Coronary Artery Disease (D Feldman and V Voudris, Section Editors)

# Coronary Revascularization in High-Risk Stable Patients With Significant Comorbidities: Challenges in Decision-Making

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This article is part of the Topical Collection on *Coronary Artery Disease*

## Abstract

*Purpose of review* There is a growing cohort of complex high-risk patients with stable ischemic heart disease (SIHD) who present for coronary artery bypass graft (CABG) surgery and percutaneous coronary intervention (PCI). These patients are older, have complex coronary disease, and a substantial comorbidity burden including frailty. The procedural risks and outcomes of CABG and PCI in these patients are more difficult to assess based on the available literature, which has generally studied a younger population with a lower comorbidity burden.
*Recent findings* There have been initiatives to recalibrate and expand risk models derived from procedural registries to inform the care of complex higher-risk patients, including patients "turned down" for CABG. There is greater recognition of the need for improved assessment of risk, quality, and benefits of coronary revascularization in higher-risk SIHD patients with a substantial comorbidity burden.

*Summary* Clinicians and patients should be aware that there are significant evidence gaps regarding revascularization in complex high-risk patients. The limitations of procedural-derived risk scores should be understood when presenting treatment options. Future randomized controlled trials and expanded registries are greatly desired and should be achievable. Meanwhile, a multidisciplinary heart team approach should be employed for proper decision-making.

## Introduction

Amidst improvements in goal-directed medical therapy (GDMT) of stable ischemic heart disease (SIHD), there remains an important role for coronary revascularization in the amelioration of symptoms and reduction of adverse events in selected patients. For several decades now, the principal methods of coronary revascularization have included coronary artery bypass graft (CABG) surgery and percutaneous coronary intervention (PCI). These therapies have been extensively studied (and frequently compared) in large multinational trials, which inform clinical guidelines. However, the practicing clinician is aware that there is a large and growing population of SIHD patients with significant comorbidities that have been under-represented in such trials.

What is the benefit, if any, of revascularization in this high-risk cohort? Which type of revascularization (CABG, PCI) is best? What is the risk of PCI in patients ineligible for CABG, and what is the risk of forgoing revascularization altogether? These are the matters whose answers patients and families demand and deserve in this era of increasing patient-centered decision-making. In this manuscript, we review the key literature on these questions, and discuss means towards achieving further insight into the management of these "sicker" patients.

# The changing face of SIHD

Recent longitudinal studies and registries have observed a gradual increase in comorbidity burden of patients who are undergoing revascularization with PCI and CABG. A 2016 analysis of the National Cardiovascular Data Registry (NCDR) of nearly a million patients admitted for outpatient PCI between 2009 and 2014 identified a significant increase (from 17 to 19.8%) in patients at risk for mortality who were not admitted to the hospital post-procedure [1]. A 2018 analysis of US veterans also observed that patients undergoing PCI between 2009 and 2015 were progressively older with gradually increasing rates of cerebrovascular disease, diabetes, heart failure, and renal failure [2]. Fortunately, in-hospital mortality did not change over this period.

Significant demographic shifts have likewise occurred in the CABG population. An observational study comparing trends in the Society of Thoracic Surgeons (STS) database between the years 2000 and 2009 noted an increase in patients with diabetes and better medical therapy [3]. Similarly, compared with 2006, patients in the 2016 STS dataset had higher rates of diabetes and prior PCI [4]. Among Medicare patients, CABG patients have had increasing comorbidities between 2000 and 2012 [5]. Between 1997 and 2011, CABG patients in the US Veterans Affairs hospitals were significantly older, had higher rates of diabetes, obesity, and advanced heart failure, and lower rates of previous myocardial infarction and advanced angina [6]. Importantly, despite the shifting comorbidity, all

of these studies identified improvement in adjusted outcomes, reflecting the advancement in surgical management [3–6].

We can speculate about some of the factors to the secular trends in patients undergoing coronary revascularization. First, there have been important advances in risk reduction, notably reductions in tobacco use (and secondhand smoke exposure), earlier and more aggressive use of anti-hypertensive and lipid-lowering therapies, and modest improvements in other lifestyle factors [7]. These improvements ought to shift the manifestations of cardiovascular disease to older populations. However, these improvements are uneven, and are affected by psychological and sociological factors that affect patient-level risk (e.g., socioeconomic status, insurance status, mental illness, isolation). Second, trials and guidelines have emphasized the importance of GDMT as a first-line management in patients with SIHD, which has led to decreasing upfront use of revascularization therapies [8]. Third, trials (reviewed below) have probably shifted referral patterns in specific subgroups (e.g., diabetes). Fourth, technical improvements in CABG and PCI may lead to their consideration in broader populations than traditionally served (e.g., the very elderly). Fifth, there have been secular increases in US rates of obesity with concomitant increases in type 2 diabetes mellitus and its sequelae. These factors, among others, likely contribute to the increasing divergence between the patients in the waiting room and those in the seminal trials of coronary revascularization.

# The trial literature

There is extensive research comparing GDMT to revascularization in SIHD, as well as comparisons between CABG and PCI. This literature arose from the earliest CABG trials in the 1970s [9] and has expanded to eventually fill lengthy clinical practice guidelines and appropriate use criteria [10, 11]. Noteworthy randomized controlled trials (RCT) from the past 15 years comparing GDMT to revascularization (any type) in SIHD include COURAGE [12, 13], BARI-2D [14], FAME-2 [15, 16], STICHES [17•], and the ongoing ISCHEMIA trial [18]. Landmark RCTs comparing CABG and PCI include SYNTAX [19], FREEDOM [20], and two trials studying patients with left main disease (EXCEL [21] and NOBLE [22]).

The key findings of these RCTs can be summarized:

1. Compared with upfront GDMT, upfront GDMT with revascularization does not appear to reduce risks of death or nonfatal myocardial infarction (MI) in most patients. There is the possibility that these outcomes are modestly improved for coronary lesions with low fractional flow reserve [FFR] [15, 16] or over time in patients with reduced left ventricular ejection fraction [17•]. Revascularization improves symptomatic angina more quickly and to a greater degree than upfront GDMT, but this difference may attenuate over time [23].

2. Compared with PCI, CABG is associated with increased risk of peri-procedural stroke but reduced risk of repeat revascularization. There does not appear to be reduction in death or nonfatal MI, except in patients with diabetes mellitus [20] (although this has been contested [24]). Anatomic and clinical patient factors ought to play a major role in deciding between these two treatment options.

However, these findings are contingent on the types of subjects who were enrolled in these trials. It is well known that trial subjects differ from the patients who present for clinical care. As has been recently observed, the highest risk patients have been frequently excluded from revascularization trials [25••]. This is quite apparent when the trials' demographics and exclusion criteria are taken into consideration (Table 1). This selection and inclusion bias also affects trial-derived risk scores such as the SYNTAX score II [26]. Clinicians are thus left with a fair degree of uncertainty regarding the applicability of the trial literature towards complex higher-risk patients.

# Registries, risk scores, and their limitations

Multiple large registries of patients undergoing PCI and CABG have existed for some time, and these have been employed to improve risk stratification for "real-world" SIHD patients, most commonly in the form of risk scores or calculators. Similar scores have been derived from large clinical trials as well as governmental and payor-based (administrative) registries. Some of the most commonly used risk scores in the USA include the STS risk score for CABG and the NCDR CathPCI risk score for PCI. However, the practicing clinician must be aware of the important shortcomings of these scores when employing them for higher-risk patients.

For patients undergoing CABG in the USA, there are multiple registries which are either state based (e.g., New York State registry) or national (e.g., STS Adult Cardiac Surgery Database). The STS risk calculator is among the most widely used score to predict complications and short-term outcomes after CABG after adjusting for comorbidity. The score has been continuously recalibrated using data from the STS database, and underwent significant revision in 2018 using patient data from nearly 460,000 surgeries performed between 2011 and 2014 [27••, 28]. Numerous variables including demographic data (age, sex, race/ethnicity), disease presentation, comorbidities, cardiogenic shock, and prior surgeries are used to calculate risks of mortality, length of stay, stroke, prolonged ventilation, sternal wound infection, renal failure, and reoperation. The STS score is not calibrated to predict long-term outcomes or complications from CABG. An alternative risk model, STS ASCERT, provides estimation of longer-term outcomes in patients aged 65 and older, and uses slightly different data elements than the STS score. This latter model was based on CABG procedures performed from 2002 to 2007 with linkages to Centers for Medicare and Medicaid Services claims data [29].

For patients undergoing PCI, the most widely used risk score to estimate adjusted in-hospital mortality was derived from over 500,000 NCDR CathPCI registry patients undergoing PCI between the years 2004–2006. Ultimately, variables included age, cardiogenic shock, heart failure, peripheral vascular disease, and lung disease [30]. To our knowledge, this score has not been recalibrated since its publication. A similar risk score for in-hospital and 30-day mortality was derived from patients undergoing PCI in New York State in 2010 [31]. These models' reliance on risk-adjusted mortality (RAM) as the principle metric and surrogate marker of quality has come under criticism. It has been observed that the NCDR's RAM is largely unstable over time with significant variation year to year [32]. This is mainly attributed to rare mortality events, low

**Table 1.  Patients in selected cardiovascular trials**

| | COURAGE [12] | BARI-2D [14] | FAME-2 [15, 16] | STICHES [17•] | ISCHEMIA [18] | SYNTAX [19] | FREEDOM [20] |
|---|---|---|---|---|---|---|---|
| Total subjects | 2287 | 2368 | 1220 | 1212 | 5179 | 1800 | 1900 |
| Enrollment years | 1999–2004 | 2001–2005 | 2010–2012 | 2002–2007 | 2012–2018 | 2005–2007 | 2005–2010 |
| Follow-up (years) | Median 4.6 | Mean 5.3 | Mean 0.58 | Median 9.8 | NA | 1 year | Median 3.8 |
| Average age (years) | 61.6 | 62.4 | 63.7 | 59.5 | NA | 65.1 | 63.1 |
| Male sex | 85.1% | 70.4% | 76.6% | 87.8% | NA | 77.7% | 71% |
| Left main disease (> 50% stenosis) | Excluded | Excluded | Excluded | 64.1% | Excluded | 39% | Excluded |
| Average EF | 60.9% | 57.2% | NA | 28.0% | NA | NA | 66.2% |
| Reduced EF | (EF ≤ 50%) 17.8% | (EF < 50%) 17.5% | (EF < 50%) 15.8% | 100 | NA | (EF < 30%) 1.9% | (EF < 40%) 1.7% |
| Diabetes | 34.0% | 100.0% | 27.0% | 39.4% | NA | 25.1% | 100% |
| Diabetes using insulin | NA | 27.9% | 8.4% | NA | NA | 10.2% | 32.4% |
| COPD | NA | NA | N/R | NA | NA | 4.9% | NA |
| CKD | NA | NA | 2.6% | 7.8% | NA | NA | 6.8% |
| ESRD | NA | NA | N/A | NA | Excluded | NA | NA |
| PVD | NA | 23.7% | 9.3% | NA | NA | NA | NA |
| Prior TIA/CVA | 8.8% | 6.6% | 6.7% | 7.6% | NA | 9.1% | 3.4% |
| Prior MI | 38.3% | 32.0% | 36.9% | 77.1% | NA | 32.9% | 25.6% |
| Prior PCI | 15.7% | 23.6% | 18.0% | 12.9% | NA | Excluded | NA |
| Prior CABG | 10.8% | Excluded | Excluded | 3.0% | NA | Excluded | Excluded |
| Selected exclusion criteria | EF < 30%, valvular disease requiring surgery, "severe noncardiovascular comorbidity limiting survival" | Serum creatinine > 2 mg/dL, NYHA Class III-IV heart failure, liver dysfunction | CABG indicated, EF < 30%, planned valvular surgery, life expectancy <2 years | Valvular disease, noncardiac illness with life expectancy < 3 years, noncardiac illness imposing "substantial operative mortality" | EF < 35%, "very dissatisfied with medical management," NYHA Class III-IV heart failure, ESRD, "reduced life expectancy" | Need for other cardiac surgery | NYHA class III-IV heart failure, prior CABG, prior valve surgery, significant anemia, dementia, noncardiac illness with life expectancy < 5 years |

COPD, chronic obstructive pulmonary disease; CKD, chronic kidney disease; CVA, cerebrovascular accident; ESRD, end-stage renal disease; EF, ejection fraction; MI, myocardial infarction; NYHA, New York Heart Association; PVD, peripheral vascular disease; TIA, transient ischemic attack. Reference numbers in the table correspond to the text

procedural volumes, and high-acuity patients (e.g., cardiogenic shock and cardiac arrest patients) skewing the data. Given the infrequency of in-hospital mortality after PCI (< 1.0–1.5% overall), it is more likely that random chance and unmeasured variables explain the small absolute difference (0.7%) between outliers and nonoutliers as opposed to procedural quality [32, 33]. The mortality that does exist occurs disproportionately in those patients who present with cardiogenic shock and emergency or salvage PCI, frequently not candidates or having been declined for CABG. Because contemporary models are statistically dominated by these high-risk patients, there has been a resounding demand to exclude this cohort from reported PCI outcomes. However, with the exclusion of such high-acuity cases, the use of this model becomes limited in low-risk patients who present with SIHD.

Unlike for patients undergoing CABG, there is no unifying NCDR calculator to predict multiple nonmortality outcomes with the same data elements (e.g., prolonged length of stay) [34•]. Given the success of the STS model in assessing surgical risk for several clinically important outcomes, it is quite remarkable that similar quantitative pre-PCI risk models do not exist [35]. NCDR calculators predicting the risk of post-procedure bleeding and acute kidney injury have also been reported, but require different variables for risk prediction and were calibrated during different time periods than the mortality model [36, 37]. This variety of calculators makes risk estimation less "user-friendly" than the STS calculator.

Nevertheless, risk scores for both CABG and PCI outcomes share some important shortcomings. First and foremost, the data are derived from patients who *underwent* procedures, not in those for whom revascularization was *indicated* or *considered*. This creates an inherent selection bias against the "sickest" patients, which may be exacerbated by public reporting initiatives [38]. Significantly, all of the current risk scores are limited in their ability to properly assess the risk and outcomes for patients with SIHD and indications for CABG (e.g., left main disease) who are deemed very high-risk or ineligible for surgery. Common reasons for "surgical ineligibility" might include frailty/cachexia, poor psychosocial support, medication noncompliance, aortic calcification, and immunosuppression [39]. Many of these factors are inherently subjective (e.g., decline to consent for CABG) and nuanced, and thus inadequately captured by registries. It is unclear to what extent such patients might benefit from revascularization by PCI [25••]. Two separate studies that analyzed patients who were turned down for surgery and subsequently underwent PCI for nonemergent unprotected left main or multivessel CAD arrived at the same conclusion that "surgical ineligibility" was independently associated with worse long-term outcomes after adjusting for standard risk scores. Patients who were turned down for cardiac surgery had a sixfold higher risk of death at 1 year after PCI compared to surgically eligible patients who underwent elective PCI [33, 40]. These observations have led to proposed changes in the NCDR CathPCI data elements to identify PCI patients who were "turned down" for surgery [41••]. However, these studies do not shed light on the mortality risk of deferring revascularization altogether [25••], and they do not adequately inform a discussion of risks and expected outcomes comparing CABG, PCI, and medical management.

Similarly, in a population where many patients are "turned down" for surgery because they are deemed too frail or old, there is a paucity of data

regarding the validation of current risk models in the very elderly. For example, in a recent study of US veteran nonagenarians undergoing PCI, the investigators concluded the subjects had worse risk-adjusted 30-day and 1-year mortality compared with younger patients [42•]. The authors observed that the NCDR risk score was a strong predictor of mortality in these patients, even though it has not been validated in nonagenarians. Importantly, veterans are not representative of the general population, with higher rates of some cardiovascular risk factors (e.g., smoking) and a near-absence of female patients. Attempts have similarly been made to improve risk prediction scores for patients undergoing CABG by incorporating fragility indices [43], and frailty will soon be a measure in the NCDR CathPCI registry [41••]. Clearly, further research is needed to improve risk and outcome prediction in the growing number of patients of very advanced age.

Finally, many outcomes important to patients and their families are not (and sometimes cannot) be predicted by use of registry-based risk scores. These include improvements in functional status, freedom from severe angina, need for rehabilitation, and predicted direct and indirect costs (to both the patient and payors). In the future, the NCDR CathPCI registry will aim to broaden its scope to include optional modules assessing post-PCI angina and quality of life metrics at longer-term follow-up durations (30 days and 12 months) [41••]. Presently, it remains to be seen how inclusion of these data elements will translate into more accurate risk-adjustment models to inform clinical decision-making. Furthermore, national registries should focus on collecting disease-specific (i.e., data for all-comers ACS patients) rather than procedure-specific data (i.e., only those undergoing PCI or CABG) in order to understand the outcomes in medically treated population.

# Future directions

As the SIHD population considering revascularization continues to age and accrue comorbidities, accurate risk stratification and patient prognostication remain important. The RCT literature, while relatively robust, has excluded many of the highest-risk patients. Observational registries only include patients who underwent revascularization, and thus cannot completely inform decisions regarding medical therapy. Furthermore, many of the highest-risk patients will be reasonably declined for CABG, which subsequently raises the difficult choice between high-risk PCI or medical management of SIHD. These conversations are often fraught with uncertainty, which is furthered by the paucity of data to guide them.

There is a recent precedent for RCTs in very high-risk patients who cannot undergo cardiac surgery. The PARTNER trial enrolled 358 patients who were not candidates for aortic valve surgery to transcatheter aortic valve replacement (TAVR) or medical management [44]. This trial firmly established the superiority of TAVR in this high-risk population with a significant comorbidity burden. A similarly designed trial for SIHD patients would be immensely helpful.

In the absence of such a trial, we agree with calls to encourage a multidisciplinary "heart team" approach drawing on the perspectives of the patient, the primary physician/cardiologist, interventional cardiology, cardiothoracic

surgery, advanced heart failure, critical care medicine, advanced imaging specialists, and nurses [25••]. This approach is increasingly used in our own institution when considering revascularization options for high-risk patients. Technical training requirements have also been proposed for specialized interventional cardiologists to perform PCI in higher-risk patients as well as improved registries to inform practice and ensure quality [25••]. It is encouraging that these calls come from many of the original PARTNER investigators, and their perspectives reflect the lessons learned from TAVR. Hopefully, greater attention will eventually translate into new initiatives and tools to address the needs of our growing cohort of "sick" patients.

## Compliance with Ethical Standards

**Conflict of Interest**
The authors declare that they have no conflicts of interest.

**Human and Animal Rights and Informed Consent**
This article does not contain any studies with human or animal subjects performed by any of the authors.

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Important updates to the NCDR CathPCI database that should improve risk estimation for higher-risk patients.

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