## **REVIEW ARTICLE**

# Severe coronary artery disease

Is there a place for percutaneous coronary intervention?

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#### KEY WORDS

#### ABSTRACT

angioplasty, bypass, prognosis, coronary disease, revascularization Management of severe coronary artery disease (CAD), defined as multivessel disease with or without significant left main artery disease remains a topic for considerable discussion. Although coronary artery bypass graft (CABG) surgery has been the mainstay of treatment, the steady pace of improvement in percutaneous coronary intervention (PCI) continues to beg the question as to whether PCI can perform as well as CABG for these patients.

This short review is intended to place the recently published SYNTAX (Synergy between PCI with Taxus and Cardiac Surgery) trial in perspective, considering the previous major clinical trials in this field and to further consider whether PCI can be used appropriately in the management of patients with advanced CAD.

The major clinical trials comparing PCI to CABG published prior to SYNTAX are briefly reviewed in chronologic order. The SYNTAX trial is reviewed in more depth and the implications of its results for contemporary clinical management are discussed.

PCI has been applied to more advanced forms of CAD as percutaneous technology has evolved from balloon angioplasty to bare metal stents to drug eluting stents. Long-term survival has remained comparable between PCI and CABG patients despite the more advanced nature of disease treated in more recent trials, recognizing that a significant number of patients are excluded from randomization because equivalent revascularization is not achievable percutaneously. Repeat revascularization is more frequently required in PCI patients than in CABG patients. PCI has a role to play, although CABG remains the mainstay of therapy for patients with advanced CAD.

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vant to percutaneous intervention Atherosclerotic coronary artery disease (CAD) is a diffuse process which manifests clinically in several ways, including angina pectoris, myocardial infarction (MI) and sudden death. Coronary atherosclerotic plaque may be classified into vulnerable plaque prone to rupture and stable plaque, less prone to rupture. Vulnerable plaques usually contain a large lipid-rich core with a thin fibrous cap, whereas stable plaque has a thicker fibrous cap.<sup>1,2</sup> Either type of plaque may obstruct the coronary lumen enough to cause exertional angina, but it is the rupture of vulnerable plaque which typically leads to unstable angina and to MI. Coronary angiography or lumenography is an excellent tool for the identification of significant

obstructive disease. While angiography often suggests the presence of focal lesions, autopsy studies and intracoronary ultrasonography demonstrate the true diffuse nature of the atherosclerotic process. Additionally, we know that coronary angiography cannot reliably distinguish between vulnerable and stable plaque. Serial angiographic studies in patients with acute MI often demonstrate that the culprit lesion responsible had a <50% diameter stenosis on the earlier imaging study.<sup>3,4</sup>

Although coronary atherosclerosis is a diffuse process, percutaneous transluminal coronary angioplasty (PTCA) and stent implantation are focal endovascular treatments. Percutaneous coronary interventions (PCI) are typically performed on atherosclerotic lesions creating a  $\geq$ 70% luminal

diameter stenosis because this is the generally accepted threshold for hemodynamic significance. This strategy successfully treats angina and is the basis for current PCI guidelines.<sup>5</sup> Because angioplasty and stents do not directly address plaque vulnerability, concomitant medical therapy directed toward coronary risk factor modification is required for the secondary prevention of future events. Likewise, CABG does not treat the underlying disease process. However, in those patients with extensive proximal disease, including severe proximal bifurcational disease, surgery can bypass a relatively long length of diseased vessel. In a sense, this approach provides a solution not only for the high-grade, proximal, angina-producing lesions but also for the intervening less obstructive plaque which may be vulnerable and may cause future clinical events. This provides a rationale for the surgical treatment of patients who present with extensive plaque burden (such as three-vessel disease).

**Historical perspective** From its inception in 1968<sup>6</sup>, CABG revolutionized the treatment of CAD. CABG proved an effective tool for the treatment of symptomatic disease, including single vessel, multivessel, and left main (LM) disease. Percutaneous coronary revascularization by PTCA became a reality in 1977.<sup>7</sup> PCI was initially applied only for anatomically non-complex, single vessel CAD. CABG remained the standard of care for those patients with severe, extensive CAD and for LM disease. However, progress in the field of interventional cardiology made it feasible to utilize PCI in more advanced lesions.

Clinicians began considering whether the combination of PCI with concomitant preventive medical therapy could provide a safe and effective alternative to CABG. The motivations for a less invasive approach to surgical revascularization include avoidance of a thoracotomy, shorter hospitalization, and faster recovery. However, a procedure which is feasible and appealing from one point of view may or may not be in the long term best interest of the patient. Various investigators initiated a series of clinical trials, beginning in the late 1980s, in order to determine the optimal role for PCI in the management of severe CAD.

Lessons from the pre-SYNTAX trial era The EAST (Emory Angioplasty versus Surgery Trial)<sup>8</sup>, RI-TA-1 (Randomised Intervention Treatment of Angina)<sup>9</sup>, GABI (German Angioplasty Bypass Surgery Investigation)<sup>10</sup>, and BARI (Bypass Angioplasty Revascularization Investigation)<sup>11</sup> trials were designed to test the hypothesis that multivessel balloon angioplasty could offer an effective alternative to CABG. These trials occurred before stents were available and generally involved patients with two- or three-vessel disease. EAST was a single center randomized clinical trial (RCT) which enrolled patients from June 1987 until April 1990. The angioplasty group contained 198 subjects and the surgical group contained 194 subjects. Survival, after 8 years of follow-up, did not differ significantly in the two treatment arms (79.3% in the angioplasty group and 82.7% in the CABG group). There was a trend for those patients with diabetes and for those with proximal left anterior descending (LAD) disease to experience better long-term survival. The generalizability of the study results were limited by the single center study design.

BARI, one of the first large multicenter RCTs, compared PTCA to CABG for the treatment of twoand three-vessel CAD. BARI's enrollment started in 1988 and reached a total sample size of 1829 randomized patients. An additional 2013 eligible patients refused randomization and these were followed in a registry along with 422 patients who were ineligible based on angiographic criteria. The 5-year results were published in 1996 and the final, 10-year follow-up was published in 2007.12 BARI found no significant mortality difference in the randomized patient cohort, and this was also true for the non-diabetic patient subgroup. In the subgroup of patients with treated diabetes, however, CABG was associated with a significantly higher cardiac survival rate (p < 0.01).

The GABI trial recruited patients (from eight centers in Germany) requiring revascularization of two or more vessels. As was typical in this era, patients with total occlusions or significant LM disease were excluded along with patients aged >75 years. A total of 8,981 patients were screened in order to achieve 359 randomized subjects. Long-term follow-up was excellent. After 13 years, PCI and CABG were found to have comparable survival and symptomatic efficacy.<sup>10</sup>

The RITA-I trial, a larger multicenter study based in the United Kingdom, was notable for an additional analysis of health care resource utilization. The patients tended to have less extensive disease than GABI. Of the 1011 patients randomized, 45% had single vessel and 55% had multivessel disease. After a mean of 6.5 years of follow-up, there was no significant difference in the composite endpoint of death or MI, although a trend favored CABG. The 5-year cumulative rate of death or MI was 14.1% for PTCA and 11.1% for CABG. The cost analysis at 5 years demonstrated a non-significant 4.8% excess cost in the CABG group, as the higher initial cost of CABG was counterbalanced over time by the cost of more frequent repeat procedures in the percutaneous intervention group.

While the results of these trials were informative, how best to utilize PCI in advanced CAD remained unresolved due, to a large extent, to the evolution of coronary interventional treatment concurrent with these trials. Progress in percutaneous techniques combined with remarkable advances in device technology and adjunctive pharmacology have made PCI safer and more effective over the last 3 decades. The introduction of bare metal stents (BMS) significantly reduced the rate of emergency surgery after failed PTCA and produced a modest reduction in the rate of restenosis. Though less publicized, CABG surgery also improved via refinement of technique, the use of arterial conduits (particularly the use of the left internal mammary graft to the LAD) and improved anesthesia. These developments spawned another series of clinical trials designed to determine the relative value of PCI vs. CABG in the management of severe CAD to evaluate the latest changes in the respective revascularization procedures.

Several trials compared PCI (utilizing BMS) with CABG. These trials generally enrolled patients with slightly more extensive disease (primarily two- and three-vessel) compared with the prior PTCA studies, while continuing to exclude LM disease. The ARTS (Arterial Revasculariztion Therapies Study)<sup>13</sup>, ERACI II (Coronary Angioplasty with Stenting versus Coronary Bypass Surgery)<sup>14</sup>, and MASS-II (Medicine, Angioplasty, or Surgery Study)<sup>15</sup> trials demonstrated no significant mortality difference between the two treatment strategies, but SoS (Stent or Surgery) trial showed a lower survival rate in PCI patients after 6 years of follow-up<sup>16</sup>. Like the balloon angioplasty vs. CABG trials, the BMS trials also showed a higher rate of repeat revascularization in those patients whose initial treatment was percutaneous.

Given the variation in results from individual trials, statisticians tried two approaches, meta-analysis and pooled analysis, to help practitioners make appropriate clinical decisions. Daemon and co-workers performed a pooled analysis of these four BMS vs. CABG trials with 5 years of follow-up.<sup>17</sup> Using a composite endpoint of cumulative incidence of death, MI, stroke and repeat revascularization, they found overall major cardiovascular and cerebrovascular events to be significantly higher in the PCI group (39.2%) compared to the CABG group (23%), p <0.001. This result, however, was driven by the higher rate of repeat revascularization in the PCI group (29%) compared to CABG (7.9%), p <0.001. The cumulative incidence of death, MI, and stroke was similar (16.7% for PCI compared to 16.9% for CABG), p = 0.69. The subgroup analysis for patients with diabetes showed similar results.

**Lessons from large scale meta-analyses** Bravata et al. published a meta-analysis of 23 studies.<sup>18</sup> The authors included 23 randomized clinical trials in their analysis with a cumulative total of 5,019 patients assigned to PCI and 4944 patients assigned to CABG. This analysis was helpful in confirming the relative increased incidence of one of the main risks associated with CABG. Procedure related stroke was significantly more common in the CABG patients – 1.2% with CABG compared to 0.6% with PCI, p <0.001. Survival over 10 years of follow-up was similar in the two groups – a less than 1% difference at 1 year, 5 years and even in those patients followed as long as 10 years. Interestingly, this analysis did not show a survival difference in diabetic patients when combining six trials that reported on this subgroup. As expected, revascularization rates were significantly higher with PCI – at 5 years, 46.1% following balloon angioplasty, 46.1% following PCI with stents, and 9.8% after CABG. Relief of angina was more common after CABG than after PCI. The difference ranged from 8% at 1 year to 5% at 5 years and was statistically significant (p = 0.001).

Lessons from pooled analysis Individual studies often lack statistical power to rigorously evaluate low frequency events or safety and effectiveness signals among subgroups. A recently published analysis of pooled patient-level data from ten randomized trials of PCI vs. CABG<sup>19</sup> showed that, with a median follow-up of 5.9 years, diabetic patients and subjects age  $\geq 65$  treated with CABG had a lower mortality than PCI; no significant mortality difference was manifest for any other clinical subgroups. Different conclusions reached by meta and pooled analyses illustrate the difficulty for clinicians in using them to make treatment decisions about individual patients. It should be noted that the meta and pooled analyses used different statistical methodology for combining trials in order to gain greater statistical power. Both methods attempt to clarify results with a goal of making clinical decisions easier with regard to important subgroups, but opposite conclusions were reached with respect to patients with diabetes.

Clinical trials in the era of drug eluting stents Drug eluting stents (DES) significantly reduce the rate of restenosis as compared to BMS. This advance was regarded as a quantum leap in PCI efficacy and offered the possibility that DES use could overcome the increased rate of repeat revascularization observed in BMS patients in prior BMS vs. CABG trials. Patients with LM disease and those with diabetes and three-vessel disease were subgroups of particular interest. Small randomized trials and other non-randomized investigations of these subgroups were performed.<sup>20,21</sup> Chieffo reported a non-randomized single center experience from Italy of 249 patients with LM disease; the PCI group consisted of 107 patients, and the CABG group consisted of 143 patients.<sup>22</sup> There were no significant differences in rate of major adverse events after 1 year of follow-up. Lee et al. performed a retrospective analysis of prospectively collected data on 205 consecutive patients with diabetes and multivessel disease undergoing either CABG or PCI with DES.<sup>21</sup> These authors found a lower incidence of major adverse cardiovascular events in the CABG group, although the mortality rate was not statistically different at 1 year (8% in the CABG group compared to 10% in the PCI group, p = 0.6). ARTS II, a multicenter nonrandomized open label trial, compared a single arm (n = 607) consisting of patients with multivessel disease treated percutaneously with sirolimus eluting stents to historical

arms of the ARTS I trial. The authors concluded, after 3 years of follow-up, that the use of sirolimus eluting stents for treatment of multivessel disease was safer and more efficacious than the use of BMS.<sup>23</sup>

Justification for SYNTAX The need emerged for a new, large-scale RCT of PCI vs. CABG which would incorporate patients with severe CAD including LM disease. Although professional society guidelines remained unchanged, interventional cardiologists began using DES to treat patients with severe, multivessel CAD with increasing frequency. A 2004 survey conducted in the United States and in Europe found a surprisingly high incidence of patients with severe coronary disease (multivessel and/or LM) treated percutaneously: 18% of patients in the United States and 29% in Europe in selected centers.<sup>24</sup> In the absence of validated RCT data, clinical practice was evolving, and practice patterns were likely related to the perceived superiority of DES compared to BMS for treating complex CAD (such as bifurcation lesions) as well as the results from several small trials. In the general enthusiasm surrounding the superior technical performance of DES, many practitioners were tempted to assume that this superior performance would translate into a clinical benefit similar to the benefit observed with CABG vs. medical therapy when applied to patients with advanced forms of CAD.

**SYNTAX** The recently reported SYNTAX trial utilized several important design features which made these results the most relevant information available to guide the management of patients with advanced CAD. SYNTAX was a large prospective RCT for patients with three-vessel or LM (or combined) CAD.<sup>25</sup> Its clinical importance is enhanced by its multicenter design (17 countries and 85 centers) and the enrollment of "all comers". Patients eligible for randomization were those in whom a consensus was reached by an interdisciplinary team of interventional cardiologists and cardiothoracic surgeons that equivalent revascularization could be achieved with either therapeutic option. Subjects were prospectively stratified by diabetic status and the presence or absence of LM disease. Patients for whom only one option was deemed appropriate were enrolled into a parallel, nested registry – either a CABG registry for PCI ineligible subjects or a PCI registry for CABG ineligible patients. With this approach, it was possible to include a very high percentage (71%) of screened patients into either the randomized portion or the registry portion of the overall trial. Importantly, all patients in this trial received contemporary revascularization procedures; patients who underwent PCI received DES (Taxus Express, Boston Scientific Corporation), and surgical patients received arterial grafts when possible.

The 1 year results from SYNTAX were generally similar to results from previous trials, despite

the use of DES. The primary endpoint was MACCE, a composite of all-cause death, stroke, MI, or repeat revascularization. A significantly higher proportion of patients randomized to PCI experienced major adverse cardiac and cerebrovascular event (MACCE) (17.8%) as compared to patients randomized to CABG (12.4%), p = 0.002. The failure of PCI to meet statistical non-inferiority criteria was driven mainly by a difference in repeat revascularization rates; at 1 year follow-up, 13.5% of PCI patients required revascularization as compared to only 5.9% of patients in the CABG group, p < 0.001. The ARTS II demonstrated that DES usage decreased target vessel revascularization rates compared to BMS. As expected, the revascularization rates in the PCI arm of SYNTAX were lower than those reported in previous BMS trials. This was true despite the fact that the mean number of lesions treated in per patient in the PCI arm was 4.3 in SYNTAX. In these SYNTAX PCI patients, however, the revascularization rates remained higher than in CABG-treated subjects. Importantly, the higher frequency of revascularization in post-PCI was not associated with increased mortality at 1 year following the index procedure.

Although the SYNTAX investigators concluded that CABG should remain the standard of care for management of patients with three-vessel or LM CAD, there is widespread agreement that PCI still has a role in the management of some patients with complex and/or multivessel disease. There will always be patients who are either ineligible for surgery, refuse surgery, or who express a strong desire to avoid surgery if at all possible. Additionally, certain aspects of SYNTAX provide important patient management insights. Of the 3075 patients included in the trial, 1275 were deemed suitable for only one treatment option, and of these, 198 were deemed suitable only for PCI. These PCI registry subjects typically had significant comorbidities including 40.4% with prior MI, 30.2% with diabetes, 19.3% with chronic obstructive pulmonary disease, 14.1% with a history of prior transient ischemic attack or stroke, and 4.7% were pacemaker dependent. This indicates one role for PCI in patients with advanced coronary disease. This subgroup of patients with significant comorbidities making them poor surgical candidates can often be managed successfully with PCI.

Going forward, insights into the selection of patients with LM or multivessel disease who can be optimally managed with PCI was provided by the SYNTAX score. The SYNTAX score was designed to reflect the complexity of coronary disease, based primarily on anatomic characteristics present on the diagnostic angiogram, with higher scores indicating more complex disease. For analysis purposes, the authors divided patients into one of three groups with respect to their SYNTAX score (low, medium and high). Among patients randomized to PCI, patients in the highest SYNTAX score tertile experienced significantly higher rates of MACCE at 1 year compared to patients in the lowest tertile (23.4% vs. 13.6%, p = 0.002). In contrast, an association between SYNTAX score and clinical outcomes was not observed in patients in the CABG group; patients with high SYNTAX scores did just as well as patients with low SYNTAX scores. Further analysis of SYNTAX data continues, but the study results suggest that the SYNTAX score or a similar metric could be used to discriminate among those patients with three-vessel and/or LM disease in order to decide who might be an appropriate candidate for PCI.

**Beyond SYNTAX** Interventional cardiology and cardiac surgery remain dynamic fields with ongoing innovation and technical advances. The pace of change in interventional cardiology has slowed since the introduction of DES, but new generations of devices continue to evolve. Stents are imperfect tools and there remains significant room for improvement. Boston Scientific Corporation, manufacturer of the Taxus stent, sponsored the SYNTAX trial and patients randomized to PCI were to receive Taxus stents. Although the Taxus stent remains a market leader, two additional DES have been approved in the US (Endeavor and Xience V) since the SYNTAX trial was initiated. The Spirit III trial was a head-to-head comparison of the Taxus (paclitaxel eluting) stent to the Xience V (everolimus eluting) stent.<sup>26</sup> This trial demonstrated a significant improvement in the rate of a composite endpoint of major adverse cardiac events (cardiac death, MI, and target vessel revascularization) for the Xience stent as compared to Taxus with 2 years of follow-up - 7.3% vs. 12.8%.<sup>26</sup> In addition to the promise of better drugs and improved stent platforms and polymers, there is the promise of bioabsorbable stents which might effectively prevent restenosis and avoid a permanent foreign body implant, thus promoting better vascular healing. SYNTAX is unlikely to be the final word in this controversial and rapidly changing field.

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## **ARTYKUŁ POGLĄDOWY**

# Zaawansowana choroba wieńcowa

Czy jest miejsce dla przezskórnej interwencji wieńcowej?

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#### SŁOWA KLUCZOWE STRESZCZENIE

angioplastyka, choroba wieńcowa, pomostowanie aortalno-wieńcowe, rewaskularyzacja, rokowanie Postępowanie u chorych z zaawansowaną chorobą wieńcową (ChW), definiowaną jako choroba wielonaczyniowa z/bez istotnego zwężenia pnia lewej tętnicy wieńcowej pozostaje tematem żywej dyskusji. Chociaż podstawę leczenia stanowi zabieg pomostowania aortalno-wieńcowego (*coronary artery bypass graft* - CABG), jednak nieustanny postęp w technikach przezskórnej interwencji wieńcowej (*percutaneous coronary intervention* – PCI) narzuca pytanie, czy PCI może być przeprowadzane w tej grupie chorych z takim samym powodzeniem jak CABG.

Celem tego krótkiego przeglądu jest przedstawienie niedawno opublikowanego badania SYNTAX (Synergy between PCI with Taxus and Cardiac Surgery) w perspektywie dotychczasowych dużych badań dotyczących tego tematu oraz ustalenie, czy PCI może być właściwym postępowaniem w leczeniu chorych z zaawansowaną ChW.

Duże badania porównujące PCI z CABG, które zostały opublikowane przed SYNTAX, są skrótowo opisane w porządku chronologicznym. Badanie SYNTAX przedstawiono bardziej wnikliwie, omówiono ponadto implikacje jego wyników dla obecnego postępowania klinicznego.

Dzięki postępowi w technikach przezskórnej interwencji od balonowej plastyki, poprzez stenty metalowe, aż do stentów uwalniających lek, PCI jest stosowane u chorych z bardziej zaawansowanymi postaciami ChW. Przeżycie odległe u pacjentów po zabiegu PCI oraz CABG pozostaje porównywalne, pomimo wzrostu liczby poddanych zabiegom chorych z ciężką postacią ChW w ostatnich badaniach. Trzeba jednak zaznaczyć, że znaczna grupa pacjentów została wykluczona z badań z powodu braku możliwości wykonania równorzędnej rewaskularyzacji drogą przezskórną. Ponadto u chorych po zabiegu PCI częściej niż po CABG konieczne jest wykonanie ponownej rewaskularyzacji. PCI odgrywa zatem pewną rolę w leczeniu pacjentów z zaawansowaną ChW, jednak leczeniem z wyboru pozostaje nadal CABG.

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