CORONARY ARTERY DISEASE

Clinical Decision Making

Defining the Length of Stay Following Percutaneous Coronary Intervention: An Expert Consensus Document From the Society for Cardiovascular Angiography and Interventions

Endorsed by the American College of Cardiology Foundation

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Percutaneous coronary intervention (PCI) is the most common method of coronary revascularization. Over time, as operator skills and technical advances have improved procedural outcomes, the length of stay (LOS) has decreased. However, standardization in the definition of LOS following PCI has been challenging due to significant physician, procedural, and patient variables. Given the increased focus on both patient safety as well as the cost of medical care, system process issues are a concern and provide a driving force for standardization while simultaneously maintaining the quality of patient care. This document: (1) provides a summary of the existing published data on same-day patient discharge following PCI, (2) reviews studies that developed methods to predict risk following PCI, and (3) provides clarification of the terms used to define care settings following PCI. In addition, a decision matrix is proposed for the care of patients following PCI. It is intended to provide both the interventional cardiologist as well as the facilities, in which they are associated, a guide to allow for the appropriate LOS for the appropriate patient who could be considered for early discharge or outpatient intervention. © 2009 Wiley-Liss, Inc.

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INTRODUCTION

Since it was first developed over 30 years ago, percutaneous coronary intervention (PCI) has become the most frequently used method of coronary revascularization. Many refinements in the technique have dramatically improved the safety and success of the procedure. One benefit of PCI is the short length of stay (LOS) following an uncomplicated procedure. In many states, reimbursement for elective PCI has shifted to Ambulatory Payment Classification billing for outpatient procedures, as opposed to the Diagnosis Related Group (DRG) reimbursement system for inpatient procedures. It is the responsibility of all parties involved in healthcare delivery to reduce unnecessary expenditures while simultaneously improving quality and maintaining safety. However, it is critical that such actions not have unintended negative consequences. As has been seen in other situations, premature discharge can result in suboptimal care and increased potential for complications [1].

At present, most patients undergoing an uncomplicated PCI typically stay overnight in a nursing unit equipped with electrocardiographic (EKG) monitoring; however, same-day discharge for such patients has been considered. The evidence supporting very early discharge following PCI is limited, and the safety and appropriate application of this approach is not firmly established. The Society for Cardiovascular Angiography and Interventions (SCAI) recognizes the need for standardization of the levels of care provided following PCI. Therefore, it was the goal of this Expert Consensus Panel to examine current practice standards for PCI in the United States and propose a rational scheme that would maintain patient safety and quality in PCI, yet also reduce unnecessary expenditures.

CURRENT PRACTICE STANDARDS FOR ELECTIVE PCI

Elective PCI refers to coronary revascularization in a low-risk, stable patient who presents to a facility from home for a planned PCI or a coronary angiogram with PCI to follow if appropriate (so-called ad hoc PCI) [2]. When PCI is performed in a patient who is admitted to the hospital for ST-segment elevation myocardial infarction (STEMI), non-STEMI, or an acute coronary syndrome with evidence of myocardial ischemia, it is not considered an elective PCI procedure.

Historically, patients often had at least a 2-day hospitalization following an uncomplicated elective PCI. Patients remained at bed rest for 12–24 hr after sheath removal, which frequently was deferred until the morning following the PCI procedure [3]. As both procedural and postprocedural care has advanced, the need

for such prolonged care following an uncomplicated elective PCI has been eliminated. However, because of the paucity of data concerning postprocedure management, the appropriate level of care and LOS remain unclear. Data from a prior SCAI survey indicated that many operators would consider outpatient PCI under certain limited circumstances [4].

The current standard of care for a patient who has undergone an uncomplicated elective PCI is an overnight stay in the facility performing PCI. This is based on the following concerns: (1) abrupt vessel closure and its resulting complications, (2) access site complications, and (3) management of comorbidities, such as renal insufficiency, diabetes, hypertension, congestive heart failure (CHF), etc. Stents, newer antithrombotic regimens, and arterial closure devices have not completely eliminated these concerns [5,6].

The terminology used to describe the patient stay following PCI has itself caused confusion, with definitions varying from hospital to hospital, state to state, and payer to payer. Therefore, it is important to specifically define and standardize these terms while also noting that a patient's condition may change during the course of an encounter and, thus, their classification may change accordingly. Care levels and locations should be determined by the clinical condition and care needs of the patient and not arbitrarily forced into payment or payer categories. The exception is an inpatient admission, which must be coded as a DRG. The need to designate a clinical care level for a patient without implying a fixed payer category has been and remains a source of confusion and misunderstanding.

Definitions

Outpatient. This is a same-day procedure. The patient undergoes PCI and returns home or to a nonmedical facility (i.e., a hotel) the same working day. The duration of supervised care seldom extends beyond 12 hr.

Observation (<24 hr). In this circumstance, the patient undergoes elective PCI and is kept in the medical facility with monitoring and nursing care overnight, but is sent home <24 hr after the procedure is completed.

Extended observation (≥24 hr). This includes two clinical scenarios:

First, the patient presents from home for an elective PCI and has a comorbidity or complication that requires further care that extends beyond 24 hr following PCI. For example, the patient may have CHF with marginal left ventricular (LV) systolic function, significant renal dysfunction, or other comorbidities that are unlikely to be completely stable within 24 hr. Alternatively, the patient may experience a peri-procedural complication that requires an extended period of observation and care to completely stabilize.

Second, there are patients who present with chest pain and are placed on observation status to exclude a myocardial infarction (MI). Many of these patients will be low-risk and will go home to have further workup as an outpatient. However, there will also be patients who have no evidence of MI, but have a very abnormal stress test that results in a recommendation for coronary angiography. Some of these patients will then require revascularization by either PCI or coronary artery bypass grafting (CABG). It would be nearly impossible for all of this to be accomplished in <24 hr and, thus, extended observation is appropriate.

Inpatient admission. In the context of a patient who presents for an elective PCI, inpatient admission may become necessary if there is an important change in clinical status requiring inpatient management. For example, patients who experience certain complications will require inpatient admission for treatment. Such complications are uncommon but include stroke, aortic dissection, major coronary vessel occlusion with MI, emergency CABG, or serious vascular complications requiring vascular or endovascular repair. In addition, patients with certain prosthetic valves will require anticoagulation with a heparin infusion while adequate anticoagulation with warfarin is reestablished.

Facility Requirements

Where the patient receives postprocedure care after PCI does not automatically dictate the level of care or LOS. Patients may receive care in a holding area of the cardiac catheterization laboratory, an inpatient telemetry bed, a chest pain evaluation unit, or an intensive care unit. To streamline the process of establishing the LOS after PCI, it is helpful to have a committed unit for patients who have undergone elective PCI. This provides not only a central location for all PCI patients but also a dedicated staff familiar with the process, expected complications, and their treatment.

The Quality Improvement (QI)/Quality Assurance (QA) Committee for the catheterization laboratory should be actively involved in all aspects of patient care beyond just assessment of complications or sentinel events. Patient follow-up that includes assessment of patient complications as well as patient satisfaction after PCI will allow the physician and the facility to evaluate and revise procedures and policies as they apply to not only procedure performance measures but also postprocedure level of care. Specific projects or programs directed at care following PCI may be needed to assess areas requiring improvement for patients with a reduced LOS after PCI.

Patient education is important to patient care following any procedure; following a PCI, it is particularly important. Interaction with the patient and family is important if early discharge is considered. Risk factor modification, instruction on smoking cessation, and assessment and treatment of lipid disorders are important to address. Understanding stents and the importance of continuing antiplatelet therapy must be emphasized and understood. Same day discharge, when patients are often still recovering from sedation and other postprocedural events, must not compromise this education process.

PCI PROCEDURE INDICATIONS AND RISK STRATIFICATION

It is not within the scope of this manuscript to evaluate the indications for PCI. It is assumed that they are consistent with published guidelines for PCI and appropriate use criteria for coronary revascularization [7,8]. These documents also help define patient characteristics that determine acuity and level of care following PCI.

The optimal situation would identify patients at risk for procedure-related complications, including mortality, and match these "at-risk" patients with an appropriate level and length of postprocedure care. Several models or scoring systems to predict the likelihood of in-hospital death and other major adverse cardiac events (MACE) after PCI have been developed [9–18]. These were developed and validated using all patients undergoing PCI, not just elective patients; thus, several of the risk factors identified in these reports would not be applicable to the elective PCI patient (Table I). For example, cardiogenic shock, MI within the past 24 hr, and urgent/emergent case status exclude patients from the elective PCI category. However, there are several recurring variables that would apply to the elective PCI patient. Although studies differ in the cut-point for age, it is clear that older patients are at increased risk. Additionally, decreased renal function (eGFR <60 ml/min), reduced left ventricular ejection fraction (LVEF; generally <30%), female gender, diabetes, heart failure (≥ New York Heart Association Class III), more complex lesion class, and a thrombus-containing lesion were found in multiple studies to identify patients at increased risk of in-hospital mortality or adverse outcomes.

Although these variables may identify the patient at risk for PCI-related complications, it is less clear how best to use this information in the setting of elective PCI. None of the studies specifically separates in-lab complications from those occurring later. In the elective setting, in-lab complications such as vessel occlusion would be noted immediately, making a longer period of care appropriate after the procedure. However, some complications, such as contrast-induced nephropathy and worsening CHF, would not develop immediately. A reasonable way to use some of these models

TABLE I. Variables Used in Models to Predict In-Hospital Mortality or Other Complications Following PCI

Outcome(s) predicted	In-hospital mortality [9]	In-hospital mortality, MACE [10]	In-hospital mortality [11]	In-hospital mortality, MACE [12]	In-hospital mortality [13]	In-hospital mortality [14]	In-hospital mortality, MACE [15]	In-hospital mortality [16]	In-hospital mortality, MACE [17]	In-hospital mortality [18]
Variables applicable to elective PCI										
Age (years)	≥50	≥65	>55	>70	>65	>50	>50	>70	≥75	>50
Diabetes	Yes				Yes	Yes				Yes
Renal insufficiency. (mg/dl)	Cr > 1.5 or dialysis	Cr > 1.4	Cr > 2.5 or dialysis		Cr > 1.5	Cr ≥ 2.0	Cr > 3.0	Cr > 1.5	Cr ≥ 2.0	Cr ≥ 2.0
LVEF (%)	<20	<45	<29			<29		<50		
MVD	Yes	Yes			Yes		Yes	Yes		
LM disease	Yes		Present	Intervention of		Yes	Yes		Intervention of	
PVD	Yes	Yes	Yes	Yes	Yes			Yes		Yes
MI	<1 month		>14 days		<14 days					Any prior
Gender			Female	Female	Female			Female		Female
CHF			Hx of				≥NYHA III		≥Class III	Any prior
Lesion factors				Intervention of bypass graft		SCAI lesion class; Balloon only	Thrombus	Thrombus	Type B2 or C	Type C
Variables not applicable to elective PCI										
Shock	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
MI	Primary PCI	<24 hr	<24 hr		<24 hrs	<24 hrs		<24 hrs	Yes	Primary PCI
CHF	Class IV	Acute	Current							
Case status				Urgent/emergent	Urgent/emergent	Urgent/emergent	Urgent/emergent	Urgent/emergent	Urgent/ emergent	Emergent
Other								Cardiac arrest		

CHF, congestive heart failure; Cr, creatinine; Hx, history; LM, left main; LVEF, left ventricular ejection fraction; MACE, major adverse cardiac events; MI, myocardial infarction; MVD, multivessel disease; NYHA, New Your Heart Association; PCI, percutaneous coronary intervention; PVD, peripheral vascular disease; SCAI, Society for Cardiovascular Angiography and Interventions.

TABLE II. Published Studies of PCI with Same-Day Discharge

Reference	Type of study	Number eligible/number discharged	Access site	Anticoagulant	Time to discharge (hr)	Major complications in first 24 hr	Comments
Kiemeneij et al. [19]	SC, NR, P	188/100	Radial	Heparin, coumadin	6	None	Palmaz–Schatz stent used; on coumadin INR > 2.5
Koch et al. [20]	SC, NR, R	1015/922	Femoral	Heparin	~8	None	Many patients "discharged" back to referring hospital for care overnight; mostly balloon angioplasty; 20% received stents; manual compression
Carere et al. [21]	SC, R, P	50/41	Femoral	Heparin	Mean 11.2	None	Suture closure of site and same-day discharge versus manual compression and discharge the following day; no difference in events
Slagboom et al. [22]	SC, NR, P	159/106	Radial	Heparin	4–6	None	Balloon angioplasty alone in some patients; exclusions from early discharge defined
Gilchrist et al. [23]	SC, NR, R	–/26	Radial	Heparin	Mean 6.5	None	Only stents used; 6 hr infusion of eptifibatide after bolus
Ormiston et al. [24]	SC, NR, P	100/26	Femoral	Bivalirudin	Mean ~7	None	Restrictions to early discharge, but safe
Dalby et al. [25]	SC, NR, P	70/51	Femoral	Heparin	~4	None	AngioSeal closure used
Banning et al. [26]	SC, NR, P	487/409	Femoral	Heparin	6–12	None	Manual compression, high-patient satisfaction
Ziakas et al. [27]	SC, NR, R	2072/943	Radial	Heparin	~4	No serious complications	Outcome data self-reported by questionnaire sent to patients
Porto et al. [28]	SC, NR, P	196/223	Femoral	Heparin	6–10	None	70% of PCIs were excluded, manual compression used, five patients discharged had an elevated troponin
Slagboom et al. [29]	SC, NR, P	644/375	Radial/Femoral	Heparin	4–6	1	Randomized radial versus femoral, exclusions from early discharge defined, one stent thrombosis with nonfatal MI after early discharge
Lasevich et al. [30]	SC, NR, P	100/51	Femoral	Heparin	8–12	None	46 patients sent to "minimal care area" after PCI
Kumar et al. [31]	SC, NR, P	150/120	Radial	Heparin	Unknown	1	Cases selected, incomplete abciximab infusions, one stent thrombosis with nonfatal MI
Bertrand et al. [32]	SC, R, P	504/444	Radial	Heparin + abciximab	4–6	None	Randomized to radial, bolus-only abciximab, and early discharge ($n = 504$) versus femoral, bolus, and infusion abciximab and overnight stay ($n = 501$)
Wiper et al. [33]	SC, NR, R	442/387	Radial	Heparin	Mean 9.75	None	Abciximab used in some, mostly bolus-only
Heyde et al. [34]	SC, R, P	403/326	Femoral	Heparin	~4	None	Randomized ($n = 800$) to early discharge versus overnight stay
Jabara et al. [35]	SC, NR, R	450/12	Radial	Heparin	Unknown	None	No adverse events occurred between 6 and 24 hr with no discharge delays in this interval

MI, myocardial infarction; NR, not randomized; P, prospective data collection; PCI, percutaneous coronary intervention; R, retrospective data collection; SC, single center; Table modified from Blankenship JC. Here today, gone today: Time for same-day discharge after PCI. Catheter Cardiovasc Interv 2008;72:626–628.

TABLE III. Exclusion Criteria for Early Discharge in Randomized Reports of Early Discharge Following PCI

Study	Carere et al. [21]	Bertrand et al. [32]	Heyde et al. [34]
Clinical	Operator did not believe early discharge appropriate	Recent (<72 hr) STEMI	Hospitalized patient
	Clinical evidence of peripheral artery disease	LVEF ≤ 30%	Acute coronary syndrome
	Pre-existing femoral artery hematoma	Allergy or intolerance to aspirin or thienopyridines	Ad hoc PCI
	Serum creatinine >150 mmol/l	INR > 2.0	Need for long-term oral anticoagulation
	BP > 180/100 mm Hg	Contraindication to abciximab	
Procedural		In-lab transient vessel closure during PCI	Catheters >6 Fr
		Hemodynamic collapse during PCI	GP IIb/IIIa inhibitors used
		Access other than radial artery	Severe dissection with failed or suboptimal stent
		PCI without stent placement	Occluded side branch
		Stented length >25 mm in one vessel	Angiographic thrombus/no reflow
		Compromised or suboccluded branch with diameter >1 mm	Suspected guidewire perforation
		Residual dissection of ≥B of NHLBI classification	Suspected CVA
		Persisting chest pain after PCI	
		TIMI flow <3 after stenting	
		Entry site complication	
		Thrombus after PCI	
		Resuscitation before PCI	
Social	Unspecified other factors		Lives >60 min from PCI center
			Difficult follow-up
			Care person not available at home
			No transportation available

CVA, cerebrovascular accident; GP, glycoprotein; INR, international normalized ratio; LVEF, left ventricular ejection fraction; NHLBI, National Heart, Lung, and Blood Institute; STEMI, ST-segment elevation myocardial infarction; TIMI, thrombolysis in myocardial infarction; PCI, percutaneous coronary intervention.

might be to identify a patient with an increased risk. Such a patient would be excluded from same-day discharge and even considered for an extended period of care following PCI.

DATA SUPPORTING THE USE AND SAFETY OF OUTPATIENT PCI

Peer-reviewed reports on outpatient PCI encompass a total of <5,000 patients and include centers reporting their outcomes in retrospective case series or prospective consecutive procedures with early discharge [19–35] (Table II). There are only three randomized studies comprising <2,000 patients in which early discharge was compared with an overnight stay [21,32,34]. Each of these employed screening criteria that excluded many patients due to clinical, procedural, or social reasons that the authors felt would preclude early discharge (Table III).

Carere et al. randomized 100 patients undergoing PCI to femoral artery access with suture closure of the access site and same-day discharge, or manual compression and an overnight period of observation [21]. There were no serious complications in either group, but 18% of those randomized to early discharge crossed over to an overnight stay, mostly because of continued access site issues.

Bertrand et al. randomized 1,005 patients who underwent successful PCI using radial artery access to early discharge versus an overnight stay [32]. All patients received a bolus of abciximab, but only those remaining overnight received the standard infusion of abciximab following the procedure. Of those in the early discharge group, 12% crossed over and required an overnight hospital stay. This study was designed as a noninferiority trial. Although numerically there were a greater number of adverse events in the early discharge group, early discharge was not inferior to the overnight stay group.

In a follow-up study of patients in this trial, Bertrand et al. compared outcomes in randomized patients and those excluded from possible randomization to same-day discharge. This study found that the MACE rate, including death, MI, and target vessel revascularization, in patients excluded from randomization was significantly higher at 30 days (10.2% vs. 1.6%), 6 months (17.5% vs. 5.6%), and 12 months (24.5% vs. 9%) as compared with randomized patients [36]. This indirectly supports the criteria used in this trial to exclude some patients from same-day discharge. After 12 months of follow-up, only transient vessel closure and a residual dissection greater than or equal to grade B after PCI were independent predictive factors of adverse outcomes in these excluded patients.

In the final randomized trial, Heyde et al. studied 800 patients scheduled for elective PCI performed with femoral artery access, allocating them equally to same-day discharge or an overnight stay. Of note, patients undergoing ad hoc PCI, which is frequently used in the United States were excluded. Of those randomized, ~20% of the patients in the early discharge group crossed over to overnight stay. However, there was no difference in the complication rate between the early discharge and overnight stay groups [34].

Jabara et al. [35] evaluated the potential impact of same-day discharge after transradial stenting in 450 patients in the Same-day TransRadial Intervention and Discharge Evaluation (STRIDE) Study. All but 12 patients were kept in the hospital overnight, as the main purpose of this study was to examine the time course of complications following the procedure. Postprocedural complications were observed in 5.3% of patients, but none occurred between 6 and 24 hr after PCI, the time differential between same-day and next-day discharge. There were a few complications after 24 hr, but these were felt not to be related to discharge on the same day as the procedure.

DEFINING THE LOS FOR POST-PCI PATIENTS

Despite limited randomized clinical data, there appear to be patients who may be candidates for early discharge following PCI. Such patients require identification from the cohort of post-PCI individuals who require a higher level of care and for whom early discharge would be inappropriate. Although the studies performed thus far provide some guidance about clinical, procedural, and social factors in considering early discharge following PCI, these factors are not consistent among studies.

Several of these factors not addressed include routine assessment of cardiac markers, definition of MI, systematic postprocedure follow up as it applies to LOS, and extent of patient education. These issues along with specific protocols will need to be developed based on individual practice patterns that extend beyond the definition of level of care alone. Additionally, reassessment of LOS with patient cross-over among the categories is expected as events may dictate.

While describing the specific services required by patients was considered, a decision matrix for the care of patients following PCI was deemed more comprehensive. The proposed length of stay presented in this document was dictated by a level of conservatism, with latitude for physician judgement and driven by the need for patient safety considered appropriate, when studies were either limited of inconclusive.

To assist facilities in defining the level of care for patients following PCI, the following classification scheme is presented (Table IV).

Outpatient

Whether the PCI is performed as a separate procedure hours or days after the original diagnostic coronary angiogram or in an ad hoc PCI fashion immediately following the diagnostic study, patients in this category should be clinically stable before the procedure and have no obvious complications during PCI. Patients in this category can be considered for an abbreviated period of observation before returning home. Detailed inclusion and exclusion criteria are shown in Table IV, with the major inclusion criteria as follows:

1. Stable angina on presentation with no cardiac biomarker elevation preprocedure;
2. Asymptomatic, with an abnormal stress test;
3. No significant comorbidities including: CHF, significant or symptomatic chronic obstructive pulmonary disease (COPD), symptomatic peripheral vascular disease (PVD), known bleeding diathesis or coagulopathy, significant other organ system disease, or history of contrast allergy;
4. Normal renal function (estimated glomerular filtration rate [eGFR] ≥60 ml/min [37]);
5. Normal or near normal LVEF in the absence of valvular regurgitation;
6. Fully loaded with a thienopyridine and no glycoprotein IIb/IIIa inhibitor used. The abbreviated bolus-only administration of glycoprotein IIb/IIIa inhibitors as has been used by some has not been adequately studied either in terms of safety or efficacy;
7. Single-vessel PCI with a <28 mm stent, no balloon angioplasty alone or other interventional devices used;
8. Successful uncomplicated procedure without the occurrence of: "no reflow," acute closure during the procedure, vessel dissection, or compromised side-branch flow; immediate postprocedure access site stabilization with the successful deployment of a closure device or secure manual compression, or PCI performed via radial artery access or brachial artery cut down;
9. A patient and family willing to consider early discharge, appropriate at-home support structure and rapid access to a healthcare facility and advanced emergency services, should unexpected complications develop.

Observation (<24 hr)

Patients in this category require a longer period of observation compared with outpatients, but <24 hr. This involves an overnight stay and monitoring for

TABLE IV. Proposed Classification Scheme for the Management of Patients After PCI

	Outpatient (same-day discharge)		Observation (<24 hr)		Extended observation (>24 hr)		Inpatient admission	
	Inclusions	Exclusions	Inclusions	Exclusions	Inclusions	Exclusions	Inclusions	Exclusions
Clinical	Stable angina; Asymptomatic but abnormal stress test; Ad hoc PCI planned; Normal LVEF; Pre-loaded with theinopyridine	Unstable coronary syndrome; Abnormal renal function (eGFR < 60 ml/min); Laboratory abnormalities (anemia, electrolytes, etc...); Insulin-requiring diabetes; Age > 70; Dialysis patient	Includes prior column plus: Increasing angina but not admitted with ACS, now stabilized; Transferred in for angiogram and possible PCI; LVEF ≥ 30%; Hgb >12 gm/dl, K >3.5 mEq/l; Abnormal renal function needing prolonged hydration; Dialysis patient	Admitted to rule out MI; Age > 80; Abnormal pre-PCI labs that require further evaluation or treatment; LVEF > 30%	Includes prior column plus: Hospitalized on OBS status to rule out MI, but no MI detected; further evaluation warranted by angiogram before discharge and need for PCI found; LVEF > 30%; Laboratory abnormalities that require further therapy	Definite STEMI or NSTEMI as a complication of the procedure	Admitted for STEMI or NSTEMI, de novo or as procedure complication; Hospitalized on OBS status to rule out MI and MI detected	None
Co-morbidities	None	Contrast allergy; PVD; CHF; COPD on medications	Treated contrast allergy with no reaction; Hx of CHF; COPD on medications	Delayed contrast reaction; Decompensated CHF; Decompensated COPD	Decompensated CHF needs Rx; Decompensated COPD needs Rx; Important valve disease, rhythm disorder	None	None	None
Anatomic	Single-vessel disease	One-vessel PCI in the setting of MV disease; LM, proximal LAD, SVG, IMA or bifurcation PCI	one-vessel PCI in the setting of MV disease; LM, proximal LAD,SVG, IMA or bifurcation PCI; MV disease	Complex anatomy (i.e., treatment of only remaining vessel)	None	None	None	None
Procedural	Single-vessel PCI; Single stent < 28 mm; Radial, brachial cutdown, or femoral access with successful use of closure device, or secure manual compression	Balloon angioplasty alone; Atherectomy (DCA, Rotablator); CTO attempt; Use of GP IIb/IIIa infusion; Need for follow-up labs	Long stents (≥28 mm); Multiple stents same vessel; Multivessel discrete lesions one-vessel CTO; Any access site used, but no vascular complications	Complex procedure; Threatened vessel closure, continued chest pain	Successful procedure but with evidence of "no reflow," persistent vessel dissection, or compromised side-branch flow; large contrast volume (>500 ml) Serial enzyme acquisition required	None	None	None

(Continued)

Table IV. Proposed Classification Scheme for the Management of Patients After PCI (continued)

	Outpatient (same-day discharge)		Observation (<24 hr)		Extended observation (>24 hr)		Inpatient admission	
	Inclusions	Exclusions	Inclusions	Exclusions	Inclusions	Exclusions	Inclusions	Exclusions
Complication	None	Threatened or abrupt closure; Distal embolization; Side-branch loss or compromise; Hematoma; Continuing chest pain; Rhythm disorders	Successful treatment of in-lab complications, but no MI occurred by enzymes or EKG changes	MI by EKG or enzyme changes; Continued rhythm disorder (i.e., atrial fibrillation)	Moderate vascular complications (hematoma requiring transfusion)	Severe vascular complications requiring surgery	Vascular complications requiring surgery	None
Other	Lives or stays <20 miles from PCI facility; Adequate home support; Adequate EMS support	Lives >20 miles from PCI facility; Inadequate home support; Inadequate local EMS	None	None	None	None	None	None

ACS, acute coronary syndrome; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; EKG, electrocardiogram; DCA, directional coronary atherectomy; EMS, emergency medical services; Hgb, hemoglobin; IMA, internal mammary artery; K, potassium; LAD, left anterior descending; LM, left main; LVEF, left ventricular ejection fraction; MV, multivessel; ; NSTEMI, non-ST-segment elevation myocardial infarction OBS, observation; PCI, percutaneous coronary intervention; PVD, peripheral vascular disease; SVG, saphenous vein graft; STEMI, ST-segment elevation myocardial infarction; eGFR, estimated glomerular filtration rate ml/min/1.73m²; CTO, chronic total occlusion.

potential complications such as abrupt vessel closure or access site bleeding, or the measurement of additional cardiac biomarkers or other laboratory studies, as needed. This care level is also appropriate when the home support structure is lacking or a healthcare facility and advanced emergency services are not readily accessible to the patient's home. Detailed inclusion and exclusion criteria are shown in Table IV, with the major inclusion criteria as follows:

1. Increasing symptoms of myocardial ischemia, but stabilized with increased oral medication;
2. Transferred from another facility for PCI, having undergone same-day diagnostic angiography;
3. History of CHF but compensated, stable COPD on medications, mild anemia (hemoglobin [Hgb] > 12 gm/dl, but otherwise normal electrolytes (i.e., serum potassium (K^+ > 3.5 mEq/l);
4. LVEF $\geq$ 30%;
5. Unstable or questionably stable access site;
6. Glycoprotein IIb/IIIa inhibitors used, and the need to complete the intravenous infusion per standard administration protocol;
7. PCI successful, but may have minor complications such as, but not limited to, transient acute closure during the procedure, small untreated vessel dissection, large volume of contrast used, compromised side-branch flow, balloon angioplasty alone;
8. Long stents ($\geq$28 mm or multiple stents in the same vessel), discrete multisite stenting, or chronic total occlusion treatment in a single vessel.

Extended Observation

Patients in this category require >24 hr of observation and monitoring in a medical facility, but not a full hospital admission. Many patients who present with chest pain syndromes are kept on observation status until it is determined whether there is evidence of an MI. A subgroup of such patients, who do not have an MI, will be felt inappropriate for early discharge without further testing. Those without MI who have clinically significant noninvasive studies will likely remain in a medical facility pending diagnostic angiography and revascularization, if appropriate. It is nearly impossible to accomplish all of this in <24 hr, so extended observation is necessary. Other situations for which extended observation is appropriate are shown in Table IV and summarized below:

1. LVEF < 30% or decompensated CHF with increased medication requirements;
2. Decompensated COPD with increased medication requirements;

3. Successful procedure with complications that include, but are not limited to, "no reflow," vessel dissection, or compromised side-branch flow necessitating serial enzyme acquisition;

4. Administration of a large volume of contrast medium (>500 ml);

5. Significant cardiac conditions, including important valvular pathology or significant cardiac rhythm disorders;

6. Significant and multiple comorbid events, including renal dysfunction (eGFR < 60 ml/min), known bleeding diathesis or coagulopathy, or significant other organ disease.

In-Patient Admission

This category includes patients admitted with STEMI, non-STEMI or an unstable acute coronary syndrome manifested by transient ischemic EKG changes or hemodynamic instability. Also included are patients who have important complications during PCI, such as side-branch occlusion with resulting MI, coronary artery perforation with tamponade, or vascular complications that require surgical intervention or repeated transfusion (e.g., retroperitoneal hematoma) or that result in hemodynamic instability. Patients who have incomplete or unsuccessful PCI and require further revascularization, either by PCI or surgery, are included if clinical instability warrants continued hospitalization. Finally, patients with significant comorbidities that also require treatment may be included in this category (Table IV).

MATCHING REIMBURSEMENT WITH LOS

The increasing costs of healthcare are a concern for payers, providers, and patients. The challenge going forward is to pay appropriately for appropriate care. PCI has become safer, but randomized clinical trials defining level of care and LOS for the patient following PCI are limited. The majority of these studies has been conducted outside of the United States and, therefore, reflects differing practice patterns and, in many cases, has utilized radial artery access. Although a viable alternative to femoral artery access, radial access is used in only 1.3% of PCI procedures, according to data from the US database of the National Cardiovascular Data Registry (NCDR). In the Elective PCI in Outpatient Study (EPOS), patients undergoing ad hoc PCI were excluded; however, an ad hoc PCI strategy is used in ~60% of PCI procedures in the United States [34,38].

Although cost containment is essential, policy decisions driven by economic pressures may have potential negative consequences. Limiting the level and duration of patient care following PCI will result in reduced hospital PCI reimbursement. This will require facilities to reexamine options to reduce the variable costs associated with performing PCI. The current standard of care in the United States for the patient undergoing PCI is not same day discharge. Rapid policy changes based on economic pressures may put patients at risk, with subsequent potential medical-legal implications. This Expert Consensus Panel believes it is appropriate to reevaluate the level of care and LOS for patients undergoing PCI as a strategy to reduce costs. We have outlined four categories of care following PCI and provide definitions as well as inclusion and exclusion criteria for each category. These were developed using the collective experiences reported in other countries and a practical working knowledge of practice patterns and common care situations that exist in the United States. The foremost concern is to develop a system that does not put patients at risk for adverse consequences by prematurely discharging patients and thus failing to provide the standard of care that is necessary following PCI. As further studies are performed in the United States, the criteria developed in this document may change, and realignment of reimbursement with the level of care necessary for patients who have undergone PCI may occur.

The patient category for which there is the greatest concern is that of extended observation. These patients have an appropriate and medically necessary need for an extended period of observation, but the current reimbursement scheme provides no additional payment for that care. Therefore, this patient group is especially vulnerable to being sent home before they are stable or before appropriate therapy is completed. The proposed criteria define the specific circumstances under which an extended period of care is appropriate and, if adopted, should provide justification for an appropriate level of reimbursement in this situation.

Fair compensation for the needed services is required. However, properly documenting these needed services is at times challenging. The current coding system with outpatient APC codes and inpatient DRG codes is often complex, confusing, and has the potential to place the patient at risk with significant impact to the hospital for coding inaccuracy. If a patient can be managed as an outpatient, then they should be discharged, and the hospital should be paid APC-level reimbursement. However, if an overnight stay or longer is required, the hospital should receive a reimbursement proportional to the additional incurred expenses. Simplification of coding with a more transparent and

straightforward payment system is instrumental to this process of defining length of stay following PCI.

CONCLUSIONS

The evaluation of patient status and the determination of required level of care following a PCI is an integral component of the revascularization procedure. Hospital reimbursement, though not the defining factor in patient status, is an important component to the success of the interventional program. Accordingly, it should be the goal of providers and payers to develop a safe and efficient clinical care structure to provide the level of care necessary for every patient, with reimbursement appropriate for the care delivered. The scheme proposed here is intended to be used as a suggestion for the appropriate LOS following PCI and is not intended to be mandatory or all-inclusive. Research focused on understanding the optimal strategy and environment for care following PCI is necessary. With patient safety the first priority, the final decision regarding LOS following PCI must remain with the physician.

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