; 95% confidence interval [CI] 0.45–0.61; $p < 0.001$).⁵

Coronary stent technology has subsequently developed and since the DES became commercially available, a number of RCTs have demonstrated notably improved outcomes, with a significant reduction in rates of restenosis compared to BMS.^{6,7} As a result of this, interventional cardiologists have gained increasing confidence in the treatment of more complex CAD, including MVD and unprotected left main coronary artery (ULMCA) disease, previously the territory of the cardiothoracic surgeons.

The landmark clinical trial comparing PCI with DES versus CABG in MVD was the SYNTAX study. This was an all-comer, international, prospective RCT, randomizing 1800 patients with MVD to either PCI with paclitaxel-eluting stents (PES) or CABG. The primary study endpoint was non-inferiority of PCI in major adverse cardiovascular and cerebrovascular events (MACCE) at one year, which was not met (PCI 17.8% vs. CABG 12.1%; $p = 0.002$), largely due to a significantly higher need for repeat revascularization in those undergoing PCI (13.7% vs. 5.9%;

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