SCAI Position Statement on Optimal Percutaneous Coronary Interventional Therapy for Complex Coronary Artery Disease

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This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1002/ccd.28994

I. Introduction

The anatomic and clinical complexity of patients with coronary artery disease (CAD) is increasing in the United States.[1–3] While the terms "complex CAD" or "high-risk CAD" have not been formally defined, they encompass both complex anatomic lesions and clinical parameters including advanced age, frailty, comorbidities, compromised hemodynamic status, depressed ventricular function and concomitant valvular disease.[4–6] Such features increase both the procedural complexity of percutaneous coronary intervention (PCI) and the risk of adverse patient outcomes. The direct relationship between CAD complexity and the appropriateness for coronary revascularization is also emphasized in current societal guidelines and appropriate use criteria documents; however precise guidance for managing this growing patient group is lacking.[7–9]

In this document, the Society for Cardiovascular Angiography and Interventions (SCAI) has produced an expert consensus with a two-fold objective: (1) to present state-of-the art clinical evidence regarding PCI in patients with complex clinical and anatomical features, and (2) to provide procedural guidance to achieve optimal outcomes for this challenging patient group. This is a companion document to the jointly published SCAI statement on the performance of PCI in ambulatory surgical centers (ASC)(insert reference upon publication). Together these documents aim to provide guidance on best practices and the performance settings for PCI across the spectrum of clinical and anatomical complexity (**Figure 1**). Below, we first discuss pre-procedural risk stratification for complex CAD patients, and then detail best interventional practices for specific complex coronary lesion subsets.

II. Methodology

This document was developed according to SCAI Publications Committee policies for writing group composition, disclosure and management of relationships with industry, internal and external review, and organizational approval.[10] The need for a SCAI position paper on treating complex CAD was identified by a working group from the SCAI Executive Committee and Ischemic Heart Disease Council. By design, the writing group included a group of multidisciplinary physicians who care for patients with complex CAD, including interventional cardiologists, general cardiologists specialized in noninvasive imaging, and cardiothoracic surgeons. Before appointment, members of the writing group were asked to disclose financial relationships from the 12 months prior to the nomination (**Supplemental Table 1**). A majority of the writing group disclosed no relevant financial relationships. Disclosures were periodically reviewed during document development and updated as needed. SCAI policy requires that writing group members with a current relevant financial interest are recused from participating in discussions or voting on relevant recommendations. The work of the writing committee was supported exclusively by SCAI, a nonprofit medical specialty society, without commercial support. This document primarily reflects expert consensus opinion.

The draft manuscript was peer reviewed in April 2020 and the document was revised to address pertinent comments. The writing group unanimously approved the final version of the document. The SCAI Publications Committee and Executive Committee endorsed the document as official society guidance in May 2020.

III. Pre-Procedural Assessment of Coronary Anatomical Complexity and Higher-risk Clinical Features

A. Scoring Systems

Defining a coronary interventional procedure as "complex" or "high-risk" usually integrates several risk domains, including both the clinical risk profile of the patient and the technical complexity of the intervention(s) planned (**Figure 2**). To go beyond the subjectivity inherent in clinical judgment, multiple methods have been validated to objectively assess patient risk prior to coronary revascularization. Clinical risk scores such as the Society of Thoracic Surgeons (STS) score, EuroSCORE II, National Cardiovascular Data Registry (NCDR), and others can provide insights into the risk of procedural complications.[11–13] In addition, integrated anatomical-clinical scores such as the Synergy Between PCI With Taxus and Cardiac Surgery (SYNTAX) II score provide additional value by assessing the comparative 4-year mortality rates of PCI and coronary artery bypass grafting (CABG) surgery.[5] Current ACC/AHA guidelines recommend calculation of a STS and SYNTAX score for patients with complex CAD or unprotected left main (LM) disease.[7]

B. Utilization of the CAD Heart Team

For multivessel or LM CAD, utilization of a heart team to guide decision-making for optimal revascularization is a Class I recommendation from both the American and European guidelines.[8,14] As interventional cardiologists, cardiac surgeons, heart failure specialists, and other cardiologists offer different treatment perspectives, integrated decision-making can facilitate patient-centered revascularization. Group discussions can center around patient-specific presentation and comorbidities, calculation of various risk scores, and implementation

of society guideline recommendations to facilitate decision-making. Moreover, a heart team approach may provide better outcomes, as suggested by favorable outcomes in the registry arms of randomized controlled trials and in routine clinical practice.[15–17] Recent evidence further shows that utilizing a structured heart team form and a formal interventional cardiology consultative service can improve the operation of a CAD heart team.[18] Therefore, the use of the CAD heart team is encouraged for guiding revascularization decision-making for patients with complex CAD.

In certain situations, PCI-based management of complex CAD may require advanced approaches such as atherectomy, chronic total occlusion (CTO) PCI capabilities, temporary or durable mechanical circulatory support, or the availability of on-site cardiac surgery. If such an approach is potentially indicated but not available at the initial planned PCI center, arrangements should be made to refer or transfer patients to a PCI center equipped with these capabilities. Collaboration with other specialized interventional cardiologists with expertise in complex PCI to discuss more complicated PCI scenarios is therefore encouraged to provide optimal outcomes for complex PCI patients.

C. Higher-risk Clinical Features

i. Multivessel Coronary Disease and Importance of Complete Revascularization

Multivessel CAD is common in patients undergoing high-risk, complex PCI.[19] Multiple observational studies of both CABG and PCI demonstrate that completeness of revascularization is associated with improved outcomes among patients with multivessel disease.[20-22] However, randomized trial data supporting complete revascularization is only available for ST-elevation myocardial infarction (STEMI) patients undergoing primary PCI, where

complete revascularization of significant non-culprit lesions reduces cardiovascular events.[21,23] If complete revascularization by PCI is indicated, a careful assessment of the risk and benefit of this approach is required to optimize patient safety. For patients with multivessel disease, this may require noninvasive ischemia or viability testing, invasive coronary physiologic testing, and considering staged revascularization to reduce the risk of any single procedure.[22,24,25] Utilizing state-of-the art PCI techniques including intravascular imaging and physiology, discussed in detail below, leads to excellent outcomes for patients with complex CAD including CTO, multivessel and LM lesions.[5]

ii. High predicted mortality by STS and/or Syntax II Score and CABG Ineligibility

A significant proportion of patients with complex CAD may be at prohibitive risk for complications with CABG. While the STS risk calculator may be useful in determining the expected complication and mortality rate with CABG, it is less useful in guiding the decision between PCI and CABG. The SYNTAX II score was created to help define the optimal revascularization strategy (CABG vs. PCI) for individual patients based on coronary anatomy and select comorbidities.[26] This score, which can be used in conjunction with a multidisciplinary heart team approach, may provide a highly evidence-based approach to determine the relative merits of PCI, CABG, hybrid strategies, or medical therapy in patients with multivessel disease.[18]

Patients with multivessel or LM coronary disease declined for cardiac surgery on the basis of high surgical risk and/or severe medical comorbidities represent a particularly high-risk subgroup of patients referred for PCI. These patients have an increased risk of mortality out of proportion to the risk assessed by traditional PCI risk stratification tools.[9,27] Randomized clinical trials comparing different revascularization strategies for such patients are lacking. The

combination of the potentially high technical complexity of PCI and compromised ability to tolerate sustained ischemia or complications make a multidisciplinary evaluation particularly valuable in such patients.

iii. Acute Coronary Syndromes

PCI reduces morbidity and mortality in acute coronary syndromes (ACS), in patients with or without ST-segment elevation.[28,29] Minimizing the time to reperfusion is critical in STEMI and requires coordinated transfer systems and early activation of the cardiac catheterization laboratory.[30,31] Additionally, an early invasive strategy is preferred for non-STEMI patients, especially for those at higher risk.[29,32] However, PCI in ACS patients is associated with higher adverse event rates compared to elective PCI. Adjunctive antiplatelet and anticoagulant therapy can help reduce the procedural risk. Furthermore, complete revascularization in the presence of multivessel CAD is associated with improved long-term clinical outcomes in STEMI.[21,23] Whether complete revascularization should be performed in patients with non-STEMI remains unknown, but may be supported by observational data.[33] Staging procedures for treatment of non-culprit stenoses appears to be safe if performed in a timely fashion.[34]

iv. Impaired Left Ventricular Function and Cardiogenic Shock

Surgical revascularization in addition to optimal medical therapy in patients with impaired left ventricular (LV) function (EF <= 35%) has been shown to reduce all-cause mortality compared to medical therapy alone.[35,36] Additionally, PCI in the setting of STEMI and concurrent cardiogenic shock has been shown to reduce long-term mortality.[37] However, performing PCI in patients with impaired LV function is associated with higher mortality rates, likely due to lack of myocardial reserve.[38] MCS devices, particularly ventricular axial and

centrifugal flow devices, aim to improve the safety and efficacy of PCI in patients at very high-risk for revascularization. This includes elective complex and high-risk procedures, emergent revascularization for acute myocardial infarction (AMI), and acute decompensated heart failure complicated by cardiogenic shock.[4,39–42]

Several proposed algorithms to guide the use of MCS incorporate the anatomic complexity of CAD, area of myocardium to be treated or at risk, estimated procedural duration, planned technical interventional strategies, underlying LV dysfunction, cardiac and systemic hemodynamic state, degree of cardiogenic shock, and major medical comorbidities and surgical eligibility.[9,39,40,43] Device selection is further guided by the ease of implantation and use, vascular complication risks, mechanism and degree of circulatory support, device and patient-specific contraindications, patient acuity and disease severity, anticipated duration of support and operator/center-specific procedural volume and expertise (**Figure 3**).[39,40] Heart team management decisions should also weigh the relative risks and benefits of both MCS-assisted and unassisted PCI compared with available surgical therapeutic options including surgical revascularization, durable LV assist device implantation, and heart transplantation. Appropriate patient selection is particularly critical in light of the potential for device-related complications.[44–46]

There are limited randomized data for elective and emergent use of MCS devices during complex PCI procedures. Observational studies demonstrate improved procedural cardiovascular hemodynamics and more complete revascularization in the presence of MCS devices despite higher-risk patient profiles. In select patients with ischemic cardiomyopathy, PCI with MCS can also improve LV function.[47] However, limitations of routinely using this

strategy include device-specific learning curves and variable device-related complication rates.[48–51] Low-dose contrast peripheral angiography, arterial duplex scans, or computed tomography angiography may be useful for pre-procedural planning in patients with suspected or known peripheral arterial disease that may require MCS support.

v. Patients with Renal Insufficiency or on Dialysis

There is an inverse relationship between eGFR and the incidence of CAD.[52] Furthermore patients with chronic kidney disease (CKD) experience a 2-3 fold higher risk of mortality from CAD.[53] However, diagnostic angiography and coronary revascularization are underutilized in patients with CKD and end stage renal disease on dialysis, illustrating a risk-treatment paradox.[53,54] This is in part due to the elevated risk of contrast-induced acute kidney injury (CIAKI) and the complexity of diffuse, calcific CAD often encountered among CKD patients.

There is a direct relationship between the amount of contrast delivered during coronary angiography/PCI and the risk for CIAKI.[55] However, intravascular volume-administration of normal saline guided by invasively measured filling pressures can reduce the risk of CIAKI.[56] Ultra-low contrast diagnostic angiography based upon calculated eGFR should also be considered, with the volume of maximum allowed contrast target ideally less than the eGFR.[57] If PCI is indicated, this can either be performed in the same setting or be staged. Regardless of setting, minimizing contrast volume to eGFR ratio of $\leq$ 2.0-3.7, has been shown to reduce the risk of CIAKI.[58–60] Contrast use during PCI can be further reduced by liberal use of intravascular imaging and/or physiology assessment to guide PCI.[61] Initial diagnostic images should be used to guide PCI to reduce the need for additional angiography at the time of PCI and co-

registration with imaging catheters and/or road mapping software to mark the proximal and distal edges of the lesion with dry cineangiography can further reduce usage of contrast.[62]

vi. Concomitant Valvular Heart Disease

Concomitant significant mitral and/or aortic valvular heart disease is not infrequent in patients with complex CAD and patients with both conditions have increased cardiovascular mortality compared with either entity in isolation.[63–65] Percutaneous MCS devices may be indicated during high-risk PCI in patients with significant valve disease due to their lower tolerance of cardiac ischemia. A multidisciplinary heart team approach is essential to evaluate this patient group in order to optimize the timing of coronary revascularization and valvular intervention.

For patients undergoing percutaneous treatment of both obstructive CAD and severe aortic stenosis, the optimal timing of PCI and transcatheter aortic valve replacement (TAVR) remains unknown. A staged approach with revascularization of significant CAD prior to TAVR may reduce the risk of the TAVR procedure and minimize issues related to coronary accessibility post-TAVR.[64] However, some studies have suggested that simultaneous PCI and TAVR have a lower 30-day mortality as compared with staged PCI and TAVR.[66] In patients with concomitant CAD and mitral valve (MV) disease, a hybrid approach with PCI and a minimally invasive MV intervention may reduce mortality and mobility.[67,68] Further studies are indicated to understand how to best manage this challenging patient subset.

vii. Diabetes

CABG is the guideline-recommended choice of revascularization in patients with diabetes mellitus presenting with multivessel or LM CAD and average surgical risk.[8,31,69,70]

However, some patients may have high surgical risk, poor targets, and/or poor conduits for surgical grafts. In addition, some patient may prefer a percutaneous approach. In such cases, PCI or even a minimally-invasive hybrid revascularization approach may be appropriate.[71]

Patients with diabetes who undergo PCI experience higher rates of periprocedural adverse events as well as stent restenosis, as compared with non-diabetics.[11] It is postulated that increased events occur due to a prothrombotic state, increased resistance to antiplatelet therapies, more diffuse atherosclerosis, and negative vessel remodeling.[72–74] Additionally, patients with diabetes requiring treatment with insulin and/or with poorly controlled hyperglycemia experience even higher event rates.[75,76] To achieve optimal outcomes following revascularization, excellent glycemic control is needed, with consideration of newer pharmacotherapies that have been shown to improve cardiovascular outcomes.[77]

IV. Interventional Treatment of Complex Coronary Artery Disease

A. Choice of Arterial Access

Radial access is associated with similar technical and procedural success compared to femoral access and often offers lower risks of major bleeding and vascular complications.[78–80] Complex interventions including LM bifurcations, CTO PCI, and large burr atherectomy may now be performed safely and effectively via the radial artery with standard or sheathless guide catheters up to 8 French in size, and incorporating additional support strategies that include guide catheter extensions and anchor balloons.[79,81] Evidence also suggests that when necessary, femoral access may still be performed safely by expert operators using optimal ultrasound-guided access, including the use of micropuncture needles.[82–85]

Multiple arterial access sites are often needed for CTO PCI or adjunctive MCS device use during complex PCI, thereby increasing the periprocedural risks of bleeding, vascular complications and mortality.[86] These hazards may be mitigated by the use of radial or ulnar artery access as the second-access site, bilateral radial access, or single-access femoral techniques for MCS-assisted PCI.[79,87,88] Radial access with newer dedicated long-shaft peripheral equipment may also be effective in both obtaining hemostasis and resolving complications during large-bore femoral access.[89] Percutaneous transaxillary or transcaval implantation of MCS devices have also been proposed as safe and feasible alternatives in cases of prohibitive femoral arterial access among select operators.[90]

B. Periprocedural Anticoagulation and Antiplatelet Therapy for Complex Coronary Artery Disease

The goal of periprocedural systemic anticoagulation is to reduce acute and subacute ischemic procedural complications while minimizing bleeding-related complications.[91] Unfractionated heparin (UFH), low molecular weight heparin, and bivalirudin are each indicated for PCI periprocedural anticoagulation. Despite the lack of head-to-head comparisons in large randomized trials of complex PCI, UFH remains the cornerstone of intravenous anticoagulation therapy in this population.[92,93] This is likely related to the ease of periprocedural monitoring using activated clotting time (ACT), reversibility in case of complications, and low cost. In the Safety and Efficacy of Enoxaparin in Percutaneous Coronary Intervention Patients (STEEPLE) trial, an ACT value of 300–350 seconds was associated with the lowest ischemic and bleeding complication rates, and high ACT values are typically targeted for procedures involving devices

in the coronaries for extended periods (e.g. retrograde CTO PCI). Bivalirudin is an option for patients with heparin-induced thrombocytopenia or a particularly high bleeding risk.[91,94,95]

Patients presenting with an acute coronary syndrome should be ideally pretreated with potent dual antiplatelet therapy (DAPT) before PCI.[93] For ACS patients not sufficiently preloaded with DAPT, adjunctive intravenous glycoprotein IIb/IIIa antagonists or intravenous cangrelor can be considered.[96,97] Considerations regarding the postoperative length of DAPT treatment are discussed below.

C. Role of Physiology and Intravascular Imaging in PCI Guidance

Intracoronary physiology and imaging are two important adjunctive procedures used in defining and achieving optimal revascularization in patients with complex CAD. Angiography alone often incompletely defines lesion morphology and hemodynamic significance, so that lesions that initially appear significant may not be, and vice versa.[98,99] To achieve optimal CAD and PCI outcomes, the contemporary interventionalist needs to be proficient in physiology and intravascular imaging performance and interpretation.[100,101]

i. Intracoronary Physiologic Testing

Physiology-based assessment of coronary lesions (adenosine-generated fractional flow reserve [FFR] or resting measures such as instantaneous wave-free ratio [iFR], resting full-cycle ratio [RFR], diastolic hyperemia-free ratio [dFR], diastolic pressure ratio [dPR]) is an important component of revascularization in patients with complex CAD. These measures help determine which lesions are hemodynamically significant and ischemia-producing, especially when non-invasive functional testing is absent or inconclusive. The use of coronary physiology to guide complex PCI impacts a patient's risk status and prognosis, the technical considerations during

PCI, and overall clinical outcomes (**Table 1**).[102] For example, FFR has been used to refine the prognostic risk estimation in patients with multivessel CAD compared to angiography alone. Additionally, FFR is particularly important in LM disease, where the consequence of missing a significant stenosis or intervening unnecessarily can be high.[103–105]

ii. Intravascular Imaging

Intravascular imaging using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) can help resolve ambiguity during angiography, assess the degree of plaque burden and calcification, and facilitate PCI through accurate vessel sizing. Additionally, imaging-guided PCI improves long-term clinical outcomes (**Table 2**).[106–109] Imaging is critical in guiding the prevention and treatment of stent failure, which is frequently due to stent underexpansion. In addition, given the clinical importance and complex nature of the LM coronary artery, intravascular imaging is particularly valuable during LM PCI.[106] Intravascular imaging can also be useful during CTO PCI, from wire crossing to stent optimization, and may be used to limit contrast use, which can be especially important in high-risk patients with diabetes, CKD, and LV dysfunction.[2,110,111]

D. Calcified lesions

Severely calcified lesions portend higher risks of both stent thrombosis and restenosis due to stent underexpansion. The treatment of these lesions is also associated with increased risk of periprocedural complications, including vessel dissection, slow/no reflow, device embolization or entrapment, vessel perforation, and higher periprocedural bleeding.[112–114] In addition, severe calcification is associated with incomplete revascularization and an overall higher risk of all-cause death.[115] For these reasons, accurate calcium assessment is crucial prior

to PCI. In most cases, adjunctive intravascular imaging or preprocedural computed tomography (CT) can be helpful to help assess the degree of lesion calcification.[116]

Current PCI options for calcified lesions include non-compliant balloons, cutting/scoring balloons, atherectomy (rotational, orbital, or laser), and potentially intravascular lithoplasty if available (not FDA approved at this time). The ideal PCI strategy for calcified lesions is still evolving, with a diagnostic and treatment algorithm suggested in **Figure 4**.[116] The ongoing randomized ECLIPSE trial (NCT03108456) may provide further guidance regarding the role of atherectomy compared with conventional balloon-based strategies. Regardless of approach, successful and safe treatment of severely calcified lesions requires competency with multiple techniques in order to adequately treat the entire range of calcified lesions, as well as expertise in anticipating and managing complications, such as coronary dissection and perforation.

E. In-Stent Restenosis

Intracoronary stent restenosis (ISR) is a progressive re-narrowing of the stented segment that occurs typically between 3 to 12 months after stent placement and usually presents as recurrent angina.[117] While ISR is less common in current practice due to the increasing use of second- and third-generation drug-eluting stents (DES), stent failure still occurs at a rate of ~2% per year after the first year; therefore, the treatment of ISR remains an important clinical challenge. Risk factors for ISR include diabetes, treatment of a saphenous vein graft (SVG) lesion, ostial lesions, prior ISR, stent under expansion, and total stent length.[107,111,118–120]

Intravascular imaging is critical in assessing the mechanism of ISR, particularly since image-guided treatment of ISR lesions has been shown to decrease rates of target lesion and

vessel failure.[107,111,121] For lesions with under-expanded stents (often from surrounding arterial calcification and insufficient vessel preparation prior to stent placement), the first step is to attain optimal expansion of the previously placed stent by utilizing high-pressure balloon inflation, laser atherectomy (often with concurrent contrast administration), and/or potentially intravascular lithoplasty (not currently FDA approved).[122,123] After the previously placed stent is optimized, additional treatment of the lesion depends on whether single versus multiple layers of stent have been previously placed at the site of the lesion. For single-layer ISR, treatment with a second layer of second-generation DES is superior to other treatment modalities.[124,125] Unfortunately, there are scant data for treating ISR lesions involving multiple previously placed stent layers.[126] Stent optimization followed by intravascular brachytherapy is the preferred treatment option currently available in the United States (US) to treat this patient group, especially given the high rate of target lesion failure when >2 layers of stent are placed at a single coronary site.[127] In the future, coronary drug-coated balloons may be available in the US and offer an alternative to DES or brachytherapy for ISR treatment.[128]

F. Saphenous vein graft disease

Due to lower rates of arterial (especially left internal mammary) graft failure, most bypass graft interventions are performed in saphenous vein grafts (SVGs).[129,130] However, SVG intervention carries high risk for distal embolization leading to no-reflow and periprocedural AMI. This risk can be reduced by use of embolic protection devices and possibly vasodilator administration, direct stenting, and the use of undersized stents.[131–136] Filters are the only embolic protection devices currently available in the United States but are unfortunately underutilized, likely due to technical challenges with their use, limited operator experience, and

added cost and procedural time. Despite some recent conflicting data from observational trials, prior randomized data suggest that embolic protection devices should be used whenever technically feasible in SVG intervention (Class I guideline - ACC/AHA).[93,129,137–140]

Long-term PCI outcomes after SVG intervention are poor for both bare metal stents and DES.[129,141] As a result, several experts recommend PCI of the corresponding native coronary artery if technically feasible, including referral to high volume CTO PCI operators if indicated.[142] In patients with AMI due to SVG failure, one strategy may be to initially recanalize the culprit SVG, followed by staged native coronary artery revascularization.[143] The native artery supplied by the failing SVG may frequently contain a complex CTO lesion, and require specialized CTO PCI techniques for revascularization. Prolonged DAPT may also be beneficial after SVG PCI in low bleeding risk patients.[144]

G. Bifurcation Lesions

Coronary bifurcation lesions involve the origin of a significant side branch and are reported in 15-20% of lesions treated by PCI.[145,146] Numerous classification schemes have been proposed to characterize coronary bifurcation lesions, with the Medina classification being the simplest and most widely used.[147] These lesions are more difficult to treat than non-bifurcation lesions due to variability in anatomy, the angle at which the side branch comes off the main vessel, differences in vessel diameters, the potential need for a two-stent strategy, and an increase in both short- and long-term major adverse events.[148] In general, multiple studies have shown that for bifurcations involving side branch disease limited to within 5 mm of the ostium of the branch, a provisional stenting technique can be employed (as opposed to an up-front two-stent strategy, **Figure 5**).[149] Bifurcation PCI involves wiring the main vessel and side

branch. Routine side branch pre-dilation is discouraged. After adequate pre-dilation of the main vessel stenosis, the main vessel is stented with a stent length to allow proximal optimization and a stent diameter based on the distal lumen diameter; this strategy avoids over-sizing at the bifurcation carina in order to reduce the risk for plaque shift. Proximal optimization technique (POT) of the proximal aspect of the stent is then performed with a post-dilation balloon to improve proximal stent expansion and facilitate re-wiring of the side branch if required. If post-PCI angiography shows thrombolysis in myocardial infarction (TIMI)-3 flow in the side branch, the procedure can be completed. Routine kissing balloons at the bifurcation are discouraged if an acceptable angiographic result is obtained.[150] However, if flow in the side branch is compromised despite side branch angioplasty, a rescue two-stent strategy can be employed, such as the T-stent and protrusion (TAP) or culotte approach.[151] For non-LM bifurcation lesions that require an upfront two-stent strategy (i.e. disease extends into the side branch beyond 5 mm from the bifurcation, heavily calcified lesions, or the angle of the side branch takeoff is unfavorable for a provisional approach), various two-stent techniques can be used, such as double kiss (DK) crush, mini-crush, culotte, or other strategies.

H. Left Main Coronary Artery Disease

Significant LM CAD is observed in 5-7% of diagnostic coronary angiography cases, with 80% of LM lesions occurring at the distal bifurcation.[152] In patients undergoing treatment of unprotected LM and multivessel CAD, intermediate and long-term major adverse cardiovascular events are comparable between PCI and CABG, provided the baseline SYNTAX score is ≤32.[153–155] However, PCI of LM lesions is associated with a higher repeat revascularization rate, especially with distal bifurcation disease, as compared with CABG.[156] Therefore, optimal PCI

technique to lower the long-term risk of restenosis for bifurcation LM disease is required when treating these lesions percutaneously. This includes routine intravascular imaging and, for complex LM bifurcations (Medina 1,1,1 or Medina 0,1,1, with side branch lesion >= 70% stenosis and length >= 10mm), upfront utilization of the DK crush (preferred) or other two-stent technique (**Figure 6**).[152,157]

Ad hoc unprotected LM PCI is discouraged and should ideally be performed at a facility with on-site cardiac surgery. Furthermore, LM PCI outcomes are best when the procedure is performed by high-volume, experienced interventionalists.[158] The 2014 ACC/AHA guidelines provide a class IIa indication for patients with stable ischemic heart disease, low procedural risk, and a low SYNTAX score < 22, and a class IIb indication for an intermediate (22-32) SYNTAX score. Additionally, a heart team approach is recommended to guide decision-making for elective unprotected LM cases.[8]

I. Chronic Total Occlusions

The prevalence of coronary CTO lesions ranges from 18-52%, depending on the clinical presentation for coronary angiography.[159] There is evidence that CTO PCI improves quality-of-life.[160] There is also conflicting data that successful CTO PCI in addition to optimal medical therapy can potentially improve LV function in patients with ischemic cardiomyopathy.[161,162] The ESC/EACTS Guidelines on Myocardial Revascularization and the ACC/AHA/SCAI Guidelines for PCI give a class IIa recommendation for CTO PCI in the presence of symptoms.[92,93]

There are several basic principles of CTO PCI.[163] First, *ad hoc* PCI should be avoided. Second, dual angiography is required for proper lesion evaluation and to determine the appropriate lesion crossing strategies. Third, the main lesion crossing strategies include:

antegrade wire escalation (AWE), anterograde dissection re-entry (ADR), retrograde wire escalation (RWE), and retrograde dissection re-entry (RDR).[164] Operators need to be facile with all four strategies in order to achieve high success rates. Fourth, after the lesion is crossed, meticulous vessel preparation, including intravascular imaging, should be utilized to achieve optimal short- and long-term outcomes.[165] Finally, CTO PCI requires operator commitment to acquire the relevant skillset. Operators should collaborate with CTO PCI experts to improve their proficiency, and refer to high-volume CTO PCI centers when appropriate. [163,166]

J. Long-term Dual Antiplatelet Therapy for Complex CAD Patients after PCI

The optimal selection of the type and duration of DAPT among patients with complex CAD undergoing PCI has been the subject of several studies. In a meta-analysis of 6 randomized trials comparing DAPT duration, Giustino et al. found that patients undergoing complex procedures (defined as having 3 vessels treated, 3 or more stents implanted or lesions treated, 2 stent bifurcation lesions, total stent length > 60 mm or CTO) had increasingly greater benefit from durations of DAPT longer than 12 months with increasing number of complex characteristics.[167] In contrast, in the international multicenter Dual Antiplatelet Therapy (DAPT) study, patients treated with 30 months of DAPT versus 12 months of DAPT derived a similar level of benefit whether or not they had complex coronary characteristics at the time of PCI.[168] Based on these data, patients with complex coronary anatomy may benefit from durations longer than 6 months based on their lesion characteristics.[169] Conversely, recent randomized data has shown that DAPT duration may be able to be shortened to monotherapy with ticagrelor alone in patients after complex PCI, which may be useful in patients with elevated bleeding risk.[169]

Decisions regarding extending durations beyond 12 months could be further governed by the risk-benefit profile of patients as assessed by risk scores such as the DAPT score or PRECISE-DAPT score rather than by the nature of the initial procedure.[144,170] No current data exist on the use of different P2Y12 inhibitors for complex coronary lesions, particularly among those with stable CAD. However, the use of more potent antiplatelet regimens within the first year or longer may be reasonable for those patients with particularly complex coronary anatomy and lower bleeding risk, particularly when coupled with other ischemic risk factors such as ACS presentation.

K. Role of Same Day Discharge and Onsite Cardiac Surgery

Same day discharge (SDD) after PCI can be safely performed without compromising safety as demonstrated in randomized clinical trials and observational registries with the added potential for cost savings.[171–173] A SCAI approach and algorithm identifying the appropriate patients and interventional procedures for SDD has been published.[174] Specific requirements for a SDD include procedural success without clinical symptoms of coronary ischemia or access site complications. Additional important factors include home proximity to a hospital capable of addressing PCI-related adverse events, an appropriate social support system, compliance with medical therapy and planned outpatient follow-up.

It is important to note that procedures performed on patients with relatively complex coronary anatomy or presentation being considered for SDD should be performed in a hospital setting (as opposed to an ASC). This allows for overnight monitoring in case of a periprocedural or post procedural adverse event. This is distinctly different from a patient who undergoes PCI in an ASC, where the pre-procedural risk profile has to be low (REF for ASC document). Despite

the low rate of emergency cardiac surgery in routine PCI, this rate is increased in complex PCI procedures and when needed, the lack of on-site surgical availability could have dire consequences.[175] This taskforce believes that the majority of complex PCI procedures with a potential for higher complication rates or should be performed at hospitals with onsite cardiac surgery (**Figure 1**) (REF for ASC document).

V. Conclusions

Patients requiring PCI have become increasingly complex in terms of coronary anatomy, presenting physiology, and clinical comorbidities. Evidence to guide the treatment of complex CAD and percutaneous treatment approaches have evolved substantially over the last decade to meet this need. As we continue to determine best treatment strategies for complex CAD, this SCAI consensus document provides an initial platform to offer guidance for achieving excellent outcomes for complex PCI and to support future investigations of this growing patient population.

Acknowledgements

We would like to acknowledge Emily Senerth for her contribution to the writing of this manuscript. We would also like to acknowledge Megan Kavy and Dr. Lawrence Ang for their contribution in creating some of the Figures in this manuscript.

Figure Legend

Figure 1. SCAI Expert Consensus Opinion Regarding PCI Risk Stratification pyramid integrating PCI complexity, clinical comorbidities, and site where PCI is to be performed.
PCI, percutaneous coronary intervention; ACS, acute coronary syndrome, SVG, saphenous vein graft; UPLM, unprotected left main; CTO, chronic total occlusion; MCS, mechanical circulatory support; EF, ejection fraction; HF, heart failure; CKD, chronic kidney disease; PAD peripheral arterial disease, NYHA, New York Heart Association; eGFR, estimated glomerular filtration rate, TIA, transient ischemic attack.

Figure 2. Clinical, Anatomic, and Procedural Domains of Complex PCI.

Figure 3. Mechanical Circulatory Support Devices. (Adapted with permission)[41]

Figure 4. Algorithm for Management of Calcified Coronary Lesions
Images provided courtesy of Boston Scientific, Cardiovascular Systems, Inc., Philips, and Shockwave Medical

Figure 5. Algorithm for Treating non-Left Main Coronary Bifurcations. (Reproduced with permission)[176]
SB, side branch; FFR, fractional flow reserve; POT, proximal optimization technique, KBI, kissing balloon inflations; DK, double kiss; MB, main branch

Figure 6. Approach for Treating Left Main Coronary Bifurcation Lesions (Reproduced with permission).[177]
DK, double kiss

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Figure 1. PCI Risk Stratification

SCAI Expert Consensus Opinion Regarding PCI Risk Stratification pyramid integrating PCI complexity, clinical comorbidities, and site where procedure is to be performed. PCI, percutaneous coronary intervention; ACS, acute coronary syndrome, SVG, saphenous vein graft; UPLM, unprotected left main; CTO, chronic total occlusion; MCS, mechanical circulatory support; EF, ejection fraction; HF, heart failure; CKD, chronic kidney disease; PAD peripheral arterial disease, NYHA, New York Heart Association; eGFR, estimated glomerular filtration rate, TIA, transient ischemic attack.

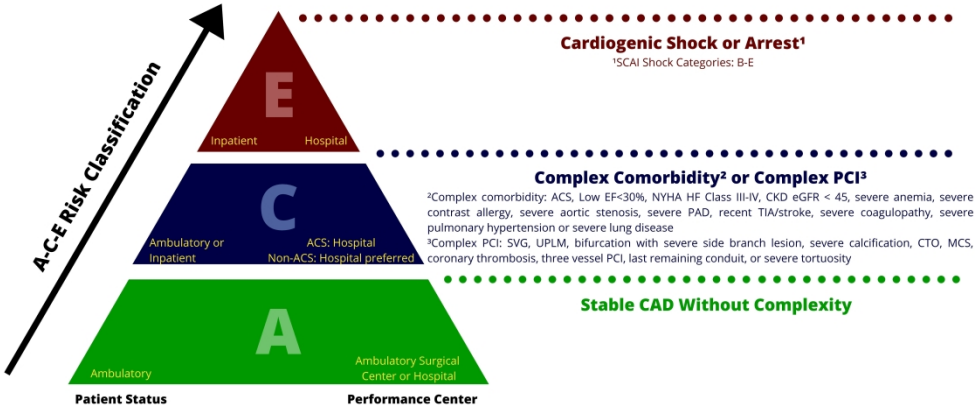


Figure 1

508x285mm (300 x 300 DPI)

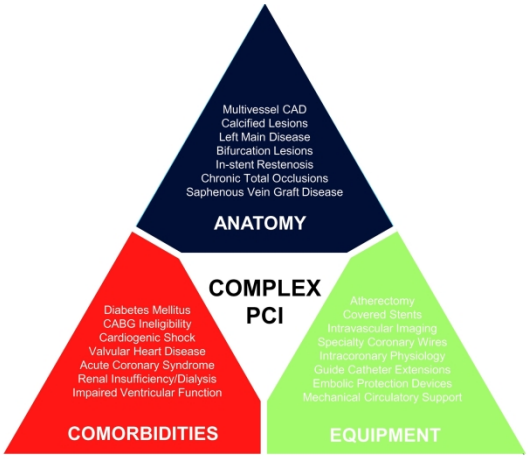
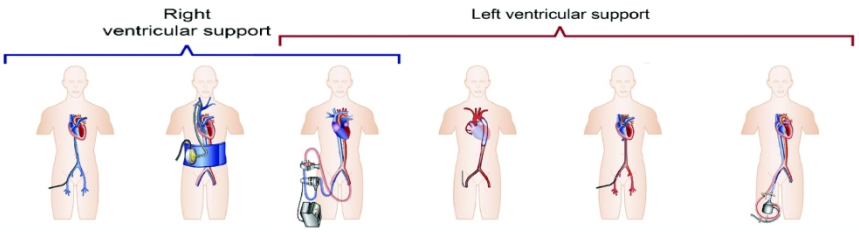


Figure 2

338x190mm (300 x 300 DPI)



	Impella RP	TandemHeart RA-PA	VA-ECMO	IABP	Impella (2.5, CP, 5.0, 5.5)	TandemHeart
Flow	max 4.0 L/min	max 4.0 L/min	max 7.0 L/min		2.5 - 5.5 L/min	max 4.0 L/min
Pump Speed	33000 rpm	max 7500 rpm	max 5000 rpm		max 51000 rpm	max 7500 rpm
Mechanism	Axial flow continuous pump (RA-to-PA)	Centrifugal flow continuous pump (RA-to-PA)	Centrifugal flow continuous pump (RA-to-AO)	Balloon inflation-deflation (AO)	Axial flow continuous pump (LV-to-AO)	Centrifugal flow continuous pump (LA-to-AO)
Cannula Size	22 Fr venous	29 Fr venous	14-19 Fr arterial 17-21 Fr venous	7-8 Fr arterial	13-21 Fr arterial	12-19 Fr arterial 21 Fr venous
Insertion/Placement	Femoral vein	Internal jugular vein	Femoral artery Femoral vein	Femoral artery Axillary artery	Femoral artery Axillary artery	Femoral artery Femoral vein
LV Unloading	-	-	-	+	++ to +++	++
RV Unloading	+	+	++	-	-	-
Miscellaneous			Provides oxygenation support	Requires stable cardiac rhythm and native heart function	Contraindicated with mechanical aortic valve, presence of left ventricular thrombus	Requires transseptal access

Figure 3

338x190mm (300 x 300 DPI)

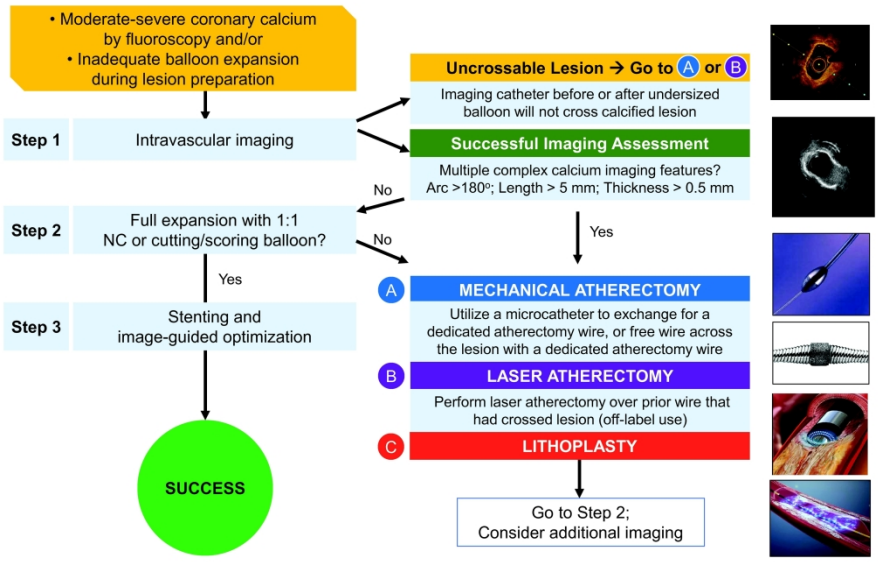


Figure 4

338x190mm (300 x 300 DPI)

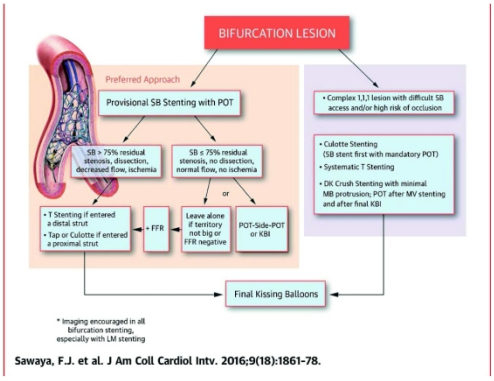


Figure 5

338x190mm (300 x 300 DPI)

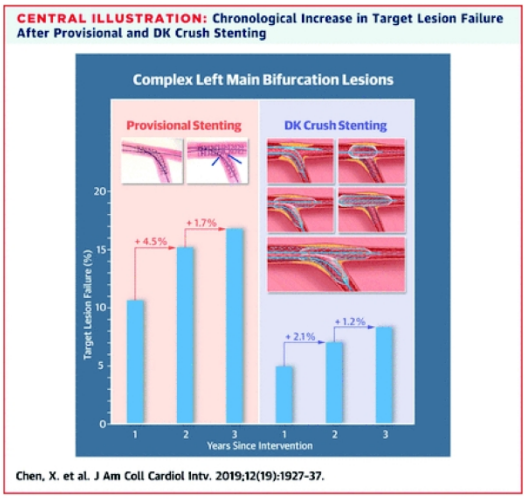


Figure 6

338x190mm (300 x 300 DPI)

	Estimated cumulative incidence at 5 years		Hazard ratio (95% CI)	*P*-value
	FFR-guided PCI	**Medical therapy**		
Cardiac death or MI[a]	10.7% (8.4–13.6%)	16.4% (13.3–20.1%)	0.72 (0.54–0.96)	0.02
Death or MI	13.9% (11.2–17.2%)	19.4% (16.0–23.4%)	0.76 (0.59–0.99)	0.04
MI	8.5% (6.5–11.1%)	13.4% (10.7–16.8%)	0.70 (0.51–0.97)	0.03
Cardiac death	3.2% (2.1–5.1%)	3.0% (1.9–4.8%)	1.04 (0.58–1.78)	0.89
All-cause mortality	7.0% (5.2–9.6%)	6.5% (4.7–8.9%)	1.03 (0.69–1.54)	0.89

[a]Pre-specified primary outcome. FFR-guided PCI ($N = 1056$) and medical therapy ($N = 1344$).

CI, confidence interval; FFR, fractional flow reserve; MI, myocardial infarction; PCI, percutaneous coronary intervention.

Table 1. Outcomes for FFR-guided PCI versus Optimal Medical Therapy for the Treatment of Intermediate Coronary Lesions. (Reproduced with permission)[102]

From new Ref. 23

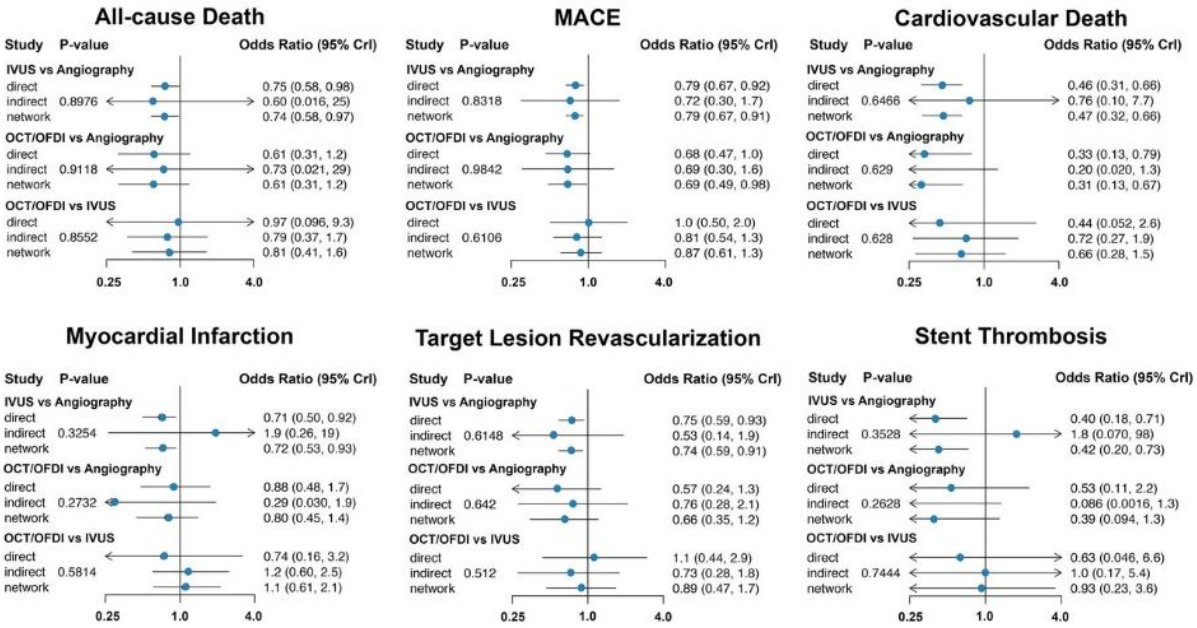


Table 2. Effects of Intravascular Imaging-Guided PCI on Clinical Outcomes (reproduced with permission).[106]