Percutaneous coronary intervention versus coronary artery bypass surgery in multivessel disease: a current perspective

Ozlem Soran a, Aarush Manchanda a, Stephan Schueler b

a Cardiovascular Institute, University of Pittsburgh Medical Center, 200 Lothrop Street, Presbyterian Hospital, PUH, F-748, Pittsburgh, PA 15213, USA
b Geisinger Medical Center, Danville, PA, USA
c Freeman Hospital, Newcastle upon Tyne, UK

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Summary

Coronary artery bypass surgery (CABG) and percutaneous coronary intervention (PCI) are both safe and established treatment modalities of invasive revascularization for patients with coronary artery disease (CAD). However, conflicting information exists when comparing the long-term efficacy of the two methods. The optimal treatment for patients with multivessel coronary artery disease (MVD) is still subject to discussion, given the lack of fairly designed, prospective, randomized data reflecting current practice in the modern era. Furthermore, the clinical outcomes after invasive revascularization differ according to the number of diseased vessels, presence or absence of diabetes, left main disease and left ventricular dysfunction. Hence, the question arises whether we should continue to use the term ‘multivessel disease’. Conflicts of available data need to be addressed and overcome so that care of patients with CAD can be successfully tailored. In this review article we try to address some of the above conflicts, in an effort to improve our understanding in the care of patients with multivessel disease. We also provide an evidence-based perspective which may differ from the current standard of practice.

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Keywords: CABG; Percutaneous coronary intervention; Multivessel disease; Drug-eluting stents

1. Introduction

Both coronary artery bypass surgery (CABG) and percutaneous coronary intervention (PCI) are safe and established treatment modalities of invasive revascularization for patients with multivessel coronary artery disease (MVD). Initial use of CABG dates back almost 50 years. PCI, on the other hand, has emerged as an impressive treatment option for coronary artery disease (CAD) in the last three decades. It is important to realize that both therapies have improved tremendously since their inception. CABG can now be performed off-pump (OPCABG) and with minimally-invasive keyhole techniques not requiring sternotomy (MIDCAB). PCI techniques have seen increasing use of stents in the last decade, which provide a rapid, less invasive option for management of CAD with quicker hospital discharge and return to daily activities. However, conflicting information exists when comparing the long-term efficacy and survival benefits of the two treatment strategies.

Optimal treatment of MVD remains a subject of debate and discussion. This is partly due to lack of extensive, well designed, prospective randomized trials, but also due to inappropriate application of randomized clinical trials (RCT) from highly-select MVD treatment groups to the general CAD patient population. It is also important to understand that clinical outcomes differ based on the total number of diseased vessels revascularized (two-vessel disease 2VD, triple-vessel disease 3VD), presence or absence of diabetes, left main disease and left ventricular dysfunction. This treatment dilemma worsens when there is patient preference issue, i.e. patients prefer PCI over CABG as it is less invasive and frightening compared to surgery and lack of patient education regarding the long-term clinical outcomes of each revascularization strategy, especially rates of repeat revascularization and improvement in survival.

In this review article we try to address some of the above conflicts, in an effort to improve our understanding in the care of patients with MVD. We also provide an evidence-based perspective which may differ from the current standard of practice.

2. CABG vs. PCI in low-risk multivessel disease

In 1994, Yusuf et al. assessed the effect of CABG on survival by performing a meta-analysis of the results of seven RCT of CABG vs. medical therapy (2650 patients followed for 10 years); results showed that CABG improved survival and symptom relief especially in three-vessel disease (3VD) [1]. Benefits were greater in the presence of severe symptoms, positive exercise ECG and impaired left ventricular function. However, there was no survival benefit for CABG over standard medical therapy if there were...
To study this further, Mercado et al. published the results of a meta-analysis on CABG vs. PCI (with stents) for multivessel disease in 2005 [3]. Investigators included four RCT (Arterial Revascularization Therapies Study, Stent or Surgery Trial, Argentine Randomized Trial of Percutaneous Transluminal Coronary Angioplasty vs. CABG in Multivessel Disease 2, and Medicine, Angioplasty, or Surgery Study 2) that compared PCI with multiple-vessel stenting \((n=1518)\) vs. CABG \((n=1533)\). Again only 4\% of the screened patients were randomized. One year after the initial procedure, PCI with multiple stenting and CABG provided a similar degree of protection against death, myocardial infarction, or stroke in patients with MVD. Repeat revascularization procedures occurred more frequently in patients in the PCI group compared to CABG (18\% vs. 4.4\%; hazard ratio 4.4 and 95\% confidence interval 3.3–5.9) [3].

Finally, analysis of the ARTS randomized trial revealed the five-year outcomes after PCI with multi-vessel stenting vs. CABG for the treatment of MVD [4]. Only 10\% of screened patients were randomized. Again 70\% had 2VD and all of them had normal LV function. Even though results of ARTS were already predicted by patient population, one-year and five-year mortality rates were similar in both arms. As expected, repeat revascularization rates were significantly higher in the stent arm. Subgroup analysis showed that patients with diabetes had a survival benefit if they got randomized to CABG. Interestingly, trials excluded patients known to benefit from CABG and patients were not representative of most CABG patients. Nevertheless, trial results have been generalized to all patients.

It is important to note that all the above meta-analyses \((2–4)\) although reported to study patients with multivessel disease, has the majority of patients with 2VD and normal LV function. The results of these meta-analyses replicate the results of initial meta-analysis by Yusuf et al. [1] published a decade before these trials were undertaken.

In summary, it would be safe to conclude that CABG and PCI are both reasonable options in patients with single or 2VD CAD with normal LV function. There may be a slight

<table>
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<th>Trial</th>
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<th>Stent</th>
<th>% 3-vessel disease</th>
<th>Proximal LAD</th>
<th>EF &gt; 50%</th>
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RCT, randomized clinical trials; PCI, percutaneous coronary interventions; CABG, coronary artery bypass surgery; LAD, left anterior descending artery; EF, ejection fraction.

Table 1
Summary of 15 RCT PCI vs. CABG in multivessel disease

single-vessel disease (1VD) or two-vessel disease (2VD) and normal LV function. These investigators recommended for future trials of PCI and GABG to include a high proportion of patients for whom surgery is known to be superior to medical therapy. The crucial question is whether we followed this recommendation or not.

Table 1 shows the summary of 15 RCT of PCI vs. CABG in multivessel disease. It demonstrates that only 5\% of screened patients were actually randomized to the two therapies. Importantly, all patients studied have ejection fractions of 50\%. The incidence of 3VD in these trials is only 35\%. It should not be surprising to find that CABG and PCI are similar in outcomes as these trials exclude all the high-risk patients which may benefit from CABG over multivessel intervention (i.e. diabetics, low LV function and 3VD or left main). However, one might argue these trials reflect the natural proportion of multivessel disease in the population, and an appropriate ratio to be representative of ‘all comers’ with CAD; but then we should be very cautious in generalizing these results to all CAD patients.

Hoffman et al. reported a meta-analysis of 13 RCT CABG vs. PCI [2]. Two-thirds of the patients had 2VD and all patients had normal LV function. High-risk patients i.e. diabetics, decreased LV function and 3VD were not enrolled. Despite being low-risk CAD, CABG resulted in a small survival advantage and a marked reduction in the need for repeat revascularization. There was a small, 1.9\%, absolute survival advantage favoring CABG over PCI for all trials at 5 years. However, it must be noted that all data at 5 years are from earlier studies that did not employ stents in the initial revascularization procedure. They also performed subgroup analyses of trials with and without stents in the initial PTCA arm where data were available from at least two trials. This trend favoring CABG disappeared when it was compared to more recent trials with stents. Whereas the risk difference of CABG vs. balloon angioplasty (POBA) repeat revascularization was 34\% at 3 years, this difference decreased to 15\% when coronary stents were used (2).
mortality benefit long-term of CABG over balloon angioplasty (POBA) which is nullified with the use of stents. However, there is approximately four times more repeat procedures in patients treated initially with PCI compared to CABG which is about half of what is seen with balloon angioplasty [2].

3. CABG vs. PCI in high-risk multivessel disease (Diabetics or low LV function)

CAD in diabetics has been shown to be more aggressive and to be associated with an impaired event-free survival after both CABG and PCI because of smaller vessel sizes, longer lesion length, greater plaque burden, and a possibly differently acting restenotic cascade than in non-diabetics [5, 6]. Given this higher-risk profile, which is most often associated with multivessel disease, CABG has been regarded by some as a preferred revascularization method because of its ability to bypass this large amount of plaque burden and to achieve more complete revascularization rates, making the need for repeat revascularizations less likely.

Many trials have demonstrated CABG to be superior compared to PCI in high-risk patient subgroup. A propensity analysis [7] of long-term survival after surgical or percutaneous revascularization in 6033 patients with MVD and high-risk features (diabetes or left ventricular dysfunction) showed that PCI had 2.3 times higher mortality rate than CABG at five-year follow-up [7]. Niles et al. [8] published the results of survival of patients with diabetes and MVD after surgical or percutaneous coronary revascularization [8]. Their results showed that in 2766 risk matched diabetics PCI increased five-year mortality by 1.5–3.9 times. In a retrospective cohort study of 6320 procedures, Pell et al. compared the survival following CABG vs. PCI in diabetic and non-diabetic patients [9]. Results showed that PCI had 3.6 times higher mortality rates at two-year follow-up in patients with diabetes. New York registry of 37,212 CABG and 22,102 PCI patients with >2VD showed that after three years, CABG significantly reduced the risk of death. If the patients had >2VD and proximal LAD surgery, patients were 35% more likely than the others to be alive after three years [10]. If the patients had >2VD but no proximal LAD lesion then surgery patients were 24% more likely than the others to be alive after three years. Van Domburgh et al. reported the results of a single-center matched–propensity control cohort study which revealed the late outcome after stenting or CABG for treatment of multivessel disease [11]. In this matched cohort study with an 8-year follow-up, survival was better and less repeat revascularizations were needed among patients undergoing elective CABG for the treatment of multivessel disease as compared with the stent group.

In a recent study of patients with multivessel disease and ≥5 years of follow-up, CABG was found to have a significant survival advantage over patients undergoing stent implantation [12]. This advantage was maintained among most subgroups, including males, those >65 years of age, patients without a history of PCI, CABG, or MI, non-diabetics, diabetics, patients with an EF >40%, patients with either 2- or 3-vessel disease, and for both complete and incomplete PCI. The only subgroups in which the survival advantage trended toward stent implantation were those with a previous history of coronary revascularization (either previous CABG or PCI). CABG patients also experienced fewer repeat revascularizations (CABG or PCI) and MI, and 41% fewer events for the composite end point of MACE. These results are consistent with the reports of other observational studies [11, 13]. However, at one year, as in the SOST trial, there was no significant difference in the outcome of mortality [14].

However, it should be noted that most of the prior trials of CABG vs. PCI included outdated technology and techniques for both procedures – this is often why trials such as BARI [15] are no longer given the same weight.

Most of the randomized clinical trials report similar 5-year mortality rates for both CABG and PCI [1–4, 11–28]. Why the results differ between the observational studies of patients seen in typical clinical practice and these randomized trials has been addressed before (such as randomized trials eliminate selection bias, and involve independent data safety monitoring board, core laboratories and clinical event committees; registry data can be complementary in that a broader cross-section of patients are enrolled, but are subject to selection bias and inability to adjust for unmeasured confounders). Patient selection could possibly explain the differing results. Typically, clinical trial participants are required to meet strict inclusion and exclusion criteria. They often have less comorbidity and may not represent the average patient presenting for a coronary intervention. Another possible explanation for the non-significant difference in mortality between the treatments may be limited to insufficient power of these trials. Nonetheless, the SOS trial found lower mortality rates during long-term follow-up among patients randomized to CABG compared with PCI with stents [14]. Other randomized trials, such as the BARI study, also have found a survival advantage for CABG among certain subgroups of patients such as diabetics [21].

In this regard, two of the largest trials of CABG vs. PCI ever performed, FREEDOM (Future Revascularization Evaluation in Patients with Diabetes Mellitus: Optimal Management of Multivessel Disease) and SYNTAX trials [30] (The Synergy between PCI with TAXUS and Cardiac Surgery), both using drug-eluting stents (DES) and minimally invasive surgery have been initiated.

Recently, presented SYNTAX Trial [30] (The Synergy between PCI with TAXUS and Cardiac Surgery) results showed that PCI with TAXUS (paclitaxel-eluting) stenting was inferior to CABG with respect to the primary composite of death, stroke, MI, or repeat revascularization among patients with left main and/or 3VD. The trial was conducted at 62 sites in Europe and 23 sites in the US and had an ‘all-comers’ design instead of a highly selected population to reflect, as much as possible, real world conditions. Limited exclusion criteria included previous interventions, acute MI with creatine phosphokinase (CPK) – myocardial band >2X or concomitant cardiac surgery. Investigators randomized 1800 subjects to CAGB (n = 897) or PCI (n = 903). Approximately 28% had diabetes, 33% prior MI, and 29% recent unstable angina. The average number of lesions was 4.4 with 66% qualifying on the basis of three-vessel disease.

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only, 3% with left main only, and 31% with both left main and three-vessel disease. Average stent implantation per patient was 4.6 with 48% receiving >5 stents. The primary end point of the trial, the rate of MACCE (Major Cardiovascular or Cerebrovascular Event Rate) as defined by all-cause death, cerebrovascular accident, documented MI, or any repeated revascularization at 12 months, occurred in more patients undergoing PCI than CABG (18% vs. 12%; \( P=0.0015 \)). Among the subgroups presented, patients with diabetes, isolated three-vessel CAD, and left main plus involvement of an additional two or three vessels tend to have better outcomes with CABG, while outcomes in patients with isolated left main disease and left main plus a single additional vessel tended to favor PCI. One interesting observation in this study is that; although 91% had three-vessel diseases, only 4% had heart failure. Even though the study did not exclude the patients with low EF, the average mean EF was higher than 40% [28]. Hence, one might think that the outcomes might have favored CABG more if a high number of patients with LV dysfunction were enrolled.

In summary, CABG remains the first-line therapy in patients with high-risk multivessel disease with diabetes and LV dysfunction.

4. CABG vs. PCI in left main disease

A significant left main stem (LMS) stenosis is considered to be a lesion occupying over 50% of the vessel diameter. LMS stenosis is theoretically an attractive target for PCI because it is the most proximal component of the left coronary circulation and because of its relatively large diameter. However, in reality, two important anatomical features carry important qualifications about the likely success of PCI and CABG in LMS stenosis: (a) LMS stenosis occurs as an isolated lesion in only 6–9% of patients, whereas over 70–80% of patients also have multivessel CAD [31–39], thereby potentially enabling more complete coronary revascularization with CABG than with stenting; (b) most LMS stenoses (40–94%) occur in the distal segment of the artery and extend into the proximal coronary arteries [31–39] and such bifurcated or trifurcated lesions have a high risk of restenosis [39], while acute occlusion at this site can have catastrophic consequences. Only two groups have reported registry data in patients with LMS stenosis undergoing CABG or PCI with DES [35, 38] with at least 1-year follow-up. In the Bologna registry of 311 patients with LMS stenosis, 68% were deemed suitable for either PCI or CABG, 19% for CABG only, and 13% for PCI only [38]. At a median follow-up of 14 months, the mortality was 12% in 154 CABG and 13% in 157 PCI patients (but 3%, respectively, in low-risk patients). The repeat revascularization rate was, respectively, 3% for CABG and 26% for PCI. In an Italian registry of 249 LMS patients, there was no difference in 1-year mortality after adjustment for baseline characteristics in the 107 PCI and 142 CABG patients, who were significantly older (68 vs. 64 years) with a higher proportion of renal failure (8% vs. 2%) [35]. Again, however, repeat revascularization was 20% in PCI vs. 4% of CABG patients, probably reflecting the fact that 87% of patients had bifurcation disease [35].

To date only one randomized trial of PCI vs. CABG has been reported [40]. The LEMANS (Study of Unprotected Left Main Stenting vs. Bypass Surgery) trial was a randomized trial of 52 PCI (35% with DES) and 53 CABG patients of whom approximately 60% had distal LMS stenosis, and of whom 75% of the CABG group and 60% of the PCI group had 3-vessel CAD \( P=0.08 \). Although, as expected, the CABG group had more short-term complications within the first month after surgery, the primary outcome of MACCE at one year was similar in the two groups, as 15% of the PCI group required further PCI or CABG. Furthermore, the fact that only 72% of the CABG group received an internal mammary artery graft despite its well established survival benefit raises questions about the quality of the surgery in the LEMANS trial, as use of this graft should approach 100% in contemporary practice. Results of a randomized trial of DES vs. CABG for LMS stenosis (the SYNTAX [Synergy between PCI and Taxus and Cardiac Surgery] trial) were recently reported [30]. The outcomes in patients with isolated left main disease and left main plus a single additional vessel tended to favor PCI. On subgroup analysis of the LM patients, the overall 12-month MACCE event rate was lower with CABG (13.7% vs. 15.8%), although patients with LM only (8.5% vs. 7.1%) and LM+1-VD (13.2% vs. 7.5%) seemed to do slightly better with PCI. Patients with LM + 2-VD (14.4% vs. 19.8%), LM + 3-VD (15.4% vs. 19.4%), or 3-VD alone (11.5% vs. 19.2%) seemed to do better with CABG than PCI.

In summary, in light of recent evidence, PCI with DES may emerge as a reasonable alternative to CABG in the near future, especially for patients with isolated unprotected LMS disease or LMS + 1-VD. However, the catastrophic consequences of stent restenosis, acute and late stent thrombosis [29, 41, 42] should be discussed at length prior to taking such an intervention.

5. Cost effectiveness: CABG vs. PCI

In 2003, eleven health economists did a systemic review and economic evaluation on stents [43]. They clearly stated that in the absence of substantive clinical evidence of the superiority of stenting with DES over CABG for two- and three-vessel disease, to encourage the widespread use of DES will drive up the cost of stenting and if allowed to displace CABG, reduce the gain in quality and possibly duration of life arising from CABG in the long term.

In a cost-effectiveness analysis of 1720 patients who were allocated to PCI, CABG or either therapy were followed for seven years. It was concluded that while the medical therapy and CABG were cost-effective at a conventional quality-adjusted life year of $560,000, PCI was not cost-effective, and the additional benefit of stenting over best medical therapy was ‘too small to justify the additional cost’. These findings are consistent with a previous report by the UK Health Technology Assessment Group, who also questioned whether the additional costs of DES were justifiable, warning that the widespread use of DES might reduce the gain in quality and possibly the duration of life arising from CABG in the long term [44, 45]. In 2006, the use of DES was 89% and 80% in Europe and in the US, respectively, and the off-label use of DES was 60%. After
FDA warnings these ratios dropped by 20–25% in 2007. However, the reality is clinical practice DES use in multi-vessel disease is currently ‘off-label’ or beyond FDA-approved use.

6. Conclusion

In determining a treatment strategy for a patient with CAD, there are a variety of considerations that need to be made when selecting the appropriate treatment to prevent iatrogenic fulminans [46]. Since the clinical outcomes differ according to the treatment choice as demonstrated above, it is important to replace ‘multi-vessel disease’ terminology with the number of diseased vessel; such as 2VD or 3VD. FREEDOM trial is now underway, which may address many of the limitations of previous studies, and be more relevant to contemporary practice. Until then, currently available data emphasize the fact that CABG remains an excellent and often superior long-term form of revascularization in some selected groups of patients with two-vessel diseases and most groups of patients with three-vessels CAD.

It is extremely important to establish a multidisciplinary team of general cardiologists, interventional cardiologists and cardiothoracic surgeons to ensure that the most appropriate advice is offered including recommendation for stenting. Steps should be undertaken to increase the representation of cardiothoracic surgeons in the various Guidelines Writing Committee Task Force on the use of PCI vs. CABG in management of CAD (Fig. 1) to represent an unbiased opinion.

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eComment: Costs of percutaneous coronary intervention versus coronary artery bypass surgery

Author: Rui M.S. Almeida, UNIOESTE, Parana’s West State University, Rua Terra Roxa 1425, Cascavel, PR 85816-360, Brazil
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I read with great interest the recent report by Dr. Soran and coworkers regarding the current perspective of treating multivessel coronary disease. Despite the fact that the authors brought into perspective a new way of analyzing the different groups that form the multivessel coronary artery disease, one point that struck me is the analysis of the cost-effectiveness of coronary artery bypass surgery (CABG) versus percutaneous coronary intervention (PCI). This seems to become a main issue for the years to come, especially in relation to governmental health services.

In 2005 we published, in Brazil, a prospective study comparing costs of CABG vs. PCI for a period of six months, in one institution which at that time used bare (70.5%) and drug-eluting stents (29.5%) – http://www.rbccv.org.br/detalhe_artigo_ingles.asp?id=457 [2]. These groups were followed for a period of 12 months for re-interventions and costs. All costs were calculated in Brazilian Reais.

The results showed that despite the fact that the initial costs were higher for CABG at the end of the follow-up period, this relation was inverted for the PCI group which was higher by 4.4% at the end of a year. In the subgroup using drug eluting stents the costs were 17.4% higher at the end of the same period. With the cost increase of stents and still a high rate of re-intervention in the PCI group, it seems that the five-year assessment of this group of patients will continue to trend higher.

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