

## Clinical Decision Making

# Staging of Multivessel Percutaneous Coronary Interventions: an Expert Consensus Statement from the Society for Cardiac Angiography and Interventions

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Percutaneous coronary interventions (PCIs) to treat multivessel coronary artery disease (MVCAD) may involve single-vessel or multivessel interventions, performed in one or more stages. This consensus statement reviews factors that may influence choice of strategy and includes six recommendations to guide decisions regarding staging of PCI [1]. Every patient who undergoes PCI should receive optimal therapy for coronary disease, ideally before starting the procedure [2]. Multivessel PCI at the time of diagnostic catheterization should be considered only if informed consent included the risks and benefits of multivessel PCI and the risks and benefits of alternative treatments [3]. When considering multivessel PCI, the interventionist should develop a strategy regarding which stenoses to treat or evaluate, and their order, method, and timing. This strategy should maximize patient benefits, minimize patient risk, and consider the factors described in this article [4]. For planned multivessel PCI, additional vessel(s) should be treated only if the first vessel is treated successfully and if anticipated contrast and radiation doses and patient and operator conditions are favorable [5]. After the first stage of the planned multistage PCI, the need for subsequent PCI should be reviewed before it is performed [6]. Third party payers and quality auditors should recognize that multistage PCI for MVCAD is neither an indication of poor quality nor an attempt to increase reimbursement when performed according to recommendations in this article. © 2011 Wiley Periodicals, Inc.

**Key words:** stenting; percutaneous coronary intervention; staging

## INTRODUCTION

Percutaneous coronary interventions (PCIs) to treat multivessel coronary artery disease (MVCAD) may involve single-vessel or multivessel interventions, performed in one or more stages. The choice of strategy may influence safety, efficacy, convenience for the patient, cost, and reimbursement. In some cases, careful consideration will lead to a single-vessel PCI with other lesions managed medically; in other cases, such consideration leads to multivessel PCI in the same procedure or in multiple stages. Although guidelines and appropriate use criteria (AUC) provide guidance regarding PCI for multivessel disease, none of these documents offer comprehensive recommendations for one-stage versus multistage approaches [1–3]. The purpose of this article is to offer guidance regarding the selection of optimal PCI strategies in patients with multivessel disease.

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Conflict of interest: There are no conflicts of interest for any author.

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Received 7 August 2011; Revision accepted 12 August 2011

DOI 10.1002/ccd.23353

Published online Month 00, 2011 in Wiley Online Library (wileyonlinelibrary.com)

### Incidence of Multivessel PCI

MVCAD was present in 40–50% of patients undergoing PCI in the 1980s, and this percentage has remained stable since then [4,5]. PCI was performed on more than one artery in 15–20% of PCI patients in the 1980s, and this percentage has also remained stable [5].

### Incidence of Multisession PCI

The prevalence of staged procedures to treat MVCAD is not precisely known. Curtis et al. analyzed 315,241 PCI procedures in Medicare patients, noting that 14.6% were readmitted within 30 days. Of these, 26% (4% of the total PCI cohort) had a revascularization procedure, and 84% had a primary diagnosis of chronic ischemic heart disease (3% of the total PCI cohort). Thus by extrapolation, about 3% of PCI patients were probably readmitted for planned additional revascularization (i.e., staged PCI) either after an initial ST elevation myocardial infarction (STEMI) or after a PCI for other indications [6].

Among patients with MVCAD who presented with STEMI in the New York State PCI registry, 87% underwent PCI of the culprit vessel only and 13% underwent multivessel intervention at the time of the primary PCI. Of patients who underwent culprit vessel PCI only, 23% returned for elective staged PCI to treat residual coronary disease [7]. Similar findings were reported from the Global Registry of Acute Coronary Events registry, with 18% of patients returning for elective staged procedures [8].

An American College of Cardiology survey of 441 cardiologists in 2010 found that the most common reasons for staging multivessel PCI were poor renal function, contrast dose, lesion complexity, and the presence of acute coronary syndrome [9]. The least frequent reason was administrative, including penalties for readmission and insurance status.

### Staged Procedures in Other Specialties

Precedents of staging of interventional procedures can be found in other fields of medicine but there seems to be no evidence that one-stage procedures are more or less dangerous than multistage procedures [10–14].

## IDENTIFICATION OF MULTIVESSEL CORONARY DISEASE

### Definitions of Significant Coronary Disease in Non-left Main Coronary Arteries

Staging PCI over multiple sessions is only an issue when multiple arteries have significant lesions. Most of the previous guidelines have defined “significant” as a particular

degree of angiographic stenosis. The 2002 guidelines for the management of chronic stable angina [3] define 70% stenosis as significant. The 2004 coronary artery bypass graft surgery (CABG) guidelines [15] use 50%, and the 2005 PCI guidelines [16] state only that a lesion <50% is not significant. The European Society of Cardiology 2005 stable angina guidelines [17] do not provide a specific definition [16], whereas the European Society of Cardiology PCI guidelines define 50–70% stenosis as “borderline” significant [18]. More recent guidelines define significant coronary disease as lesions >70% by angiography, or lesions that are hemodynamically significant by stress testing, fractional flow reserve (FFR), or intravascular ultrasound [19,20].

Many of the studies on which current guidelines are based are listed in Table I. About half use 50% as a threshold for lesion significance and the other half use 70%. Many large trials fail to report the percent stenosis that defined the significance of a lesion in their final publications.

### Methods of Determining Significance of Coronary Disease

Angiographic percent stenosis is a notoriously poor measure of a lesion’s functional significance. Interobserver variability in the interpretation of coronary angiograms further limits its utility as a gold standard [37,38]. Because PCI of nonsignificant lesions does not decrease major adverse events or improve symptoms [39,40] functional tests should be used to decide whether PCI is warranted for angiographically stable, intermediate severity (50–70%) lesions. Although most 50% stenoses by angiography are not functionally significant, several factors (eccentricity, length, or presence of serial lesions) can render a 50% stenosis hemodynamically significant [41–44].

Physiologic significance of a lesion can be demonstrated either noninvasively by stress testing or invasively. Many patients with stable coronary disease undergoing angiography will have functional testing results available. Stress imaging may underestimate the extent of significant coronary artery disease [42,45,46]. When precatheterization stress testing is not available or is thought to underestimate the severity of coronary disease, physiologic testing with FFR may be helpful. An FFR of <0.75 correlates well with ischemia on stress testing [40,42,47–50]. For patients with an FFR between 0.75 and 0.80, angina at follow-up was less prevalent in those who underwent PCI compared with those treated conservatively [50]. An FFR of >0.75 or >0.80 correlates with excellent long-term outcomes if PCI is deferred [40,43,51–53]. FFR has also been shown to predict physiologic significance of left main coronary lesions, although the data are not as robust [54–56].

TABLE I. Definitions of Significant Coronary Artery Disease in Various Studies and Guidelines

Publication/study	Lead author	Date	Angiographic definition of significant coronary disease
<b>Guidelines</b>			
2002 stable angina [3]	Gibbons	2002	≥70%
2005 PCI	Smith	2005	Not defined (but insignificant disease is defined as “less than 50%”)
2005 European PCI [17]	Silber	2005	Not defined
2006 European stable angina [18]	Fox	2005	“Borderline”=50–70%
<b>PCI Studies</b>			
ACME [21]	Parisi	1992	≥70%
Rita-2 [22]	RITA-2 investigators	1997	≥50% in two views, or 70% in one view
VA Coop study [23]	Folland	1997	≥70%
AVERT [24]	Pitt	1999	≥50%
COURAGE [25]	Boden	2008	≥70%
<b>PCI versus CABG</b>			
Duke [26]	Whalen	1982	≥75%
EAST [27]	King	1994	≥50%
CABRI [28]	CABRI investigators	1995	50%
ERACI [29]	Rodriguez	1996	≥70%
French monocentric study [30]	Carrie	1997	≥70%
BARI [31]	BARI investigators	2000	≥50%
ERACI II [32]	Rodriguez	2001	≥70% is severe and 50% is significant
MASS II [33]	Hueb	2004	≥70%
Duke database [34]	Smith	2006	≥75%
Intermountain heart registry [35]	Bair	2007	≥60%
New England cardiovascular study group [36]	Dacey	2007	≥70%

The value of intravascular ultrasound (IVUS) for determining the physiologic significance of intermediate coronary lesions is less well established. A threshold of 3–4 mm<sup>2</sup> minimal cross-sectional area has been proposed [57–60]. Cross-sectional areas of <3 [57] and <4 mm<sup>2</sup> [58] correlate well with an FFR of <0.75. A cross-sectional area of <4 mm<sup>2</sup> correlated well with ischemia on myocardial perfusion imaging [59], and a cross-sectional area of >4 mm<sup>2</sup> predicted a benign course if PCI was deferred [60]. Compared with FFR-guided PCI, IVUS-guided PCI of intermediate coronary lesions resulted in significantly higher revascularization rates (33.7 vs. 91.5%) without differences in 1-year clinical outcomes [61].

## STRATEGIES FOR MULTIVESSEL PCI

### Complete Versus Incomplete Revascularization

**Definition of complete revascularization.** There is no universally accepted definition for complete revascularization (CR). Ong et al characterized CR as anatomic/unconditional (all stenotic vessels are revascularized), anatomic/conditional (all stenotic vessels greater than a certain diameter are revascularized), functional (all stenotic vessels supplying viable myocardium are revascularized), and numerical (for CABG, the number of graft anastomoses equals the number of major diseased vessels) [62].

CABG studies tend to define CR as a graft to each major coronary artery with >50% stenosis. PCI studies have defined CR to include arteries with diameter greater than 1.5 [63], 2.0 [64], 2.25 [65], or 2.75 mm [66] with >50 or >70% stenoses. The Writing Group suggests the following definition of CR relevant to PCI: “revascularization of all significant arteries (as assessed by the angiographer) that threaten viable myocardium with stenoses either >70% diameter narrowing by angiography or of hemodynamic significance by stress testing or invasive assessment.” Artery size is not included in this definition, as there is no consensus on the size of an artery considered “significant,” and artery caliber is difficult to assess due to the diffuse nature of atherosclerosis.

**Outcomes after CR (vs. incomplete revascularization).** CR is relevant to the extent that CR improves clinical outcomes. However, the clinical benefits of CR using angiographic criteria are uncertain, with some [65,67–70] but not all [71–73] studies reporting superior outcomes with CR. CR does reduce the incidence of subsequent CABG [66,74] or subsequent PCI [64] (Table II). CR using FFR testing to identify significant stenoses improved outcomes compared with CR based only on angiographic analysis [41]. If an incomplete PCI revascularization strategy is used, stress testing may identify a high-risk subset of patients for whom additional revascularization procedures reduce subsequent ischemic events [86,87].

**TABLE II. Impact of Completeness of Revascularization by PCI on Subsequent Outcomes**

Lead author	Date	n	Revascularization technique	Presentation	CR (%)	Follow-up time (years)	Complete versus incomplete revascularization
Bell [75]	1990	867	Balloon angioplasty	Stable angina	41	2.2	Similar incidence of death. Angina and CABG more frequent with IR
Bourassa [72]	1998	757	Balloon angioplasty	Stable angina and ACS	17	9	Similar incidence of death and MI. CABG more frequent with IR
Bourassa [76]	1999	896	Balloon angioplasty	Stable angina and ACS	65	5	Similar incidence of death and MI
Mariani [73]	2001	208	Balloon angioplasty and bare metal stents	Stable angina and ACS	24	1	Similar incidence of death, MI, and repeat revascularization
Kloeter [77]	2001	250	Balloon angioplasty and bare metal stents	Stable CAD	40	2.5	Similar incidence of cardiac events. Revascularization less frequent with IR
Van den Brand [66]	2002	576	Bare metal stents	Stable angina and ACS	70	1	Similar incidence of death or MI. CABG more frequent with IR
Brener [78]	2002	290	Bare metal stents	NSTEMI ACS	23	0.5	Similar incidence of death or MI
Nikolsky [79]	2004	352	Balloon angioplasty and bare metal stents	Stable angina and ACS	26.7	3.1	Higher incidence of death with IR
Palmer [80]	2004	151	Bare metal stents	NSTEMI ACS	47		Similar incidence of death or MI. Angina more frequent with IR
Ijsselmuiden [64]	2004	219	Bare metal stents	Stable angina and ACS	51 (randomized trial)	4.6	Similar incidence of death, MI, CABG
Hannan [67]	2006	21,945	Bare metal stents	Stable CAD patients	31.1	3	Higher mortality with IR
Kong [69]	2006	1,982	Bare metal stents	Acute MI	32	In-hospital	Higher in-hospital mortality with IR
Kalarus [70]	2007	798	Bare metal and drug-eluting stents	Acute MI	24.2	1	Death and MACE more frequent with IR
Srinivas [71]	2007	1,781	Bare metal and drug-eluting stents	Both stable angina and ACS	17.7	1	Similar incidence of death and repeat revascularization
Shishebor [68]	2007	1,240	Bare metal stents	NSTEMI ACS	39	2.3	Similar incidence of death and MI
Tamburino [65]	2008	508	Drug-eluting stents	Stable angina and ACS	41.7	2.25	Death, myocardial infarction, and target vessel revascularization more frequent with IR
Varani [81]	2008	399	Bare metal and drug-eluting stents	STEMI	46	30 days	Higher mortality with IR
Qarawani [82]	2008	120	Balloon angioplasty and bare metal stents	STEMI	79	1	Similar mortality. Reinfarction more frequent with IR
Hannan [83]	2009	11,294	Drug-eluting stents	Stable CAD patients	31	1.5	Higher mortality with IR
Yang [84]	2010	324	Bare metal and drug-eluting stents	ACS	31	1.5	Similar incidence of death, myocardial infarction, and repeat revascularization
Politi [85]	2010	214	Bare metal and drug-eluting stents	STEMI	66	2.5	More frequent MACE with IR

CR, complete revascularization; IR, incomplete revascularization; CABG, coronary artery bypass graft surgery, HR, hazard ratio; CI, confidence intervals; ACS, acute coronary syndrome; MI, myocardial infarction; NSTEMI, non-ST elevation; MACE, major adverse cardiac events.

### One-Stage Versus Multistage PCI for MVCAD

Multivessel PCI can be performed in one or multiple stages. The second stage of a multistage PCI may be planned or unanticipated. This article focuses only on multivessel PCI that is planned to occur during a single stage or multiple stages.

One-stage multivessel PCI is reasonable when the following conditions have been met: (a) multiple vessels have hemodynamically significant lesions (either angiographically severe or, if intermediate, proven by stress testing or invasive testing to be significant), (b) indications for PCI are present (e.g., to relieve symptoms in stable angina or to prevent death or recurrent ischemic events for acute coronary syndrome patients), (c) adequate informed consent was obtained and consideration of alternatives has occurred, (d) the first stage of PCI is uncomplicated and without excessive radiation or contrast doses, (e) the patient and the operator are willing to proceed with multivessel PCI, and (f) the impact of resulting delays for other patients and operators has been considered.

Strategies of one-stage versus multistage PCI are difficult to compare by retrospective analysis of large databases. Databases do not easily distinguish a planned staged PCI from an unplanned multisession PCI, where the second session is due to acute closure, early restenosis, or an additional significant stenosis detected by further invasive testing at the time of the initial procedure. Also, databases cannot identify a planned multistage PCI for which the second session is aborted due to complications from the first stage, complete relief of symptoms, or patient preference.

**Multivessel PCI in the same session as diagnostic catheterization.** PCI is frequently undertaken at the time of diagnostic catheterization, termed “ad hoc” PCI. This is the most convenient for patients, and compared with a staged strategy, it is much preferred by patients. However, when ad hoc PCI is multivessel, there are special risks to consider [88,89]. First, contrast and radiation used during the diagnostic catheterization may limit the additional doses that can be used during PCI. Second, the complexity of decision making increases with the number of lesions and vessels considered for PCI. Ad hoc multivessel PCI thus requires complex decision making that may not be optimal in the ad hoc scenario. Third, the informed consent before diagnostic catheterization may be inadequate for multivessel PCI. Patients scheduled for “cath possible PCI” should be informed about the risks of average single-vessel PCI, but it is unlikely that in-depth discussions of the pros, cons, and risks of multivessel PCI and the alternatives of medical therapy and bypass surgery have occurred. Fourth, logistical concerns may pose a special problem. If the patient is scheduled for a diag-

nostic catheterization time slot, the laboratory must be able to adjust to the addition of a multivessel PCI without undo delay to other patients, physicians, and catheterization laboratory staff. Finally, multivessel PCI done ad hoc does not allow input from cardiac surgeons, other specialists, or family members that might contribute to optimal decision making by the patient and interventionist. Recent guidelines have strongly encouraged a “heart team” approach for patients with unprotected left main or complex MVCAD [17,20]. The “heart team” approach includes giving the patient, interventionist, and cardiac surgeon an opportunity to talk about various revascularization strategies. This cannot occur when PCI is performed ad hoc at the time of diagnostic catheterization.

#### **Necessity of the second stage of a multistage PCI.**

When PCI of the primary stenosis is completed, the interventionist must consider whether to proceed to a second stenosis. Even if a second stenosis is proven to be hemodynamically significant by FFR testing, the clinical need for additional vessel PCI may remain questionable and a rational strategy may be to defer the second PCI. This allows additional time to reassess the patient’s symptoms and their improvement after the first PCI, as well as to provide a trial of medical therapy or additional testing to confirm the need for the second procedure. A second informed consent process is necessary before proceeding with the second stage.

**Unfavorable risk-to-benefit ratio for the second stage of a multistage PCI.** Occasionally, the risk-to-benefit ratio for PCI is favorable for one lesion but unfavorable for additional lesions. For example, a patient with a 95% type A proximal right coronary lesion and a 70% type C distal circumflex calcified bifurcation lesion may gain complete relief of symptoms with right coronary artery PCI. The safest approach may be the single-vessel PCI, with a second stage only if needed for refractory angina.

## GUIDELINES AND AUC

### **Guidelines Related to Multivessel PCI**

The performance of multivessel PCI has been addressed in numerous guideline documents [1,3,16,19,20,90,91]. Although there are several class I, class IIa, and class IIb recommendations related to multivessel PCI, the majority of these recommendations do not specifically address one-stage versus multistage PCI. The 2004 STEMI guidelines provide a class III recommendation that PCI should not be performed in a noninfarct artery at the time of primary PCI in patients without hemodynamic compromise [92]. The 2009 focused PCI update supports the use



**TABLE III. Appropriateness Criteria Relevant to Staged Multivessel PCI**

Indication #7	After STEMI PCI, “Revascularization of a noninfarct-related artery during index hospitalization” is “inappropriate”.
Indication #8	After STEMI/NSTEMI culprit PCI, “symptoms of recurrent myocardial ischemia and/or high-risk findings on noninvasive stress testing performed after index hospitalization, revascularization of one or more additional coronary arteries” is “appropriate”. [8]
Indication #10	In patients with UA/NSTEMI and high-risk features for short-term risk of death or nonfatal MI, “revascularization of multiple coronary arteries when the culprit cannot be clearly determined” is “appropriate” [9]
Indication #11	In patients with STEMI or NSTEMI and cardiogenic shock, “revascularization of one or more coronary arteries” is “appropriate”.
Indication #19	PCI for “one or two vessel coronary artery disease with borderline stenosis 50–60%, no noninvasive testing performed, and no further invasive evaluation performed (i.e., FFR, IVUS)” is “inappropriate”
Indication #20	PCI for “one or two vessel coronary artery disease with borderline stenosis 50–60%, no noninvasive testing performed or equivocal test results present, and FFR <0.75 and /or IVUS with significant reduction in cross-sectional surface area” is “appropriate” for class III/IV angina and “uncertain” for class I/II angina.
Indication #21	PCI for “one or two vessel coronary artery disease with borderline stenosis 50–60%, no noninvasive testing performed or equivocal test results present, and FFR or IVUS findings do not meet criteria for significant stenosis” is “inappropriate”.

of FFR measurements (class IIa, level of evidence A) and intravascular ultrasound imaging in the context of multivessel disease to determine the need for PCI in vessels with angiographically intermediate lesions [19].

### AUC and Multivessel PCI

The AUC for coronary revascularization complements practice guidelines and addresses many clinical situations encountered in daily practice for which there are insufficient data to support guideline development (Table III) [2]. However, most of the AUC evaluate only the appropriateness of revascularization without the mention of single-stage versus multistage strategies. As in the 2009 focused PCI update, the AUC identify nonculprit vessel PCI in the context of STEMI as inappropriate in the absence of ongoing symptoms or clinical instability. They also encourage the use of testing, such as FFR, to decide if additional vessel PCI is appropriate in stable patients.

Catheterization and Cardiovascular Interventions DOI 10.1002/ccd.

Published on behalf of The Society for Cardiovascular Angiography and Interventions (SCAI).

## SPECIFIC PATIENT SUBSETS

### ST Elevation Myocardial Infarction

PCI of nonculprit lesions at the time of STEMI PCI in the absence of ongoing pain or clinical instability is currently a class III indication in the guidelines for acute myocardial infarction [92]. This is due to the concern that noninfarct vessel PCI at the time of PCI for STEMI may increase the risk of adverse events [93,94], although other studies suggest it may be safe [95–97]. In the American College of Cardiology (ACC) survey, only 2% of cardiologists advocated noninfarct-related PCI of severely stenosed vessels at the time of the initial PCI [9].

Occasionally, multiple arteries may occlude nearly simultaneously, so that patients present with multiple infarct-related arteries [98,99]. In this case, one-session multivessel PCI for STEMI is appropriate.

PCI of significant nonculprit lesions at a later session during initial hospitalization for acute MI has been deemed appropriate only if there are symptoms of ischemia or high-risk findings on stress testing [2]. These lesions may be identified at the time of STEMI PCI by FFR testing, as FFR at time of STEMI PCI correlates quite well with FFR obtained later when the patient is stable [100]. In the ACC survey, 80% of cardiologists advocated scheduling non-infarct-related artery (IRA) PCI at a separate session (most commonly during a separate hospitalization within a month of the index admission), and 14% suggested non-IRA PCI should only be done if indicated by symptoms or ischemia [9].

### Cardiogenic Shock

Among patients with cardiogenic shock, one-stage multivessel PCI was associated with worse outcomes compared with single-vessel culprit PCI [101] and was associated with more complications than culprit stenosis PCI followed by delayed nonculprit stenosis PCI [106,107]. Culprit stenosis PCI with subsequent PCI of additional important stenoses during the same hospitalization has been recommended as the best strategy in patients with cardiogenic shock [102]. For patients who remain in shock after PCI of the culprit stenosis and have other stenoses limiting flow at rest to large myocardial regions, immediate (same session) multivessel PCI has been advocated [103].

### Acute Coronary Syndromes (Unstable Angina/ Non-STEMI)

In patients with acute coronary syndromes, ad hoc PCI of the culprit vessel is often performed at the time of diagnostic catheterization. Occasionally, multiple unstable lesions will be identified [104], and multivessel one-stage PCI may be necessary for these patients. However,

ad hoc PCI patients may enter the interventional phase of treatment with a considerable contrast agent load and radiation dose. When renal function is abnormal or the diagnostic procedure unusually prolonged, deferring PCI of nonculprit lesions to a later session may be preferable to avoid contrast nephropathy or radiation burns.

The ACC survey found that for unstable angina/non-STEMI (NSTEMI), 42% of cardiologists advocated one-stage PCI, 37% advocated staged PCI (most commonly with the second stage occurring within a month), and 14% suggested a second stage of PCI be scheduled only for recurrent angina or ischemia [9].

### Stable Ischemic Heart Disease

PCI does not decrease the risk of mortality or future ischemic events for most patients with stable coronary disease. Multivessel PCI should be directed only at lesions that are hemodynamically significant. One-stage multivessel PCI is often tolerated well by stable patients, but may be performed over multiple sessions due to the technical considerations mentioned below. The strategy of staging multivessel PCI appears to be safe [79].

The ACC survey found that 21% of cardiologists advocated one-stage PCI for stable patients, 50% advocated PCI of a nonculprit vessel at a later session, and 17% suggested it to be done only if indicated for ischemia or symptoms [9].

## PROCEDURAL CONSIDERATIONS

### Managing Radiographic Contrast

Several studies have associated total contrast load with the incidence of contrast-induced nephropathy (CIN) [105,106]. Contrast doses  $<100 \text{ cm}^3$  rarely cause CIN [107] in patients with normal or mildly impaired renal function, but the incidence of CIN increases by 14% for each  $50 \text{ cm}^3$  increase in contrast volume [108], and contrast doses over  $260 \text{ cm}^3$  particularly predispose patients to CIN [109].

When considering multivessel PCI, the interventionist should know the patient's glomerular filtration rate, assess the risk of CIN [110], provide adequate hydration before contrast administration, and carefully monitor contrast dose during the procedure. If PCI is performed ad hoc after cardiac catheterization, the interventionist may wish to avoid ventriculography, aortography, or peripheral angiography. Multivessel PCI requires higher contrast doses than single-vessel PCI and may increase the risk of CIN. This risk may be mitigated by staging multivessel PCI, particularly when contrast volumes are high or the patient is at increased risk for CIN. The second stage should be scheduled only after the CIN from the first stage has been excluded or resolved.

### Managing Radiation Doses

Radiation dose management requires an informed patient before the procedure, a knowledgeable operator during the procedure, and appropriate protocols in place for patient follow-up if required. Interventionists should strive to minimize radiation doses during PCI [111–114] as outlined in Table IV. A radiation safety program that uses a qualified physicist, dosimetry monitoring, shielding, and training is essential [113].

Since 2006, all new imaging equipment has included time monitoring displays for total air kerma at the interventional reference point ( $K_{a,r}$ ) in Gray (Gy). This measurement provides an assessment of radiation doses, known as  $K_{a,r}$ . No observable effects are present with  $K_{a,r} < 2 \text{ Gy}$ . Radiation skin burns are more common above 5 Gy, and significant tissue injury is possible with  $>15 \text{ Gy}$ , particularly in patients who have received previous radiation, radiation from an X-ray source close to the skin entry site, or radiation from a nonmoving X-ray source [115]. In clinical practice, higher dose is tolerated before the occurrence of skin burn by radiation because of the multiple angles of imaging that reduce the radiation dose at any one skin site to subclinical levels. If  $K_{a,r} > 10 \text{ Gy}$  is delivered during a procedure, a qualified physicist should calculate the actual peak skin dose and assess potential tissue injury (Table IV). Appropriate steps for patient follow-up based on radiation dose should be followed [113].

When high radiation doses have been used during PCI of the first vessel of multivessel PCI, staging may be necessary to limit the radiation dose from that session. PCI of additional vessels should be delayed for 1–6 months, as recommended by a qualified physicist.

### Challenging Access

Multistage PCI puts the patient at increased risk of vascular complications as compared to one-stage PCI. Operators must weigh this disadvantage of multistage PCI against possible benefits. In cases where vascular access is difficult, one-stage PCI may be relatively more attractive, and the risk/benefit ratio may shift in the direction of one-stage PCI. Compared with radial access, this is a larger issue with femoral access, which has a vascular complication rate of 2–4% and is currently used in  $>90\%$  of PCIs in the United States [116–119].

### Complications

When intervention on the first artery results in an important complication, it is often best to defer the second vessel to a different session. If PCI leads to

**TABLE IV. Radiation Dose Management in PCI**

Preprocedure
Radiation safety program for catheterization lab
Dosimeter use, shielding, training/education
Imaging equipment and operator knowledge
On screen dose assessment ( $K_{a,r}$ , $P_{KA}$ )
Dose saving: store fluoro, adjustable pulse and frame rate, and last image hold
Preprocedure dose planning
Assess patient and procedure including patient size and lesion(s) complexity
Informed patient with appropriate consent
Procedure
Limit fluoro: step on petal only when looking at screen
Limit cine: store fluoro when image quality not required
Limit magnification, frame rate, and steep angles
Use collimation and filters to fullest extent possible
Vary tube angle when possible to change skin area exposed
Position table and image receptor: X-ray tube too close to patient increases dose; high image receptor increases scatter
Keep patient and operator body parts out of field of view
Maximize shielding and distance from X-ray source for all personnel
Manage and monitor dose in real time from beginning of case
Post procedure
Document radiation dose in records (fluoroscopy time, $K_{a,r}$ , $P_{KA}$ )
Patient and referring physician notification for high dose
$K_{a,r} > 5$ Gy, chart document; inform patient; arrange follow-up
$K_{a,r} > 10$ Gy, qualified physicist should calculate skin dose
PSD $> 15$ Gy, Joint Commission sentinel event
Adverse skin effects should be referred to appropriate consultant

$K_{a,r}$ , total air kerma at reference point;  $P_{KA}$ , air kerma area product; PSD, peak skin dose.

myocardial damage or sustained ischemia in one territory, complications arising from PCI in a separate vascular territory have an increased chance of causing hemodynamic compromise or death. Appropriate termination of multivessel PCI when complications occur should be considered as the standard for all multivessel interventions. Complications that may justify early termination include significant side branch occlusion, transient or sustained no-reflow due to presumed distal embolization, sustained chest pain or ST elevation even in the absence of angiographic slow flow, access site complications such as hematoma expansion during the procedure, perforation of coronary artery, or any hemodynamic instability during the procedure.

## LOGISTICAL ISSUES

### Cath Lab Scheduling

One-stage PCI is more efficient for catheterization laboratory operations than staging PCI on different days. However, staging PCI may be necessary due to scheduling constraints for laboratories that follow strict block scheduling. In general, the Writing Group agrees that scheduling concerns should not dictate the choice of one-stage versus multistage PCI.

Catheterization and Cardiovascular Interventions DOI 10.1002/ccd.

Published on behalf of The Society for Cardiovascular Angiography and Interventions (SCAI).

## Patient Convenience

One-stage PCI is preferred by most patients over multistage PCI. The inconvenience of taking time away from normal responsibilities and the anxiety of awaiting the procedure are increased by staging PCI. However, convenience for the patient should not override concerns about patient safety and medical necessity.

## Operator Factors

Although one-stage PCI procedures may be more convenient for the interventionist than staged PCIs, patient issues of safety, efficacy, and convenience should have priority over operator issues. One exception is operator fatigue. Interventionists should be aware of their ability to focus and perform, and should terminate procedures after the first stage of a planned multivessel procedure if their ability to complete the procedure is questionable.

## Economic Ramifications of One-Stage Versus Multistage PCI

Medicare reimbursement to hospitals and physicians is greater for multistage PCI compared to one-stage PCI (Table V) [120]. However, following the ethical and legal principles outlined below, the Writing Group believes that the physician and hospital reimbursement should not be a factor in physicians' decisions regarding single-stage versus multistage PCI.

## ETHICAL AND LEGAL PRINCIPLES

The three important principles of medical ethics are beneficence (doing what is best for the patient and avoiding harm), autonomy (respecting and facilitating the patient's right and ability to make informed decisions about the patient's own care), and justice (considering how the patient's treatment will affect others in the healthcare system).

### Beneficence

The interventionist is obligated to keep the patient's interests foremost. The revascularization strategy must be individualized for the patient and their clinical situation. When multivessel PCI is clearly indicated and can be performed quickly and with low risk, one-stage PCI is probably in the patient's best interest. When one-stage multivessel PCI may be unsafe due to contrast or radiation dosing, or the need for multiple vessel PCI is unclear, a staged strategy may be in the patient's best interest.



**TABLE V. Payments to Physicians for Same-Sitting Multivessel PCI Versus Multisititting Multivessel PCI in 2011**

	CPT codes	RVUs (2011 transitioned facility total RVUs) <sup>a</sup>	Total RVUs <sup>b</sup>	Physician medicare payment <sup>c</sup>	Ambulatory Payment Classification (APC) payment <sup>b</sup>	Diagnosis Related Group (DRG) payment
Scenario 1: multivessel PCI, one stage						
Diagnostic catheterization	93458	9.42	37.55	\$1,276	\$9,847	\$15,573
+ Stent	92980	25.70				
+ Stent additional artery	92981	7.14				
Scenario 2: multi-vessel PCI, staged (separate sessions)						
Diagnostic catheterization	93458	9.42	56.11	\$1,906	\$12,674.49	\$31,146
+ Stent	92980	25.70				
+ Staged separate stage stent	92980	25.70				
Scenario 3: PCI one vessel and pressure wire but no PCI of second vessel, one stage						
Diagnostic catheterization	93458	9.42	33.21	\$1,128	\$7,018.96	\$15,573
+ Stent	92980	25.70				
+ Pressure wire	93571	2.80				

<sup>a</sup>Includes physician work relative value units (RVUs), practice expense RVUs, and malpractice insurance RVUs.

<sup>b</sup>When RVU values are added, they are discounted according to the multiple procedures rules.

<sup>c</sup>National average based on 2011 conversion factor \$33.9764.

2011 National Physician Fee Schedule Relative Value File (RELEASED 12/21/2010).Addendum B.-OPPS Payment by HCPCS Code for CY 2011.

### Autonomy

Patient autonomy is optimized by providing information to the patient, allowing time for the patient to consult with others, and taking the patient's wishes into consideration in medical decision making. These critical aspects should be part of obtaining informed consent. Preserving patient autonomy may be challenging when patients request a convenient strategy (e.g., one-stage PCI) over an inconvenient strategy (e.g., multistage PCI) that would offer better efficacy or safety. In cases where respecting patient autonomy would lead to suboptimal care, the physician must resolve this conflict.

### Informed Consent Regarding Risk

When patients are scheduled to undergo diagnostic catheterization with possible PCI "to follow," the physician has a responsibility to obtain fully informed consent. The presence of MVCAD increases the risk of PCI-related death by 50–137% and increases the risk of complications by 32–86% [120] as compared to patients undergoing single-vessel PCI. Informed consent must be provided not only for the most typical scenario (single-vessel PCI) but also for the higher risk scenarios (multivessel PCI), if they are to be undertaken ad hoc at the time of catheterization [88]. It would be unethical to perform high-risk multivessel PCI on a patient after informed consent was given only for a much lower risk procedure.

### Informed Consent Regarding Alternative Treatments

The presence of multivessel disease raises questions of appropriateness of PCI versus bypass surgery and

the preference of patients for each. For the patient to be able to make a deliberate informed decision, termination of the procedure after diagnostic catheterization may be appropriate [88,89].

### Justice

Distributive justice requires consideration of how the patient's treatment affects the interests of others. One-stage multivessel PCI, particularly if it proves to be longer or more complicated than initially expected, may delay subsequent procedures and cause inconvenience for other patients, other physicians, and technical staff. In some cases (e.g., when an ambulance with a STEMI patient is minutes away), the requirements for the care of other patients may dictate a strategy of staged PCI for the patient on the catheterization laboratory table.

### Legal Aspects

The importance of determining and documenting the necessity for coronary intervention has assumed legal importance as several health systems and individual cardiologists have been prosecuted by the Department of Health and Human Services Office of the Inspector General and the Federal Bureau of Investigation for performing allegedly unnecessary coronary stenting procedures [121].

### RECOMMENDATIONS

The Writing Group concurs with recommendations regarding the use of multivessel PCI as outlined in guideline documents and the AUC. In addition, the Writing Group makes the following recommendations:

1. Medical therapy: every patient who undergoes PCI should receive optimal therapy for coronary disease, ideally before starting the procedure (20). For patients with residual significant lesions and angina after the first stage of planned multistage PCI, therapy should include a trial of antianginal agents to control symptoms. "Optimal therapy" was not defined by the Writing Group.
2. Informed consent: multivessel PCI at the time of diagnostic catheterization should be considered only if informed consent included the risks and benefits of multivessel PCI and the risks and benefits of alternative treatments.
3. PCI strategy: when considering multivessel PCI, the interventionist should develop a strategy regarding which stenoses to treat or evaluate, and their order, method, and timing. This strategy should maximize patient benefits, minimize patient risk, and consider the factors described in this article.
4. Flexibility of PCI strategy: the PCI treatment strategy should be flexible. For planned multivessel PCI, additional vessel(s) should be treated only if the first vessel is treated successfully and if anticipated contrast and radiation doses and patient and operator conditions are favorable. Otherwise, deferral of PCI of the additional vessel(s) is reasonable. For patients with STEMI or cardiogenic shock for whom single-vessel culprit lesion PCI fails to relieve ongoing ischemia, conversion to a multivessel PCI strategy may be appropriate.
5. Reassessment between stages of multistage PCI: after the first stage of planned multistage PCI, the need for subsequent PCI should be reviewed before it is performed.
6. Regulatory and reimbursement status: third party payers and quality auditors should recognize that multistage PCI for MVCAD is neither an indication of poor quality nor an attempt to increase reimbursement when performed according to recommendations in this article. Although the revascularization strategy should be justifiable, the judgment of the operator in selecting the best strategy for the patient must be protected.

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