

November 22, 2022

Ms. Debra Savage, Chair
Illinois Health Facilities and Services Review Board
525 West Jefferson Street, 2nd Floor
Springfield, IL 62761

Re: Springfield Clinic – Springfield Ambulatory Surgery Center
Establishment of Cardiac Catherization, Project 22-027

Dear Chairwoman Savage:

As a physician at Springfield Clinic and in central Illinois, Springfield Clinic's application for a Certificate of Need to **establish cardiac and vascular catherization services** at our surgery center in Springfield will continue to strengthen care while expanding services and improving patient access for life-saving procedures in the greater Springfield and central Illinois area. Additionally, it allows for physicians to guide their patients to choose the location best suited for their time in need.

Clinical Overview of PCI Procedures

Percutaneous Coronary artery Interventions (PCIs or coronary stents) have been performed in US hospitals for over 4 decades. Over a decade, peripheral vascular interventions have been safely and efficiently performed in ASC settings in the US. Diagnostic heart catheterization has been approved for ambulatory surgical setting for decades. Of note, diagnostic cardiac catheterization was approved in outpatient settings in Springfield as a joint venture between cardiologists and hospitals in 2004. However, most diagnostic cardiac catheterization continued to be performed at hospitals to reduce the need of another procedure at hospital for performing stents when needed.

In this context, PCIs at hospitals without CT surgery backup have been performed for decade with similar safety. This has offered valuable experience to prepare for safe, efficient, and cost-effective care in ASC setting. Advancements such as our ability to use radial artery in wrist as access site for >90% of elective procedures rather than femoral artery in groin site, improvement and availability of fluoroscopy equipment, catheters, wires, and stent technology, and drugs have drastically improved the safety and success of intervention. With appropriate patient selection, patients can be discharged same day after procedure which has been supported by multiple studies. Encouraged by improved safety landscape, CMS approved PCIs in ASC settings in 2019 for selected patients.

How having the option of having a coronary angiogram and stent in outpatient setting could improve patient care in greater Springfield area

Broadly, cardiac catheterization laboratory is addition to our ambulatory surgical center which is preferred destination of patients with high ratings due to quality and safety culture. During COVID,

patients have deeply appreciated the availability of safer environment, convenience, and cost savings when their procedures are performed in the ASC setting. Let me illustrate using case example of how a patient experience will change with availability of cardiac procedures at ASC in Springfield.

Ms. X1 is 65-year-old female with diabetes and has a positive stress test requiring diagnostic cardiac catheterization as next step. The current wait time to get the procedure scheduled at hospital A is about 3 weeks. She is aware that her stress test is abnormal. Given her continued symptoms and anxiety, she decides to go to the ER in Lincoln. She waits for 2 days at the local hospital before getting transferred to hospital in Springfield where this procedure can be performed. Alternative scenario, she gets cardiac cath scheduled within a week at the ASC.

Mr. Y1 is a 70-year-old male with chest pain and found to have minor heart attack and went to Carlinville area hospital ER and got transferred to a hospital in Springfield at midnight. Since the hospital has elective cases scheduled till 5pm, they can't accommodate a procedure for this patient until late in the evening or recently until 2 days later unless the patient becomes critical. This would change quickly with 20-30% shift of elective patient volume to ASC setting.

Ms. X2 arrived at 6 am for her elective coronary angiogram procedure scheduled at the hospital at 10 am. She has been NPO after midnight. Another patient with a major heart attack arrives to the hospital at 9:30 am. Ms. X2's procedure is postponed as no lab is available until 1pm. She is getting very anxious and irritated especially in the setting of diabetes and not having anything to eat since midnight. Such delays are commonplace at hospitals both before and post COVID. The hospital environment has high infection rate due to patient mix, no pre-procedure or post procedure area next to catheterization lab and this brings significant inefficiency and wait times due to use of common elevators.

Mr. Y2 is a 68 year old male and is wanting the cardiac procedure to be performed in the clinic ASC setting as his positive experience of getting colonoscopy at ASC at Springfield Clinic was much better than trying to get this done in the 'maze of hospital'.

In summary, having a catheterization lab in the ASC will reduce wait time for scheduling of procedure, thus reducing patient anxiety after positive stress test results and may reduce ER visits. It will allow for timely transfers and timely procedures for patients with heart attacks in rural and outreach areas. Not only do patients obtain excellent experience for procedures performed at an ASC setting, the experience of elective procedures at the hospitals will improve by unburdening systems. Springfield Clinic ASC has a proven track record of safety and patient satisfaction and provides solid foundation for addition of cardiac procedures to improve access and quality and to reduce cost of healthcare.

Appropriate Patient Selection

Our Cardiology & Vascular Surgery care teams have developed rules and policy to determine the most appropriate location for each patient. We know not all patients can have procedures in an ASC

setting due to health constraints and concerns regarding their health. We take our patients' health seriously and those that would be better served in a hospital setting will be scheduled at the hospital.

Trend to Cardiac Cath Procedures in Outpatient Setting

Many academic articles and research have been positive on the transition of appropriate care for cardiac cath in the ASC setting including data around patient access, safety and cost savings. According to MedPAC's March 2021 report to Congress, there were 88 single-specialty cardiology ASCs billing Medicare in 2019 (*the latest year with reportable data*), which is a significant uptick from just 18 such ASCs in 2017. While ASCs accounted for an estimated 10% of all cardiology procedures, Bain & Company expects that they will account for 30-35% of such procedures by the mid-2020s as lower costs and favorable outcomes drive change.

Productivity standards show an average of 31.8 minutes saved per procedure in an ASC versus a hospital. Medicare and commercial insurance companies have developed new policies over the last year that will drive more surgeries to ASCs. In 2021, CMS migrated 267 types of procedures to the ASC-payable list from the inpatient –only list. CMS aims to eliminate the inpatient-only list by 2024. ASCs are driven by efficiency, patient choice, convenience, and a keen focus on driving down total medical expenses frequently absorbed by the patient. Patients see ASCs as safer than hospitals, with the added benefit of shorter stays, minimally invasive techniques, faster recovery, and lower costs. If just half of the eligible procedures moved from hospital outpatient to ASCs, Medicare would save an additional \$2.4 billion a year. Likewise, Medicaid and other insurers benefit from services performed in the ASC setting.

New ASC Cath Labs Opening in 2022

In further review, Becker's ASC Review shared that cardiology has a huge opportunity for growth for ASCs as procedures move outpatient. Here are a few of the single-specialty cardiology ASCs announced or opened in 2022.

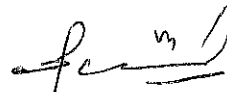
- Hattiesburg, Miss.-based Forrest General Hospital, and the Hattiesburg Clinic partnered to open Mississippi's first ambulatory cardiovascular surgery center.
- The Heart & Vascular Institute of Alabama was cleared to build a \$4.8 million single-specialty ASC in Montgomery after facing opposition from other health systems and ASCs in the area.
- Pacific Cardiovascular Surgical Center in Salem became the first single-specialty cardiovascular ASC certified in Oregon.
- Chicago-based Regent Surgical Health and Amarillo-based Northwest Texas Healthcare System are opening a joint-venture cardiovascular ASC in Amarillo.
- Cardiovascular Experts of Central Pennsylvania opened a cardiology ASC in Camp Hill thanks to eased restrictions.
- In July, Aetna dropped its policy to not cover cardiac PET/CT scans following a joint letter from the American Society of Nuclear Cardiology and the Society of Nuclear Medicine and Molecular Imaging.

- In Texas, Atlas Healthcare Partners and Banner Health have partnered in the acquisition of two Arizona ASCs in Scottsdale and Tucson. Tucson-based acquisition Banner Cardiovascular Center was converted from a laboratory to an ASC that focuses on vascular and endovascular surgery.

The research and data supports ensuring our communities have the access to safe procedures locally and close to home and at a cost saving. Approval of establishing cardiac catheterization services at our surgery center in Springfield will allow for us to have dedicated cath labs, with a dedicated team, dedicated nursing staff, and dedicated imaging to ensure that our catheterization procedures will to be done in a safe, timely, and economic manner for the community we serve.

Thank you for your time and consideration.

Very truly yours,



Sunil Agarwal, MD

cc: John Kniery, Administrator

Enclosures:

Article: SCAI expert consensus update on best practices in the cardiac catheterization laboratory (1)

Article: Length of Stay following percutaneous coronary intervention: An expert consensus document update from the society for cardiovascular angiography and interventions (2)

Article: SCAI position statement on the performance of percutaneous coronary intervention in ambulatory surgical centers (3)







Article: Cardiac Interventions Today, Navigating Coronary Procedures in ASDC During the COVID-19 Era (4)

Article: Cardiac Interventions Today, Managing the Shift to Elective PCI in the ASC Setting (5)

Article: JAMA Cardiology - Outcomes and Temporal Trends of Inpatient PCI at Centers with and without On-Site Cardiac Surgery in the US (6)

Article: JAMA Cardiology - Same-Day Discharge After PCI Current Perspectives and Strategies for Implementation (7)

Length of stay following percutaneous coronary intervention: An expert consensus document update from the society for cardiovascular angiography and interventions

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Abstract

Since the publication of the 2009 SCAI Expert Consensus Document on Length of Stay Following percutaneous coronary intervention (PCI), advances in vascular access techniques, stent technology, and antiplatelet pharmacology have facilitated changes in discharge patterns following PCI. Additional clinical studies have demonstrated the safety of early and same day discharge in selected patients with uncomplicated PCI, while reimbursement policies have discouraged unnecessary hospitalization. This consensus update: (1) clarifies clinical and reimbursement definitions of discharge strategies, (2) reviews the technological advances and literature supporting reduced hospitalization duration and risk assessment, and (3) describes changes to the consensus recommendations on length of stay following PCI (Supporting Information Table S1). These recommendations are intended to support reasonable clinical decision making regarding postprocedure length of stay for a broad spectrum of patients undergoing PCI, rather than prescribing a specific period of observation for individual patients.

KEYWORDS

outpatient, percutaneous coronary intervention, quality improvement, same-day discharge

1 | BACKGROUND/INTRODUCTION

Percutaneous coronary intervention (PCI) is one of the most frequently performed medical procedures, yet there is considerable variability in the duration of hospitalization following such procedures. Traditionally, most patients undergoing elective uncomplicated PCI were admitted as inpatients and monitored overnight because of concerns about post-procedural complications. Discharging patients the same day following an uncomplicated procedure was uncommon, as the safety of this approach was not firmly established.

In 2007, the Centers for Medicare and Medicaid Services (CMS) and many payers changed their criteria for inpatient care such that PCI for indications other than acute coronary syndromes (ACS) was no longer eligible for inpatient facility reimbursement. Payment for elective PCI at the reduced outpatient rate increased financial pressures to eliminate short overnight admissions, eliciting concerns that patient safety and prudent medical practice were at risk. Accordingly, in 2009 the Society for Cardiovascular Angiography and Interventions (SCAI) published an Expert Consensus Document titled "Defining the Length of Stay (LOS) Following Percutaneous Coronary Intervention" [1]. The document specified that the standard of care was an overnight stay following uncomplicated elective PCI, and proposed that safeguarding patient welfare required LOS criteria be "dictated by a level of conservatism" in the absence of definitive studies.

Since the publication of the 2009 document, PCI practice has continued to evolve and rates of postprocedural complications have declined. In addition, studies have demonstrated the safety of same-day discharge (SDD) in patients undergoing PCI [2,3]. Many patients prefer to recover from a PCI procedure at home rather than spend a night in the hospital [4]. SDD has therefore become a reasonable, patient-centered approach for uncomplicated elective procedures. However, the use of SDD varies considerably around the world according to a recent survey [5]. For example, in the United Kingdom and Canada, 57% and 32% of cardiologists, respectively, utilized SDD as a routine practice, whereas in the US only 14% of respondents reported doing so. Among US respondents, 48% stated that they did not have standards for SDD after PCI at their respective institutions.

In response to these data and reflecting current practice, SCAI developed this update to the 2009 Consensus Statement to offer contemporary guidance on LOS following PCI. In contrast to the prior document, the current update addresses LOS across the spectrum of clinical presentations including ACS. Recommendations in this document replace those of the 2009 Consensus Statement and are patient-centered, evidence-based wherever possible, and focused on ensuring the best outcomes by establishing the critical milestones on the path to discharge.

2 | DEFINITIONS

Various and potentially overlapping terms from the medical literature, medical societies, and payers may cause confusion and require clarification (Table 1, Figure 1). For the purposes of this document, SDD

specifically refers to a patient who presents for elective PCI, undergoes the procedure, and after a period of supervised recovery is sent home on the same calendar day. While this is frequently equated with an outpatient procedure, "outpatient" refers to a reimbursement classification and does not relate to a specific LOS. In the United States, inpatient and outpatient are the only two status determinations recognized by CMS for reimbursement purposes [6]. Other terms such as *extended recovery* and *outpatient in a bed* are not CMS terms; rather, they are terms developed by hospitals to classify patients for billing purposes or distinguish between certain outpatient areas. CMS policies make it clear that when patients with known diagnoses enter a hospital for a specific minor surgical procedure or other treatment that is expected to keep them in the hospital for <24 hr, they are considered outpatients for coverage purposes regardless of the hour they came to the hospital, whether they used an inpatient bed, or whether they remained in the hospital past midnight.

Thus, "outpatients" may remain in the hospital on *observation* status following PCI when appropriate. Observation after an elective PCI could be considered for a number of medical reasons such as prolonged or adverse effects from sedation, fluid or electrolyte imbalance, or ongoing pain, bleeding, ischemia, or dysrhythmia after the procedure. In addition, some patients may be considered higher risk for complications based on coronary anatomy, left ventricular dysfunction, procedural complexity, and comorbidities. Finally, there may be appropriate logistical reasons that require a patient to remain in the hospital overnight, such as procedures that end too late in the day for a safe discharge the same day, lack of transportation, or inadequate social support at home. Interpretation of these policies may vary by payer and region, and can potentially impact hospital reimbursement and patient copayments.

3 | PCI COMPLICATIONS AND RISK STRATIFICATION

The justification for a period of observation following uncomplicated PCI is to detect and manage potential complications that are not apparent during the procedure, especially bleeding, vascular access complications, stent thrombosis, and recurrent ischemia. Over the past 30 years, the incidence of complications following PCI has declined. The overall incidence of in-hospital complications in the most recent report of the NCDR CathPCI registry (2016 Q4–2017 Q3) comprising over 600,000 patients without ST-segment elevation myocardial infarction (STEMI) or coronary artery bypass surgery (CABG) was 4.8%. Specifically, stroke was 0.2%, bleeding within 72 hr was 1.4%, pericardial tamponade was 0.1%, heart failure was 0.9%, and acute kidney injury (AKI) requiring hemodialysis was 0.2%. PCI complications that resulted in emergency CABG occurred in 0.2% of patients. Overall in-hospital mortality was 0.93% (including patients undergoing CABG).

The specific timing of adverse events after elective PCI has been the focus of several cohort studies. In the STRIDE study, a cohort of 450 patients undergoing transradial PCI was evaluated for adverse events between 6 and 24 hr postprocedure. There were 24 postprocedural complications (5.3% of total), with most (20) occurring within 6 hr

TABLE 1 Definitions

Definition of cardiac catheterization/PCI status per NCDR		
Cardiac catheterization/PCI status	Elective	The procedure can be performed on an outpatient basis or during a subsequent hospitalization without significant risk of infarction or death. For stable inpatients, the procedure is being performed during this hospitalization for convenience and ease of scheduling and NOT because the patient's clinical situation demands the procedure prior to discharge.
	Urgent	The procedure is being performed on an inpatient basis and prior to discharge because of significant concerns that there is risk of ischemia, infarction and/or death. Patients who are outpatients or in the emergency department at the time that the cardiac catheterization is requested would warrant an admission based on their clinical presentation.
	Emergency	The procedure is being performed as soon as possible because of substantial concerns that ongoing ischemia and/or infarction could lead to death. "As soon as possible" refers to a patient who is of sufficient acuity that you would cancel a scheduled case to perform this procedure immediately in the next available room during business hours, or you would activate the on-call team were this to occur during off-hours.
	Salvage	The procedure is a last resort. The patient is in cardiogenic shock at the start of the procedure. Within the last ten minutes prior to the start of the procedure the patient has also received chest compressions for a total of at least sixty seconds or has been on unanticipated extracorporeal circulatory support (e.g., extracorporeal membrane oxygenation, cardiopulmonary support)
Definitions of admission status per CMS criteria		
Admission status inpatient	Inpatient	<ul style="list-style-type: none"> • A patient who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services. • Formally admitted as inpatient with the expectation that he or she will require hospital care that is expected to span at least two midnights. • The patient will occupy a bed even though it later develops that he or she can be discharged or transferred to another hospital and not actually use a hospital bed overnight.
Admission status outpatient	Outpatient (Same Day Discharge falls under this category)	<ul style="list-style-type: none"> • This status is for most outpatient procedures. • Routine observation is an inherent part of the procedure and the hospital cannot bill for it separately. • CMS does not define how long observation should be as long as it is less than 24 hr. • There is no additional reimbursement for overnight stay and/or nursing care.
	Observation	<ul style="list-style-type: none"> • Observation status cannot be defined preprocedure i.e. a patient cannot come as outpatient for a procedure and expect to be placed in observation. • A patient can remain in observation status for up to 48 hr if one of six CMS criteria for additional monitoring/care, beyond what is necessary for the procedure performed, are met. • The hospital may bill for additional nursing care and procedures to treat the patient

and none between 6 and 24 hr after PCI [7]. In the DISCHARGE study, over 2,000 transradial PCI patients were assessed for timing of post-procedural adverse events. Among the 1,174 higher-risk patients admitted overnight, all complications were identified either within 6 hr of procedure completion (3.4%) or after 24 hr (1.9%) [8]. Taken together these data corroborate the low incidence of postprocedural complications in elective PCI and support the notion that adverse events, when they do occur, are usually within the first 6 hr after PCI or after 24 hr and therefore not impacted by routine overnight observation.

The ability to predict PCI complications through risk stratification can inform decisions regarding LOS. Contemporary risk models and bedside scoring systems for mortality (Table 2), bleeding, and AKI have been developed and validated using the NCDR [9–11]. These models were derived from all patients undergoing PCI, including urgent and

emergent PCI, rendering some variables less applicable to elective cases. Nevertheless, a number of risk factors emerge as recurrent variables and remain useful for risk stratification. Cardiogenic shock, renal function, and age are the strongest predictors of mortality. Although angiographic factors are generally less predictive of poor outcome, left main or proximal left anterior descending lesions are associated with increased mortality risk during elective PCI. Bleeding within 72 hr of PCI was most strongly predicted by female sex, baseline chronic kidney disease and hemoglobin levels, as well as clinical presentation (i.e., shock or salvage PCI). AKI and risk of dialysis was largely predicted by STEMI presentation, shock, and baseline chronic kidney disease.

The very low rates of in-hospital mortality and complications after elective PCI are reassuring for the development of SDD policies. The main challenge with risk scores is deciding how to incorporate them into LOS and discharge criteria. Acceptable thresholds for safety of

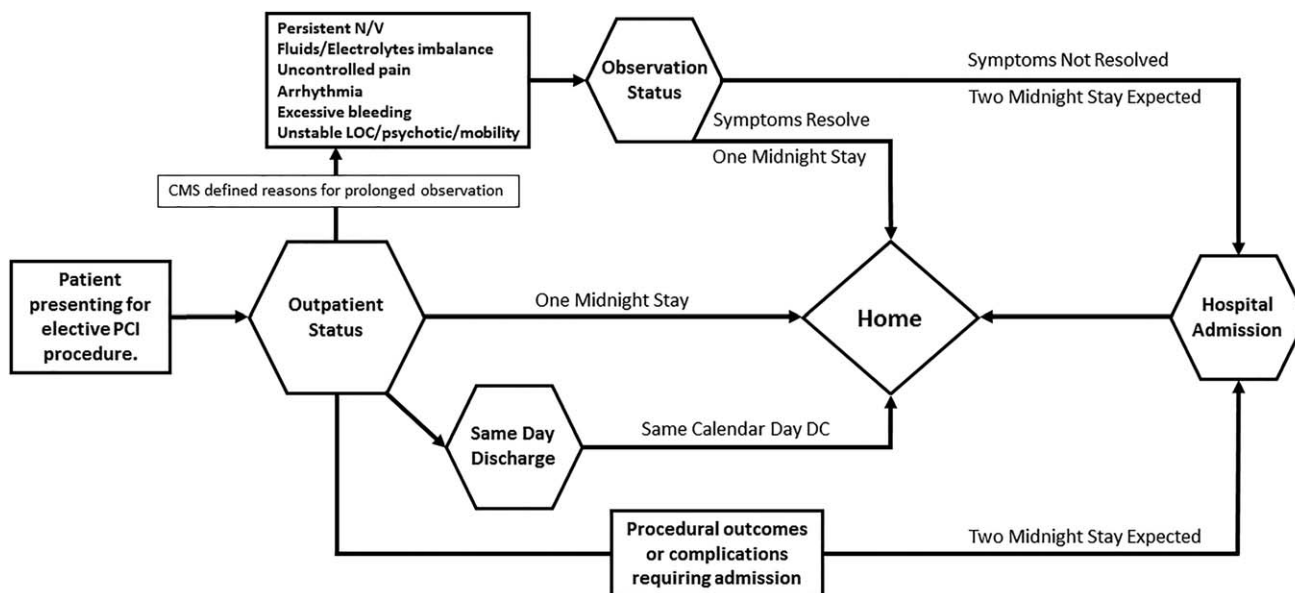


FIGURE 1 Flowchart of patient status following elective PCI

discharge based on risk of mortality, bleeding, and kidney injury have not been standardized. Moreover, risks of AKI are generally not evident until several days post-PCI, rendering decisions about SDD less of a contributing factor toward improving outcomes. On the other hand, the value of risk scores lies in early identification and implementation of strategies, such as bleeding avoidance strategies and preprocedure hydration, in patients who are at elevated risk of bleeding and AKI, respectively, which impacts postprocedural complications and LOS.

4 | PRACTICE EVOLUTION

Short-term post-PCI outcomes have improved significantly in the last decade mainly due to advances in arterial access, antithrombotic/antiplatelet therapy, and drug-eluting stent (DES) technology. Transradial PCI has played an important role in decreasing associated complications across a broad range of clinical presentations. In one meta-analysis of 24 studies, compared with femoral access, radial access was associated with a lower rate of mortality (odds ratio [OR] 0.71), major adverse cardiovascular events (MACE) (OR 0.84), major bleeding (OR 0.53), and vascular complications (OR 0.23) [12]. Transradial access has increased steadily in the United States from 1.2% in 2007 to as high as 37% in 2017 (2017 NCDR outcomes report).

The decline in post-PCI bleeding rates may be partly related to changes in procedural anticoagulation. Bivalirudin use is associated with a reduction in major bleeding rates (OR 0.52) compared with heparin plus routine administration of glycoprotein IIb/IIIa inhibitors (GPI) [13], with GPIs implicated as the major cause of increased bleeding. Data from the CathPCI Registry indicate that bivalirudin utilization increased and GPI use declined between 2009 and 2013, and since 2013 heparin monotherapy use increased and bivalirudin use has declined [14]. Newer P2Y₁₂ inhibitors (prasugrel and ticagrelor) provide faster, more potent, and more reliable P2Y₁₂ receptor inhibition compared with clopidogrel and are superior in preventing ischemic events

in ACS [15]. The use of such agents may alleviate concerns of inadequate platelet inhibition and acute stent thrombosis following PCI.

DES have undergone several advancements in the last decade including improved deliverability and flexibility of the metallic stent scaffold, thinner and more biocompatible polymers, and newer anti-proliferative drugs. These changes in second-generation DES have contributed to the low late lumen loss and thrombotic risk, resulting in lower rates of restenosis and stent thrombosis rates compared with bare metal stents and first generation DES [16].

5 | CLINICAL DATA ON SHORT LOS FOLLOWING PCI

5.1 | Clinical trials

There have been several prospective randomized trials comparing outcomes in patients undergoing SDD compared with overnight observation (Table 3). Most have focused on lower risk patients. In the EPOS study [17], 800 patients underwent randomization prior to PCI to either SDD or overnight observation. This study excluded ACS patients, but many patients underwent multivessel PCI. Some in the SDD group crossed over to the overnight group due to procedural complications or for issues that developed during the first few hours of observation. There were no differences between the groups for the composite primary endpoint of MACE, blood transfusion and access site complications within 24 hr. Notably, these patients all underwent PCI using transfemoral access and hemostasis was achieved using manual compression.

In the EASY trial, investigators randomized 1,005 ACS patients who underwent successful transradial PCI to abciximab bolus only plus SDD or abciximab bolus and infusion plus overnight stay. This trial recruited a higher-risk cohort of patients, with 18% having elevated troponin values at baseline. The study noted no difference in the

TABLE 2 CathPCI mortality risk scoring system [10]

	Scoring response categories					Total points	Risk of in-patient mortality, %	
STEMI	No	Yes				0	0.0	
	0	6				5	0.0	
						10	0.1	
Age	<60	60–70	70–80	≥80		15	0.1	
	0	4	9	15		20	0.2	
						25	0.3	
BMI	<20	20–30	30–40	≥40		30	0.6	
	5	1	0	3		35	0.9	
						40	1.4	
CVD	No	Yes				45	2.3	
	0	2				50	3.7	
						55	5.9	
PAD	No	Yes				60	9.2	
	0	3				65	14.2	
						70	21.2	
Chronic lung disease	No	Yes				75	30.4	
	0	3				80	41.5	
						85	53.6	
Prior PCI	No	Yes				90	65.2	
	3	0				95	75.3	
						100	83.2	
Diabetes mellitus	No	Noninsulin	Insulin			105	88.9	
	0	2	3			110	92.9	
						115	95.5	
GFR	Renal failure	30–45	45–60	60–90	≥90	120	97.2	
	16	11	7	3	0	125	98.2	
						130	98.9	
EF	<30	30–40	40–50	≥50		135	99.3	
	9	4	2	0		139	99.5	
Cardiogenic shock/PCI status	Sustained shock and salvage	Sustained shock alone or salvage alone	Transient shock but not salvage	Emergency PCI without shock/salvage	Urgent PCI without shock/salvage	Elective PCI without shock/salvage		
	54	43	37	22	11	0		
NYHA class within 2 weeks	NYHA class IV	NYHA class <IV	No HF					
	7	3	0					
Cardiac arrest within 24 hr	No	Yes						
	0	13						

BMI, body mass index; CVD, cerebrovascular disease; EF, ejection fraction; GFR, glomerular filtration rate; PAD, peripheral artery disease; NYHA, New York Heart Association.

TABLE 3 Randomized clinical trials of SDD following elective PCI

Study	Reference	Sample size	Access site	Findings	Time to discharge	Inclusion	Exclusion
Bertrand et al. (EASY)	Circulation. 2006;114:2636-2643	1005	TR	<ul style="list-style-type: none"> No difference in 30 day clinical events 88% of patients assigned to SDD were discharged home the same day 	4–6 hr post PCI	<ul style="list-style-type: none"> Successful TR-PCI with abciximab bolus 	<ul style="list-style-type: none"> STEMI within 72 hr EF \leq 30% Vessel closure or hemodynamic collapse during PCI Femoral artery sheath External consideration precluding SDD Allergy, intolerance to aspirin or thienopyridines INR $>$ 2.0
Heyde et al. (EPOS)	Circulation. 2007;115:2299-2306	800	TF without VCD	<ul style="list-style-type: none"> No difference in 24-hour safety endpoint between groups 19% of patients assigned to SDD developed indication for extended observation during/after PCI 	4 hr post PCI	<ul style="list-style-type: none"> Elective planned PCI Home factors allowed SDD 	<ul style="list-style-type: none"> Preprocedure factors: <ul style="list-style-type: none"> Acute coronary syndrome Ad hoc PCI Catheter $>$ 6Fr Oral anticoagulant therapy Glycoprotein inhibitor use Residence $>$ 60min from center Difficult follow-up Procedural <ul style="list-style-type: none"> Occluded coronary artery or side branch Suboptimal angiographic result Residual dissection Angiographic thrombus No-reflow/slow-flow Perforation Clinical <ul style="list-style-type: none"> Ischemic symptoms ECG changes Puncture site abnormalities Congestive heart failure Complicated hemostasis
Slagboom et al.	Cath and Cardiovasc Int. 2005;64:421-427	644	TF with MC and TR	<ul style="list-style-type: none"> SDD PCI safe either TR or TF Larger proportion of TR discharged due to fewer access site complications 38% received only balloon angioplasty 	4–6 hr after PCI	<ul style="list-style-type: none"> Stable or unstable angina 6Fr equipment Normal Allen test 	<ul style="list-style-type: none"> Suboptimal PTCA <ul style="list-style-type: none"> Dissection Unstented Type C lesion Unstented CTO Intracoronary thrombus Side branch occlusion/jeopardy General <ul style="list-style-type: none"> Transient vessel closure Hemodynamic collapse Prolonged chest pain, post-PCI Persistent ECG changes Multivessel PCI if $>$ 1 vessel remains unstented Entry site complication

(Continues)

TABLE 3 (Continued)

Study	Reference	Sample size	Access site	Findings	Time to discharge	Inclusion	Exclusion
Kim et al. (ABCD-PCI)	Circ Cardiovasc Qual Outcomes. 2013;6:186-192	298	TF + VCD	<ul style="list-style-type: none"> After 7 days, no difference in coping ability, medication adherence, safety outcomes Significant (79% vs 49%) patient preference for SDD 	3 hr post PCI	<ul style="list-style-type: none"> Elective PCI <65 years of age Type A or B coronary lesions 	<ul style="list-style-type: none"> Recent ACS >= 3 stents Difficult femoral access Use of anticoagulants other than unfractionated heparin or bivalirudin Suboptimal angiographic outcome or clinical complication PCI of bypass graft Angiographic thrombus INR >2, Platelets <100,000 or Hematocrit <25 Occlusion of major side branch EF ≤30% Known allergy to PCI medications Patient unable to ambulate 4 hr postprocedure Vascular complication (dissection, hematoma, bleeding) Pregnancy Infection Creatinine ≥1.5 mg/dL
Clavijo et al.	Cardiovasc Revasc Med. 2016 Apr-May;17(3): 155-61.	100	TF with VCD	<ul style="list-style-type: none"> No differences in clinical outcomes Similar patient satisfaction scores SDD associated with \$1200 cost savings per patient 	6 hr after PCI	<ul style="list-style-type: none"> Stable angina, unstable angina, or NSTEMI with troponin-T <1 ng/mL Pretreatment with P2Y12 inhibitor Anticoagulation with heparin or bivalirudin Femoral access with VCD Normal coronary flow EF ≥30%. Lives <60 min from the hospital 	<ul style="list-style-type: none"> Clinical Age <30 or >80 years STEMI Non-STEMI with documented troponin-T > 1 ng/mL Severe valvular heart disease Cardiogenic shock or hemodynamic instability Pregnancy Bleeding diathesis Creatinine >1.5 mg/dL not on hemodialysis INR >1.5 Unable to consent or follow-up Inadequate social support Life expectancy of <1 year Pharmacological Received a IIb/IIIa inhibitor or thrombolytics within 24 hr of the procedure

(Continues)

TABLE 3 (Continued)

Study	Reference	Sample size	Access site	Findings	Time to discharge	Inclusion	Exclusion
Carere et al.	Am Heart J 2000;139:52-8	100	TF	<ul style="list-style-type: none"> • 8F Prostar suture closure facilitated earlier discharge (7.1 vs. 15.5 hr with C-Clamp) • 20% hematoma rate in both groups • Patients preferred closure 	11 hr (from sheath removal)	Elective or urgent PCI where operator felt SDD was reasonable	<ul style="list-style-type: none"> • Received low molecular weight heparin within 12 hr of the procedure • Oral anticoagulation • Angiographic and procedural • Treatment of >2 lesions in >2 vessels • Major site branch occlusion • CTO, left main or vein graft PCI • Intracoronary thrombus • Dissection type C-F not stented • Target lesion is >55 mm in length or heavily calcified • Access site-related • Uncontrolled hypertension (>160 mm Hg systolic) • Recent prior TF-VCD • Hematoma, pseudoaneurysm, arteriovenous fistula, or graft present • Severe common femoral calcification • Small femoral arteries (<5 mm in diameter) • Femoral artery stenosis >50%
Knopf et al.	J Invasive Cardiol 1999;11:290-5.	90		<ul style="list-style-type: none"> • Similar procedural and clinical outcomes • Patient preference for SDD 	N/A		
Falcone et al.	Proc (Bayl Univ Med Cent). 2011 Jul;24(3):192-4.	44	TF with VCD	<ul style="list-style-type: none"> • No significant differences for pain, tenderness, numbness, bruising • No difference in adverse events at 7 and 30 days 	3 hr after PCI	<ul style="list-style-type: none"> • ≤75 years of age • Type A or B lesion • Femoral access site amenable to vascular closure device • >2 hr since PCI 	<ul style="list-style-type: none"> • Life expectancy <12 months • Acute myocardial infarction

(Continues)

TABLE 3 (Continued)

Study	Reference	Sample size	Access site	Findings	Time to discharge	Inclusion	Exclusion
				<ul style="list-style-type: none"> 6/7 events were related to femoral access site complications 			<ul style="list-style-type: none"> Anticoagulants besides heparin or bivalirudin used during procedure PCI to nonnative vessel Evidence of thrombus Implantation of >3 stents INR ≥2, platelets ≤100,000/μL, or hematocrit ≤25% Occlusion of side branch during PCI EF ≤30% Residence >30 min from a hospital Dissection, hematoma, or bleeding Pregnancy Infection Creatinine ≥1.5 mg/dL

CTO, chronic total occlusion; ECG, electrocardiogram; EF, ejection fraction; INR, international normalized ratio; MC, manual compression; STEMI, ST-elevation myocardial infarction; TF, transfemoral; TR, transradial; VCD, vascular closure device.

primary composite endpoint of MACE, bleeding, rehospitalization, and access site complications at 30 days and 1 year [18].

The largest observational study of SDD from the CathPCI registry involved 107,018 patients aged 65 years or older undergoing elective PCI [2]. The primary outcome of 30-day death or rehospitalization was similar between patients discharged home the same day and those observed overnight.

Three systematic reviews and meta-analyses have been performed to assess differences between SDD and overnight observation from randomized trials alone [19,20] and randomized trials plus observational studies [3]. Each of these analyses demonstrated no difference in acute or medium-term mortality, myocardial infarction and MACE between groups (Figure 2). Rates of rehospitalization were also no different, according to one meta-analysis.

5.2 | Impact of access site on LOS

In the large observational CathPCI study noted above, nearly 96% of the patients underwent PCI via transfemoral access [2]. Femoral vascular closure devices were used in 65% of the patients undergoing SDD. While vascular closure devices are likely similar to manual compression with respect to vascular complications and bleeding, they do facilitate early postprocedure ambulation [21]. Other studies, like the EASY trial, included only patients who underwent transradial PCI. Radial approach is associated with significantly lower risks of vascular complications and bleeding compared with femoral approach and also leads to faster postprocedure recovery [12]. Ultimately, the choice of access site or method of hemostasis does not appear to directly influence the success of a discharge strategy. Moreover, the overall cost savings associated with radial access and SDD appear to be primarily related to SDD rather than to the use of radial access [22].

5.3 | Clinical data on LOS following primary PCI for STEMI

The studies summarized above included patients with non-ST-segment elevation ACS (NSTEMACS). Primary PCI (PPCI) for STEMI, however, presents a higher risk clinical cohort due to the elevated risk for both acute ischemic and bleeding events. The United States has a very low median LOS (3 days) for these patients compared with other countries (esp. Germany, 8 days) [23], but there is significant variation in discharge practice within the United States [24].

A large observational study of 33,920 patients from the CathPCI registry provides insights into discharge patterns and associated outcomes after PPCI. LOS was divided into short (≤3 days), medium (4–5 days), and long (>5 days) groups. No significant differences were noted in 30-day mortality or MACE between the short and medium LOS groups. Long LOS was associated with higher mortality and MACE compared with the short LOS group, as was a very short LOS (<48 hr) [24]. Several clinical features were associated with either increased LOS (vascular complications, transfusion, preoperative balloon pump, shock, renal insufficiency) or decreased LOS (male sex, absence of diabetes).

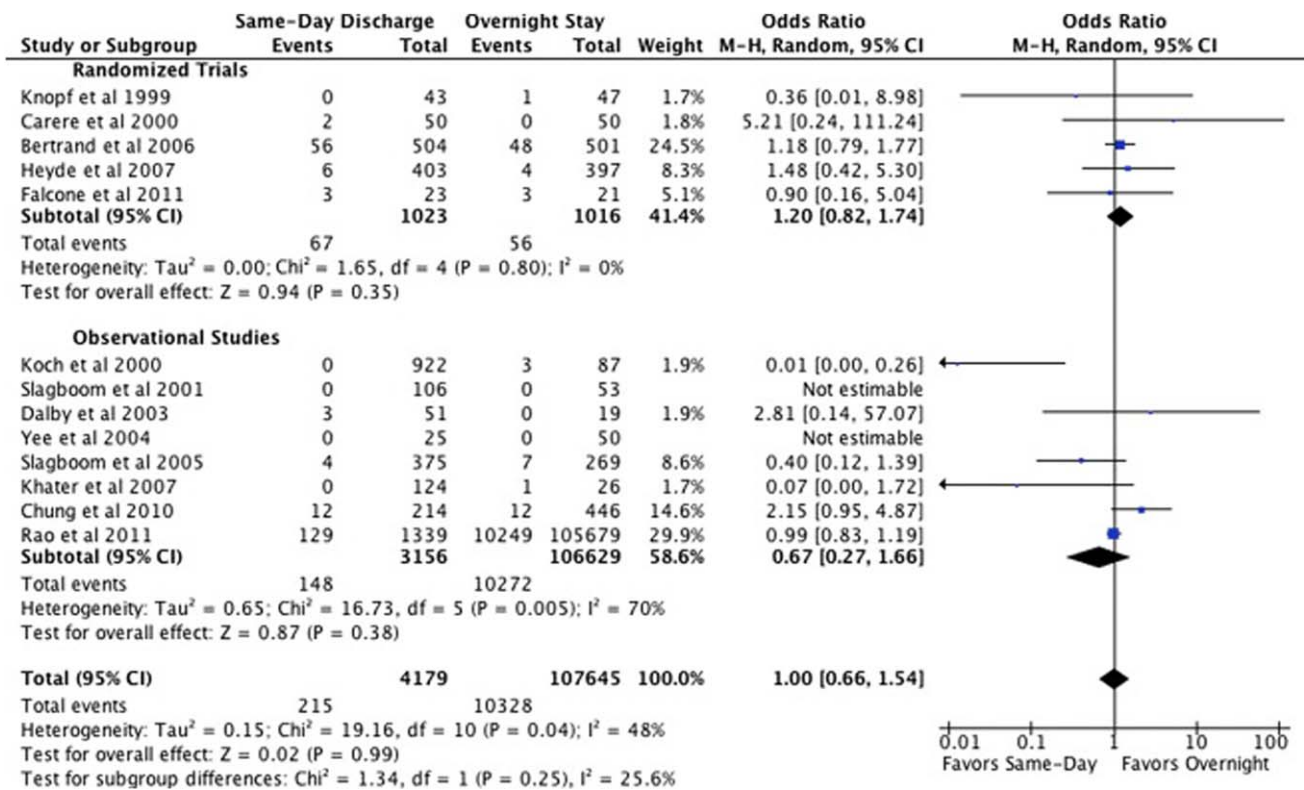


FIGURE 2 Total 30-day complications comparing SDD with overnight stay. From Abdelaal et al. [3] [Color figure can be viewed at wileyonlinelibrary.com]

Several observational and a few randomized studies have studied which patients might be candidates for early discharge after PPCI (Figure 3). In one study of 228 patients, patients with a low CADILLAC score, a validated STEMI risk assessment tool, had a lower rate of MACE beyond 3 days after PPCI compared to those with an intermediate or high score (0% vs 11.4%, $P = .0002$) [32]. In another study of 845 STEMI patients, the addition of N-terminal pro-brain natriuretic peptide (NT-pro-BNP) levels improved the prognostic value of the Zwolle risk score (ZRS) in predicting 30-day mortality. Based on a ZRS (<2) or NT-proBNP at 18–24 h (<2500 pg/mL), the study suggested that 75% of patients could be safely targeted for early discharge at 48 hr [33].

There are limited randomized trials comparing LOS in patients undergoing PPCI. In a Norwegian study, the ZRS was used to identify low-risk PPCI patients ($n = 215$) who were then randomized to early (≤ 3 days) or “routine” discharge [25]. Another trial used the ZRS to identify 54 low-risk patients and randomized them to routine care, or discharge within 72 hr with advanced practice nurse follow-up [26]. In both studies, there were no deaths and no difference in rehospitalization between groups, suggesting that low-risk STEMI patients can be safely discharged within 72 hr.

6 | REIMBURSEMENT AND LEGAL CONSIDERATIONS

6.1 | Reimbursement

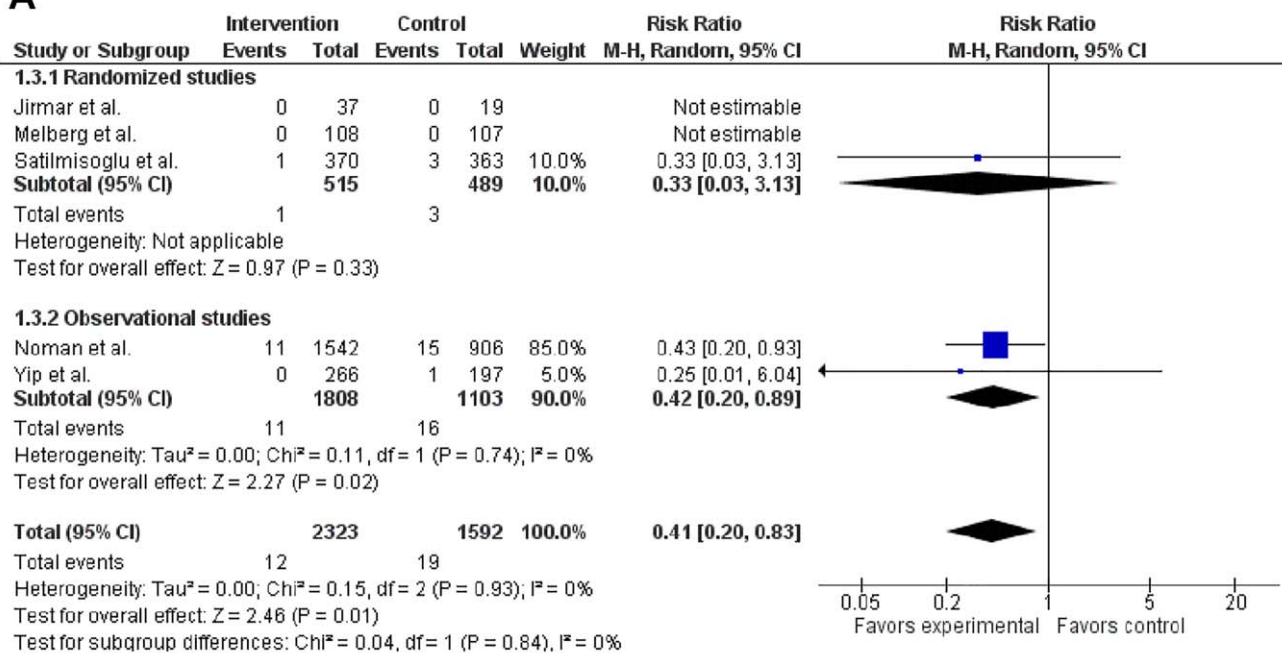
Discharge planning after PCI is ultimately a medical decision and should be based on what is the best care for the patient. While reimbursement

should not affect discharge decisions, the financial impact of LOS decisions merits a review of the relevant policy issues.

Any discussion of PCI reimbursement is limited by the variety of systems and policies present across different countries. Even in the United States, CMS reimbursement policies for PCI have changed over time and are likely to continue to change, creating confusion for patients, physicians, and hospitals. Hospital payments vary across different PCI procedures, but for any particular procedure, payments are higher for inpatients than outpatients (Supporting Information Table S2). Payments to physicians or facilities do not directly correlate with LOS. While CMS inpatient status is usually applied to patients staying two midnights or more, it may be also applied to patients staying only one night if the physician’s judgment and documentation support inpatient classification (i.e., due to ACS). (Supporting Information Table S3) Elective PCI is reimbursed as an outpatient procedure, and there is no increase in reimbursement for patients who stay overnight or who are designated as observation status. Elective patients with a complication requiring more than one night in the hospital may be classified as inpatients with adequate documentation of the cause for admission.

While payment does not vary by LOS, facility costs may increase with longer LOS. In a Canadian study of outpatient PCI, the average charge for SDD was C\$1117 versus C\$2258 for next day discharge [34]. Payment models may continue to evolve over time, but reimbursement under alternative payment models, episode payment models, or other bundled payment systems will likely continue to follow the same principles with fixed payments and facility costs increasing with longer LOS. Thus hospital margins, defined loosely as the difference

A



B

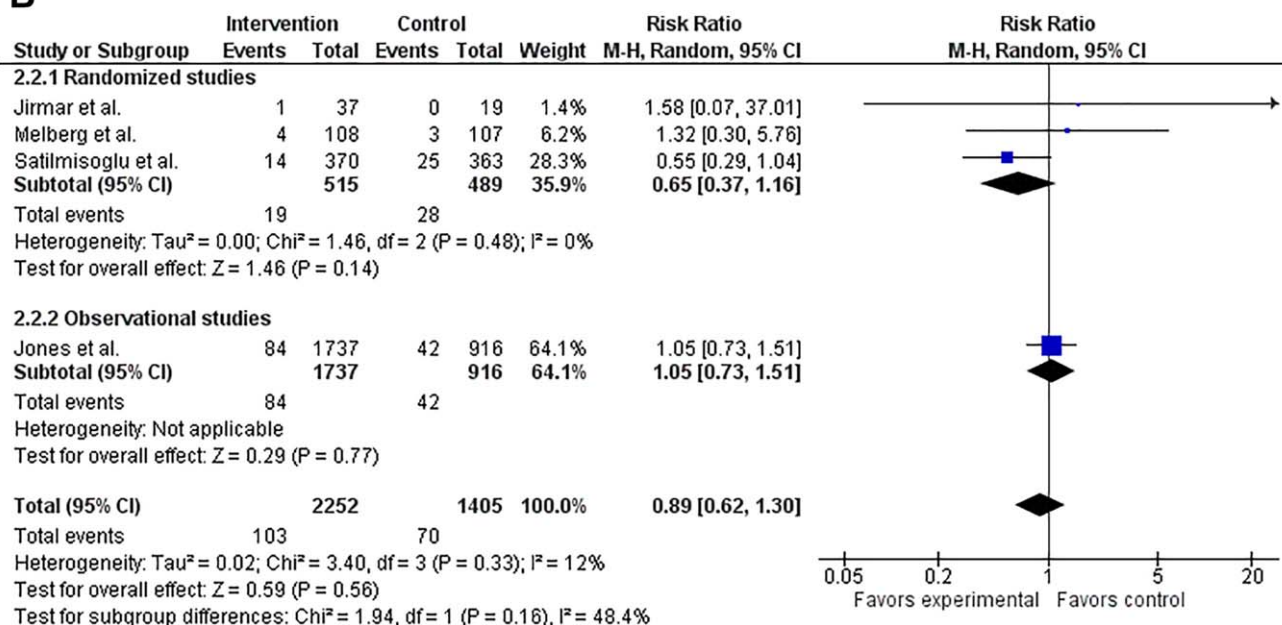


FIGURE 3 Forest Plots (random-effects model) of pooled risk ratios of (A) 30-day mortality and (B) 30-day hospital readmission from 6 studies of early discharge (intervention) following STEMI [References #25,26,27–31]. [Color figure can be viewed at wileyonlinelibrary.com]

between what the facility gets paid and what it “spends” to take care of patients, may be affected by earlier or later discharge.

6.2 | Legal issues

The primary medicolegal concern surrounding LOS after PCI is the occurrence of complications that may manifest after discharge. Most readmissions after PCI are not due to complications of the PCI procedure itself [35], but an adverse event that occurs after discharge may raise the question of whether a longer stay could have prevented or

mitigated the complication. However, as described above, data supporting the safety of early appropriate discharge are robust and should overcome medicolegal concerns. Interventionalists should communicate to patients, families, and referring physicians that early discharge is safe and generally preferred by patients. Such communication is the foundation of the physician-patient relationship and reduces misunderstandings should adverse events occur. Each facility should have a policy regarding discharge after PCI describing the criteria for selecting patients and procedures suitable for SDD or early discharge. A thoughtful post-PCI discharge policy will not only facilitate the

TABLE 4 Consensus recommendations for discharge following PCI

	Expedited and same-day discharge requirements and milestones	Factors unfavorable for same-day discharge
Patient	Clinically stable	Chronic kidney disease requiring prolonged hydration
	At baseline functional and mental status	Decompensated CHF or fluid overload
	Baseline comorbidities (e.g., diabetes, CHF, COPD, PAD, ESRD) stable	Decompensated COPD
		Continuing angina Contrast reaction with ongoing symptoms
Procedure	Successful procedure, including: <ul style="list-style-type: none"> • Single or multivessel PCI, proximal LAD, or bifurcation PCI • Uncomplicated CTO attempt • Regardless of number, length of stents used 	Angiographic complication (slow/no reflow, side branch closure, dissection, perforation) Inability to deliver stent/balloon angioplasty only Last remaining coronary artery PCI
	Adequate hemostasis	Bleeding complication
	Effective dual-antiplatelet therapy administered <ul style="list-style-type: none"> • Pretreatment not required 	Vascular complication Large contrast volume
		Need for GP IIb/IIIa infusion
		Periprocedural MI
		Left ventricular support device used
		Large-bore (≥ 9 French) or brachial access Atherectomy
Program	Meets PCI program operational requirements for postprocedure care	Inadequate home support
	<ul style="list-style-type: none"> • Adequate caregiver support 	No transportation home
	<ul style="list-style-type: none"> • Patient and caregiver education 	Discomfort of patient, caregiver, or physician with same-day discharge
	<ul style="list-style-type: none"> • Provision of P2Y12 inhibitor and medication instruction • Contact information and follow-up appointment 	Inadequate access to emergency medical care following PCI

Abbreviations per Tables [1–3]; CHF, congestive heart failure; COPD, chronic obstructive lung disease; ESRD, end-stage renal disease.

discharge process, but also reduce medicolegal concerns if adherence to the policy is demonstrated.

7 | DETERMINING THE LENGTH OF STAY AFTER PCI

General principles of discharge readiness apply to all patients undergoing PCI regardless of whether the indication is elective, urgent, or emergent. These include, but are not limited to, clinical stability and arrangement of follow-up. While the 2009 consensus document made specific recommendations for LOS for different patient and procedure subgroups, the resulting exclusions to SDD have proven with time to be overly prescriptive and conservative, evident in the poor (<50%) agreement with the recommendations [5].

It is more prudent to identify the essential milestones that should be met before considering a patient ready for discharge, regardless of their presentation, with a focus on patient safety and good clinical judgment. One straightforward paradigm to assess readiness for discharge is to address the “three P’s”: Procedure, Patient, and Program, which serves as the framework for the updated consensus recommendations (Table 4).

7.1 | Procedure

The cornerstone of discharge readiness after a PCI procedure is a stable procedural outcome. In most cases this means a successful PCI defined traditionally as a residual stenosis <20% with Thrombolysis In Myocardial Infarction flow of 3 with no angiographic complications. In cases of unsuccessful PCI (e.g., unsuccessful wiring of a chronic total occlusion), the patient should be clinically stable (see below) prior to

TABLE 5 Sample nursing discharge checklist (adapted from the Ohio State University Medical Center)**Preprocedure**

- Confirm transportation home
- Confirm someone will be home with patient the night of the PCI

Postprocedure

- Obtain postprocedure ECG if ordered
- Provider has checked access site and readiness for discharge
- Notify Cardiac Rehab if ordered
- Notify ACS educator if available
- Provide and document education on antiplatelet therapy
- Add applicable discharge instructions to After Visit Summary
 - ✓ Cardiac Cath, Care after Leg Site, Care after Wrist Site
 - ✓ Dual antiplatelet therapy
 - ✓ What to do if you have chest pain
 - ✓ Medicines for heart disease
- Patient has copy of stent card
- Follow up appointments are listed in After Visit Summary including:
 - ✓ Cardiac Rehab
 - ✓ Cardiology
 - ✓ Primary Care Physician
- For Same Day PCI: Aspirin, P2Y12 (Clopidogrel, Ticagrelor, Prasugrel), Statin, and Nitroglycerin are ordered as medically appropriate
- For STEMI: Aspirin, P2Y12 (Clopidogrel, Ticagrelor, Prasugrel), Statin, Nitroglycerin, Beta-Blocker, ACEI/ARB and Aldosterone Antagonist (if EF <40%) are ordered as medically appropriate
- Medications have been delivered from Pharmacy
- Work/School Excuse

Print and Review the After Visit Summary

discharge. Hemostasis of all vascular access sites should be achieved with no vascular complications or bleeding. Even with clinically stable results, certain high-risk angiographic or procedural situations like supported PCI, last remaining vessel, and use of atherectomy should still be considered for overnight observation. Any patient requiring prolonged postprocedure antithrombotic therapy (e.g., GPI infusion) should also be considered for overnight observation.

7.2 | Patient

The patient should be clinically stable, at their baseline mental status and vital signs, and have completed the appropriate recovery period for conscious sedation. In cases of procedures that are canceled or incomplete, the patient should be at their preprocedure level of symptoms. Baseline conditions such as diabetes, left ventricular dysfunction, and kidney disease should be stable and compensated. While such conditions may be risk factors for complications, overnight observation does not modify this risk, so well-controlled comorbidities need not preclude a safe discharge following a typical observation period.

7.3 | Program

Post-PCI discharge management should take place within the context of a program that encompasses: (1) safe monitoring in the immediate post-PCI period, (2) appropriate guideline directed medical therapy including dual antiplatelet therapy and counseling on treatment duration, (3) compliance with PCI performance measures including secondary prevention and education on risk factor modification, and (4) timely follow-up, including a phone call within 24–72 hr and a scheduled clinic appointment within 2–4 weeks. A responsible adult should be available to escort the patient home. Patients should be discharged to a location

where there is a caregiver with instructions to monitor any potential late complications. For many patients, the PCI procedure may be the first indication that they have ischemic heart disease, and education and counseling are particularly important.

8 | ELECTIVE VERSUS NONELECTIVE PCI

8.1 | Elective PCI

As outlined elsewhere in this statement, patients undergoing elective PCI may either be discharged home (SDD) or observed overnight. Regardless of their length of stay, the paradigm and goals regarding the milestones above should be met before the patient is ready for discharge. Studies have shown that a 4- to 6-hour post-PCI observation period is typically sufficient to identify most potential complications. Thus, if the “three Ps” can be met on the same calendar day as the procedure, then the patient may be eligible for SDD. Checklists (Table 5) can be helpful in ensuring that all milestones are met for a safe discharge. A handout that includes a brief summary of the procedure, a summary of medications including duration of dual-antiplatelet therapy (DAPT), a contact number for questions and/or complications, and specific postprocedure follow-up appointments should also be provided to the patient and caregivers. It is essential to coordinate with pharmacy and provide medication education and DAPT to patients prior to discharge.

8.2 | PCI for acute coronary syndrome including primary PCI for STEMI

Although some patients with ACS were included in the observational studies of SDD, many patients are hospitalized for longer than one day

to confirm the diagnosis of NSTEMI, undergo invasive risk stratification, and ensure adequate recovery. If PCI is performed, discharge can proceed once a patient meets the milestones outlined previously, whether that occurs the day of or following the PCI procedure. Patients who present with or develop complications including (but not limited to) recurrent ischemia, heart failure, AKI, or ventricular dysrhythmias may require additional evaluation and longer LOS.

Patients undergoing primary PCI for STEMI represent a higher risk group depending on presenting clinical characteristics. As summarized above, several risk scores are available for use but randomized and observational studies generally support a 48-to 72-hour hospitalization in patients who undergo successful primary PCI and are clinically stable after the procedure. Again, the milestones of recovery, education, and follow-up should be met before the patient is ready for discharge.

9 | CONCLUSIONS

Advances in practices and technologies have made discharge following PCI demonstrably safe when milestones of clinical stability, procedural success, and process measures have been achieved. Ultimately, the duration of observation following PCI for an individual patient must be a professional medical decision based on individual procedural and patient factors. The schema proposed here is intended to support the reasonable judgment of physicians to allow expedited discharge following PCI, and should not be interpreted as prescribing a specific period of observation for individual patients.

ACKNOWLEDGMENT

The committee thanks Stavros Stavrakis for assistance with the pooled meta-analysis.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

How to cite this article: Seto AH, Shroff A, Abu-Fadel M, et al. Length of stay following percutaneous coronary intervention: An expert consensus document update from the society for cardiovascular angiography and interventions. *Catheter Cardiovasc Interv*. 2018;92:717–731. <https://doi.org/10.1002/ccd.27637>

SCAI position statement on the performance of percutaneous coronary intervention in ambulatory surgical centers

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Abstract

The Centers for Medicare & Medicaid Services (CMS) began reimbursement for percutaneous coronary intervention (PCI) performed in ambulatory surgical centers (ASC) in January 2020. The ability to perform PCI in an ASC has been made possible due to the outcomes data from observational studies and randomized controlled trials supporting same day discharge (SDD) after PCI. In appropriately selected patients for outpatient PCI, clinical outcomes for SDD or routine overnight observation are comparable without any difference in short-term or long-term adverse events. Furthermore, a potential for lower cost of care without a compromise in clinical outcomes exists. These studies provide the framework and justification for performing PCI in an ASC. The Society for Cardiovascular Angiography and Interventions (SCAI) supported this coverage decision provided the quality and safety standards for PCI in an ASC were equivalent to the hospital setting. The current position paper is written to provide guidance for starting a PCI program in an ASC with an emphasis on maintaining quality standards. Regulatory requirements and appropriate standards for the facility, staff and physicians are delineated. The consensus document identified appropriate patients for consideration of PCI in an ASC. The key components of an ongoing quality assurance program are defined and the ethical issues relevant to PCI in an ASC are reviewed.

KEYWORDS

angioplasty, percutaneous coronary intervention, ambulatory surgery center

1 | INTRODUCTION

Interventional cardiology has undergone tremendous evolution since the initial percutaneous coronary intervention (PCI) was performed in

1977. In the early stages of procedural development, acute vessel closure occurred in almost 10% of patients, and therefore onsite cardiothoracic surgical support was required for provision of interventional coronary procedures. Over the ensuing years, advancements in

procedural technique, devices, and pharmacotherapy have led to a high proportion of procedural success with a low rate of major complications.^{1,2} During this time, the complexity of patients and procedures has increased.^{2,3} PCI without cardiothoracic surgical backup has transitioned from a Class III indication to a Class IIa indication^{4,5} and is routinely performed in the outpatient hospital setting. Furthermore, the high safety profile of the procedure and success of same-day discharge (SDD) programs have made it possible to perform elective PCI in nonhospital outpatient facilities.⁶ Performance of PCI in lower acuity settings reduces its cost.^{6,7} Because of the excellent safety profile of elective PCI and the opportunity for lowering cost, the Centers for Medicare & Medicaid Services (CMS) initiated reimbursement for PCI performed in ambulatory surgical centers (ASC) on January 1, 2020.⁸

The Society for Cardiovascular Angiography and Interventions (SCAI) supported CMS' proposal to reimburse elective PCI in the ASC setting during the public comment period in 2019.⁹ This support is contingent on the maintenance of high-quality standards as patients undergoing PCI in an ASC should receive the same quality of care as those receiving PCI as an outpatient in the hospital. This is a companion document to the SCAI Optimal PCI Therapy for Complex Coronary Artery Disease Consensus Statement differentiating appropriate patient care for PCI in the hospital and ASC setting.³ It is intended to provide guidance for the development of an ASC-based PCI program, and for established programs seeking to maintain a high standard of care.

2 | METHODS

The need for a SCAI position paper on PCI performed in an ASC was identified by a working group of the SCAI Government Relations Committee. The writing group included members of the SCAI Government Relations Committee, the SCAI Quality Committee, the SCAI Executive Committee and SCAI members with significant prior experience with PCI in an ASC.

Before appointment, members of the writing group were asked to disclose financial relationships from the 12 months prior to their nomination. Author disclosures are included in Supporting Information Table S1. Consistent with the SCAI Publications Manual of Standard Operating Procedures, <50% of the writing group had any relevant conflict of interest.¹⁰ Disclosures were periodically reviewed during document development and updated as needed. Writing group members with a current financial interest were recused from primary authorship of any relevant section of the document. The work of the writing committee was supported exclusively by SCAI, a nonprofit medical specialty society, without commercial support. Writing group members contributed to this effort on a volunteer basis and did not receive payment from SCAI.

The Writing Group found no substantive data regarding the safety and efficiency of performing PCI in the ASC setting. Therefore, this document primarily reflects expert consensus opinion. The writing group reviewed relevant clinical guidelines and consensus papers^{4,11-17} as were available regarding performing PCI in an outpatient site of service and issues relevant to SDD after outpatient PCI.

The draft manuscript was peer reviewed in February 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.

3 | PCI IN AN AMBULATORY SURGERY CENTER

The ability to perform PCI in an ASC has been made possible due to the outcomes data from observational studies and randomized controlled trials supporting SDD after PCI.^{7,18-23} In appropriately selected patients for outpatient PCI, clinical outcomes for SDD or routine overnight observation were comparable without any difference in short-term or long-term adverse events. No safety signals were observed^{7,18-23} and SDD was associated with a lower cost of care in both the Early Discharge After Transradial Stenting of Coronary Arteries (EASY) randomized clinical trial and observational registries.^{7,22,24,25} These studies provide the framework and justification for performing PCI in an ASC.

3.1 | Potential benefits

The value proposition for performing outpatient PCI in an ASC versus the hospital outpatient environment, while dependent on consistent procedural efficacy and safety, offers improved efficiency of care, increased access to care, better patient satisfaction, and reduced cost. Advances in clinical decision making, adjunctive pharmacotherapy, and procedural technology have continuously improved the safety profile of outpatient PCI. Data from the National Cardiovascular Data Registry (CathPCI) from 1,612 hospitals ($n = 667,424$) reveal that major complications after PCI are rare, and exceedingly so for elective PCI.¹ Cautious case selection based on patient and lesion characteristics can further reduce the risk of complication in the ASC setting.

A single randomized controlled trial from Canada and an observational registry in the United States show some cost savings with SDD after elective PCI, primarily by eliminating the cost of an overnight hospital stay.^{7,22,25} The 2020 CMS-approved PCI reimbursement rates for the ASC setting are reduced by 30% as compared to the hospital outpatient setting. CMS anticipates \$20 million saved in cost, and \$5 million saved in copays, if just 5% of PCIs shift to ASCs.²⁶

3.2 | Potential drawbacks of outpatient PCI in the ASC setting

While there are potential benefits of outpatient PCI in the ASC setting, it is important to consider the drawbacks. There are extensive published data on the safety of outpatient PCI in a hospital setting, but none available for outpatient PCI safety in an ASC setting. The shift in procedural volume from hospitals to ASCs will have financial

implications for hospitals that could potentially impact their ability to provide other necessary services. Although it is expected that PCI in an ASC would decrease overall expenditure, it is possible that the actual number of PCI procedures performed may increase. It is the goal of this document to provide guidance on reducing the possibility of any negative clinical or financial outcomes.

4 | REGULATORY CONSIDERATIONS

Outpatient PCI can be currently performed in four different types of outpatient environments as defined by the CMS Place of Service (POS) Code system: POS 11 Office (ie, Office Based Lab-OBL); POS 19 Off Campus-Outpatient Hospital; POS 21 On Campus-Outpatient Hospital; and POS 24 Ambulatory Surgical Center (ASC).²⁷ Prior to the new rule, Medicare only provided reimbursement for PCI in hospital-based settings. The rule enacted by CMS adds Medicare payment for PCI in the ASC setting but not in office-based labs (OBLs). An ASC must meet the criteria outlined by Medicare found in the Code for Federal Regulations (CFR) Title 42: Public Health, Part 416: ASCs.²⁸ The ASC must also meet any additional state level requirements, which are typically more stringent than those for OBLs.²⁹ The CMS rule has added coronary angioplasty and coronary stenting codes to the ASC Covered Procedure List establishing payment for six PCI Current Procedural Terminology (CPT) codes (Table 1).⁸ Notably, PCI for coronary artery bypass grafts, chronic total occlusions (CTO), myocardial infarction or coronary atherectomy will not be reimbursed in an ASC site of service. It was the expressed written opinion by SCAI to CMS that these higher risk lesion subsets not be reimbursed in the ASC setting until more safety data are available regarding PCI in an ASC for lower-risk lesions.⁸ However, SCAI strongly endorses reimbursement for physiologic and intravascular imaging studies, such as fractional flow reserve (FFR), intravascular ultrasound (IVUS) and Optical Coherence Tomography (OCT), respectively, in an ASC. The reimbursement, availability and utilization of these studies would likely lead to reduced inappropriate PCI and improved clinical outcomes.

Before an ASC can serve governmental payor beneficiaries, the entity must have an agreement with CMS to participate in Medicare as an ASC. Specific federal conditions for coverage can be found on the CMS website.³⁰ The first condition for coverage states that "The ASC must comply with State licensure requirements," and, therefore, to be eligible for CMS ASC Certification, the Catheterization Laboratory (Cath Lab) must first be licensed as an ASC in that individual state. Furthermore, regulation of the performance of PCI is under state jurisdiction and state licensing criteria that ASCs must meet prior to certification. Not all states allow the performance of PCI in the ASC setting. Some states require a certificate-of-need for a new Cath Lab, which is issued based on proof that the facility fulfills an unmet need in the community. Those considering starting an ASC-based PCI program should understand the legal requirements within their state.

Many ASCs choose to go through voluntary accreditation processes. Accreditation is sometimes referred to as a "third party survey" and is not mandatory for ASCs by federal regulations or to be

TABLE 1 CPT codes approved for reimbursement by CMS

CY 2020 procedural code	CY 2020 procedural code long descriptor
CPT Code 92920	Percutaneous transluminal coronary angioplasty; single major coronary artery or branch
CPT Code 92921	Percutaneous transluminal coronary angioplasty; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)
CPT Code 92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch
CPT Code 92929	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)
HCPCS Code C9600	Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch
HCPCS Code C9601	Percutaneous transcatheter placement of drug-eluting intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)

Abbreviations: CPT, Current Procedural Terminology; HCPCS, Healthcare Procedure Coding System.

contracted with CMS Medicare/Medicaid. However, accreditation may be mandatory in some states and with some payers. ASCs can seek accreditation from one of several accrediting bodies: The Accreditation Association for Ambulatory Health Care, Inc (AAAHC), The Joint Commission, or The American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), and Healthcare Facilities Accreditation Program (HFAP).

Finally, the ASC's governing body must appoint an individual who has appropriate qualifications in accordance with State and Federal regulations to provide oversight of radiation issues.

5 | STANDARDS

This writing group believes that a PCI Cath Lab in an ASC needs to meet the standards outlined in the 2012 ACC/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards.¹¹ The document describes facility design and standards for safe performance of PCI with assurance of staff safety. The document also addresses the requirement of adequate staffing to provide the required level of procedural and periprocedural care and operator competency standards.

5.1 | Facility and equipment standards

Cath Labs must be designed in accordance with industry standards. National organizations, such as the Facilities Guidelines Institute, may be used as a resource to evaluate Cath Lab design and construction.^{6,31} Proper safety precautions including adequate radiation shielding for patients and personnel and personal radiation monitoring devices must be maintained.³² There must be a distinct room within the ASC where patients recover immediately postprocedure. A “room” consists of an area with at least semipermanent walls from floor to ceiling separating it from other areas of the ASC. Adequate equipment for postprocedure monitoring such as telemetry, automated blood pressure cuffs, and pulse oximetry must be available.

The ASC must be equipped with the necessary supplies for PCI. Equipment must also be available to address potentially catastrophic complications, including:

- Pericardiocentesis tray.
- Echocardiography/ultrasound capable of assessing for pericardial effusions.
- Temporary transvenous pacemaker.
- Covered stents.
- Mechanical circulatory support (eg, intra-aortic balloon pump).
- Advanced Cardiac Life Support (ACLS) supplies, medications, and equipment including a defibrillator and a ventilator.
- On-site ASC provider with expertise in endotracheal intubation and airway management.

In addition to emergency equipment, the facility should be capable of performing physiologic lesion assessment. Either IVUS or OCT should also be available for anatomic lesion and stent assessment. Peripheral vascular ultrasound availability is important for safe access and the ability to measure point-of-care activated clotting time is essential.

5.2 | Procedural and periprocedural standards

The SCAI 2016 Best Practices in the Cardiac Catheterization Laboratory document should serve as a guide for clinical management.¹⁴ All staff involved in direct patient care should be ACLS certified. The ASC must ensure that the nursing service is directed under the leadership of an RN. There must be sufficient nursing staff with the appropriate qualifications to address the nursing needs of all the patients. A mechanism to notify other health care personnel in the ASC of any patient emergency should be in place. Finally, the ASC must follow the American Society of Anesthesiology guidelines for sedation.³³

5.3 | Transfer protocols

For medical emergencies requiring care beyond the capabilities of the ASC, an efficient procedure must be in place to facilitate immediate

patient transfer from the ASC to an appropriate receiving hospital. A receiving facility should be located within 60 min travel time by ground or air transportation.¹³ Ideally, a written transfer agreement would be in place between the ASC and the receiving facility even though this formality is not mandated by CMS.³⁴ The local receiving hospital must be either a Medicare-participating hospital, or a nonparticipating hospital meeting emergency services payment requirements per CMS guidelines. An “effective procedure” for immediate emergency transfers includes having an established written policy that addresses the circumstances warranting transfer, parties involved in the transfer decision on both the transferring and receiving end, accompanying documentation, emergency medical services (EMS) communication, and communication with the receiving facility at both a physician and nursing level. The ASC must also have an effective protocol with ambulance services and/or medical flight services to transfer patients requiring emergency services to a management capable hospital in an expedited fashion. An appropriate communication plan must be in place between the ASC and emergency transfer services. There must be evidence that the staff are aware of, and can implement the ASC’s policy immediately upon development of, a medical emergency. The ASC must provide emergency care within its capabilities and initiate stabilizing treatment until the patient is transferred.

5.4 | Operator standards

The interventional cardiologist performing the PCI procedure must be licensed in the state in which the ASC is located and must practice within the scope of his/her license. Each physician performing procedures in the ASC must have been determined to be qualified and have been granted privileges under rules established by the governing body of the ASC. The ASC must have written policies and procedures that address the criteria for clinical staff privileges in the ASC and the process that the governing body uses when reviewing physician credentials, determining whether to grant privileges and defining the scope of privileges for each physician. Although all credentialing decisions are local, SCAI strongly endorses interventional fellowship training, board certification, and a minimum annual volume of at least 50 PCI procedures per operator.¹⁶ SCAI also cautions against newly trained interventional cardiologists performing PCI in the ASC setting. The initial guideline for PCI without on-site surgical backup suggested >500 interventions as a primary operator.³⁵ It is recognized that this number may be difficult to reach in the current era, but it is the opinion of SCAI that PCI in an ASC be performed by experienced operators with an established record of acceptable outcomes. These concerns are of even greater importance in an ASC where additional providers may not be available to assist as the clinical need of the patient dictates.

The governing body is required to solicit the opinion of qualified medical personnel on the competence of the applicant for privileges. ASCs should consider seeking the recommendation of qualified outside physicians when they do not have the appropriate in-house expertise to evaluate the competency of the applicant for privileges. Medical staff privileges must be periodically reappraised by the ASC.

An explicit written policy should indicate how the medical staff is held accountable by the governing body. It is possible for an ASC to be owned and operated by one physician who is both the sole member of the governing body and also the sole member of the ASC's medical staff. In such cases, the physician owner must still implement a formal process for complying with all medical staff regulatory requirements.

6 | SCOPE OF PROCEDURES

Although many cardiovascular procedures can potentially be performed in an ASC, this position paper addresses adult PCI and diagnostic cardiac procedures only. Previously, procedures that may be unsuitable for PCI without on-site cardiac surgery have been described^{11,13} and similar cautions apply to ASCs. As in the hospital setting, PCI may be performed "ad hoc" with a similar decision-making process.¹² However, there are additional concerns unique to the ASC setting that must be considered when proceeding to PCI.

6.1 | Appropriate patients and procedures

A concurrent SCAI document detailing state-of-the-art practice for complex CAD provides guidance regarding site performance locations for such patients.³ PCI in patients with high-risk clinical features should be avoided in the ASC setting (Table 2). Lesions with complex features and those associated with higher complication rates should also be avoided in an ASC setting (Table 3). Elective procedures possibly requiring mechanical circulatory support should not be performed in ASCs, although the ability to emergently insert an intra-aortic balloon pump should be readily available.

TABLE 2 Unfavorable patient conditions warranting PCI deferment to the hospital setting

- 1 Decompensated CHF (NYHA class 3–4)
- 2 Recent TIA/stroke (<8 weeks)
- 3 Left ventricular ejection fraction <30%
- 4 Chronic kidney disease with an estimated glomerular filtration rate < 45 ml/min/1.73 m²
- 5 Anemia (Hgb < 9 g/dl) or coagulopathy (eg, INR >1.5 or platelet count <100 K)
- 6 Acute coronary syndrome
- 7 Severe pulmonary hypertension or disease (advanced COPD or patients on supplemental oxygen)
- 8 Unprotected left main stenosis or three-vessel CAD
- 9 Any cardiac or noncardiac signs of clinical instability
- 10 Significant PAD limiting femoral and radial access
- 11 Severe aortic stenosis
- 12 Severe contrast allergy
- 13 Operator judgment on other condition(s)

Abbreviations: CAD, coronary artery disease; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; Hgb, hemoglobin; INR, international normalized ratio; PAD, peripheral artery disease; TIA, transient ischemic attack.

Diagnostic procedures (eg, left and right heart catheterization, coronary and graft angiography) are appropriate for ASCs. Invasive diagnostic testing that involves intravascular imaging (IVUS and/or OCT) or functional evaluation (FFR and/or resting indices) and coronary angioplasty and stenting are appropriate in an ASC. As discussed earlier, bypass graft PCI, coronary atherectomy, CTO PCI and PCI for acute coronary syndromes have higher complication rates and should be avoided in the ASC setting. These procedures are also not reimbursed by CMS when performed in an ASC. Until safety for lower risk PCI in an ASC can be demonstrated across the country in large populations, these and other more complex interventions should be restricted to a hospital environment.³ The SCAI PCI risk calculator may be a useful tool for guiding decisions regarding the most appropriate setting for a specific patient. The calculator can be accessed at www.scaipciriskapp.org.

Only patients who are appropriate for SDD should be considered for intervention in an ASC. The 2018 SCAI Expert Consensus Document on Length of Stay Following PCI provides guidance on patient suitability for SDD.¹⁷ However, not all patients that might be suitable for SDD in the hospital setting are appropriate for ASC-based PCI. The ASC setting does not provide the option of easily converting a patient to overnight observation. For example, a bifurcation intervention might be suitable for SDD but if there is side branch loss it would need to be converted to an overnight stay. The probability of such an event must be carefully considered in the ASC setting. Another consideration is the lack of ancillary support in the ASC setting. Patients that might require additional resources postprocedure (eg, respiratory therapy, dialysis) would not be appropriate for the ASC setting. Patients must also have transportation home, adequate social support and reliable follow-up.

It is recommended that all ASC PCI facilities have a protocol in place that guides patient selection and procedural decision making. All operators should be educated on the protocol and monitored for adherence. Copies of the protocol should be kept on-site and readily accessible to all operators and staff. A suggested protocol is depicted in Figure 1 and Table 4. It is also encouraged that a "radial first" approach be utilized for ASC PCI. Radial access is ideal in the ASC setting to minimize bleeding, access site complications, reduce staff workload, and decrease the risk of an overnight observation for femoral access site concerns.¹⁵

TABLE 3 Complex or high-risk lesion characteristics warranting PCI deferment to the hospital setting

- 1 Bifurcation lesions with significant side branch involvement
- 2 Severe lesion calcification
- 3 Extremely angulated segment or excessive proximal tortuosity
- 4 Bypass graft lesions
- 5 Chronic total occlusions
- 6 Other vessel characteristics that the operator judges would impede stent deployment
- 7 Thrombus in target vessel or lesion
- 8 Unprotected left main lesions
- 9 Last remaining conduit
- 10 Possible need for upfront mechanical circulatory support

7 | ONGOING QUALITY

PCI in the ASC site of service should be performed with the same expectations for quality as in the hospital. A quality program must be in place to evaluate procedure appropriateness, technical performance, and assurance of quality of care. The SCAI/ACC/AHA Expert Consensus Document on PCI Without On-Site Surgical Backup contains recommendations applicable in the ASC setting.¹³ In addition, key components of a recommended quality program have been recently outlined by SCAI but would need to be modified to account for the ASC environment.¹⁴ Key topics to cover for ASCs are outlined in Table 5.

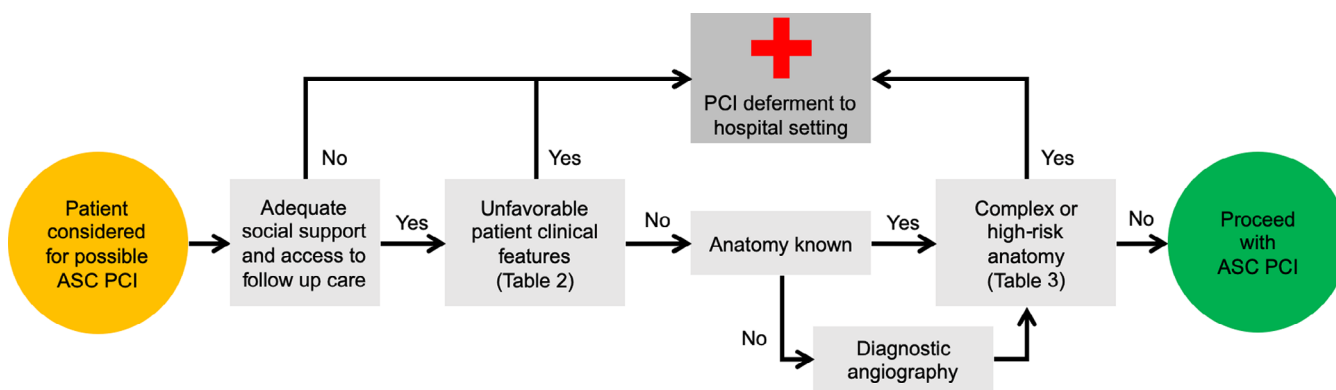
Participation in a PCI registry that is specifically designed or modified for the ASC setting will be necessary for ongoing quality assurance. This can be accomplished by the creation of a new outpatient PCI registry or through leveraging existing national cardiovascular registries, such as the NCDR CathPCI registry. Registry data should be used to monitor PCI operator and institutional volumes, outcomes, and procedural appropriateness.³⁶ This would allow benchmarking, establishment of performance standards and appropriate risk adjustment for evaluation of outcomes. There is no current registry specific to PCI in an ASC. The Outpatient Endovascular and Interventional Society (OEIS) has developed a national registry that is a Qualified Clinical Data Registry (QCDR) focused on outcomes within outpatient interventional suites (OIS) and ASCs.^{37,38} While this QCDR only supports a peripheral vascular interventional module, the OEIS plans to offer a single cardiac module specifically focused on all cardiac interventions performed in the OIS and ASC. The NCDR CathPCI registry is well established but does not yet accept submission of data from ASCs and does not include metrics specific to the ASC site of service. The development of a registry suitable for assessing ASC PCI quality metrics is needed. It is imperative that such a registry be developed with consideration of the potential administrative burden that participation might have on an ASC and should only include essential quality assurance metrics.

Data abstraction teams, as are typically found in the hospital setting, may not be financially sustainable in the ASC environment at the current reimbursement rates.

CMS is finalizing the Ambulatory Surgical Center Quality Reporting (ASCQR) Program to enhance the quality of care in the outpatient surgical setting. The ASCQR Program is a pay-for-reporting quality program for the ASC setting that requires an ASC to meet quality reporting requirements or else undergo a 2.0 percentage point reduction in its annually updated fee schedule. Relevant patient safety measures that are currently reported to CMS include all-cause hospital transfer/admission.³⁷ These measures for ASCs were developed because the transfer or admission of a surgical patient from an outpatient setting to an acute care setting could be an indication of a complication, serious medical error or other unplanned negative patient outcome. The ASCQR program should be improved with specific SCAI-recommended measures that would help better evaluate the safety of PCI in the ASC setting.

8 | ETHICAL CONSIDERATIONS

All ASC operations and clinical care must be conducted consistent with The American Medical Association Code of Medical Ethics.³⁹ The physician and the ASC have an ethical duty to place patient's interests first. This core value should guide the ASC's code of conduct. Ownership in an ASC presents a potential conflict of interest that requires active guidance, policy development and approaches to address this issue. ASC ownership may include a combination of physician investors and/or a regional/national business enterprise. In addition to the ownership of the ASC, physician-owned intermediaries (POI) have been developed to provide additional potential financial compensation via the sale of medical devices to the ASC. This provides a potential conflict as medical decision making could be impacted by implanting devices that result in a financial benefit to the



ASC=Ambulatory Surgical Center; PCI=percutaneous coronary intervention; Table 2. Unfavorable Patient Conditions Warranting PCI Deferment to the Hospital Setting; Table 3. Complex or High-Risk Lesion Characteristics Warranting PCI Deferment to the Hospital Setting

FIGURE 1 Patient pathway for ambulatory surgical center percutaneous coronary intervention (ASC PCI; Tables 2 and 3)

TABLE 4 Ambulatory surgical center PCI performance checklist

Prescheduling assessment:
<ul style="list-style-type: none"> Confirmed transportation after procedure Adequate social support at home. Adequate caregiver at home the evening of discharge Patient resides or stays in close geographic proximity (≤ 30 min driving time) to a hospital capable of providing emergency care for complications that could occur after discharge No unfavorable patient clinical features or PCI indications (Table 2) No known complex/high-risk anatomical features (Table 3) Patient fully understands plans for ASC PCI and same day discharge
Morning of procedure assessment:
<ul style="list-style-type: none"> Transportation, social support and postdischarge geographic location confirmed Patient signed informed consent and disclosures regarding relevant financial interests of the interventional physician Patient evaluated by physician and confirmed to be appropriate for ASC PCI
Post-PCI assessment:
<ul style="list-style-type: none"> Favorable PCI features: <ul style="list-style-type: none"> Successful PCI: $<30\%$ residual stenosis with final TIMI 3 flow Transradial approach (preferred but not mandatory) Successful access site hemostasis Unfavorable PCI features (consider patient transfer to hospital setting if present) <ul style="list-style-type: none"> Loss of side branch >1 mm in diameter Significant no-reflow during the procedure NHLBI Type B-F dissection in the target vessel at the end of the procedure Intracoronary thrombus that arose during the procedure Transient vessel closure during the procedure likely to precipitate significant infarction Vascular access complication Any cardiac or noncardiac instability during PCI At the discretion of the attending physician Patient preference to stay overnight
Predischarge assessment:
<ul style="list-style-type: none"> Absence of chest pain, access site hematoma and cardiac rhythm abnormalities Four hours of observation completed ECG prior to dismissal reviewed and without significant change Follow-up appointment scheduled within 1–2 weeks Patient is able to obtain DAPT and other prescriptions by the following morning Patient accompanied by an adult at the time of discharge and at home

Abbreviations: ASC, ambulatory surgical center; DAPT, dual antiplatelet therapy; ECG, electrocardiogram; NHLBI, National Heart Lung and Blood Institute; PCI, percutaneous coronary intervention; TIMI, thrombolysis in myocardial infarction.

physician and/or ASC. The three types of POI include the distributor POI, manufacturer POI and the group purchasing organization.

Important principles to consider in order to address this issue are as follows:

TABLE 5 Key features of a high-quality ASC PCI program

Preprocedural	Procedural	Postprocedural
Appropriate informed consent including risk of transfer for complications	Established criteria for high-risk coronary anatomy that require transfer for safe PCI performance	Appropriate documentation of required data elements for cath and PCI reporting
Appropriately trained staff and PCI operators	Appropriate training/supplies for conscious sedation	Registry participation to evaluate procedural outcomes and appropriateness
Established quality insurance program for continuous peer review of quality and outcomes	Emergency preparedness protocols in place	Established criteria for clinical indications for transfer to acute care facility
Written transfer agreements with hospitals and surgeons	Mock transfer drills with EMS and "receiving" hospital	Evaluation of acute care required within 1 month after discharge
Established clinical criteria for determination of high-risk patients	Ability for real-time image review for CT surgical consultation	Appropriate clinical follow-up scheduled within 1–2 weeks of PCI

Abbreviations: EMS, Emergency Medical Services; PCI, percutaneous coronary intervention.

- Remuneration should not be based on utilization and/or referrals. Neither the ASC, nor other investors, should provide loans to potential new physician investors.
- Fee splitting is illegal. Payment by a physician to another physician/clinician for referrals should not occur.
- A robust quality assurance and utilization review program should be implemented to monitor physician self-referral.
- Referral to the ASC versus hospital should be determined by medical policy developed on evidence- or consensus-based principles.
- Administrators/management should not pressure physician investors who select alternative sites for patients to receive care.
- Policies should be developed that support the ability of physicians to care for patients more likely to experience disparities in care based on social demographics and/or insurance status.

Federal law, including Stark Law exceptions and Anti-Kickback Statute safe harbors, coupled with ethical principles, dictate that the physician must disclose both ownership and additional compensation factors to patients making informed choices. Ideally, disclosures would be performed before the patient arrives at the ASC for a procedure. Best practices would include:


- Disclosure to the patient of ownership interest.
- Disclosure to the patient of additional structure, which impacts physician compensation.

3. Disclosure, when requested by the patient, of a full list of investors.
4. Information regarding alternative choices including other ASCs and hospitals for patients.

9 | CONCLUSION

Interventional cardiology continues to be an innovative and rapidly evolving field that offers increasing safety for selected patients undergoing PCI. As performing PCI in an ambulatory environment can be performed safely and is now reimbursed, it is important to establish the optimal strategy and model to keep doing so. The decision to perform PCI in an ASC must be made in the context of the local healthcare environment, while initiation of an ASC PCI program requires transparent adherence to state and federal regulations and operational standards. Patients should receive the same quality of care regardless of the procedural site of service and ongoing quality assurance monitoring will be imperative for the long-term success of this endeavor. This SCAI writing group believes that it has laid a foundation of principles to promote safe performance of elective PCI in ambulatory surgery centers.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

How to cite this article: Box LC, Blankenship JC, Henry TD, et al. SCAI position statement on the performance of percutaneous coronary intervention in ambulatory surgical centers. *Catheter Cardiovasc Interv*. 2020;96:862–870. <https://doi.org/10.1002/ccd.28991>

SCAI expert consensus update on best practices in the cardiac catheterization laboratory

This statement was endorsed by the American College of Cardiology (ACC), the American Heart Association (AHA), and the Heart Rhythm Society (HRS) in April 2021

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Abstract

The current document commissioned by the Society for Cardiovascular Angiography and Interventions (SCAI) and endorsed by the American College of Cardiology, the American Heart Association, and Heart Rhythm Society represents a comprehensive update to the 2012 and 2016 consensus documents on patient-centered best practices in the cardiac catheterization laboratory. Comprising updates to staffing and credentialing, as well as evidence-based updates to the pre-, intra-, and post-procedural logistics, clinical standards and patient flow, the document also includes an expanded section on CCL governance, administration, and approach to quality

metrics. This update also acknowledges the collaboration with various specialties, including discussion of the heart team approach to management, and working with electrophysiology colleagues in particular. It is hoped that this document will be utilized by hospitals, health systems, as well as regulatory bodies involved in assuring and maintaining quality, safety, efficiency, and cost-effectiveness of patient throughput in this high volume area.

KEYWORDS

appropriate use, evidence-based medicine, economics/cost-effectiveness, electrophysiology, health care outcomes, health care policy

1 | INTRODUCTION

This update to the Society for Cardiovascular Angiography & Interventions (SCAI) Expert Consensus Statement on Best Practices in the cardiac catheterization laboratory (CCL) builds upon previous statements in 2012 and 2016. Key tenets have remained, including patient-centric approach to the flow of patients through the laboratory, consistency with the requirements of regulatory and accreditation bodies, and contemporary standards incorporating new evidence. This clinical expert consensus statement pertains primarily to diagnostic and therapeutic coronary artery procedures, with somewhat less attention to structural or other procedures. Nonetheless, the general principles established here would apply to most structural and endovascular procedures, and a section on the collaboration with electrophysiology has also been included. Importantly, the purpose of this document is not to represent all acceptable practices, but to provide a consensus on “best practices” as goals for CCL. It is anticipated that regulatory bodies, accrediting organizations, hospitals and health systems, CCL directors and managers, as well as hospital administrators will reference this document for process improvement and standardization. Moreover, this document should serve as a guide for new CCLs, including both outpatient (ambulatory) and inpatient facilities.

2 | METHODOLOGY

This document has been developed according to SCAI Publications Committee policies for writing group composition, disclosure and management of relationships with industry (RWI), internal and external review, and organizational approval.¹

The writing group has been organized to ensure diversity of perspectives and demographics, multi-stakeholder representation, and appropriate balance of RWI. Relevant author disclosures are included in Table S1. Before appointment, members of the writing group were asked to disclose all financial RWI from the 12 months prior to their nomination. 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 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. Writing group members contributed to this effort on a volunteer basis and did not receive payment from SCAI.

Literature searches were performed by group members designated to lead and contribute to each section and initial section drafts were authored by the respective section teams. Recommendations were discussed by the full writing group during a series of virtual meetings until all authors agreed on the text and qualifying remarks. All recommendations are supported by a short summary of the evidence or specific rationale.

The draft manuscript was peer reviewed in December 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 April 2021.

3 | INSTITUTIONAL AND OPERATOR QUALIFICATIONS AND COMPONENTS OF AN OPTIMAL CCL PROCEDURAL TEAM

3.1 | Provider/institutional competence and documentation

All physicians must maintain procedure-specific credentialing and privileging by their institution, typically requiring certification by the American Board of Internal Medicine (ABIM), American Osteopathic Association (AOA), or National Board of Physicians and Surgeons (NBPAS).² Each CCL should have a procedure for recertification of privileges. This is usually required every 2 years by accrediting bodies in health care. The most commonly used accrediting agency, The Joint Commission (TJC), also requires the completion of ongoing professional practice evaluations, typically performed twice yearly, for all physicians. TJC also mandates completion of a focused professional practice evaluation for newly hired operators, established operators requesting permission to perform a new procedure, and established operators performing a procedure in case of a perceived problem.³ Case volume should be documented by CCL administration on a biannual basis. In addition, procedural outcomes including success rates and observed in-hospital complications, should be documented. Risk adjustment models are recommended to put these observed

outcomes in perspective.^{4,5} Participation in national or regional quality improvement registries, such as the National Cardiovascular Data Registry (NCDR) Cath-percutaneous coronary intervention (PCI) registry, is necessary to meet quality standards.⁶ In addition, physicians should participate in at least quarterly quality improvement, peer review, and/or morbidity and mortality (M&M) meetings with film review as appropriate to maintain privileges, as well as participate in post-procedural appropriateness evaluations. Other members of the team may be invited to participate in these meetings as appropriate. Technologists are strongly encouraged to obtain Registered Cardiovascular Invasive Specialist certification, and nursing staff ideally should have a minimum of 1 year of critical care experience. In addition, nursing, physician assistant (PA), and technologist staff must comply with continuing education requirements for their state(s) or certifying bodies, which may include ongoing certification for ACLS and/or BLS.

Clinical competence guidelines state that to maintain proficiency while keeping complications at a low level, a minimum volume of 200 PCIs/year be achieved by all institutions.² In addition, although the clinical competence guidelines acknowledge only a moderate correlation between operator PCI volume and mortality, for each operator a minimum PCI volume of 50/year is recommended, averaged over 2 years. That said, a recent report from the NCDR showed that around 40% of operators in the United States perform less than 50 PCIs/year.⁷ The performance of primary percutaneous coronary intervention (PPCI, PCI in the setting of acute ST-elevation myocardial infarction [STEMI]) requires an additional cognitive and technical skill set for both operator and CCL team; therefore, it is recommended that operators perform 11 PPCI/year and that institutions should perform 36 PPCI/year.²

It is recognized that the breadth of procedures performed in the CCL continues to expand and includes peripheral vascular and structural heart procedures. In addition, some labs also perform transcatheter aortic valve replacement (TAVR), as well as electrophysiological procedures including diagnostic studies, therapeutic ablations, and device implantation. It follows that issues of involvement in appropriate registries, institutional and physician volume requirements, and quality assurance (QA) be tailored to include the entirety of procedures offered in any laboratory. In alignment with the current CMS National Coverage Determination (NCD) for reimbursement of TAVR, it is recommended that institutions perform ≥ 30 surgical aortic valve replacements (SAVRs)/year (or 60 over 2 years), ≥ 300 PCIs/year, and ≥ 50 TAVRs/year (or 100 over 2 years). In regards to transcatheter edge-to-edge repair procedures such as MitraClip, the 2019 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Mitral Valve Intervention recommends that an institution should perform ≥ 20 transcatheter mitral valve interventions/year (or ≥ 40 interventions every 2 years); ≥ 20 mitral valve surgeries per year (or ≥ 40 every 2 years); and perform ≥ 300 PCIs per year.⁸ SCAI guidance on PFO and LAO procedures have also been published.^{9,10} As new procedures develop, similar types of standards will undoubtedly evolve.

For hospitals without on-site cardiac surgery, oversight to ensure the quality of procedures is paramount.^{2,11} Less experienced operators should have additional oversight, such as backup support. The

CPORT-E Trial serves as a model for facilities performing PCI without on-site cardiac surgery.¹² Consistent with its design, such facilities should participate in national registries, routinely utilize risk adjustment tools, have immediately available consultation with a tertiary care center, implement cross training of personnel, and have a well-developed system for emergent transfer if clinically indicated. In addition, CMS provides reimbursement for PCI procedures in freestanding ambulatory surgical centers (ASCs). These freestanding facilities have important differences in infrastructure and oversight that have implications for standards. The recent SCAI position statement on the performance of PCI in ASCs addresses the issues important to safe performance of procedures in this novel setting.¹³ In brief, such laboratories should meet the same standards of design as those within acute care hospitals. Of importance, and similar to hospitals without on-site cardiac surgery, ASCs should have protocols in place for immediate consultation and transfer to tertiary care centers in case of untoward outcomes. In addition, the scope of procedures in ASCs should exclude patients who have unfavorable clinical characteristics and coronary anatomy.¹⁴ For both hospitals without on-site cardiac surgery backup and ASCs, high-risk EP procedures such as complex VT ablation and lead extraction should be avoided.

3.2 | Optimal catheterization laboratory team

A multidisciplinary approach within the CCL is necessary. The primary operators must be adequately trained and credentialed. They are usually assisted by a physician trainee and/or physician extender (e.g., certified radiology or cardiovascular technologist, PA, or nurse). Typically, one to two non-physician CCL staff are tableside when there is no physician trainee, with an additional two CCL staff serving in “circulating” and “monitoring/recording” roles, with flexibility on the non-physician staffing ratio depending on the complexity of the case. For primary PCI, three non-physician staff are required. Tableside assistants must be trained in the setup of manifolds, automatic contrast injectors, the use and preparation of wires, catheters, balloons, and other devices, as well as in radiation safety and sterile technique. Appropriate staffing to ensure an adequate nurse-to-patient ratio should be ensured. A nurse administering moderate sedation during the procedure should not have other responsibilities that could compromise patient assessment. In cases where more than moderate sedation is used, an anesthesia provider should be present, and policies should be drafted for the administration of medications that are consistent with hospital credentialing and state guidelines.

3.3 | The heart team

The concept of the Heart Team stems largely from the design of large, randomized trials where specialists from different disciplines have been asked to render opinions regarding equipoise between two procedural approaches. The 2014 ACC/AHA/AATS/PCNA/SCAI/STS Focused Update of the Guideline for the Diagnosis and Management of Patients with Stable Ischemic Heart Disease elevated the Heart

Team approach to a IC recommendation for patients with diabetes mellitus and complex coronary artery disease.¹⁵ This approach is consistent with a number of clinical trials for coronary disease and is routinely utilized in TAVR. With regards to stable coronary artery disease, the team centers around cardiac surgeons and interventionalists, although other stakeholders including general cardiologists, imagers, anesthesiologists, and palliative care providers often play a role. It is recommended that hospitals have a formal process for Heart Team consultations on those patients with clinical or anatomical complexity.

3.4 | Maintenance of qualifications

ABIM or AOA certification in interventional cardiology is required for operators who completed fellowship training after 1993 and is strongly recommended for all operators. After the first certification, ongoing recertification by either ABIM or NBPAS is also strongly recommended. Utilization of national benchmarking and self-assessment tools such as the NCDR registries, hospital or CCL quality data, and patient satisfaction data is highly encouraged. Physician and CCL staff membership in professional societies such as SCAI and the American College of Cardiology (ACC) is highly encouraged. CCL staff should obtain, at a minimum, the continuing education units as required by the respective state. Physicians should also complete appropriate continuing medical education and/or maintenance of certification hours/points to satisfy hospital, state, and board regulations.

4 | PRE-PROCEDURE BEST PRACTICES

4.1 | Procedure indications and history and physical examination

Procedural indications should be well documented and reconciled with published appropriate use criteria (AUC). Key variables (e.g., anginal class and medication use) must be documented to confirm appropriateness.^{16,17} An on-line application is available to assist in this process.¹⁸ Supporting data, such as a pre-procedure electrocardiogram (ECG), prior cardiovascular procedures or surgeries, echocardiography, coronary computed tomography (CT) angiography, and/or stress testing results should be described.¹⁶ For procedures with “rarely appropriate care” ratings, additional documentation should be included to explain why the procedure is appropriate for the particular patient.

All patients must have a history and physical examination (H&P) prior to the procedure, performed by either a physician or an advanced practice professional (APP) (e.g., PA or nurse practitioner). For emergency procedures, a targeted history and limited physical examination are reasonable, with more complete information added following the procedure. For outpatient procedures, a timed and dated H&P within 30 days or according to local hospital policy is acceptable, with a focused update by the attending physician or APP within 24 h prior to the procedure. This update should reflect any changes in history, physical examination findings, test results, or

medications. For inpatients, an H&P should be performed within 24 h of admission or registration. This H&P should include the history of the present illness along with Canadian Cardiovascular Society angina and New York Heart Association heart failure classes as appropriate, documentation of relevant medications, including those received within the last 48 h, relevant comorbidities, and a focused review of systems, concentrating on the systems encountered during cardiac catheterization. Any history of contrast reaction or other allergies should be documented, including the specific reaction. Potential issues related to antiplatelet or anticoagulant therapy, such as a concomitant requirement for long-term oral anticoagulation, and barriers to long-term dual antiplatelet therapy (DAPT) adherence should be noted. The history should note any prior airway or moderate sedation issues.

The physical examination should be focused on the cardiopulmonary and vascular system and document peripheral pulses.^{19,20} In addition, because the patient may undergo sedation, airway assessment should be performed as described below. Orthopedic, neurologic, or other conditions that might impact the performance of the procedure (e.g., an inability to remain supine) should be noted.

4.2 | Informed consent process

Informed consent (IC) is a legal, patient-oriented process. The patient must be competent and voluntarily provide consent; otherwise, a person with power of attorney may act as a surrogate. Any barriers to understanding should be evaluated and addressed, such as language, health literacy, and cultural issues.²¹ A patient who has been sedated is not considered competent to provide IC. IC is necessary before every procedure and is consistent with the ethical principles of patient autonomy.²² Each institution should have a written policy on IC that describes the process used to obtain consent, including timing, documentation, and surrogate decision-maker issues, as well as circumstances that would allow for exceptions to obtaining IC, such as emergency STEMI in a patient unable to provide consent.

Ideally, the IC process should include a shared decision-making discussion prior to arrival in the CCL and IC itself should be performed in a neutral environment. According to the 2012 ACC/SCAI Expert Consensus Document on Cardiac Catheterization Standards Update, “the written informed consent may be obtained by trained secondary operators or APPs, but the major concerns should be reiterated when the primary operator discusses the procedure with the patient.”²³ The IC discussion should be in the patient's native language, using terms that allow a layperson to understand what the procedure entails; the risks, benefits, and alternatives to the procedure proposed, including the risks of alternative or no treatment; and potential outcomes and complications that may occur during and after the procedure.^{24,25} For procedures occurring without onsite surgical backup, or without the ability to perform same sitting coronary intervention, alternatives should also be discussed with the patient during the consent process.

Potential treatments that may result from the findings of a diagnostic procedure (e.g., ad hoc PCI and its attendant risks) should be

reviewed, as well as issues surrounding DAPT and restenosis for coronary interventions. As a discussion of all possible risks may not be possible, the standard is that the risks that a reasonable person would want to know to make a decision regarding the procedure should be discussed, usually defined as the most serious risks (e.g., death, stroke, heart attack, transfusion, vascular injury), the most common risks (e.g., bleeding, defibrillation), and any elevated risks specific to the patient. The consent should also indicate a risk of complications that could result in treatment with emergency procedures or even transfer to another facility in unusual circumstances.

The consent may be obtained within 30 days of a procedure but must be reaffirmed on the day of the procedure and recorded in the medical record. It is important to review institutional policy on timing of the consent document, requirement for a witness, and requirements surrounding documentation of code status. If the patient has a do not resuscitate (DNR) code status, it is important to discuss temporary suspension with the patient or health care proxy and document the terms and duration of the temporary suspension. Ideally all aspects of the IC discussion should be documented, including details disclosed to the patient, questions asked and answered, and persons present during the IC discussion.

4.3 | Pre-procedure risk assessment and decision-making tools

SCAI has developed an online risk calculator (<http://scaipciriskapp.org/porc>) that uses pre-procedural patient information to estimate post-intervention risks for mortality, acute kidney injury, and transfusion. Ideally, risk calculators should be used to estimate pre-procedure risk prior to IC and specific risks should be discussed with the patient and be documented.^{18,26,27} These tools can aid in the IC process by increasing patient knowledge, understanding, and engagement in the decision-making process.^{25,28-30}

4.4 | Sedation, anesthesia, and analgesia evaluation

While some procedures require general anesthesia, including complex valve procedures and complex ablations, moderate sedation/analgesia is frequently sufficient to minimize patient discomfort and anxiety and is usually ordered by the performing physician. The need for moderate sedation can be individualized by the treating physician, and anxiolysis or pain control alone may suffice for coronary artery procedures. The American Society of Anesthesiologists (ASA) has defined a continuum of depth of anesthesia and has established guidelines in this area for the training and credentialing of physicians.³¹ Physicians in the CCL should be credentialed by their hospital for providing moderate sedation/analgesia, typically referred to as “conscious sedation.” Monitoring of the level of sedation, pulmonary ventilation, and oxygenation should be performed during the procedure and documented by the staff. ASA and Mallampati classification as part of the pre-sedation

assessment is required in some hospitals, although there is no direct evidence to support this process in the CCL. For elective procedures, the 2017 guidelines from the ASA are typically followed, although there is growing consensus that they may be too stringent for the CCL. These guidelines recommend that clear liquids may be ingested up to 2 h prior to a procedure and light meals up to 6 h prior to a procedure (and 8 h for heavier meals).³² However, a recent study compared safety and clinical outcomes of a non-fasting strategy as compared to the current standard fasting preparation, and found no difference in clinical outcomes.³³ Further investigation will be required to evaluate this finding as this practice is not yet supported by guidelines. It is important to note that nothing by mouth (NPO) instructions are typically waived for emergency procedures, recognizing some potential increased risk of aspiration.

4.5 | Patient preparation within 48 h and immediate pre-procedure checklist

4.5.1 | Medications

Patient medications should be reviewed with attention to those that could impact the conduct or outcome of the procedure.

Anti-platelet agents

When PCI is planned or anticipated, loading with aspirin 324 mg po (chewed) should be performed before the procedure if the patient is not already on daily aspirin. Loading before the procedure with a P2Y12 inhibitor is reasonable, although there is no evidence that pre-loading decreases ischemic complications compared to loading at the time of PCI or at its conclusion. Delaying P2Y12 loading until anatomy is known may prevent delays if that anatomy demonstrates a need for CABG.

Anticoagulants

When weighing the decision for interrupting anticoagulation therapy, the operator must balance the risk for access site bleeding with risks for ischemic or thrombotic events. This will include assessing the choice of access site, the projected risk of bleeding, the indication for the anti-coagulation, and the urgency and complexity of the procedure. When femoral access is planned, warfarin therapy is generally held until the international normalized ratio (INR) is <1.8, although there is little direct evidence to support this. For femoral access, direct oral anti-coagulants (DOACs) should be discontinued at least 24–48 h before the procedure based on operator perception of bleeding risk.³⁴ DOACs should be discontinued >48 h before the procedure if the GFR is reduced resulting in prolonged half-life. When radial access is planned, similar guidelines are followed, although evidence has shown that PCI with continuation of warfarin is generally safe when using radial access and PCI on warfarin is as safe as a bridging strategy while causing less minor bleeding.^{35,36} Importantly, as radial access is feasible in the majority of cases, a routine strategy of continuing anti-coagulation may also be reasonable, recognizing that non-access site

bleeding may also occur. If radial access fails when anticoagulation has not been discontinued, the procedure may need to be delayed until anticoagulation is normalized. In emergency situations, Vitamin K or fresh frozen plasma may be considered for patients on warfarin and reversal agents can be used for patients taking DOACs.³⁷ There is a growing body of literature in electrophysiology suggesting maintenance of anticoagulation is safe for device placement, generator changes, and in AF ablations to minimize risk of stroke.³⁸

Statins

High dose statins before PCI have a IIA recommendation in the 2011 ACCF/AHA/SCAI PCI guidelines to decrease the incidence of periprocedural MI and therefore should be considered.^{39–41}

Hypoglycemics

Long-acting insulin doses should be held starting the night before PCI. Short-acting insulin doses should be reduced by half on the morning of the procedure. Oral hypoglycemics should be held on the morning of the procedure and metformin should be held for 48 h after the procedure in those at risk of CKD or with contrast-induced nephropathy (CIN).^{23,42} SGLT2 inhibitors and GLP-1 receptor antagonists may have beneficial effects during PCI and are unlikely to cause hypoglycemia, so they should not be held before PCI.^{43,44}

Renin angiotensin blockers

Angiotensin converting enzyme inhibitors and angiotensin receptor blockers can be nephrotoxic and it has become common practice to hold them before catheterization.^{45,46} Withholding these medications may cause hypertension during the procedure, and impact resting hemodynamics, and therefore the decision to hold or continue them should be individualized.

Diuretics

Diuretics are commonly held before PCI to prevent dehydration, which is a risk factor for acute kidney injury. However, in patients for whom determination of accurate steady-state hemodynamics and filling pressures are required, it may be reasonable to continue diuretics.

4.5.2 | Pre-procedural studies

Blood tests

Outpatients should have a complete blood count and metabolic profile within 30 days of the cath lab procedure. Ideally results would be available before the day of the procedure so that the procedure can be re-scheduled if unexpected abnormalities are identified. Patients with baseline renal insufficiency or on chronic warfarin (or liver dysfunction) should have glomerular filtration rate and prothrombin time (PT)/INR respectively checked on the day of the procedure. Routine PT/INR is not needed for healthy patients not taking warfarin. Serum or urine pregnancy testing (beta HCG) must be offered to women of child-bearing age and should be obtained prior to the procedure.⁴⁷

Electrocardiograms

ECG should be obtained within 30 days prior to the procedure and should be repeated on the day of the procedure if there has been any recent change in clinical status.

Chest X-ray

Chest X-rays are not routinely needed before catheterization laboratory procedures but are appropriate if the pre-procedural evaluation suggests pulmonary congestion or new lung pathology.

Prior catheterization laboratory imaging

When available, angiograms from prior procedures should be reviewed along with prior catheterization or CT chest reports to identify problems with vascular access or coronary cannulation and how they were resolved. Records of coronary bypass graft surgeries should be reviewed, with careful attention to details of origin and distal anastomoses of grafts.

4.5.3 | Chronic kidney disease

Patients with baseline renal insufficiency (eGFR <60 ml/min/1.73 m²) and/or elevated risk scores are at increased risk of developing CIN. The only strategies consistently shown to reduce the risk of CIN are hydration and minimizing the contrast dose.^{39,48} Pre-procedure intravenous (IV) hydration with normal saline should be provided in patients at increased risk for CKD if not contraindicated. Administration of N-acetylcysteine does not offer a significant benefit and is no longer recommended.^{39,48,49} In addition, the total contrast dose should be monitored, and risk scores can be helpful in identifying a suggested limit.^{27,50} One tool uses the ratio of contrast volume to creatinine clearance (CrCl), with a ratio of contrast volume/CrCl >3.7 as predictive of renal injury.^{50,51} In addition, particularly for those with compromised renal function, a strategy of recording the left ventricular end diastolic pressure and using it to guide fluid administration during the procedure should be considered.⁵² Recent literature suggests that optimal use of intracoronary imaging may reduce contrast dose and is a developing strategy.⁵³

4.5.4 | Allergies

Allergies to latex, contrast, heparin (and history of heparin-induced thrombocytopenia), aspirin, narcotics, anti-platelet agents, and other medications should be reviewed, and type of allergy documented. If an allergy is present, avoidance of the offending agent is the ideal strategy with use of alternatives, such as use of bivalirudin in heparin allergic patients. However, if contrast allergy or aspirin allergy is present, alternatives are limited, and appropriate precautions need to be taken.

Contrast allergies can be addressed with upfront use of steroids though there are no randomized trials, and a small risk remains despite pre-treatment. Each CCL should have a protocol for preventing contrast reactions including the use of oral

prednisone over at least 13 h prior to the procedure (50 mg prednisone at 13, 7, and 1 h prior to procedure) and a protocol for urgent/emergent IV steroid administration.^{39,54,55} For emergent catheterization procedures of patients with a history of prior contrast reactions, a strategy of using an emergency medication preparation followed by immediate catheterization appears to be associated with a very low risk of break-through contrast reactions.⁵⁶ In addition to steroids, diphenhydramine and H2 blockers can be considered.^{57,58} Shellfish allergy is not a predictor of contrast reactions and does not require pretreatment.

If an aspirin allergy is present, an aspirin desensitization protocol should be considered prior to stent placement when possible or after emergency placement with consideration of an IV antiplatelet agent in the interim.⁵⁹ Alternatively, non-aspirin monotherapy using oral P2Y12 inhibitors may be considered but large trials of this approach are lacking and this approach is not well studied.⁶⁰

4.6 | Considerations for the choice of vascular access

It is recommended that all operators develop and maintain competency in both radial and femoral arterial vascular access, and that vascular ultrasound should be available for universal use. Several randomized controlled trials have demonstrated better vascular and bleeding outcomes with radial as compared to femoral access, particularly when performing PCI in the setting of ACS, and therefore many CCLs have adopted a radial-first approach when feasible. In addition, the specific choice of right- versus left-radial access should depend upon variables such as the age and height of the patient (higher incidence of right subclavian tortuosity in older and shorter patients), the presence of hemodialysis fistula grafts, the presence of internal mammary artery bypass grafting that would favor ipsilateral radial access, or any information about difficulty occurring during a prior procedure.¹⁹ In patients in whom femoral access is being considered, careful assessment of prior history of peripheral arterial disease that may impact femoral access should be made, along with assessment of bleeding risk. Ultrasound guidance should be considered to decrease bleeding complications. A useful reference is the SCAI Vascular Access, Management, and Closure: Best Practices Manual.⁶¹ Considerations for dual arterial access for chronic total occlusion procedures requiring dual coronary injections and large bore access for hemodynamic support also require careful planning of the route of access site(s) based on the size of catheter required.

5 | INTRA-PROCEDURE BEST PRACTICES

5.1 | Patient preparation in the procedure room

Upon arrival to the procedure room, the pre-procedure checklist (Table 1) should be reviewed by a member of the clinical team. If a

checklist was not performed, a thorough review of the medical record, including documentation of NPO status and duration, access site concerns, allergies, results of blood tests, recent medications (such as heparin and other anticoagulants), advance directives, IC, and living wills must occur. All these items must be documented in the medical record prior to the procedure or as part of the checklist mentioned above. NCDR-related (or equivalent) preprocedural information should be entered into the electronic health record by the CCL staff member monitoring the case with confirmation by the attending physician as needed for accuracy. Noninvasive hemodynamic and oximetric monitoring of patient vital signs should be routine. Defibrillation pads should be placed on all STEMI patients and those at increased risk of cardiac arrest. CCL staff should ensure that at least one working IV is in place prior to the start of the procedure. The plan for the vascular access site should be discussed with the physician operator and the site(s) prepared accordingly.

5.2 | Sedation, anesthesia, and analgesia administration and documentation

All patients should have documentation of their suitability to receive moderate sedation according to five classes categorized by the ASA guidelines.⁶² Moderate sedation should be considered for all patients with attention to patient preferences.⁶³ Delivery of oxygen via nasal cannula should be considered for all patients in whom moderate sedation is utilized. A nurse, or provider with equivalent credentials, should be continuously present during administration of sedation to monitor for side effects, hemodynamic or electrical instability, and changes in respiration and/or oxygenation. A combination of opioids, such as fentanyl 25–50 mcg, and benzodiazepines, such as midazolam 0.5–2 mg, is most frequently utilized, but dosage should be carefully considered based on age, body size, and comorbidities. Additional doses of sedation should be verified with the approval of the primary operator prior to administration. Reversal agents should be readily accessible. Naloxone 0.4 mg IV can be utilized and titrated to reverse narcotic analgesics, and re-bolus may be required, given its short duration of action. Flumazenil, a pure benzodiazepine antagonist, can be given at a dose of 0.2 mg IV every 1–2 min to a maximum of 1 mg. All drugs must be recorded in a procedure log or electronic record and signed by the attending physician, and such records should be easily accessible, particularly when the patient leaves the CCL.

5.3 | Infection control in the catheterization laboratory

Infectious complications resulting from cardiac catheterization are exceedingly rare; however, best practices for sterile technique are essential. Electric clippers should be used to prepare the femoral access site. A variety of antimicrobial agents are available, and chlorhexidine-based preparations with appropriate time-delayed use are most commonly used due to their demonstrated efficacy.⁶⁴ Patient

TABLE 1 Pre-procedure checklist for cardiac catheterization

Patient name: _____ MRN: _____
Procedure date: _____
<i>Planned procedure:</i>
Diagnostic cardiac catheterization
Diagnostic cardiac catheterization with possible PCI
Percutaneous coronary intervention
<i>History and physical examination:</i>
Elective outpatient procedures:
H&P documented within 30 days? Yes No
Inpatient procedures:
H&P documented within 24 h of admission? Yes No
History of prior PCI or CABG: Yes No
If yes, were reports obtained? Yes No
<i>Allergies:</i>
Contrast: Yes No
If yes, was the patient pre-treated? Yes No
Aspirin: Yes No
If yes, does the patient need desensitization? Yes No
Heparin (HIT) Yes No
If yes, consider alternative anti-thrombotic agents
Latex Yes No
If yes, remove all latex products from procedural use
<i>Medications:</i>
Is the patient taking aspirin chronically? Yes No
Is the patient taking clopidogrel or another P2Y12 inhibitor chronically? Yes No
Did patient take metformin within the past 24 h? Yes No
Did patient take sildenafil (or equivalent) within the past 24 h? Yes No
Did patient receive LMWH within the past 24 h? Yes No
If yes for LMWH, time and dose of last administration:
<i>Informed consent:</i>
Was informed consent obtained per institutional policy and updated on the day of procedure? Yes No
If the patient has DNR or DNI status, is it revoked for the procedure? Yes No
<i>Sedation, anesthesia and analgesia:</i>
Are ASA and Mallampati class documented? Yes No
Is there any contraindication to sedation present? Yes No
<i>Bleeding risk assessment:</i>
Is patient on chronic anticoagulation (e.g., warfarin, direct acting oral anticoagulants)? Yes No
<i>Laboratories and studies:</i>
CBC and basic electrolytes within 30 days (outpatient) or 24 h (inpatient)? Yes No
Was EKG performed within 24 h? Yes No
PT/INR performed within 24 h (for patients on warfarin or with liver disease)? Yes No
Does the patient require pre-procedure hydration? Yes No

Abbreviations: ASA, American Society of Anesthesiologists; CBC, complete blood count; HIT, heparin induced thrombocytopenia; LMWH, low molecular weight heparin.

drapes that adhere to skin around the access site without loosening during the procedure are important. Physicians may use chlorhexidine/ethyl alcohol FDA-approved surgical hand antiseptic solutions, which can be used for the first scrub of the day and all subsequent scrubs. However, a traditional surgical scrub with water and soap is an alternative. Although their efficacy remains unproven it is generally accepted that hats, masks, and gowns should be worn for every invasive procedure. For personnel who will rotate between cath and EP labs, attention must be paid to specific requirements for sterile implantation technique for cardiac implantable electronic devices. Antibiotic prophylaxis is not indicated for routine coronary procedures, but is often used before permanent implantations other than coronary stents and, at some institutions, before vascular closure device (VCD) placement in high-risk subsets, such as immunocompromised individuals or those with diabetes.⁶⁵

5.4 | Radiation exposure and occupational hazards

All CCL procedures should be performed with the goal of keeping radiation doses as low as reasonably achievable and minimizing chronic orthopedic injuries.⁶⁵⁻⁶⁷ All personnel in the room should wear radiation protection, including lead aprons and thyroid shields as well as radiation badges. For team members closest to the radiation source, leaded glasses should be used. Tableside radiation shields should be routinely employed. Staff should be frequently re-educated about radiation safety, including considerations for pregnant patients and staff, and radiation exposure should be carefully monitored. Table 2 summarizes best practices to lower radiation exposure to patients, operator, and CCL staff. A complete description of strategies to reduce radiation exposure to patients and operators is beyond the scope of this article.^{67,68}

CCLs should record total radiation doses in Gray (Gy) in real time and inform the operator when thresholds indicative of potential radiation damage are reached.⁶⁵ Every CCL must develop and conform to a radiation safety policy based on published guidelines.^{69,70}

5.5 | Angiographic contrast administration

Nonionic, low-osmolar contrast (e.g., iohexol, iopamidol, ioversol) should be utilized for most cases. While iso-osmolar contrast agents (e.g., iodixanol) could be considered for patients with chronic kidney disease, data suggest this approach may have no benefit.⁷¹ Total contrast volume administered to the patient must be monitored in real time and limited to as low as clinically possible. In conjunction with a CIN risk score, contrast volume to eGFR ratio >3.7 can be used as an upper limit of acceptable contrast dose during a single procedure to help limit the risk of CIN.^{50,51} CCL staff should inform physicians when these limits have been reached. The use of automated contrast injector systems can be considered over manual devices (i.e., manifold). Automated contrast injector systems have been associated with reduced contrast exposure, risk of acute kidney injury and radiation exposure to operators.⁷²⁻⁷⁴

TABLE 2 Summary of methods to decrease radiation dose and exposure to patient and CCL staff

1. Select low dose settings on fluoroscope, such as lower dose per frame, lower frame rate (4–7.5 fps for fluoroscopy, 7.5–15 fps for cine)
2. Use “Fluoro Save” instead of cine when possible
3. Use collimation to lower radiation dose and scatter to patient and staff
4. Avoid working in steep angles and change working angles to “spread the dose”
5. Raise table height to decrease patient dose, and minimize distance between patient and detector to decrease patient dose and scatter to operator
6. Use lower magnification (example 22 cm FOV instead of 19 cm)
7. Keep patient's extremities out of the beam path and away from the x-ray tube
8. Maintain furthest possible distance from x-ray tube by using long tubing, especially for radial cases, and “taking a step back”. Ensure proper use of moveable lead shields and under-table drapes
9. Consider moveable lead screens to protect CCL staff
10. Consider use of real-time radiation monitoring, radiation protection drapes and robotic PCI to lower operator radiation exposure
11. Regular assessment and upgrading of equipment (hardware and/or software) to minimize radiation dose

Note: Adapted from Fiorilli et al.⁶⁸

Abbreviations: FOV, field of view; fps, frames per second.

5.6 | Universal protocol and “time out” procedure

All team members should understand the intended procedure and the sequence of that procedure. This should be confirmed during a dedicated “time out” protocol, performed before vascular access or moderate sedation is initiated, when all members of the team are present. Patient identification should be confirmed with unanimous agreement on the procedure to be performed. Since the goal is to access the heart and its associated vasculature, “wrong site” procedures are generally not a concern (access to the coronary arteries can be gained via radial, ulnar, brachial, and femoral arteries) and therefore site marking is not indicated for cardiac procedures.^{75,76} Table 3 provides a sample “time out” checklist. If team members rotate out, then it is their responsibility to brief their replacement, who must introduce themselves to the team and announce their role.

Universal infection precaution protocols should be followed by the staff. All solutions on the table must be labeled in real-time (not pre-labeled), including syringes specifically used for lidocaine and other agents (e.g., iodinated contrast). Preprinted labels of common medications should be incorporated into drape kits, and sheets of blank labels and felt-tip markers must also be available as part of the sterile field. For ad-hoc coronary interventions, a “Pre-PCI time out” should be considered, during which there is consideration of: (1) appropriate use classification; (2) radiation exposure and contrast dose; (3) appropriateness or need for intravascular imaging or physiologic assessment; (4) issues regarding dual-antiplatelet therapy; (5) adequate pretreatment with aspirin and P2Y12-receptor inhibitors; and (6) baseline hemodynamics. A pre-PCI time out assumes more importance if

another operator is performing the PCI. For structural heart interventions, procedural-specific considerations should be incorporated into the time out. For example, the time out for TAVR procedures should include valve type, size, implantation angle, and surgical bailout strategy. The implanting physician must ensure proper valve orientation prior to device insertion. Finally, appropriate documentation of the physician's verbal orders needs to be carried out by the recording technologist or nurse and these orders confirmed by the performing physician at the close of the case with a signature.

5.7 | Intraprocedural anticoagulation monitoring

For patients who receive heparin for PCI, an activated clotting time (ACT) should be checked to document adequate anticoagulation. While it is recognized that ACT measurement may lack precision, and there are differences between the two main ACT measurement

TABLE 3 The Joint Commission Standards for the pre-procedural checklist and “time-out”^a

Requirements for the pre-procedure “time-out”

1. The organization determines the exact items to be reviewed in the time-out
2. The time-out procedure is standardized
3. The patient should be involved in the time-out when possible
4. Performed immediately before starting the invasive procedure with all of the immediate members of the procedure team present
5. All relevant members of the procedure team actively communicate during the time-out
6. Team members agree on correct patient identity, procedure to be done, and anticipated access site
7. When the same patient has two or more procedures: If the person performing the procedure changes, another time-out needs to be performed before starting each procedure
8. Document the completion of the time-out. The organization determines the amount and type of additional documentation
9. The procedure is not started until all questions or concerns are resolved

Items typically reviewed during the time-out

1. Patient's identity (name and medical record number or date of birth)
2. Procedure to be performed (e.g., left heart catheterization, coronary angiography, right heart catheterization)
3. Planned primary and backup access site (e.g., right femoral artery)
4. Confirm that the equipment needed, including for potential complications, is available
5. Patient's allergies, pre-medication if appropriate, and recommended maximal contrast dose (e.g., heparin-induced thrombocytopenia, contrast allergy, aspirin, P2Y12 inhibitors)
6. Special laboratory or medical conditions (e.g., elevated INR, chronic kidney disease)
7. Appropriate documentation is completed and available (e.g., history and physical updated within the past 24 h), informed consent form signed

^aConsiderable additional requirements may be imposed by individual institutions. For example, some institutions require a separate conscious sedation informed consent, require all members of the team to introduce themselves during the time-out, or require calculation of a “fire score” to assess the likelihood of a fire arising during the procedure.

devices currently in use (Hemochron and Hemotech), data have suggested decreased thrombotic complications with higher ACT values albeit at some increased risk of bleeding.^{77,78} It is reasonable to target ACT >200 s in the presence of IV anti-platelet therapy, >250 s in the presence of adequate oral anti-platelet therapy, and potentially >300 s in the absence of both.⁷⁷ This should be repeated as appropriate to be sure that the ACT is maintained at or above goal for patients on heparin. A single initial acceptable ACT is used for patients receiving bivalirudin to ensure adequate drug delivery. Results and timing of such testing should be recorded in the procedure log.

5.8 | Procedural data recording

All elements of the procedure should be recorded into an electronic record that documents the procedure and events that took place. The record should contain the patient's vital signs during the procedure, the access site, the time and dosage of medication administration, the ACT values during the procedure, what catheters were used and when, hemodynamic measurements, the target lesion or valve for PCI or structural intervention and equipment that was used, the names of the CCL staff, and whether a closure device was used at the end of the procedure. This record should be immediately available to the staff in the next level of care.

NCDR-specific information (or equivalent) is critical for maintenance of quality standards in the CCL. Accordingly, methods to facilitate the transfer of information collected in the CCL during procedures should be established among physicians and CCL staff. Prior to closure of the case, the physician should be responsible for reviewing all the pre- and intra-procedural data entered for NCDR purposes to ensure accuracy and completeness.

5.9 | Collaboration between interventional cardiology and cardiac electrophysiology

Collaboration between interventional cardiology and cardiac electrophysiology is increasingly commonplace, especially for procedures with complementary skillsets (left atrial appendage occlusion), or when a post-procedure pacemaker is likely (high-risk TAVR). An invasive or interventional cardiologist may be requested in the cardiac electrophysiology laboratory to assist with emergencies, provide angiography, or as a true partnership in select procedures.⁷⁹ Interventional cardiologists may be called to assist by performing coronary angiography to help define the coronary artery anatomy during a catheter ablation procedure, or to assist or provide emergent pericardiocentesis. Epicardial catheter ablations as well as ablations performed at the aortic root may require application of radiofrequency energy close to the epicardial coronary arteries and it is important that the electrophysiologist avoid energy delivery within close proximity of these vessels. Two potential issues arise in these situations: consent and having proper coronary angiographic

equipment in the electrophysiology laboratory. Institutions are encouraged to anticipate this possible need prior to the procedure so that appropriate consent is obtained in advance from the patient as well as having equipment for the interventional cardiologist readily available.

6 | POST-PROCEDURE BEST PRACTICES

6.1 | Direct communication of procedure results

For outpatients, the operator should discuss findings, interventions performed, complications and post-procedure management plans directly with the patient and family. After routine inpatient procedures the operator may discuss these findings or delegate these discussions to the managing physician, but when a complication has occurred it is best for the operator to discuss this directly with the patient and family, making sure that opportunities for additional communication are clearly defined. Discussions with patients should be delayed until cognitive impairment due to sedation has resolved.

Although an invasive cardiologist performs the procedure, noninvasive cardiologists, internists/hospitalists, and nursing personnel can subsequently assume patient care. When the procedural operator is not the managing inpatient physician, it is good practice for the operator to discuss results of the procedure and recommendations for care directly with the managing physician.

6.2 | Procedure report

A procedure report should be generated immediately post-procedure and included in the patient's chart prior to transferring to the next level of care. If a procedure report cannot be placed in the medical record immediately after the procedure, then a brief progress note should be entered with sufficient information for immediate post-procedure care, including the name of the operator, indication and type of procedure, access site and hemostasis method, findings, estimated blood loss, specimens removed if appropriate, complications, post-procedure diagnosis, and initial recommendations. In this instance, a formal procedure report should be completed within 24 h of the procedure and include essential elements mandated by TJC for operative procedures, as well as comprehensive documentation of indications for PCI to satisfy AUC metrics.^{80,81} Since terminology is critical for a quality procedure report, we recommend that key data elements and definitions from the 2013 ACCF/AHA Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients with Acute Coronary Syndromes and Coronary Artery Disease be adopted.^{82,83} For a comprehensive procedure report consistent with CathPCI, we recommend including the additional information outlined in Table 4. The writing committee concurs with the ACC/AHA/SCAI 2014 Health Policy Statement on Structured Reporting for the CCL, which states that a structured report is the optimal format for generating procedure reports.⁸⁴

6.3 | Access site management and closure devices

Hemostasis for radial access site is usually obtained with wristband compression devices. Sheaths are removed immediately after the procedure, regardless of anticoagulation status. The patent hemostasis technique should be used for radial access sites.^{19,61,85–87} Employing evidence-based techniques and establishing standardized institutional hemostasis protocols for radial access sites improves efficiency and patient safety. After recovering from sedation, ambulation is not restricted with radial access, but patients should avoid carrying objects or excess activity of the arm for 2–4 h after sheath removal. Further information is available in a separate expert consensus statement on transradial best practices from SCAI.¹⁹

Manual compression and VCDs may be used for hemostasis after femoral access unless contraindicated. Selection of technique or device should be guided by clinical characteristics and femoral angiography. Unless contraindicated, femoral angiography should be

performed after obtaining access to guide management of vascular access site after procedure and is mandatory prior to VCD placement.^{20,88} While VCDs are noninferior to manual compression with respect to access site complications, infection rates may be higher. Shorter time to hemostasis, earlier ambulation and reduced resource utilization are among the potential advantages.^{20,61,89}

Large bore access or mechanical circulatory support (MCS) require special post procedure considerations with access site management. In cases where MCS is left in place after the procedure, access site assessment should include confirmation of distal limb perfusion with plans for limb perfusion techniques when needed. Proper MCS positioning should be confirmed at the conclusion of the case and the device secured. Post procedure care should be protocolized and include instruction on limb immobilization and patient activity. Large bore vascular access closure can include various techniques including assisted manual compression, suture based or dedicated large bore closure devices and a proximal balloon occlusion technique. Further information and details on large bore vascular access

TABLE 4 Select elements of the procedure report

Element	Notes
Patient demographics	<ul style="list-style-type: none"> Age, gender, risk factors, medications
Primary operator and CCL team members	<ul style="list-style-type: none"> Primary and assisting physician, fellows, nurses, technologists, anesthesiologists
Procedures performed	<ul style="list-style-type: none"> Right/left heart catheterization, PCI, pressure wire, IVUS, OCT, peripheral angiography
Indications	<ul style="list-style-type: none"> Clinical presentation, symptoms, exam findings, prior studies
Access site	<ul style="list-style-type: none"> Specify vessel accessed and if ultrasound used, specify if access was obtained using direct visualization, description of vessel patency, image archiving
Equipment	<ul style="list-style-type: none"> Sheaths, catheters, balloons and other interventional equipment, wires
Drugs and doses	<ul style="list-style-type: none"> Cardiac medications, sedation and amount of fluid administered
Contrast data	<ul style="list-style-type: none"> Type and amount used
Radiation exposure	<ul style="list-style-type: none"> Dose
Complications	<ul style="list-style-type: none"> Clear description of complications, otherwise report “none”
Hemodynamics	<ul style="list-style-type: none"> Computer generated measurements must be verified by the operator. Reports may include initial and end aortic pressure, left ventricular systolic and end-diastolic pressure, valve gradients and areas, right sided chamber pressures, pulmonary artery pulsatility index, cardiac output, cardiac power output, mixed venous saturation, arterial oxygen saturation, shunt data
Left ventriculogram	<ul style="list-style-type: none"> Ejection fraction, wall motion abnormalities, valvular abnormalities
Coronary angiography	<ul style="list-style-type: none"> Detailed anatomy, lesions, variants, size of vessels, collaterals; include graphic if available
Interventional procedures	<ul style="list-style-type: none"> Procedure description including equipment, results and complications. TIMI flow pre- and post-PCI; include graphic if available
IVUS, OCT	<ul style="list-style-type: none"> Indication, artery segment evaluated, vessel diameter measurement and methodology used, plaque morphology, stent expansion, stent apposition, presence of dissection, changes in management
FFR, iFR, RFR	<ul style="list-style-type: none"> Indication, documentation of vasodilator used and route, location of lesion evaluated, results, pullback findings, assessment for drift, interpretation
Method of hemostasis	<ul style="list-style-type: none"> If VCD, comment on whether or not device successful. If hemostasis band used, comment on type of band and use of adjunctive therapy that is, hemostatic disc, gauze, and so forth
Summary of findings, diagnosis and follow up	<ul style="list-style-type: none"> Management plan, admission or observation status, follow up
Communication	<ul style="list-style-type: none"> Report that results and complications were discussed with the patient and/or family, receiving team, consultants and referring provider.

Abbreviations: FFR, fractional flow reserve; iFR, instantaneous wave-free ratio; IVUS, intravascular ultrasound; OCT, optical coherence tomography; RFR, resting full-cycle ratio; VCD, vascular closure device.

management and closure can be found in the SCAI Vascular Access Management, and Closure: Best Practices eBook.⁶¹

6.4 | Appropriate monitoring and length of stay

Patients should be monitored on telemetry in a unit specializing in the care of patients receiving cardiac procedures. Vital signs should be monitored every 15 min for the first 2 h post procedure by personnel trained in recovery from moderate/conscious sedation and access site management. Telemetry is continued throughout the hospital stay, unless specified otherwise by the attending physician. Following PCI, electrocardiography should be performed immediately after the procedure. Length of stay for diagnostic catheterization ranges from 2 to 6 h, depending on the access site used and the nursing assessment of patient ambulation and wellbeing. The length of stay for PCI is dependent on access site complications, patient comorbidities, the need for further procedures or therapy, absence of ischemic symptoms, and absence of new ECG changes or testing.^{90,91} Selected patients after elective PCI should be considered for same-day discharge after appropriate monitoring (usually 4–6 h) and the assessment of discharge readiness following the framework outlined in the SCAI and ACC consensus documents on length of stay and same day discharge following PCI.^{91–93} Select EP procedures may also be considered for same day discharge.^{94–97}

6.5 | Discharge instructions and patient information

At the time of discharge, a summary of the procedure should be provided to the patient and caregivers. If a patient received a stent, a card with the device information should be provided. Routine instructions regarding secondary prevention should be provided (e.g., DAPT, A1c < 7, systolic blood pressure control to <130 mmHg, high intensity statin therapy, threshold for additional lipid lowering therapy, etc.). Limitations on physical activity and driving, which may vary by access site, along with instructions for the follow-up appointment and further tests should be discussed and included with discharge instructions. Patients at increased risk for CIN should have serum creatinine checked within 3–5 days. All patients, especially those having same-day discharge post-PCI, should be given a contact number for questions and/or complications and ideally contacted by a CCL team member within 24–72 h of the procedure to ensure that no complications have occurred, medication adherence is reinforced, and to answer questions.

In cases with radiation exposure greater than 5 Gy, patients should be educated regarding potential skin changes (e.g., erythema) and arrangements for follow up should be made to detect any late radiation damage. For >10 Gy exposure, a qualified medical physicist should promptly calculate peak skin dose with skin examined at 2–4 weeks. TJC considers exposures over 15 Gy a sentinel event for

which hospital risk management and regulatory agencies should be contacted within 24 h.⁹⁸ Suspected tissue injury should be referred to a specialist and a biopsy performed if required.

6.6 | Medication reconciliation

Medication reconciliation and review of appropriate guideline directed medical therapy is necessary before discharge to update all medications, including those deleted or added during the procedure, and must be clearly documented on the discharge instructions and discussed immediately with the referring physician. Bedside delivery of new medications may be helpful. The expected duration of DAPT should be based on current guidelines and documented as part of the medication reconciliation. This should also be discussed with the patient and the importance of adherence stressed. Particular attention should be given to patients requiring “triple therapy” (antiplatelets/anticoagulants), and duration of each medication should be explicitly stated. Due to increased bleeding risk, triple therapy should be maintained for the least amount of time possible (e.g., 1 week to 1 month).⁹⁹ There is growing experience with using a single antiplatelet agent along with oral anticoagulation to minimize bleeding risk and this should be considered.¹⁰⁰ Patients previously on a direct oral anticoagulant can restart the same or next day. Patients previously on warfarin should restart their standard regimen immediately and arrange for follow-up PT/INR within 1 week of discharge. LMWH as a bridge to therapeutic warfarin is not routinely recommended due to the potential for bleeding, except in patients at high risk of thrombosis including those with mechanical prosthetic valves, or recent deep venous thrombosis or pulmonary embolism.¹⁰¹ Metformin should be held for 48 h in those at risk of CKD or with CIN.¹⁰² Proton-pump inhibitors should be considered for patients with prior history of gastrointestinal bleeding or at increased risk of bleeding who are discharged on DAPT, and should be routinely prescribed for all patients on triple therapy.³⁹

6.7 | Appropriate follow-up evaluation

The patient should have a follow-up visit with a provider (physician or APP) who is competent in the management of post-procedure care within 2–4 weeks of discharge. For patients with baseline renal insufficiency, anemia, or procedural complications, follow-up should be earlier, with indicated studies performed prior to or during the visit. It is good practice to assess the access site for symptoms and potential complications. The patient's medical therapy should be assessed for effectiveness, side effects, compliance, and conformity with guidelines. Additional outpatient care should address lifestyle modifications and smoking cessation and reinforce the plan for long-term follow-up based on procedural results.³⁹ All patients following PCI should be referred to cardiac rehabilitation.³⁹

7 | CATHETERIZATION LABORATORY GOVERNANCE

7.1 | Role of CCL medical director and administrative/nursing director or manager

Management of the CCL presents unique challenges due to the volume and complexity of patients treated, the diversity of procedure types, and the multidisciplinary (e.g., anesthesia, surgery) coordination required. In addition, use of advanced and continuously evolving technologies and resultant magnitude of resources required, including complexities of staffing ratios and diversity of necessary skills and expertise must be considered. Ideally, all CCLs should have a physician medical director and an administrative/nursing director or manager working in a dyad partnership and in collaboration with relevant stakeholders, personnel, and hospital administration. Hospital administration is critical to providing requisite resources for the CCL to perform its duties safely and efficiently and within all regulations and policies. These include not only staffing and capital needs but also the personnel required for collection, maintenance, submission, and retrieval of accurate quality data for both internal and external purposes.

An important aspect of CCL governance is keeping senior leadership and administration abreast of the CCL as it pertains to business development, innovation, cost containment strategies, and stakeholder satisfaction, including patients, physicians, and staff, in addition to managing the logistics of the day-to-day operation of the CCL. Ongoing communication is required to align vision and set both attainable and aspirational goals for the CCL, as well as advocate for necessary resources.

The medical director should be a licensed, board-certified invasive or interventional cardiologist with a minimum of 5 years' experience.²³ Likewise, the administrative/nursing director or manager should have a minimum of 5 years' CCL and/or critical care cardiology experience, and administrative expertise to participate in institutional and CCL decision making. The medical director role requires dedicated administrative time, with larger labs requiring more resources, and potentially including a team of other medical, clinical, and administrative/nursing leaders with assigned expertise and responsibilities. In general, for the medical director, a total of one half-day per week is a minimum requirement for administrative time dedicated to the CCL, with larger and busier labs requiring a full day. Medical director administrative time should be compensated by the institution at a level commensurate with the physician's roles, responsibilities, dedicated time, and capabilities and consistent with fair market value. In addition to the primary focus on the CCL, the dyad should meet regularly with stakeholders who interface with the catheterization laboratory to identify their unique needs including but not limited to interventional radiology, heart failure and transplantation, anesthesia, electrophysiology, cardiothoracic and vascular surgery, the emergency department, intensive care unit, operating room, and other relevant areas and teams.

The medical and administrative leadership dyad is responsible for setting an example, assigning respective roles, responsibilities, expectations, and culture for all other medical, clinical, and administrative personnel. Along with other stakeholders, the medical and administrative/nursing leaders are also responsible for developing policies, establishing criteria for granting and renewing privileges, reviewing physician performance, and overseeing clinical and administrative personnel. Additionally, the medical and administrative/nursing leaders should partner with all relevant stakeholders on quality improvement, operational excellence, fiscal performance, patient throughput, personnel recruitment and retention, onboarding, provision of debrief and feedback after adverse events, delegation of authority, and facilitating education and mentorship to all personnel (Table 5). In many cases this takes the form of regularly scheduled meetings that are both informational and feedback-generating from all relevant stakeholders. During these meetings, all aspects of CCL management should be discussed, including but not limited to quality reporting, supplies and equipment, physical plant, staffing, efficiency, policies and procedures, and new research, procedures, and developments.

7.2 | Management of industry relationships

Industry often provides, supports, and/or facilitates meaningful functions, including FDA, CMS or other entity-required proctoring, training and education (particularly for new and/or seldom-utilized technologies, and those where a NCD is applicable), and sharing of best CCL practices. Maintenance of equipment such as imaging or cardiovascular information systems is also often performed by industry, as is real-time clinical support for device use (structural heart procedures, electrophysiologic device implantation). To achieve these objectives, it can be beneficial to have industry interaction with CCL medical and administrative/nursing leadership. Beyond that, there may be value in industry interaction and presence with broader CCL personnel to facilitate the above objectives or more effectively provide clinical care. In addition, in order to ensure sound decision-making for the contracting, use and comparisons between high-value healthcare products, the CCL (especially the medical and administrative/nursing leadership) should collaborate closely to understand supply chain pricing, clinical and operational value of and differences between products.

However, industry influence at the point of care may raise a number of ethical issues and it has been shown that even small gifts may influence physician behavior.^{103,104} Industry representatives in the CCL have been shown to influence use of products, and this effect may be variable among physicians.¹⁰⁵ Accordingly, many institutions set strict limits on the presence of industry.^{106,107} To the extent possible, professional societies, such as SCAI, may be better suited to provide some of the above functions (e.g., trans-radial education; cath lab bootcamp administrative education), when feasible. Organizations representing industry have established codes of ethics to define appropriate interactions between industry and physicians.^{108–110}

TABLE 5 Responsibilities of CCL medical director and the administrative/nursing director or manager**Administrative**

- Co-lead CCL administrative meetings including representatives of pre- and post-procedure areas
- Resolve personnel problems in collaboration with CCL nurse manager
- Attend CCL staff meetings and serve as liaison between CCL personnel and physicians
- Lead administrative meetings of CCL physicians
- Resolve CCL issues among CCL physicians
- Coordinate CCL physician call schedule
- Co-lead (with CCL nurse manager) CCL Quality Committee meetings, including reporting data on NCDR outcomes, M&M conferences, adverse event reports, root cause analyses, Department of Health inspections and TJC or other accreditation body surveys
- Assist CCL nurse manager to prepare for Department of Health and TJC or other accreditation body surveys
- With CCL nurse manager and administration, assist in cost effectiveness and efficiency strategies

Quality improvement

- Oversee QI data collection and reporting processes for NCDR PCI Registry, review quarterly reports from NCDR and communicate with CCL physicians, perform annual review of individual physician data
- Quality review of non-registry procedures (e.g., atrial septal defect closures)
- Arrange for random case reviews and monitor results of reviews
- Ensure review of adverse events either by M&M conference or CCL Quality Committee
- Coordinate/oversee CCL M&M conference, report minutes to appropriate hospital committees
- Co-chair (with CCL manager) CCL Quality Committee responsible for all other aspects of CCL quality, including door to balloon initiatives
- Set criteria for privileging for CCL procedures
- Review physician performance as necessary for bi-annual re-credentialing for procedures

Academic responsibilities

- Oversee (with program director) fellows' CCL rotation, provide evaluations
- Oversee research in the CCL
- Oversee acquisition and launch of new technologies, medications and programs

Abbreviations: CCL, cardiac cath lab; M&M, morbidity and mortality; QI, quality improvement; TJC, The Joint Commission.

General principles regarding industry representatives or clinical specialists in the CCL include the following:

1. Their role in individual CCLs should be consistent with policies set by the hospital, under the oversight of medical and administrative/nursing leadership, in conjunction with other relevant stakeholders.
2. They should not handle equipment in the CCL, except for compliant, defined educational purposes (clinical support), device preparation, and/or maintenance. This is particularly the case for structural procedures but may be relevant to other technologies or techniques.
3. They should always provide information and advice that is in the best interests of the patient, regardless of other considerations.

4. Their presence in the CCL is reasonable when it is helpful to the physician in providing patient care. Hospital policies should not prohibit these interactions. In fact, the complete absence of industry in these settings may be detrimental to patient care and scientific advancement.
5. Their presence in the CCL without specific purpose, (e.g., to "observe"), is of uncertain appropriateness and is discouraged, as is their presence solely for the purpose to enhance sales relative to competitor products.

7.3 | Incorporation of guidelines, new data, and new procedures

The CCL is a dynamic environment shaped by everchanging technologies, guidelines, and clinical data. As such, the entire CCL team, led by the medical and administrative/nursing leaders, should review and regularly update CCL policies and processes to reflect new high-quality evidence-based information and evolving standards of care, and provide appropriate education and training to medical, clinical and administrative personnel. Protocols for new technology or techniques should define the roles of all relevant personnel. When appropriate, related process and/or outcome metrics should be reviewed for continuous quality improvement. A nurse educator is particularly suited to keeping nursing and clinical staff updated and competent in procedures and techniques that are vital yet seldom used, as well as new technologies approved for use. Industry, as noted above, may also serve in this role if abiding by the above principles and supervised by members of the clinical staff.

7.4 | Cost and revenue considerations

Providing the highest value healthcare is a major element of healthcare reform and the medical and administrative/nursing directors should be highly engaged in advancing this objective.¹¹¹ Components of high-value care include appropriateness, efficiency and throughput, reducing complications, and the judicious use of resources. Cost reduction efforts may target CCL operating costs and/or costs of care outside the CCL.¹¹¹⁻¹¹³ Specific recommendations include the following:

1. CCL physicians should collaborate with the medical and administrative/nursing directors to understand and reduce in-lab expenses through consolidation of products, negotiating lower prices, assisting in volume-related discounts and supply-chain management, reduction of turnover times, and minimizing unused open products, procedural time, and overtime pay.
2. When two products differ in cost but not clinical performance, it is reasonable for physicians to preferentially use the most cost-effective, higher value option. Cost reduction efforts should not compromise patient care, but physicians should be aware of the cost consequences of their decisions. Tracking and discussing physician-

- specific cost data (e.g., cost per case) in order to better understand physician-specific variability may be useful, but should be adjusted for relevant factors such as case complexity and should be anonymized outside of directors and hospital administration.
3. The medical and administrative/nursing directors, along with other medical, clinical and administrative stakeholders should have a leadership role and/or participate on hospital technology assessment committees to coordinate access to and acquisition of equipment.¹¹⁴
 4. Leadership should remain up to date on relevant knowledge and evolving strategies to reduce out-of-lab costs and evaluate and/or employ them when appropriate.¹¹⁵ Additionally, novel technology and clinical advancements should be routinely reviewed to determine whether incorporation confers a financial advantage, balancing device and procedural costs with turnaround times, procedural times, hospital reimbursement, as well as indirect benefits such as competitive market share advantage and so-called “halo effects” of innovative technology and techniques.¹¹¹

7.5 | QA and performance improvement: Registry participation, M&M conference and public reporting

Every CCL must have a continuous QA program, which includes appropriate quality registries and, at least quarterly, scheduled conferences comprising QA, case review, and/or M&M conferences. Quality registries may be regional or national and should allow for institution-level and anonymous, operator-specific benchmarking of process and outcome metrics against other operators and institutions. The medical and administrative/nursing directors should have or delegate a leadership role in ensuring these processes. Procedure-based registries are available for cardiac catheterization and PCI, peripheral arterial catheter-based interventions, and transcatheter valve replacement/repair procedures (e.g., ACC NCDR, <http://cvquality.acc.org/NCDR-Home/Registries.aspx>). Outpatient registries (e.g., ACC NCDR PINNACLE) may provide additional pre- and post-procedure data and allow for linkage of follow up with procedural data. Institutions should provide dedicated, trained personnel and/or processes to perform data abstraction, data entry, registry query, and report generation/distribution. Registries should be utilized to monitor operator and institutional volumes and outcomes as well as procedural appropriateness. It is important that when comparing outcomes (e.g., bleeding, CIN, mortality) across operators/institutions that these rates be risk adjusted.^{116–118}

All major CCL and in-hospital complications should be reviewed at an M&M conference, held at least quarterly.¹¹⁹ Cases requiring review may be identified using procedural registries such as those cited above, assuming that data are entered in timely fashion. CCL M&M should be distinct from Clinical Cardiology M&M, as the former may emphasize technical aspects of the procedure. Presentation of more serious events (e.g., death) should take precedence over less serious (e.g., vascular complications) events, and review should occur as soon as feasible after an adverse event has occurred, especially when a preventable cause is suspected. A formal phase of care (pre-procedure, intra-procedure, post-

procedure) analysis is recommended, in which various aspects of care at each stage are critically analyzed and where consensus is reached over preventability of the complication.¹²⁰

The aim of review conference is process of care and outcome improvement; thus, it is critical that the environment remain non-punitive. Ideally, physicians, physician trainees, APPs, nursing, technical staff, and hospital quality representatives should be required to attend. A statement of confidentiality should appear on any material distributed in print or electronically. Applicable state and federal laws should also be cited, and unauthorized disclosure or duplication should be prohibited.

Each CCL should have a quality process or a committee that includes the medical and administrative/nursing directors and representatives of other stakeholders. This committee is responsible for reviewing complications not discussed in M&M conferences and other metrics of CCL quality, such as completion of time-outs, moderate sedation reporting, monitoring accuracy of data reported to registries including those used for public reporting, QA checks of equipment, door to balloon times, and others as required by the hospital, state department of health, and TJC or other accreditation bodies.¹²¹ Procedures for initial credentialing and ongoing practice assessment have been established by TJC, including use of focused professional practice evaluations and ongoing professional practice evaluations, and are well described in the literature.³

Public reporting of PCI outcomes may be mandatory or voluntary depending on institutional location. Public reporting emerged as a method to prompt institutions and providers to improve care delivery and to empower patients to make more informed decisions on healthcare. While controversy exists on the benefits of public reporting without clear data supporting an improvement in clinical outcomes, and an unintended consequence of physician risk aversion, public reporting is now commonplace and anticipated for most CCLs. Performance measures used for public reporting are developed by cardiovascular societies through specific methodology and endorsed by the National Quality Forum. For PCI, these include PCI risk-adjusted mortality, composite therapy with aspirin, P2Y12 inhibitor, and statin at discharge following PCI in eligible patients, and hospital 30-day risk-standardized readmission rate following PCI. There is recognition that risk adjustment is imperfect and methods to address this have been proposed, and in some cases implemented. These include the ability to exclude the highest risk patients, report at the institutional not operator level, extend time interval of accumulated data, present disease related (i.e., acute MI) rather than procedure related mortality, and include variables such as “compassionate use” within models. Public reporting should be supported while physicians and societies remain committed to assuring that relevant data is available to the public and that improvements in outcomes are ultimately realized.^{122,123}

7.6 | Preparedness for high risk, low frequency events: Protocols and simulation drills

Though serious complications are rare, they can have devastating consequences if not addressed in a methodical and timely manner. In

TABLE 6 Examples of high risk, low frequency complications for protocol implementation and simulation drills

Emergency complication topics	Elements to include: (1) Location of diagnostic tools for rapid assessment (2) Activation numbers of key participants (3) Location and inventory of therapeutic tools
Vascular complications	Anticoagulation and antiplatelet reversal protocols Paging protocol for immediate assistance from surgery or an endovascular specialist Protocol for manual compression, blood availability, and immediate invasive angiography to allow balloon tamponade or stenting of bleeding vessel where available (e.g., covered stent) Protocol for obtaining emergency imaging such as non-contrast computed tomography for suspected retroperitoneal bleed or computed tomography angiography to identify bleeding site, as examples Protocol for severe forearm hematoma management
Acute stroke	Protocol for calling stroke alert and activating stroke team (including a neurologist, neurological interventionalist, and access to emergent neuroimaging), including rapid brain imaging protocol Protocol for emergent transfer to institutions for higher level care when appropriate
Emergency pacing	Protocol for emergency transcutaneous and transvenous pacing
Ventricular fibrillation/ Cardiac arrest	Protocol for emergency defibrillation Protocol for obtaining immediate anesthesia care and intubation in CCL Protocol for initiation of standard or mechanical cardiopulmonary resuscitation (e.g., LUCAS device) Protocol for running a code including location of crash cart and roles of key players
Coronary perforation	Protocol for immediate locations of echocardiography machine, supply of covered stents and/or coils and pericardiocentesis kit Protocol for placement of covered stent or coils (including second access site, larger guide catheter, and so forth.) Protocol for obtaining emergency echocardiography Protocol for emergency pericardiocentesis
Contrast reaction	Protocol for emergent treatment of contrast allergy Protocol for emergency treatment of anaphylactic/anaphylactoid reaction including IV fluids, IV steroids, and epinephrine (1 ml 1:10,000 epinephrine IV over 1 min for life-threatening reactions) Protocol for obtaining immediate anesthesia care and intubation in the CCL
Tamponade	Protocol for emergency pericardiocentesis
Sudden cardiogenic shock or cardiac arrest	Protocol for alerting cardiac surgery as needed for emergency CABG or ECMO (i.e., SHOCK TEAM alert, if available) Protocol for obtaining immediate anesthesia care and intubation in the CCL Protocol for emergency IABP, Impella or peripheral ECMO
Emergency transfers	Protocol for transferring patient to the OR for emergency surgical procedure Protocol for transferring patient to another hospital for emergency procedure Protocol for converting procedure to an emergency open procedure in a hybrid cardiac cath lab

addition to emphasizing prevention strategies, it is important to maintain preparedness strategies. Select complications for which specific protocols should be developed are listed in Table 6. Protocols should include how to activate the key participants and the location and inventory of diagnostic and therapeutic tools.

Simulation drills with all team members together should be performed at routine intervals in the CCL to practice response to these high risk, low frequency events, and may be coordinated by the medical and administrative/nursing directors as well as a nurse educator. These simulation drills should include rapid assessment of a complication, activation of emergency protocols as well as mobilization of therapeutic interventions. Simulation centers or simulation-based programs can be engaged to initiate or maintain skills and have been shown to improve team communication and clinical competency outside of the patient care setting. In the case of an actual complication in the CCL, tools such as same-day or next-day debriefing, root-cause analysis, and M&M case reviews should be

implemented to optimize protocol to improve CCL readiness and patient outcomes.

Emergency preparedness protocols may also be required for unexpected circumstances which affect the safety of cath lab personnel and patients or dramatically alter procedural volume. Examples include natural disasters and infectious outbreaks, such as the recent response to the COVID-19 pandemic.¹²⁴⁻¹²⁸

7.7 | Patient experience optimization

Patient experience and satisfaction may impact clinical outcomes. All hospitals participate in a patient survey process that measures patients' perceptions of their hospital care, known as Hospital Consumer Assessment of Healthcare Providers and Systems, (HCAHPS, <http://www.hcahpsonline.org>). HCAHPS is designed and regulated by CMS, endorsed by the National Quality Forum, and results are

TABLE 7 Key techniques for enhancing patient satisfaction in the CCL

Pre-procedure

- Prompt, easy scheduling and pre-admission testing requirements for outpatients
- Minimize or eliminate NPO period before procedure (some institutions allow clear liquids until 2 h before procedure as per ASA guidelines, or no longer require NPO)⁶²
- Pre-procedure patient education tools to aid informed consent
- All outpatient suite and CCL personnel introduce themselves by name
- Update patients when delays are anticipated
- Emphasize comfort and privacy, including of family members
- Respect confidentiality

Intra-procedure

- Careful attention to adequate sedation and pain control during the procedure
- Time out with introduction of all team members to the patients

Post-procedure

- Full explanation of results of procedure to patients and, when appropriate, family
- Prompt food and drink when tolerated after procedure
- Discuss follow-up plans, provide instructions for emergency help after discharge, and provide appointment before discharge
- Provide prescriptions and, if available, important medications prior to discharge
- Follow-up call to answer questions and identify post-procedure problems

publicly available on the website hospitalcompare.hhs.gov. However, these surveys do not directly measure patient satisfaction with CCL services. CCL physicians interested in assessing the CCL patient experience would need to develop and administer a unique survey for this purpose. In this regard, some CCLs assign nurses to contact patients after their procedure to query about complications, follow-up appointments, medication adherence and overall satisfaction with the CCL services, and this process is encouraged and should be adequately resourced.

CCL team members as well as those involved in scheduling and post-procedure care all have the ability to impact the overall patient experience and, thus, overall outcome. Some techniques for enhancing patient satisfaction are listed in Table 7.¹²⁹

8 | CONCLUSIONS

From the patient, physician, physician extender, and hospital or facility perspective, these “best practices” help assure the consistent delivery of high-quality care in the CCL. These measures are critical to patient safety, laboratory efficiency, patient and referring physician satisfaction, as well as CCL governance and economics. Health care systems should provide resources through adequate staffing, equipment, and information technology, inclusive of physician extenders where appropriate, to assure the performance of these practices and their ongoing review.

CONFLICT OF INTEREST

Please see author disclosures in Supplemental Table 1.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

How to cite this article: Naidu SS, Abbott JD, Bagai J, et al. SCAI expert consensus update on best practices in the cardiac catheterization laboratory. *Catheter Cardiovasc Interv*. 2021; 98:255-276. <https://doi.org/10.1002/ccd.29744>

Outcomes and Temporal Trends of Inpatient Percutaneous Coronary Intervention at Centers With and Without On-site Cardiac Surgery in the United States

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IMPORTANCE There are concerns whether percutaneous coronary intervention (PCI) at centers without on-site cardiac surgery is safe outside of a tightly regulated research environment.

OBJECTIVE To analyze the outcomes and temporal trends of inpatient PCI at centers without on-site cardiac surgery in an unselected and nationally representative population of the United States.

DESIGN, SETTING, AND PARTICIPANTS A national inpatient sample (N = 6 912 232) was used to identify patients who underwent inpatient PCI in the United States from January 1, 2003, to December 31, 2012. Hospitals that performed 1 or more coronary artery bypass graft surgeries in a given calendar year were classified as centers with on-site cardiac surgery, and weighted sampling of all inpatient hospitalizations was performed. Data analysis was performed from February to May 2016.

EXPOSURES Inpatient PCI.

MAIN OUTCOMES AND MEASURES In-hospital mortality.

RESULTS Of the 6 912 232 inpatient PCIs performed, 2 336 334 patients (33.8%) were women and 4 575 898 (66.2%) were men; their mean (SD) age was 64.5 (12.3) years. Of these PCIs, 396 741 (5.7%) were conducted at centers without on-site cardiac surgery. The rate of in-hospital mortality was significantly lower at centers with on-site cardiac surgery compared with centers without on-site cardiac surgery (1.4% vs 1.9%; unadjusted odds ratio [OR], 0.74; 95% CI, 0.72-0.75). After adjustment, there was no significant difference in in-hospital mortality between centers with and without on-site cardiac surgery (OR, 1.01; 95% CI, 0.98-1.03; $P = .62$) for acute coronary syndromes and elective procedures requiring inpatient hospitalization. In addition, there were no significant differences in the risk-adjusted, in-hospital mortality between the 2 groups in prespecified subgroups after adjusting for multiple comparisons, including ST-elevation myocardial infarction (OR, 0.99; 95% CI, 0.96-1.03; $P = .65$), non-ST-elevation acute coronary syndrome (OR, 0.99; 95% CI, 0.93-1.05; $P = .66$), and elective PCI (OR, 0.93; 95% CI, 0.84-1.03; $P = .17$). There was a significant increase in the proportion of PCIs at centers without on-site cardiac surgery within the study period (from 1.8% to 12.7%; $P < .001$ for trend by Cochran-Armitage test) reflected across all the indications.

CONCLUSIONS AND RELEVANCE There was a 7-fold increase in the proportion of PCIs at centers without on-site cardiac surgery from 2003 to 2012 in the United States, with the adjusted in-hospital mortality after inpatient PCI being similar at centers with and without on-site cardiac surgery. These data provide evidence that PCI at centers without on-site cardiac surgery may be safe in the modern era.

JAMA Cardiol. 2017;2(1):25-33. doi:10.1001/jamacardio.2016.4188
Published online November 23, 2016.

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Percutaneous coronary intervention (PCI) centers without on-site cardiac surgery (CS) backup were established to reduce the door-to-balloon time and increase the availability of primary PCI. Small single-center studies,¹ registry-based studies,²⁻⁴ and meta-analyses^{5,6} have reported no significant differences in the rate of in-hospital or long-term mortality after primary PCI at centers with and without on-site CS. Randomized clinical trials concluded that nonprimary PCI at centers without on-site CS was noninferior to PCI at centers with on-site CS.^{7,8} However, these trials represent highly selected patient populations and excluded a large number of high-risk patients.

A previous study reported an increase in the number of PCIs performed at centers without on-site CS from 2001 to 2004 in the United States.⁹ More recently, data from the United Kingdom showed an increase in the number of PCIs at centers without on-site CS from 2006 to 2012.³ A similar increase would be expected in the United States as well^{10,11}; however, to our knowledge, no study has evaluated these trends in the contemporary era.

The objective of this study was to analyze the safety and dissemination of PCI at centers without on-site CS outside of a tightly regulated research environment in the United States. We utilized the National Inpatient Sample (NIS)¹² database to assess the outcomes and temporal trends of PCI at centers with and without on-site CS in the United States from January 1, 2003, to December 31, 2012.

Methods

Data Source

The NIS is the largest publicly available all-payer database of hospitalized patients in the United States and is sponsored by the Agency for Healthcare Research and Quality as a part of the Healthcare Cost and Utilization Project.¹² The NIS includes deidentified data on primary and secondary discharge diagnoses and procedures from more than 7 million hospitalizations annually. The NIS database covers all nonfederal US hospitals (excluding rehabilitation and long-term acute care hospitals) in the participating states (n = 44) and represents more than 95% of the US general population. The NIS does not include robust data on interhospital transfers; thus, the number of patients who were transferred from centers without on-site CS could not be determined. Data quality assessments are performed annually to maintain internal validity of the database. Furthermore, estimates from the NIS database have been externally validated against data from the American Hospital Association Annual Survey Database, the National Hospital Discharge Survey, and the Medicare Provider Analysis and Review inpatient data from the Centers for Medicare & Medicaid Services.¹³ Further sampling details are presented in the eMethods in the Supplement. This study was deemed exempt by the institutional review board guidelines of Mayo Clinic and New York Medical College because the NIS is a publicly available database that contains deidentified patient information.

Study Population

From 2003 to 2012, a total of 79 185 729 records were included in the NIS, corresponding to a national estimate of

Key Points

Question Is percutaneous coronary intervention safe at centers without on-site cardiac surgery?

Findings In this cross-sectional study of 6.9 million percutaneous coronary interventions performed in the United States from 2003 to 2012, there was no significant difference in the adjusted in-hospital mortality between centers with and without on-site cardiac surgery.

Meaning Percutaneous coronary interventions at centers without on-site cardiac surgery may be safe for all indications.

388 442 328 hospital discharges in the United States. We used the *International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM)* procedure codes 00.66, 36.01, 36.02, 36.05, 36.06, 36.07, and 17.55 to identify all patients 18 years or older who underwent PCI (n = 6 914 256). The use of the NIS database for PCI numbers in the United States has been validated by Epstein et al,¹⁴ who reported a mean difference of only 0.2% in quarterly PCI counts between Medicare claims and the NIS. Patients with missing data on in-hospital death, length of stay, or both (n = 2024) were excluded, giving us our final study cohort of 6 912 232 (eFigure 1 in the Supplement). Hospitals that performed 1 or more coronary artery bypass graft (CABG) surgeries (*ICD-9-CM* code, 36.1 × for CABG) in a given calendar year were classified as centers with on-site CS. All other hospitals that did not perform any CABG in a calendar year were classified as centers without on-site CS.

Patient and Hospital Characteristics

The following patient characteristics were extracted from the NIS database: demographics (age, sex, race, primary expected payer, admission day, and median annual household income), clinical risk factors associated with increased mortality in patients undergoing PCI (smoking, dyslipidemia, family history of coronary artery disease, prior myocardial infarction [MI], prior PCI, prior CABG, atrial fibrillation, and carotid artery disease),^{15,16} and 29 Elixhauser comorbidities. The Elixhauser comorbidity index is a validated measure of comorbidities in large administrative databases as defined by the Agency for Healthcare Research and Quality.^{17,18} Patients undergoing PCI for acute coronary syndromes (ACSs) were identified using respective *ICD-9-CM* codes for ST-elevation myocardial infarction (STEMI) and non-ST-elevation ACS (NSTEMI-ACS). Those without diagnosis codes for ACS were presumed to have undergone elective PCI for stable ischemic heart disease. The *ICD-9-CM* codes and Clinical Classification Software codes used to identify patient and procedural characteristics are provided in eTable 1 in the Supplement.

Outcomes

The primary outcome was all-cause, in-hospital mortality defined as *died* in the NIS database. Secondary outcomes were hemorrhage requiring blood transfusion, transient ischemic attack or stroke, vascular complications, and mean length of stay. The *ICD-9-CM* codes used to identify these conditions are provided in eTable 1 in the Supplement.

Statistical Analysis

Weighted estimates were obtained by applying trend weights to the unweighted discharge data and were used for all statistical analyses. Between-group differences were analyzed using Pearson χ^2 test for categorical variables and *t* test for continuous variables. To examine differences in in-hospital mortality and in-hospital complications between patients undergoing PCI at centers with and without on-site CS, multivariate logistic regression models were constructed with the use of generalized estimating equations to account for clustering of outcomes within hospitals. Variables included in the regression models were demographics, hospital characteristics, 29 Elixhauser comorbidities, clinical risk factors (smoking, dyslipidemia, family history of coronary artery disease, prior MI, prior PCI, prior CABG, atrial fibrillation, and carotid artery disease), and indication for PCI. Given the positively skewed distribution of length of stay, we used log transformation of length of stay as the dependent variable. All patients were included in primary regression models except those with missing data on primary expected payer (0.1%), socioeconomic status (2.3%), hospital characteristics (0.4%), and Elixhauser comorbidities (0.7%). A sensitivity analysis including the entire study population was conducted for both the primary and secondary outcomes by replacing the missing values for these variables with the dominant category. Race was also included in the sensitivity analysis, and the missing values for race were treated as a separate category in the regression models.^{19,20} A priori subgroup analysis was performed for in-hospital mortality by age, sex, indication of PCI, clinical risk factors, and procedural and hospital characteristics. In the generalized estimating equations models for in-hospital mortality in STEMI and NSTEMI-ACS subgroups, we additionally adjusted for cardiogenic shock.

Temporal trend analyses were performed using the Cochrane-Armitage test. Statistical analysis was conducted using SPSS Statistics, version 21.0 (IBM Corp). All *P* values are 2-sided with a significance threshold $<.05$. For subgroup analyses, the *P* value threshold for significance was $<.002$ after Bonferroni adjustment for multiple subgroup comparisons. Data analysis was performed from February to May 2016.

Results

Patient and Hospital Characteristics

A total of 6 912 232 weighted records of inpatient PCIs were detailed in the NIS database from 2003 to 2012. Of these, 396 741 procedures (5.7%) were performed at hospitals without on-site CS, and 6 515 491 procedures (94.3%) were performed at hospitals with on-site CS. **Table 1** and eTable 2 in the [Supplement](#) summarize the differences in demographics, risk factors, comorbidities, and procedural and hospital characteristics between centers with and without on-site CS. A total of 2 336 334 patients were women (33.8%) and 4 575 898 were men (66.2%); their mean (SD) age was 64.5 (12.3) years.

Centers without on-site CS performed a significantly higher proportion of PCIs for STEMI (34.4% vs 20.0%) and a signifi-

cantly lower proportion of elective PCIs (24.0% vs 37.7%) compared with centers with on-site CS (both $P < .001$). Use of drug-eluting stents, percutaneous ventricular assist devices, and multivessel PCI was significantly higher at centers with on-site CS centers compared with centers without on-site CS (Table 1). A total of 80.7% of the PCIs at on-site CS centers were performed at hospitals doing 400 or more annual PCIs compared with only 9.0% of the PCIs at centers without on-site CS ($P < .001$) (Table 1).

In-Hospital Outcomes

In the overall study cohort, unadjusted in-hospital mortality was lower at PCI centers with on-site CS (1.4% vs 1.9%; odds ratio [OR], 0.74; 95% CI, 0.72-0.75). **Figure 1B-D** presents the unadjusted in-hospital mortality at centers with and without on-site CS by indication of inpatient PCI. However, after multivariate adjustment, there was no significant difference in the rate of in-hospital mortality between centers with and without on-site CS (OR, 1.01; 95% CI, 0.98-1.03) for ACSs and elective PCIs requiring inpatient hospitalization. The incidence of in-hospital transient ischemic attack or stroke was the same in both centers (0.8%; adjusted OR, 1.03; 95% CI, 0.99-1.07). Although the incidence of vascular injury was higher at centers with on-site CS (1.1% vs 0.9%; adjusted OR, 1.31; 95% CI, 1.26-1.35), there was no difference in the incidence of hemorrhage requiring blood transfusion (0.7% vs 0.8%; adjusted OR, 1.02; 95% CI, 0.98-1.06) (**Table 2**). Sensitivity analysis was performed accounting for missing values and showed largely similar results (eTable 3 in the [Supplement](#)). More patients were discharged home at centers with on-site CS (91.2% vs 87.1%), whereas a significantly higher proportion of patients were discharged to either a short-term hospital (0.5% vs 3.6%) or a skilled care facility at centers without on-site CS (3.6% vs 4.4%), respectively ($P < .001$) (eFigure 2 in the [Supplement](#)).

There was an inverse association between procedural volume and in-hospital mortality both at centers with and those without on-site CS (eTable 4 in the [Supplement](#)). Among the centers without on-site CS, patients undergoing PCIs at hospitals with annual volumes of 201 to 400 PCIs annually (adjusted OR, 0.87; 95% CI, 0.82-0.92) or more than 400 PCIs annually (adjusted OR, 0.84; 95% CI, 0.75-0.93) had a significantly lower in-hospital mortality rate compared with hospitals performing 200 or fewer PCIs annually. A similar association between annual PCI volume and in-hospital mortality results was noted at centers with on-site CS (eTable 4 in the [Supplement](#)).

Subgroup Analyses

There was no significant difference in adjusted in-hospital mortality between centers with and without on-site CS for different indications of PCI, including STEMI, NSTEMI-ACS, or stable ischemic heart disease. After adjusting for multiple comparisons ($P < .002$ threshold), in-hospital mortality was similar at centers with and without on-site CS in various subgroups detailed in **Table 3**.

Trends in Proportion of PCIs

Overall, the total number of PCIs being performed annually declined from 776 388 in 2003 to 535 890 in 2012 ($P < .001$ for

Table 1. Descriptive Characteristics of Patients Undergoing PCI at Centers With and Without On-site Cardiac Surgery^a

Variable	On-site CS, No. (%)		P Value
	Without (n = 396 741)	With (n = 6 515 491)	
Demographics			
Age, mean (SD), y	63.5 (12.7)	64.6 (12.3)	<.001
Women	134 099 (33.8)	2 202 235 (33.8)	.27
Race^b			
White	281 108 (81.3)	3 959 772 (79.3)	<.001
African American	25 882 (7.5)	383 769 (7.7)	
Hispanic	18 869 (5.5)	339 231 (6.8)	
Asian or Pacific Islander	6494 (1.9)	106 051 (2.1)	
Native American	1569 (0.5)	25 949 (0.5)	
Other	11 649 (3.4)	177 599 (3.6)	
Primary insurance			
Medicare	185 691 (47.0)	3 343 184 (51.4)	<.001
Medicaid	22 895 (5.8)	347 889 (5.3)	
Private insurance	145 794 (36.9)	2 319 533 (35.6)	
Self-pay	26 474 (6.7)	290 015 (4.5)	
No charge	2268 (0.6)	28 746 (0.4)	
Other	12 157 (3.1)	177 232 (2.7)	
Weekend admission	79 327 (20.0)	944 000 (14.5)	<.001
Median household income, percentile^b			
0-25th	84 002 (21.7)	1 668 666 (26.2)	<.001
26th-50th	109 667 (28.3)	1 684 703 (26.5)	
51st-75th	96 672 (24.9)	1 589 588 (25.0)	
76th-100th	97 299 (25.1)	1 422 102 (22.3)	
Comorbidities^b			
Smoking	150 770 (38.0)	2 114 930 (32.5)	<.001
Dyslipidemia	253 689 (63.9)	4 133 094 (63.4)	<.001
Family history of CAD	35 414 (8.9)	571 399 (8.8)	.001
Prior MI	45 406 (11.4)	843 132 (12.9)	<.001
Prior PCI	63 346 (16.0)	1 181 265 (18.1)	<.001
Prior CABG	21 430 (5.4)	494 604 (7.6)	<.001
Atrial fibrillation	36 619 (9.2)	613 154 (9.4)	<.001
Congestive heart failure	59 202 (14.9)	952 256 (14.6)	<.001
Diabetes			
Uncomplicated	108 694 (27.4)	1 846 124 (28.6)	<.001
Complicated	15 494 (3.9)	232 428 (3.6)	<.001
Hypertension	266 003 (67.0)	4 388 510 (67.9)	<.001
Obesity	50 129 (12.6)	704 226 (10.9)	<.001
Carotid artery disease	5349 (1.3)	104 470 (1.6)	<.001
Peripheral vascular disease	35 251 (8.9)	646 111 (10.0)	<.001
Chronic renal failure	34 222 (8.6)	527 596 (8.2)	<.001
Chronic pulmonary disease	64 181 (16.2)	955 269 (14.8)	<.001

(continued)

trend). Of the total number of PCIs being performed every year, the proportion of PCIs at centers without on-site CS increased significantly from 1.8% in 2003 to 12.7% in 2012 ($P < .001$ for trend). This increase in the proportion of PCIs at centers without on-site CS was reflected in all of the 3 clinical subgroups ($P < .001$ for trend for all) (Figure 2).

Discussion

There are 4 main findings of this study. First, there was a 7-fold increase in the proportion of PCIs being performed at centers without on-site CS from 2003 to 2012 in the United States.

Table 1. Descriptive Characteristics of Patients Undergoing PCI at Centers With and Without On-site Cardiac Surgery^a

Variable	On-site CS, No. (%)		P Value
	Without (n = 396 741)	With (n = 6 515 491)	
Procedural Characteristics			
Stent type			
BMS	112 283 (28.3)	1 587 588 (24.4)	<.001
DES	252 539 (63.7)	4 451 443 (68.3)	
Angioplasty alone	31 919 (8.0)	476 461 (7.3)	
Multivessel PCI ^c	46 186 (13.7)	751 449 (17.7)	<.001
IABP	13 070 (3.3)	190 996 (2.9)	<.001
Percutaneous VAD ^d	108 (0.05)	6668 (0.3)	<.001
Hospital Characteristics^b			
Bed size ^e			
Small	54 776 (13.9)	431 423 (6.6)	<.001
Medium	146 157 (37.0)	1 228 750 (18.9)	
Large	193 948 (49.1)	4 832 143 (74.4)	
Location			
Rural	74 189 (18.8)	290 161 (4.5)	<.001
Urban	320 963 (81.2)	6 202 156 (95.5)	
Teaching hospital	97 456 (24.7)	3 735 961 (57.5)	<.001
Region			
Northeast	70 220 (17.7)	1 225 782 (18.8)	<.001
Midwest	93 638 (23.6)	1 679 488 (25.8)	
South	154 540 (39.0)	2 541 970 (39.0)	
West	78 342 (19.7)	1 068 252 (16.4)	
Annual PCI volume			
≤200	241 983 (61.0)	243 152 (3.7)	<.001
201-400	118 907 (30.0)	1 012 709 (15.5)	
>400	35 850 (9.0)	5 259 631 (80.7)	

Abbreviations: BMS, bare metal stent; CABG, coronary artery bypass grafting; CAD, coronary artery disease; CS, cardiac surgery; DES, drug-eluting stent; IABP, intra-aortic balloon pump; MI, myocardial infarction; PCI, percutaneous coronary intervention; VAD, ventricular assist device.

^aeTable 2 in the Supplement provides the full list of baseline characteristics.

^bData were missing for race in 22.8% of the records, primary insurance provider in 0.1%, socioeconomic status in 2.3%, Elixhauser comorbidities in 0.7%, and hospital characteristics in 0.4%. Data for these variables are reported in records with available information on these characteristics.

^cDiagnostic codes for multivessel PCI were introduced in October 2005; therefore, the proportion of patients undergoing multivessel PCI is reported in data from 2006 onward (n = 335 974 for centers without on-site CS and n = 4 251 682 for centers with on-site CS).

^dDiagnostic codes for percutaneous VADs were introduced in October 2008; therefore, the proportion of patients undergoing percutaneous VAD placement is reported in data from 2009 onward (n = 224 732 for centers without on-site CS and n = 2 055 341 for centers with on-site CS).

^eBed size categories are specific for hospital location and teaching status.

Second, there was no significant difference in the rate of adjusted in-hospital mortality after inpatient PCI between centers with and without on-site CS in the United States. Third, this finding was consistent among patients with ACS, those undergoing elective inpatient PCI, and other prespecified subgroups. Fourth, procedural volume was inversely associated with in-hospital mortality, both at centers with and those without on-site CS.

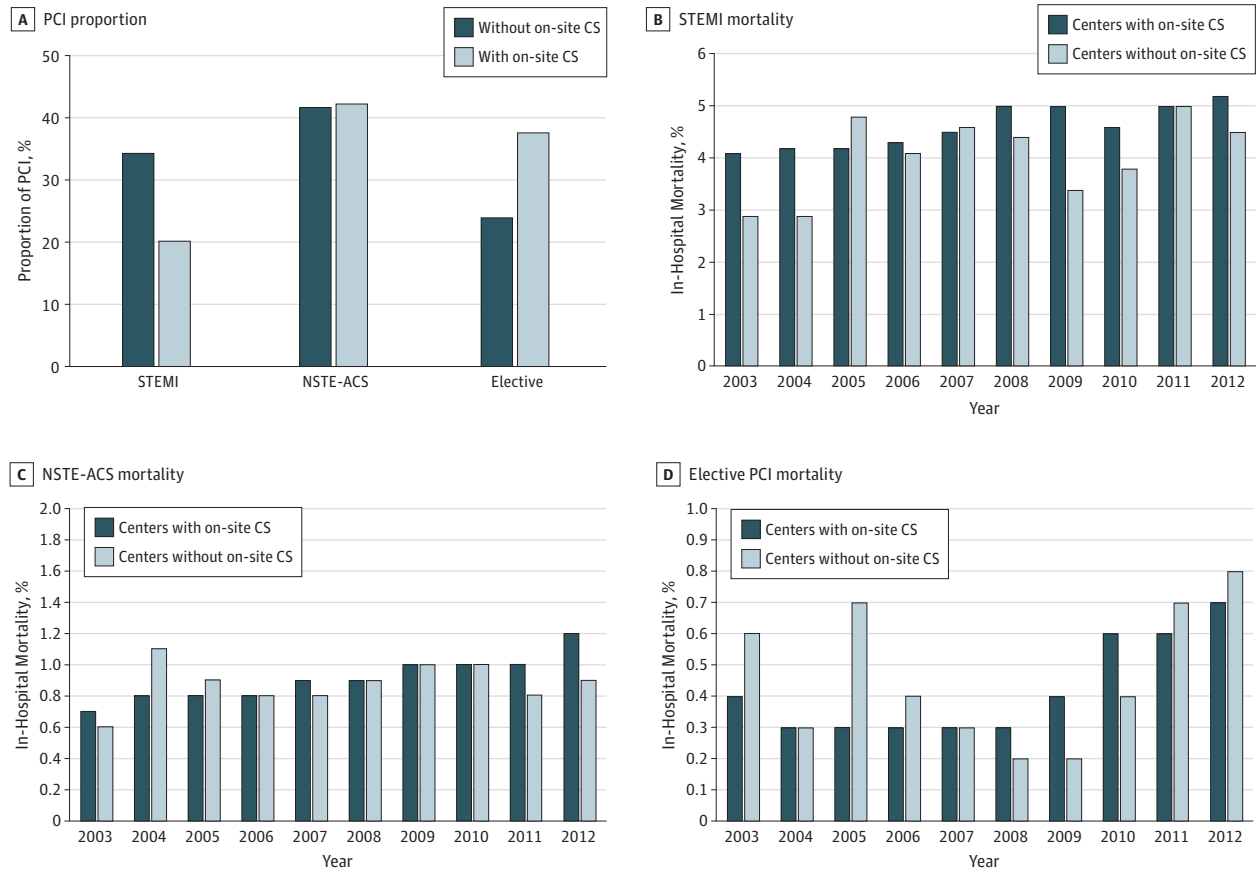
Our study has several strengths. To our knowledge, this is the largest study to date evaluating the in-hospital outcomes of PCI at centers with and without on-site CS including the analysis of 6 912 232 PCIs. Previous evaluations have been limited by small sample sizes,¹ registry-based studies in countries other than the United States,³ or US-based registry studies that evaluated outcomes before 2006 that may not be applicable to the contemporary era.^{4,21} Two randomized trials have been performed in nonprimary PCI patient populations; however, these were highly selected patients and hospitals.^{7,8} The present study provides data from a nationally representative population of patients undergoing PCI in the United States.

In-Hospital Outcomes

The rate of in-hospital mortality in the present study was similar to that of other studies in patients undergoing PCI, thus validating the overall results.^{22,23} Unadjusted in-hospital mortal-

ity was significantly lower at centers with on-site CS compared with centers without on-site CS, with an absolute risk reduction of 0.5%. After adjusting for patient-level, procedural, and hospital characteristics, there was no significant difference in the rate of in-hospital mortality between centers with and those without on-site CS after PCI for ACS or elective PCI requiring inpatient hospitalization. Similar in-hospital mortality after risk adjustment was most likely due to a small absolute risk difference in the unadjusted analysis and a significantly higher percentage of patients with STEMI at centers without on-site CS who had much higher in-hospital mortality rates (4.6%) compared with those undergoing PCI for NSTEMI-ACS (0.9%) or stable ischemic heart disease (0.4%). Our findings are similar to those of previous studies,^{1-8,21} including a recent meta-analysis of 23 studies reporting no difference in the rate of in-hospital mortality for primary and nonprimary PCI between centers with and without on-site CS.⁵ Two randomized trials have evaluated the safety of nonprimary PCI at centers without on-site CS.^{7,8} Approximately one-third of the patients in these trials presented without ACS; however, no subgroup analysis was provided. These trials had stringent criteria for inclusion of centers without on-site CS (eg, hospitals should have been capable of performing >200 PCIs per year and perform >300 diagnostic cardiac catheterizations per year).⁸ In our study, 60% of PCIs at centers without on-site CS were

Figure 1. Proportion of Percutaneous Coronary Interventions (PCIs) and Unadjusted In-Hospital Mortality by Indication of PCI at Centers With and Without On-site Cardiac Surgery (CS)



NSTEMI-ACS indicates non-ST-elevation acute coronary syndrome; STEMI, ST-elevation myocardial infarction.

Table 2. In-Hospital Outcomes of Patients Undergoing PCI at Centers With and Without On-site CS

Characteristic	Without On-site CS (n = 396 741)	With On-site CS (n = 6 515 491)	OR (95% CI)		P Value ^b
			Unadjusted	Adjusted ^a	
In-hospital mortality, No. (%)	7710 (1.9)	93 538 (1.4)	0.74 (0.72-0.75)	1.01 (0.98-1.03)	.62
In-hospital complications, No. (%)					
TIA/stroke	3352 (0.8)	50 158 (0.8)	0.91 (0.88-0.94)	1.03 (0.99-1.07)	.21
Hemorrhage requiring transfusion	3269 (0.8)	47 488 (0.7)	0.88 (0.85-0.92)	1.02 (0.98-1.06)	.28
Vascular injury	3496 (0.9)	72 161 (1.1)	1.26 (1.22-1.30)	1.31 (1.26-1.35)	<.001
Length of stay, mean (SD), d	3.3 (0.01)	3.2 (0.01)	0.94 (0.93-0.94) ^c	1.01 (1.01-1.01) ^c	<.001

Abbreviations: CS, cardiac surgery; OR, odds ratio; PCI, percutaneous coronary intervention; TIA, transient ischemic attack.

^a Adjusted for demographics, hospital characteristics, comorbidities, and indication for PCI.

^b Reported for adjusted comparisons.

^c Unadjusted and adjusted parameter estimates reported for length of stay represent the antilog of the β coefficients ($\exp[\beta]$) obtained from the log-transformed linear regression models.

performed at hospitals with an annual PCI volume of less than 200 and would have been excluded in these trials. The trials also excluded high-risk patients, such as those with ejection fractions of less than 20%, high-risk coronary anatomy, left main disease, or saphenous vein graft interventions. Of the patients who initially provided consent in the Cardiovascular Patient Outcomes Research Team trial, 75% were excluded and the final study population was a low-risk cohort.⁸ Although the

NIS does not have data pertaining to hemodynamics or coronary angiography, it is an unselected population.

The incidence of vascular complications was higher at centers with on-site CS compared with centers without on-site CS, as was noted in a previous study using the National Cardiovascular Database Registry database.⁴ Patients undergoing PCI at centers with CS were older, had more vascular risk factors, and had a higher prevalence of

Table 3. Subgroup Analysis of In-Hospital Mortality at Centers With and Without On-site CS

Subgroup	Died During Hospitalization, No./Total No. (%)		Adjusted OR (95% CI)	P Value ^{a,b}	P Value for Interaction ^b
	Without On-site CS	With On-site CS			
PCI indication ^c					
STEMI	5784/136 624 (4.2)	59 899/1 304 896 (4.6)	0.99 (0.96-1.03)	.65	.39
NSTE-ACS	1466/164 902 (0.9)	24 630/2 754 696 (0.9)	0.99 (0.93-1.05)	.66	
Elective	460/95 213 (0.5)	9009/2 455 899 (0.4)	0.93 (0.84-1.03)	.17	
Age, y ^d					
<75	4034/309 851 (1.3)	51 448/4 966 213 (1.0)	1.06 (1.02-1.10)	.002	<.001
≥75	3676/86 890 (4.2)	42 090/1 549 278 (2.7)	0.94 (0.90-0.97)	.002	
Sex ^d					
Men	4441/262 266 (1.7)	53 384/4 312 486 (1.2)	0.99 (0.95-1.02)	.46	.08
Women	3269/134 455 (2.4)	40 154/2 202 455 (1.8)	1.04 (1.00-1.08)	.08	
Diabetes ^d					
Yes	2392/124 189 (1.9)	28 305/2 129 367 (1.3)	0.94 (0.89-0.98)	.007	<.001
No	5318/272 552 (2.0)	65 233/4 386 124 (1.5)	1.04 (1.00-1.07)	.03	
History of HF ^d					
Yes	3074/59 202 (5.2)	40 245/952 256 (4.2)	1.02 (0.98-1.07)	.30	<.001
No	4636/337 539 (1.4)	53 293/5 563 235 (1.0)	1.00 (0.97-1.04)	.93	
Prior MI ^d					
Yes	522/45 406 (1.1)	6001/843 133 (0.7)	0.92 (0.83-1.03)	.14	.004
No	7188/351 335 (2.0)	87 537/5 672 358 (1.5)	1.01 (0.99-1.04)	.39	
Prior PCI ^d					
Yes	602/63 346 (1.0)	6885/1 181 264 (0.6)	0.99 (0.90-1.09)	.86	.04
No	7108/333 395 (2.1)	86 653/5 334 227 (1.6)	1.01 (0.98-1.04)	.60	
Prior CABG					
Yes	280/21 430 (1.3)	3335/494 605 (0.7)	0.83 (0.72-0.96)	.01	<.001
No	7430/375 311 (2.0)	90 203/6 020 886 (1.5)	1.02 (0.99-1.04)	.29	
Chronic renal failure ^d					
Yes	1496/34 221 (4.4)	18 520/527 596 (3.5)	1.04 (0.98-1.11)	.18	.21
No	6214/362 519 (1.7)	74 417/5 937 080 (1.3)	0.99 (0.97-1.03)	.95	
Procedural characteristic ^{d,e}					
PCI					
Single-vessel	5622/289 788 (1.9)	54 902/3 500 233 (1.6)	1.01 (0.98-1.04)	.53	.18
Multivessel	917/46 186 (2.0)	11 525/751 499 (1.5)	1.11 (1.03-1.20)	.01	
Stent type ^d					
BMS	3298/112 282 (2.9)	36 506/1 587 588 (2.3)	1.04 (0.99-1.08)	.10	.001
DES	2804/252 540 (1.1)	38 013/4 451 442 (0.9)	1.07 (1.03-1.12)	.002	
Angioplasty alone	1608/31 919 (5.0)	19 019/476 461 (4.0)	0.90 (0.85-0.96)	.001	
Hospital bed size ^f					
Small	918/54 777 (1.7)	5365/431 423 (1.2)	1.04 (0.96-1.13)	.33	.19
Medium	2941/146 158 (2.0)	18 065/1 228 750 (1.5)	0.97 (0.93-1.02)	.18	
Large	3817/193 947 (2.0)	69 615/4 832 142 (1.4)	1.03 (0.99-1.07)	.12	
Teaching hospital ^f					
Yes	2199/97 457 (2.3)	52 319/3 735 961 (1.4)	0.95 (0.90-0.99)	.03	.01
No	5477/297 425 (1.8)	40 726/2 756 354 (1.5)	1.05 (1.01-1.08)	.006	

Abbreviations: BMS, bare metal stent; CABG, coronary artery bypass grafting; CS, cardiac surgery; DES, drug-eluting stent; HF, heart failure; MI, myocardial infarction; NSTE-ACS, non-ST-elevation acute coronary syndrome; OR, odds ratio; PCI, percutaneous coronary intervention; STEMI, ST-elevation MI.

^a Reported for adjusted comparisons.

^b Threshold for significance for subgroup analyses was <.002 after Bonferroni adjustment for multiple subgroup comparisons.

^c Risk adjustment performed for demographics, hospital characteristics, and comorbidities in PCI indication subgroups. Additional adjustment was performed for diagnosis of cardiogenic shock in STEMI (8.0% off site vs 8.7% on site, *P* < .001) and NSTE-ACS (1.2% off site vs 1.1% on site, *P* = .03) subgroups.

^d Risk adjustment performed for demographics, hospital characteristics, comorbidities, and PCI indication.

^e Diagnostic codes for multivessel PCI were introduced in October 2005; therefore, subgroup analyses for single-vessel or multivessel PCI were performed in data from 2006 onward.

^f Risk adjustment performed for demographics, comorbidities, and PCI indication.

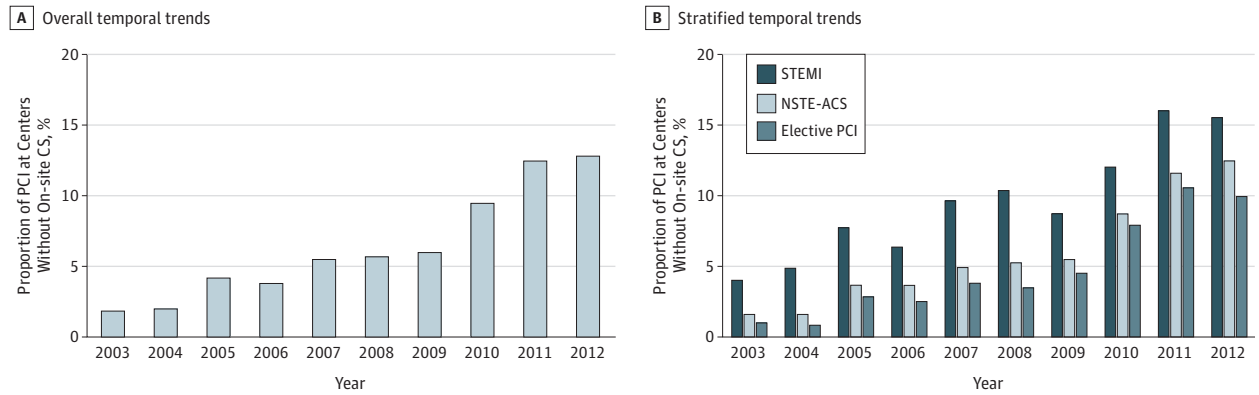
peripheral vascular disease, which could potentially explain this finding. However, the rate of hemorrhage requiring transfusion was similar at both centers.

Trends

A previous study from the US-based National Cardiovascular Database Registry showed that there was a significant in-

crease in the number of elective and nonelective PCIs at centers without on-site CS from 2001 to 2004.⁹ Coronary revascularization has changed significantly in recent years with a decline in the total number of PCIs,²⁴ availability of second-generation drug-eluting stents, and worsening risk profile of patients.^{25,26} However, to our knowledge, no contemporary data are available regarding the performance of PCI at centers

Figure 2. Temporal Trends



A, Temporal trends in the proportion of all percutaneous coronary interventions (PCIs) being performed at centers without on-site cardiac surgery (CS).

B, Temporal trends in the proportion of all PCIs being performed at centers

without on-site CS stratified by indication of PCI. NSTEMI-ACS indicates non-ST-elevation acute coronary syndrome; STEMI, ST-elevation myocardial infarction.

without on-site CS in the United States. We found that there was a significant increase in the proportion of PCIs being performed at centers without on-site CS: from 1.8% in 2003 to 12.7% in 2012. Centers performing PCI without on-site CS were initially developed for the STEMI population to reduce the door-to-balloon time. With experience, the procedural indications have been expanded to include NSTEMI-ACS and elective PCI. Our data show that the highest surge in the proportion of PCIs at centers without on-site CS over the 10-year period was for elective PCIs followed by NSTEMI-ACS and STEMI. Although the proportion of PCI for STEMI was significantly higher than centers with on-site CS, NSTEMI-ACS still constituted the highest proportion of all PCIs performed at centers without on-site CS.

Implications

This large study shows that it is safe to perform PCI at hospitals without on-site CS for STEMI and NSTEMI-ACS. These results have important clinical and policy implications because they are applicable to the general US population requiring acute interventional care. Similar in-hospital mortality in patients with stable ischemic heart disease undergoing elective inpatient PCI should be interpreted with caution because the criteria for inpatient hospitalization at centers with and without on-site CS may be different and are biased by physician opinion, local hospital policies, and patient preferences. We also found that higher procedural volume was associated with lower in-hospital mortality at centers without on-site CS. Therefore, it is imperative to select the appropriate centers that can sustain high volumes for better outcomes. The present study also highlights the importance of using a large administrative database, such as the NIS, to answer relevant clinical questions across different practice sites and clinical presentations in a timely manner.

Limitations

This study has important limitations that are related to the observational design and unavailability of detailed clinical and angiographic information. Data on PCIs that were performed on an outpatient basis were not available because the NIS records only inpatient hospitalizations. The Healthcare Cost and Utilization Project statistical briefs from 28 states (not all states collect these data) reported that the proportion of outpatient percutaneous transluminal coronary angioplasty procedures is low, increasing from 3.2% in 2003 to 11.9% in 2012.²⁷ There is a possibility that the in-hospital mortality rate at the centers without on-site CS might have been underestimated since sicker patients may have been transferred out and recorded as alive during that hospitalization in the NIS database. Based on prior studies, the number of transfers may be less than 0.1% and is unlikely to influence our findings.³ Another limitation of the present analysis is the lack of data on door-to-balloon time in patients with STEMI, procedural success, recurrent ischemia, target vessel revascularization, or long-term follow-up since the NIS includes only in-hospital outcomes.

Conclusions

In this nationally representative US population, there was no significant difference in the adjusted in-hospital mortality after PCI for ACSs and elective procedures requiring inpatient hospitalization between centers with and without on-site CS. Higher procedural volume was associated with lower in-hospital mortality at both types of centers. From 2003 to 2012, there was a 7-fold increase in the proportion of PCIs being performed at centers without on-site CS spread across all indications of PCI. These data provide support for further thoughtful and careful expansion of centers without on-site CS.

ARTICLE INFORMATION

Accepted for Publication: September 14, 2016.

Published Online: November 23, 2016.
doi:10.1001/jamacardio.2016.4188

Author Contributions: Drs Goel and Gupta contributed equally to this study, had full access to all the data in the study, and take responsibility for

the integrity of the data and the accuracy of the data analysis.

Study concept and design: Goel, Gupta, Fonarow, Rihal.

Acquisition, analysis, or interpretation of data: All authors.

Drafting of the manuscript: Goel, Gupta, Rihal.

Critical revision of the manuscript for important intellectual content: All authors.

Statistical analysis: Goel, Gupta, Kolte.

Administrative, technical, or material support: Goel, Gupta, Rihal.

Study supervision: Goel, Rihal.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr Bhatt is a member of the advisory boards of Cardax, Elsevier Practice Update Cardiology, Medscape Cardiology, and Regado Biosciences; a member of the board of directors of Boston Veterans Affairs Research Institute, Society of Cardiovascular Patient Care; chair of the American Heart Association Quality Oversight Committee; a member of data monitoring committees for the Duke Clinical Research Institute, Harvard Clinical Research Institute, Mayo Clinic, and Population Health Research Institute; has received honoraria from the American College of Cardiology as senior associate editor of *Clinical Trials and News*, Belvoir Publications as editor in chief of *Harvard Heart Letter*, Duke Clinical Research Institute as a member of clinical trial steering committees, Harvard Clinical Research Institute as a member of the clinical trial steering committee, HMP Communications as editor in chief of *Journal of Invasive Cardiology*, *Journal of the American College of Cardiology* as a guest editor and associate editor, Population Health Research Institute as a member of the clinical trial steering committee, Slack Publications as chief medical editor of *Cardiology Today's Intervention*, the Society of Cardiovascular Patient Care as secretary/treasurer, and WebMD as a member of the continuing medical education steering committees. He also reported being deputy editor of *Clinical Cardiology* and chair of the NCDR-ACTION (National Cardiovascular Database Registry-Acute Coronary Treatment and Intervention Outcomes Network) Registry Steering Committee and the VA CART (Veterans Affairs Cardiovascular Assessment, Reporting, and Tracking) Research and Publications Committee; receiving research funding from Amarin, Amgen, AstraZeneca, Bristol-Myers Squibb, Eisai, Ethicon, Forest Laboratories, Ischemix, Medtronic, Pfizer, Roche, Sanofi, and The Medicines Company; receiving royalties from Elsevier; serving as a site co-investigator for Biotronik, Boston Scientific, and St Jude Medical; serving as a trustee of the American College of Cardiology; and performing unfunded research for FlowCo, PLx Pharma, and Takeda. No other disclosures were reported.

Disclaimer: Dr Fonarow is the associate editor for Health Care Quality and Guidelines, *JAMA Cardiology* but was not involved in the editorial review or the decision to accept the manuscript for publication.

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Review

Same-Day Discharge After Percutaneous Coronary Intervention

Current Perspectives and Strategies for Implementation

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IMPORTANCE The evolution of percutaneous coronary intervention (PCI) has led to improved safety and efficacy, such that overnight observation can be avoided in some patients. We sought to provide a narrative review of the current literature regarding the outcomes of same-day discharge (SDD) PCI and to describe a framework for the development of an SDD program.

OBSERVATIONS A literature search of PubMed was performed for human studies on SDD PCI published in English from January 1, 1995, to July 31, 2015. We reviewed the studies between June and September 2015. After literature review, we included reports of randomized clinical trials, observational studies, meta-analyses guidelines, and consensus statements in a narrative review. Compared with overnight observation, there was no increase in adverse events (bleeding, repeat coronary procedures, death, or rehospitalization) among patients in these studies who were discharged on the same day of their PCI procedure. Same-day discharge was associated with significant cost savings and was preferred by patients.

CONCLUSIONS AND RELEVANCE The available evidence supports the safety of SDD in selected patients after PCI. Specific programmatic features are important to the successful implementation of SDD after PCI. Greater adoption of SDD programs after PCI has the potential to improve patient satisfaction, increase bed availability, and reduce hospital costs without increasing adverse patient outcomes.

JAMA Cardiol. 2016;1(2):216-223. doi:10.1001/jamcardio.2016.0148
Published online March 30, 2016.

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The primary benefits of same-day discharge after percutaneous coronary intervention (SDD-PCI) are related to improved patient satisfaction, decreased length of hospital stay (LOS), and better resource use of health care dollars. Historically, PCI has been considered an inpatient or short-stay procedure, usually involving up to 24 hours of observation. The clinical basis of this practice is rooted in the short history of PCI when acute ischemic events from abrupt vessel closure or vascular access complications were common and occasionally life threatening. Technological advances, such as systematic stent implantation and improvements in adjunctive pharmacotherapy, have addressed the risk of acute ischemic events.¹⁻³ In this context, a shorter period of postprocedural observation appears reasonable based on published data evaluating short-term outcomes.⁴⁻⁶

The aim of this document is to highlight how SDD-PCI in appropriate patients is the natural next step in the evolution of PCI. Specifically, this article will review the existing literature on this topic, discuss the economic ramifications of this modification

in clinical practice, detail commonly cited barriers to widespread adoption, and provide a framework to develop an SDD-PCI pathway.

Limitations of the Current Consensus Statement

In 2009, the Society for Cardiovascular Angiography and Interventions published the first formal consensus statement attempting to define appropriate use of same-day and outpatient status in the catheterization laboratory.⁷ Using the existing literature, the authors put forth a classification scheme for estimating the appropriate level of care after a successful coronary intervention. Exclusions for SDD-PCI included abnormal renal function, age older than 70 years, insulin-requiring diabetes mellitus, contrast allergy, presence of any chronic comorbidity, multivessel disease, proximal left anterior descending disease, bifurcation disease, left main disease, saphenous vein graft or internal mammary disease, and use of glycoprotein IIB/IIIa inhibitors.

This consensus document has 2 important limitations. First, it conflates the term *outpatient* with *same-day discharge*. *Outpatient*, in this context, refers to a reimbursement classification and is not necessarily based on either the origin of the patient before PCI or the destination of the patient after PCI. It also does not refer to a specific LOS after the procedure. Second, the conservative recommendations would exclude most patients now undergoing PCI regardless of their procedural outcome from SDD. Indeed, the limitations of these exclusion criteria were illustrated in a case series⁸ of 100 consecutive patients discharged safely on the same day as their PCI during a period just predating the publication of the 2009 guidelines.⁷ Only 15% of these patients actually fit the definitions for appropriate SDD, with most having features considered higher risk by the consensus statement.⁸ A priori factors based on age and other preexisting conditions should not necessarily present a barrier to SDD unless those conditions necessitate hospitalization.^{9,10}

Clinical Data on SDD After PCI

Evidence Review

The primary objective of this article is to provide a narrative review of data related to SDD-PCI. A literature search of PubMed was performed for human studies in English from January 1, 1995, to July 31, 2015. We used the terms "angioplasty" or "PCI" and "outpatient," "day-case," "ambulatory," and "same day." We reviewed the studies between June and September 2015. Three of us (A.S., J.K., and S.V.R.) reviewed the results. Randomized clinical trials, observational studies, meta-analyses, and guidelines statement or consensus opinion documents were included. Searches were not limited to specific journals, no formal quality criteria were applied, and formal meta-analytic techniques were not used.

Timing of PCI-Related Complications

The timing of procedural complications is an important consideration in the discharge process. Early complications include abrupt vessel closure (including major side branches), acute stent thrombosis, and access site complications. Delayed complications that might occur several hours after a successful PCI include access site bleeding, non-access site bleeding, development of congestive heart failure, delayed contrast reactions, subacute stent thrombosis, complications related to sedation, and arrhythmias. In a cohort study¹¹ of 450 PCI patients, most complications that would result in delayed discharge were identified within 6 hours of PCI. A larger, higher-risk patient cohort corroborated these earlier findings.¹² Both studies noted that the likelihood of complications occurring beyond 6 hours after PCI, especially during the period of overnight observation, was extremely low.

Randomized clinical trials comparing SDD with overnight observation after PCI have found SDD to be safe (Table). For example, the Elective PCI in Outpatient Study (EPOS)¹⁴ compared SDD-PCI with overnight stay in 800 patients undergoing elective PCI. Same-day discharge after PCI was not inferior to overnight stay with respect to the primary end point of 24-hour death, myocardial infarction, coronary artery bypass surgery, repeat PCI, or puncture-related complications. Overall, 18% of patients in the SDD-PCI group were transitioned to extended stay because of procedural complications, such as acute vessel closure (1%), coronary dissec-

tion (1%), occlusion of major side branch (2%), exchange to guiding catheters greater than 6F (2%), and suboptimal angiographic result (2%). A similar finding was noted in the observational Same-Day TransRadial Intervention and Discharge Evaluation (STRIDE) study¹¹ of patients undergoing transradial PCI.

The Canadian Early Discharge After Transradial Stenting of Coronary Arteries (EASY) Study¹³ randomized patients who had undergone a successful PCI to overnight stay vs SDD-PCI and included 1005 patients (18% with elevated cardiac troponins at baseline), representing a higher-risk cohort. At 30 days¹³ and at 1 year,¹⁸ there was no difference in the composite primary end point, defined as death from any cause, myocardial infarction, unplanned revascularization, major bleeding, access site complications, or rehospitalization. The results suggest that, after a successful transradial PCI, patients could be safely discharged home the same day of their procedure even in a high-risk cohort treated with an aggressive anticoagulation regimen.

In a systematic review and meta-analysis comparing SDD-PCI with overnight stay,¹⁹ the clinical risk profile of patients in the SDD group was similar to that of those hospitalized overnight. No clinically important differences in comorbidities, procedural characteristics, multivessel PCI, high-risk lesions, access site, or use of vascular closure devices were noted between the 2 groups. At 30 days, there were no measurable differences in the incidence of total complications or major adverse cardiovascular events between the 2 groups. These results were subsequently confirmed in a separate meta-analysis.²⁰

Choice of Access Site

The choice of radial or femoral access does not appear to influence the safety of SDD-PCI.^{14,21,22} A large, nationally representative study⁵ from the US National Cardiovascular Data Registry compared patients who had PCI and then were discharged the same day of the procedure with those who were observed overnight. Overall, 1.25% (1339 of 107 018) of eligible patients were discharged the day of the procedure. Femoral access was used in 96% of these cases, and 33% had interventions on high-risk lesions. In-hospital bleeding complications occurred at a similar frequency in both groups (0.37% in the SDD cohort and 0.41% in the overnight stay group). At 2 days and 30 days after the procedure, there were no differences in the incidence of death or rehospitalization between the 2 cohorts. These data demonstrate that SDD-DC is not necessarily dependent on the specific route of vascular access but on ensuring that hemostasis is achieved without vascular or bleeding complications.

In summary, there are considerable peer-reviewed published data showing that SDD-PCI in appropriately selected patients is safe. The overall incidence of bleeding and vascular-related complications is low, and there does not appear to be increased risk of mortality or rehospitalization related to the index procedure.

Economic Impact of SDD

Strategies to safely shorten LOS in selected patients has resulted in cost savings across many procedural specialties. For example, SDD after uncomplicated appendectomy or thyroid surgery has been shown to reduce resource use and costs without compromising

Table. Randomized Clinical Trials Comparing SDD With Overnight Observation After PCI

Source	Location	Sample Size	Access Site	Findings	Time to Discharge	Inclusion Criteria	Exclusion Criteria
Bertrand et al, ¹³ 2006	Canada	1005	Transradial	At 30 d, no difference in the primary composite end point between groups; 88% of patients assigned to SDD were discharged home the same day	4-6 h After PCI	Successful transradial PCI	ST-segment elevation MI within 72 h, ejection fraction \leq 30%, transient vessel closure, hemodynamic collapse during PCI, femoral artery sheath, any other outside consideration precluding SDD, allergy or intolerance to aspirin or thienopyridines, INR $>$ 2.0, and contraindication to abciximab
Heyde et al, ¹⁴ 2007	the Netherlands	800	Transfemoral	No difference in the primary composite safety end point between groups; 19% of patients assigned to SDD were identified for extended observation	4 h After PCI	Elective PCI	Any of the following preprocedural factors: acute MI, unstable angina, ad hoc PCI, catheters $>$ 6F, long-term oral anticoagulant therapy, elective use of glycoprotein IIb/IIIa receptor blockers, residence $>$ 60 min from center, follow-up difficult to obtain, caregiver not present at home, and no transportation. Any of the following angiographic findings or occurrences: occluded coronary artery, suboptimal angiographic result, dissection type C to E, residual dissection after stent implantation, occlusion of major side branch, angiographic thrombus, no-reflow or slow-flow phenomenon, perforation with guidewire, persistent or recurrent chest pain, ECG changes, congestive heart failure, and complicated hemostasis after PCI. During observation period, patient must demonstrate lack of symptoms, absence of ECG changes, and no puncture-site abnormalities
Kim et al, ¹⁵ 2013	United States	298	Transfemoral	At 7 d, patients reported similar coping ability between groups; medication adherence and safety outcomes were also similar; significant patient preference for SDD	3 h After PCI	Elective PCI, age $<$ 75 y, type A or B coronary lesions, and vascular closure device	Recent ACS, \geq 3 stents, femoral access is difficult, site has been used $>$ 2 times in the past, use of anticoagulants other than unfractionated heparin or bivalirudin, suboptimal angiographic outcome or clinical complications during PCI, PCI occurred in something other than a native coronary artery, angiographic evidence of thrombus, INR $>$ 2, and a platelet count $<$ 100 \times 10 ³ / μ L, hematocrit $<$ 25%, occlusion of major side branch during PCI of $>$ 1.5 mm, ejection fraction \leq 30%, known allergy to PCI procedural medications, unable to ambulate with supervision at 4 h after procedure but before he or she is randomized into the study, evidence of vascular complications (eg, dissection, hematoma, or bleeding) pregnancy, periprocedural infection (eg, fever, pus, or swelling), chronic renal insufficiency (eg, serum creatinine level \geq 1.5 mg/dL).
Carere et al, ¹⁶ 2000	Canada	100	Transfemoral	Following PTCA, patients' suture closure facilitated earlier discharge than manual compression (mean [SD], 7.1 [5.3] vs 15.5 [3.9] h); high complication rate in both groups; patients preferred closure	11 h After sheath removal	Elective or urgent coronary angioplasty with or without stenting if the operator believed SDD would be reasonable	Clinical evidence of peripheral arterial disease, preexisting femoral hematoma, serum creatinine level $>$ 1.70 mg/dL, and blood pressure $>$ 180/100 mm Hg
Knopf et al, ¹⁷ 1999	United States	90	NA	NA	NA	NA	NA

Abbreviations: ACS, acute coronary syndrome; ECG, electrocardiogram; INR, international normalized ratio; MI, myocardial infarction; NA, not available; PCI, percutaneous coronary intervention; PTCA, percutaneous transluminal coronary angioplasty; SDD, same-day discharge.

SI conversion factors: To convert creatinine level to micromoles per liter, multiply by 88.4; hematocrit to proportion of 1.0, multiply by 0.01; and platelet count to $\times 10^9/L$, multiply by 1.0.

quality.^{23,24} Similarly, SDD-PCI has the potential to offer economic advantages and substantial cost savings.

Using data from the Canadian EASY Study,²⁵ SDD-PCI was associated with a 50% relative reduction in health care system costs (mean saving, Can \$1141 [US \$1086] per patient). Savings were mainly attributable to a reduction in resource use that accompanies an over-

night stay. European studies have also reported cost savings. For example, savings in the EPOS¹⁴ amounted to approximately US \$350 per patient, while those reported by Le Corvoisier et al¹⁰ were in the range of €1210 (US \$1523) per patient. The differences in cost savings between trials may reflect variations in patient populations, absence of randomization and use of historical controls, radial vs fem-

oral access, and lack of a standard costing methodology between hospitals and countries.

The subgroup of PCI patients who are typically considered for SDD are classified as outpatients with respect to reimbursement. In the United States, federal hospital reimbursement for outpatient procedures (including PCI) falls under the Outpatient Prospective Payment System by the Centers for Medicare & Medicaid Services. For 2015, Medicare reimbursements for an outpatient PCI with 1 or 2 drug-eluting stents (Ambulatory Payment Classification O229 and O319) were US \$9624 and US \$14 841, respectively.²⁶ Under this bundled payment system, strategies that can reduce costs will result in a more favorable economic outcome for the medical center. It has been estimated that the US health care system could save between US \$200 and US \$500 million per year if 50% of the patients undergoing PCI in the United States were discharged the same day.²⁷ It should be noted that the shift of PCI to an outpatient procedure has also shifted some of the cost to the patient, primarily in the form of increased copayments.

While these savings may change as the reimbursement landscape continues to evolve, it is clear that SDD after uncomplicated PCI has the potential to use fewer hospital resources and decrease the intensity of care without compromising safety. In addition, there are indirect cost savings associated with SDD-PCI, such as the potential for reducing medical errors and complications, increasing bed availability for new patients, and cost-savings for medical centers.

Implementation of SDD After PCI

The successful implementation of SDD-PCI relies on 5 essential domains. These include (1) accurate assessment of suitability for SDD; (2) excellent procedural outcomes; (3) rapid and reliable stabilization of the vascular access site, allowing for early and safe ambulation; (4) reliable provision of dual antiplatelet therapy (DAPT); and (5) postprocedural patient education, routine early follow-up, and tracking of outcomes.

Assessment of Suitability for SDD

A number of tools have been developed to help aid in predicting PCI-related risk and mortality based on a combination of clinical, anatomic, and procedural characteristics.²⁸⁻³⁰ Although these models are well studied and validated, they were not developed for low-risk outpatient PCI, nor were they designed to measure the short-term residual risk after a successful PCI procedure. Percutaneous coronary intervention–related mortality risk is primarily driven by clinical acuity, such as urgency of the procedure, presence of shock, advanced symptomatic heart failure, and cardiac arrest within 24 hours—features that are unlikely to be present in patients referred for outpatient coronary PCI. Most of the PCI risk attributable to global risk factor models occurs during the actual PCI procedure, but among patients with an uncomplicated procedure and the absence of unstable clinical features, the residual postprocedural risk appears to be low and clusters primarily around vascular access issues and hemostasis. Factors like frailty, health literacy (understanding the nature of the procedure), and the presence of social support may be more important in determining suitability for SDD-PCI.

Procedural Outcomes

The evolution in PCI equipment (eg, the use of smaller-profile equipment), techniques, and adjunctive pharmacology has led to more reliable acute PCI results, which in turn has allowed for SDD to be considered. In the era before the routine use of coronary stents, the results of balloon dilation were not always predictable and often complicated by vessel dissection, recoil, and acute closure, resulting in myocardial infarction or necessitating urgent or emergent coronary artery bypass graft (CABG) surgery.³¹ With the introduction of coronary stents, acute procedural success became more reliable; however, the aggressive use of antithrombotic therapy and large-bore arterial access increased the risk of vascular access complications and bleeding.^{32,33} At that time, aspirin, dipyridamole, low-molecular-weight dextran, and high-dose heparin were frequently used during and immediately after the procedure while transitioning to dose-adjusted oral anticoagulation therapy. As a result, vascular access site complications were common, and LOS after PCI averaged 5.8 days.

The development of techniques for optimal stent deployment, smaller-profile catheters, and more potent oral platelet inhibitors, along with the use of lower doses of unfractionated heparin, significantly changed the clinical landscape and the need for extended hospitalization after coronary stenting. Studies demonstrated that using DAPT yielded similar rates of stent thrombosis, with fewer vascular complications compared with the dose-adjusted anticoagulation therapy.³⁴ The LOS in the DAPT group was 3.1 days vs 7.4 days in the warfarin sodium–treated group. Ongoing advancements have led to a steady increase in the safety profile of PCI. The most recent data from the National Cardiovascular Data Registry CathPCI Registry show that elective PCI has a success rate of 99.2%, a 0.17% risk of emergent CABG, a 0.47% risk of urgent CABG, and in-hospital mortality of 0.65%.³⁵

Any patient considered for SDD-PCI should have an optimal procedural outcome, defined as a successful PCI (excellent angiographic result, without significant residual stenosis after stenting, and Thrombolysis in Myocardial Infarction 3 flow without dissection or thrombus), no compromise (ie, reduced flow) of a side branch at least 2 mm in diameter, and no postprocedural chest pain. The occurrence of any of these events should prompt consideration of longer postprocedural stay.

Stabilization of Vascular Access

Anticipation of vascular complications related to access site bleeding or vessel disruption has been one of the main drivers of extending the hospital observation period. However, a reduction in vascular access site complications has occurred steadily during the past decade, primarily due to (1) adoption of radial access, (2) refinement of femoral access and sheath removal, (3) reduction in the size of the arterial sheath, and (4) use of vascular closure devices to achieve femoral hemostasis, as well as a combination of these measures.

After transradial access for cardiac catheterization was first reported in a 1989 study,³⁶ Kiemeneij et al³⁷ described its application for PCI. Adoption of transradial access has progressed steadily during the past 2 decades.^{38,39} The primary benefits of radial access include reduced vascular access complications, improved patient comfort, and decreased recovery time compared with femoral access. Several other clinical trials have demonstrated reduced mortality compared with a femoral approach in high-risk patients.⁴⁰⁻⁴⁴

Femoral access has also become safer during the past decade.⁴⁵ Complication rates initially in the range of 3% to 6% have been reduced to approximately 2% in several studies.⁴⁶⁻⁴⁸ Improved safety with femoral access during this time was likely due to refinement in arterial access (including routine fluoroscopy, micropuncture techniques, and ultrasound), development of improved pharmacologic therapy, reduction in sheath size, and changes in sheath removal techniques.⁴⁹⁻⁵³ For example, reducing the French size of the arterial sheath may reduce vascular access-related complications and bleeding by 50%.^{3,54} Although controversy may still exist regarding the safety of vascular closure devices, the available data show that vascular closure devices reduce the time to hemostasis and ambulation compared with manual compression, thus making them attractive when considering SDD-PCI.^{55,56}

Provision for DAPT

Dual antiplatelet therapy is essential after PCI with stents. Its use is a core component in the prevention of stent thrombosis as well as recurrent myocardial infarction. When stent thrombosis occurs, nonadherence to DAPT is commonly cited as a risk.⁵⁷ Patient education surrounding the indication, adverse effects, and duration of DAPT after PCI is an integral activity during the patient's stay. There are several common factors that contribute to nonadherence, including lack of patient understanding of the importance of DAPT, cost, and medical errors, and nonadherence is common after PCI.⁵⁸⁻⁶⁰ Therefore, it is imperative that health care professionals develop a plan to ensure that each patient has a clear understanding of what medications, including DAPT, are to be taken and to facilitate the procurement of the patient's medications, preferably before discharge.⁶¹

Postprocedural Process

Based on the available data, a period of 4 to 6 hours of postprocedural observation appears sufficient. Centers may also need to consider the time of day in the decision to send a patient home the same day as the PCI. Written discharge instructions with definite prompts or teach-backs and pictures can assist patients and families to understand common complications and how to manage them. All of this information should also be provided to patients and their caregivers as enduring content in printed form (eAppendix in the [Supplement](#)). Patients should also be provided with a contact name and number that can serve as a safety net if complications occur overnight. Informed patients will decrease the need for readmission.⁶² All patients must be contacted the following day to assess for complications, address any further questions, and confirm receipt of and adherence to DAPT.

Programmatic Imperatives

In terms of the mechanics of developing the program, the details need to be tailored to each medical center or group of health care professionals. The focus should be on developing a standardized protocol to identify patients with favorable clinical features who undergo successful PCI procedures and have not developed complications during a specified observation period. Based on published data, between 25% and 35% of low-risk PCI patients may not be suitable for SDD.¹³

The Table lists the published, randomized clinical trials as well as their respective inclusion and exclusion criteria. These published articles, in combination with existing guidelines, can serve as a starting point that can be modified to fit the needs of any specific program. The development of this clinical pathway requires the input of several groups within the medical center. Physicians, care extenders, nursing, hospital administration, and recovery unit staff are all stakeholders. Creating a protocol and care pathway with the involvement of these groups will improve the likelihood of a successful program.

As a general principle, patient selection should focus on patients not requiring prolonged observation due to comorbid conditions or particularly high-risk features that could be exacerbated during the PCI procedure. Suitable patients should have an uncomplicated PCI procedure, without requirement for prolonged parenteral antithrombotic agents, and a stable vascular access site. They should be at their baseline level of ambulatory ability at the time of discharge. If complications develop during the recovery period or there is any concern that the patient or his or her social support is unable to provide safe care at home, the patient should remain in the hospital overnight. A clear provision to obtain DAPT, postprocedural education, and follow-up are required elements of an SDD program.

Nursing Perspectives

Preprocedural staff should have an important role in facilitating SDD protocols. Well-developed screening tools established by each institution can assist in the identification of higher-risk patients who will require overnight care or observation or have limited cognitive or social resources. Suitable patients should be targeted to undergo procedures earlier in the day, which will allow recovery or observation to be completed at a reasonable time.

Catheterization laboratory professionals (nurses and technologists) serve as the next step in the care pathway. There may be procedural events that deem otherwise eligible patients to no longer be candidates for SDD. At the completion of the case, the catheterization laboratory personnel should discuss the patient's eligibility and timing for discharge with the attending physician. Dedicated postprocedural order sets will greatly facilitate the remainder of the patient's stay and direct the care efficiently.

Recovery area staff will observe for procedural complications, such as bleeding, access site complications, chest pain, heart failure, and contrast reactions. Before discharge, patients should be at their baseline functional status. Clear discharge protocols and criteria should exist so that caregivers can send patients home efficiently.

Barriers

Change in Traditional Practice Patterns

In the United States, most patients are observed overnight after elective PCI. Therefore, one barrier to adoption of SDD-PCI is physician inertia with respect to changing practice. Because a growing body of evidence suggests a real hazard of hospitalization from adverse events, such as infectious colonization, accidents, drug errors, and

posthospitalization stress syndromes,⁶³⁻⁶⁵ one approach to overcoming this barrier is to realize that the patient may be safer at home than in the hospital. In addition, emerging data confirm a patient preference for SDD.^{15,66-68}

Medicolegal Issues

A recent analysis of malpractice claims against cardiologists identifies that the most common causes of lawsuits involve failure to diagnose conditions, particularly acute coronary syndromes and aortic dissections.⁶⁹ An analysis of cardiac catheterization-related litigation in the United States suggests that most of the legal risk is a direct result of adverse events during the procedures (improper performance), with the outcome of death most likely to result in a lawsuit.⁷⁰ Expected risks of a procedure do not equate to malpractice, but deviations from standard practice expose the physician to a potential lawsuit if an adverse outcome results. Clear communications with the patient and family about the potential risks after discharge and a plan on how to react to an unexpected event, including a safety net, are important measures for both patient safety and the prevention of legal liability.

Other Barriers

In the clinical trials (Table), crossover to overnight admission may have underestimated some of the potential adverse outcomes of SDD. Indeed, some adverse events, such as acute stent thrombosis, could have devastating consequences if they occur outside the

hospital setting. However, clinical judgment is critical to the real-world success of such a program. If there is any concern about an adverse outcome or a suboptimal angiographic PCI result, the patient should not be discharged home. Nonetheless, as with all findings of clinical trials, health care professionals will likely apply the results to a broader patient population than that represented in the trials. A patient may misperceive his or her own risk and medical condition because the procedure (ie, PCI) was short and painless. Patient education and medication review are critical during the recovery period and should be reinforced at subsequent follow-up visits.

Conclusions

Due to advancements in technique, pharmacology, and technology, PCI is much safer and is commonly practiced throughout the world. Length of stay has decreased steadily since the procedure was first introduced, such that most patients are now discharged within 24 hours of their procedure. Although the current practice is to observe patients overnight to monitor for complications, many patients can be safely discharged on the same day of their PCI. In this article, we have assembled the recent scientific literature on this topic and set forth the present opportunities and barriers to implementation of this practice. Promoting early discharge for stable PCI recipients will benefit patients, caregivers, medical centers, and payers. Same-day discharge after low-risk cases is the next step in the evolution of PCI.

ARTICLE INFORMATION

Accepted for Publication: January 27, 2016.

Published Online: March 30, 2016.

doi:10.1001/jamacardio.2016.0148.

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Author Contributions: Dr Shroff had full access to all the data in the study and takes responsibility for

the integrity of the data and the accuracy of the data analysis.

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Study supervision: Shroff, Gilchrist, Bertrand, Rao.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for

Disclosure of Potential Conflicts of Interest, and

none were reported.

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Managing the Shift to Elective PCI in the ASC Setting

Is your interventional cardiology program prepared?

BY TERRI McDONALD, RN, MBA, CPHQ

After years of debating how interventional cardiology should fit into an ambulatory strategy for the cardiovascular service line (CVSL), we must recognize the clear signaling from the Centers for Medicare & Medicaid Services (CMS) of an expectation to provide lower-cost interventional care in the nonhospital ambulatory setting.

In November 2019, CMS issued its final rule on percutaneous coronary intervention (PCI) in the ambulatory surgical center (ASC) setting by approving the addition of six CPT codes to the ASC-covered procedures list for calendar year (CY) 2020 (Table 1).¹ CMS considers these procedures clinically similar to those that do not require an overnight stay and are currently covered under the Outpatient Prospective Payment System (OPPS). As in the hospital outpatient department/facility setting, “additional branch of a major coronary artery” codes are not reimbursed; however, organizations such as the American College of Cardiology (ACC) encourage continued reporting of these services.

In the comment period before the final rule for CY 2020, the ACC and the Society of Cardiovascular Angiography and Interventions (SCAI) offered comments that were generally supportive of PCI in the ASC setting for a limited subset of patients, with some reservations around patient risk stratification, infrastructure, patient safety, and reimbursement.^{2,3}

It’s important to recognize that there are challenges to overcome related to cost, regulation, and reimbursement for the ASC environment. State regulations governing ASCs and PCI in the ASC setting vary across the country, and a new ASC will require 12 to 24 months from concept to fully functional. There are some programs with an existing ASC space where adding imaging equipment is possible. However, even in this scenario, structural renovation may be necessary to accommodate PCI services. Although hospital programs will see a substantial reduction in reimbursement for Medicare patients, many markets will see early adopters enter the ASC space to defend market share in the elective outpatient PCI population. Private payers traditionally follow the lead of CMS in coverage determinations and, predictably, will be quick to do so with PCI. They are also

likely to emphasize the Medicare coverage determination as evidence that care in the ASC setting is safe for cardiovascular care. Programs that have not determined how and when PCI in the ASC setting will fit into their CVSL ambulatory strategy should act now.

BACKGROUND

In the proposed rule for the CY 2020 Medicare Hospital OPPS and ASC Payment System, CMS indicated its intent to redesign the ASC-covered procedures list to “improve physicians’ ability to determine the setting of care as appropriate for a given beneficiary situation.”⁴ In the final rule,

TABLE 1. APPROVED CPT CODES FOR PCI PROCEDURES IN THE ASC SETTING

CPT Code	Descriptor
92920	Percutaneous transluminal coronary angioplasty; single major coronary artery or branch
92921	Percutaneous transluminal coronary angioplasty; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)
92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch
92929	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)
C9600	Percutaneous placement of drug-eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch
C9601	Percutaneous transcatheter placement of drug-eluting intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)

Abbreviations: ASC, ambulatory surgery center; CPT, Current Procedural Terminology; PCI, percutaneous coronary intervention.

CMS notes the success and safety of programs that have performed peripheral vascular intervention procedures in nonhospital ambulatory settings for more than a decade. In its comments to CMS, the ACC referenced the 2014 SCAI/ACC/American Heart Association (AHA) expert consensus statement that addressed the performance of PCI without surgical backup as a source of guidance for performing PCI in an ASC setting.⁵

PROGRAM ASSESSMENT

As CVSL leaders begin to develop a strategy for PCI in the ASC setting, a comprehensive assessment of existing infrastructure and resources is critical—both within the service line and within the larger organization/system.

Operator Experience

CMS previously required ASCs to have a transfer agreement with an acute care hospital, and physicians practicing at ASCs were required to have privileges at the acute care hospital. Both requirements were eliminated in the final rule for CY 2020.

The published guidance in the 2014 SCAI/ACC/AHA expert consensus statement for performing PCI addresses programs that care for ST-segment elevation myocardial infarction and primary PCI.⁵ The recommendations for performing PCI in a setting without surgical backup describe requisite minimum interventional cardiology operator experience, an affiliation with a hospital that performs PCI, and a “working relationship” with cardiac surgeons at another facility who can provide surgical backup in the event of an emergency.

Below are the guidance details for requisite operator experience included in the consensus statement:

- Operators performing PCI in a setting without surgical backup should perform ≥ 50 PCIs annually (averaged over 2 years), including ≥ 11 primary PCIs annually.
- Ideally, the procedures should be in institutions performing > 200 total and > 36 primary PCI procedures annually.

Although patients who will undergo PCI in an ASC will be a lower-risk population collectively, this published guidance should be used as a resource in planning the transition to the ASC setting.

Ambulatory Practice Adaptation: Patient Selection

In the final rule, CMS states the importance of making PCI payable in the ASC setting, acknowledging that “a majority of Medicare beneficiaries may not be suitable candidates to receive these procedures in an ASC setting due to factors such as age and comorbidities.”¹ They note that the decision of whether to furnish services in the ASC setting should be based on the physician’s clinical assessment of the patient’s risk factors.

Processes used in many CVSLs to determine eligibility for PCI in the hospital outpatient setting are often limited to whether an overnight stay will be required. Although this provides a starting point in planning for PCI services in an ASC, a much smaller population of patients will be suitable for it—at least initially. The 2014 consensus statement provides guidance for excluding patients and coronary lesions potentially considered inappropriate for elective PCI in a setting without surgical backup (Table 2). The published guidance may assist programs in planning a formal risk stratification process to guide in assessing which patients are appropriate candidates for care in the ASC setting. Additional clinical considerations, insurance coverage, and socioeconomic factors that may impact same-day discharge (SDD) are also important in determining if the ASC setting is appropriate.

Transradial Access

Transfemoral access has been safely performed and managed in patients undergoing peripheral vascular interventions in the nonhospital outpatient setting for many years. However, planning for the routine use of transradial access in the ASC setting will support better patient experience and reduced postprocedure length of stay. Understanding what percentage of your program’s elective outpatient PCIs are likely to be transradial access versus transfemoral access is important in planning infrastructure, care processes, and patient flow for an ASC setting.

Same-Day Discharge

SDD postprocedure is an obvious need for the ASC setting. This practice has also been safely demonstrated in the nonhospital outpatient setting for peripheral vascular interventions. As a result of being pressured for hospital bed space for years, many CVSLs have made progress toward creating an evidence-based approach for SDD in the low-risk, elective, outpatient PCI population. Planning this process for the subset of lower-risk patients eligible to move to the ASC setting should be easily accomplished.

MEDICARE REIMBURSEMENT

Impact on Elective Outpatient PCI Medicare Rates

In the final rule, CMS estimates that if 5% of coronary interventions shift to the ASC setting in 2020, Medicare payments will be reduced by \$20 million. The impact on the hospital CVSL revenue line is approximately 50% to 60% reduction in Medicare reimbursement per case moved to the ASC setting—roughly, \$6,000 per case (Table 3).

Although more shifts from the hospital outpatient department will result, programs may look to additional strategies for generating revenue in the lower-cost ASC setting.

TABLE 2. PATIENT AND LESION CHARACTERISTICS THAT COULD BE UNSUITABLE FOR NONEMERGENCY PROCEDURES AT FACILITIES WITHOUT ON-SITE CARDIAC SURGERY

High-Risk Patients	Source
Decompensated congestive heart failure (Killip class \geq 3) without evidence for active ischemia	PCI-GL AHA ECD
Recent (< 8 weeks) cerebrovascular accident	
Advanced malignancy	
Known clotting disorders	
LVEF \leq 30%	
Chronic kidney disease (creatinine > 2 mg/dL or creatinine clearance < 60 mL/min)	
Serious ongoing ventricular arrhythmias	
Patients with left main stenosis (> 50% diameter) or three-vessel disease unprotected by prior bypass surgery (> 70% stenoses in the proximal or mid segments of all major epicardial coronary arteries), treatment of any or all stenoses; scoring systems, such as SYNTAX, may be useful in defining the extent of disease and type of revascularization procedure	
Patients with a single target lesion that jeopardizes an extensive amount of myocardium	
Patients undergoing intervention on the last remaining conduit to the heart	
High-Risk Lesions	Source
Unprotected left main stenosis	PCI-GL ECD <i>New</i>
Diffuse disease (> 20 mm in length)	
Extremely angulated segment (> 90%) or excessive proximal or in-lesion tortuosity	
More than moderate calcification of a stenosis or proximal segment	
Inability to protect major side branches	
Degenerated older vein grafts with friable lesions	
Substantial thrombus in the vessel or at the lesion site	
Any other feature that could, in the operator's judgment, impede successful stent deployment	
Anticipated need for rotational or other atherectomy device, cutting balloon, or laser	<i>New</i>
<i>The characteristics listed above identify high-risk patient and lesion features but are not absolute contraindications to performing PCI at a facility without on-site surgery. For example, an elevated creatinine level increases the procedure risk for the patient, but this is not unique to facilities without on-site surgery and treatments to mitigate this complication can be used at all facilities. Ultimately, the operator should consider all factors and make a decision about the suitability of the patient for PCI at the facility.</i>	
Strategy for Surgical Backup Based on Lesion and Patient Risk	Source
High-risk patients with high-risk lesions should not undergo nonemergency PCI at a facility without on-site surgery	PCI-GL
High-risk patients with non-high-risk lesions: Nonemergency patients with this profile may undergo PCI, but confirmation that a cardiac surgeon and operating room are immediately available is necessary	
Non-high-risk patients with high-risk lesions require no additional precautions	
Non-high-risk patients with non-high-risk lesions require no additional precautions. Best scenario for PCI without on-site surgery	
<p>Note: Italics indicates new or modified recommendation in the document.</p> <p>Abbreviations: AHA, American Heart Association; ECD, 2012 expert consensus document on cardiac catheterization standards; PCI-GL, 2011 ACCF/AHA/SCAI PCI guidelines; LVEF, left ventricular ejection fraction; PCI, percutaneous coronary intervention; SYNTAX, Synergy Between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery.</p> <p>Reprinted with permission from Dehmer GJ, Blankenship JC, Cilingiroglu M, et al. SCAI/ACC/AHA expert consensus document. 2014 update on percutaneous coronary intervention without on-site surgical backup. <i>J Am Coll Cardiol.</i> 2014;63:2624-2641.</p>	

Cardiac rhythm management (CRM) procedures. CRM device implants have been approved for payment in the ASC setting for some time. In the fiscal year 2019, payment rates for CRM device procedures improved, making a move to the ASC setting more attractive from a revenue perspective for some programs. However, patient selection requires the same level of detail as PCI.

Peripheral vascular interventions. Approved for more than a decade, physicians have successfully managed device costs to provide lower-cost interventional peripheral vascular care in a nonhospital outpatient setting. This population will be attractive to CVSLs across several physician specialties. Patient selection criteria for the nonhospital ambulatory setting are well established.

REGULATORY AND ACCREDITATION CONSIDERATIONS

To say that regulatory and accreditation considerations for new ASCs are complex would be an understatement. They are subject to numerous, often overlapping, federal and state regulatory requirements. Certificate of Need laws are in flux in several states. Third-party accreditation is required in some states and voluntary in others; it is also highly valued by third-party payers, some of whom have already approved payment for PCI in the ASC setting. The addition of PCI services to an existing ASC will be subject to many of the same regulations. Accordingly, new construction or renovation will require specific state-dependent planning early in the strategic planning process.

STRATEGIC RELATIONSHIPS

Receiving Hospitals and Surgical Programs

Although CMS eliminated the requirement for ASCs to have a transfer agreement with an acute care hospital in the CY 2020 final rule and the risk of untoward events in the patient population is low, a hardwired process to collaborate with a cardiothoracic surgery team is a need in the early transition of PCI services to the ASC setting. In planning the transition, CVSL programs should create a multidisciplinary team to plan for the possibility of urgent transfer for surgical evaluation. The team should include administrative and clinical leaders of the CVSL and ASC, as well as representation from interventional cardiology, cardiothoracic surgery,

cath lab, cardiovascular operating room, transfer services, emergency department, nursing leadership, emergency medical services, and any other representation necessary to plan and execute urgent patient transfer from the ASC for surgical evaluation. Flowcharting the process can provide a simple but consistent guideline, and periodic mock drills may be incorporated into the ASC's quality management program.

Physician Partners

ASC ownership by physicians and hospitals is on the rise. The decision about whether to partner with physicians in a joint venture model is highly market-driven. Because the joint venture model can implicate federal and state antikickback statutes, knowledgeable legal resources are needed in the strategic planning process if physician partnerships will be considered.

Payers

As programs prepare for Medicare patients, commercial payers will have an interest in providing the ASC site of service as a lower-cost option for their beneficiaries. Strategically, CVSL leaders will need to work with finance to exert influence in contracting to the extent possible. Primary considerations will be patient selection criteria and payment rates.

FACILITY AND PERSONNEL CONSIDERATIONS

The 2014 SCAI/ACC/AHA expert consensus statement provides straightforward recommendations for facilities performing PCI without surgical backup (Table 4). Although the document was aimed at hospitals performing PCI without surgical backup, several recommendations are applicable in the ASC setting and others will require consideration. The equipment and inventory of supplies will be developed as the scope of services to be provided in the ASC setting is developed. Adjunct services, such as intravascular ultrasound and fractional flow reserve, will need to be considered within the restraints of cost.

Nursing and Ancillary Personnel

The shift to PCI in the ASC setting brings the additional challenge of nursing and ancillary staffing. When selecting personnel for the ASC lab, experience in a cath lab is highly recommended as part of the minimum competency criteria. Hospital programs are experiencing critical shortages in the cath lab setting, with most programs relying, to some level, on temporary travel staff to serve in registered nurse and tech roles. There will be fewer team members required to staff the ASC program, and without call and weekend responsibilities, positions in the ASC setting will be attractive to experienced members of the hospital cath lab and recovery teams. These factors put the recruitment and

TABLE 3. IMPACT ON ELECTIVE OUTPATIENT PCI MEDICARE RATES	
Site of Service	Estimated Blended Average
Hospital	\$12,000
ASC	\$6,200
Abbreviations: ASC, ambulatory surgical center; PCI, percutaneous coronary intervention.	

TABLE 4. FACILITY REQUIREMENTS FOR PCI PROGRAMS WITHOUT ON-SITE SURGERY

General Recommendations	Source
Requisite support equipment must be available and in good working order to respond to emergency situations.	PCI-GL PCI-CS ML
Should demonstrate appropriate planning for program development and should complete both a primary PCI development program and an elective PCI development program; program developments to include routine care process and case selection review.	AHA D2B
Full support from hospital administration in fulfilling the necessary institutional requirements, including appropriate support services such as intensive care, advanced imaging (CT, MR, and other vascular imaging), respiratory care, blood bank and nephrology consultation with access to dialysis.	PCI-GL PCI-CS ECD
The institution should have systems for credentialing and governing the PCI program. On-site data collection, quality assessment, quality improvement and error management are essential. Each institution must establish an ongoing mechanism for valid and continuous peer review of its quality and outcomes. A quality improvement program should routinely (1) review quality and outcomes of the entire program; (2) review results of individual operators; (3) include risk adjustment; (4) provide peer review of difficult or complicated cases; and (5) perform random case reviews. The review process should assess the appropriateness of the interventional procedures. Evaluation should include the clinical indications for the procedure, technical performance and the quality and interpretation of the coronary angiograms.	PCI-CS AHA PCI-GL ECD
Written agreements for emergency transfer of patients to a facility with cardiac surgery must exist. Transport protocols should be tested a minimum of two times per year involving both the referring and receiving facility. Develop agreements with a ground or air ambulance service capable of advanced life support and IABP transfer that guarantees a transport vehicle will be on-site to begin transport in ≤ 30 min <i>and arrival at the surgical hospital within 60 min of the decision to declare the need for emergency surgery</i> . Tertiary facility must agree to accept emergent and nonemergent transfers for additional medical care, cardiac surgery, or intervention. <i>Tertiary centers should be able to establish cardiopulmonary bypass on emergency transfer patients within < 120 min of an urgent referral.</i>	PCI-GL AHA PCI-CS ECD <i>New</i>
Well-equipped and maintained cardiac catheterization laboratory with high-resolution digital imaging capability. The capability for real-time transfer of images and hemodynamic data (via T-1 transmission line) as well as audio and video images to review terminals for consultation at the facility providing surgical backup support is highly recommended.	PCI-GL PCI-CS ML
Appropriate inventory of interventional equipment, including guide catheters, balloons, and stents in multiple sizes; thrombectomy and distal protection devices; covered stents; temporary pacemakers; and pericardiocentesis trays. <i>Access to other diagnostic modalities such as intravascular ultrasound and fractional flow reserve is required.</i> Rotational or other atherectomy devices and the treatment of CTOs should not be performed in facilities without on-site surgery.	PCI-GL PCI-CS <i>New</i>
Meticulous clinical and angiographic selection criteria for PCI.	PCI-GL AHA
Participation in a national data registry, such as the ACC NCDR in the United States is required. This allows benchmarking, risk adjustment, and facilitates outcomes analysis of local data.	PCI-GL ECD AHA
A program should be in place to track and ensure treatments with ACC/AHA guideline-based class I therapies, both acutely and at discharge.	PCI-CS ML
Full-service laboratories (both primary and elective PCI, with and without on-site cardiac surgery) performing < 200 cases annually must have stringent systems and process protocols with close monitoring of clinical outcomes and additional strategies that promote adequate operator and catheterization laboratory staff experience through collaborative relationships with larger-volume facilities. Both physicians and staff should have the opportunity to work at a high-volume center to enhance their skills. The continued operation of laboratories performing < 200 procedures annually that are not serving isolated or underserved populations should be questioned and any laboratory that cannot maintain satisfactory outcomes should be closed.	PCI-CS
<i>Geographic isolation exists if the emergency transport time to another facility is > 30 min.</i>	<i>New</i>
Satisfactory outcomes should be defined by each local facility as part of their quality review process and should be based on national or regional benchmarks. Programs that fail to meet their established criteria for satisfactory performance for two consecutive quarters must undertake efforts to improve engaging outside experts if necessary. Failure to improve quality metrics should also be grounds for program closure regardless of the location.	ML PCI-CS D2B
As part of the local continuous quality improvement program, there should be a regular review of all patients transferred for emergency surgery with the outcome of surgery and identification of improvement opportunities.	PCI-GL
<p>Note: Italics indicates new or modified recommendation in the document.</p> <p>Abbreviations: ACC, American College of Cardiology; AHA, American Heart Association; CTO, chronic total occlusion; D2B, Door-to-Balloon Alliance; ECD, 2012 expert consensus document on cardiac catheterization standards; IABP, intra-aortic balloon pump; ML, Mission Lifeline; MR, magnetic resonance; NCDR, National Cardiovascular Data Registry; PCI-CS, 2013 PCI competency statement; PCI-GL, 2011 ACCF/AHA/SCAI PCI guidelines; PCI, percutaneous coronary intervention.</p> <p>Reprinted with permission from Dehmer GJ, Blankenship JC, Cilingsiroglu M, et al. SCAI/ACC/AHA expert consensus document. 2014 update on percutaneous coronary intervention without on-site surgical backup. J Am Coll Cardiol. 2014;63:2624-2641.</p>	

retention of the nursing and ancillary team high on the list of priorities when expanding a program to the ASC setting.

Evidence-Based Care and Patient Education

ASCs bring some welcomed relief by scaling back the administrative processes required in the hospital outpatient department, but it is important to ensure the same level of attention is given to evidence-based care, patient and family education, and access to follow-up care after PCI.

Medication management processes should follow regulatory requirements for the ASC, but planning should accommodate processes to ensure that evidence-based guidelines are used for managing medication in the ACS population, including aspirin, thienopyridine/P2Y12 inhibitors, and statin prescribed at discharge.

Many programs have worked to ensure that patient education is consistent across the physician practice setting and the hospital. Much of that work can and should be duplicated for patient education in the ASC, including:

- Understanding risk factors and reducing the event of a cardiovascular event
- Diet and exercise
- Medication
- Self-care
- Referral to cardiac rehab

OUTCOMES MONITORING AND PEER REVIEW

Hospital-based labs have a substantial amount of data related to coronary angiography and interventions. Many programs participate in the ACC's National Cardiovascular Data Registry (NCDR) CathPCI Registry, which has tracked millions of inpatient and outpatient PCIs and coronary interventions. Physicians and CVSL leaders are accustomed to reports that provide benchmarked, risk-adjusted rates of mortality and complications, appropriate use measures, length of stay, resource use, and cost of care. Currently, there are no registries that support reporting and benchmarking PCI in the ASC setting. In its comments to CMS, the ACC highlighted this void and stated that participation in a national data registry should be required to allow for a similar level of benchmarking, risk adjustment, and outcomes analysis.

ASCs are regulated under the Medicare Conditions for Coverage, which include requiring a program for ongoing assessment and improvement of quality and patient safety. Additionally, monitoring quality and patient safety may vary from one accrediting body to another or from state to state under licensure requirements. However, as the ACC points out, there is an absence of measures specific to the PCI population that have been defined by a national registry or CMS. CVSL leaders will need to plan a strategy to measure clinical and financial performance, appropriateness,

and patient experience in the ASC setting. NCDR CathPCI Registry and/or merit-based payment system measures may serve as sources to identify potential measures. It will be important to formally define measures and the means and frequency of data collection, analysis, and reporting. Ideally, these measures will be incorporated into the required CMS, state, and accreditation quality monitoring program.

Consistent with the 2014 SCAI/ACC/AHA expert consensus statement, there should be a mechanism for peer review, including random and individual operator case reviews and review of untoward outcomes. All cases transferred for emergency surgery should be reviewed to identify opportunities for improvement.

CONCLUSION

ASCs are a step forward in providing outpatient elective PCI in a lower-cost setting. This comes as a result of the experience afforded through millions of cases in the hospital setting over more than 4 decades, achieved despite repeated draconian cuts to reimbursement. That clinical experience has prepared us to thoughtfully design and implement safe, evidence-based care in the nonhospital ambulatory setting. However, unless or until CMS revises the payment rates and policies, the shift to the ASC setting will likely be limited in many markets. CVSL leaders will need to be strategic and aggressive to mitigate the level of impact on the structure and margins of our hospital programs. But plan we must, because PCI in the ASC setting will help us ring in the new decade. ■

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Disclosures: None.

Navigating Coronary Procedures in ASCs During the COVID-19 Era

One center's experience in a crisis.

BY DONALD (BUCK) CROSS, MD, AND KELLY BEMIS, RN, BSN

There is an ancient Chinese saying: "May you live in interesting times." Be it a blessing or a curse, there is no doubt that we have all been living in interesting times lately—particularly those of us who've chosen to work in health care.

BACKGROUND

When COVID-19 first appeared on our radar screens in early 2020, the information we had about the virus was very limited. We knew it was likely spread through airborne and possibly surface transmission, but at the time, we were told it was not nearly as dangerous or deadly as the seasonal flu. It didn't take long to discover that the information was wrong.

By mid-March, cases were present in all 50 states. In early April, more than one million people around the world were diagnosed with COVID-19, the death toll was rising, and United States cities were beginning to shut down.

As the number of cases continued to climb, our hospitals were hit particularly hard. Filled to capacity with gravely ill patients, short-staffed, and running out of basic personal protective equipment (PPE), hospitals scrambled for ventilators and were often forced to conserve, substitute, or even reuse resources.

With the pandemic raging and no end in sight, hospital administrators began to reduce, and in most cases, altogether stop performing elective cases. As a physician, I absolutely understand and support that decision, but as a cardiovascular specialist, I worried that delaying "elective" cardiac treatment of some patients would allow their disease to advance unabated, resulting in an emergency situation with far worse outcomes.

As my colleagues can attest, outpatient cardiac procedures are often considered "elective" simply because

the procedure can be performed and the patient is discharged in the same day. In many cases, the word "elective" does not fully convey the necessity or urgency of the procedure, nor its significance to the health of the patient.

THE IMPORTANCE OF ASCs

Ambulatory surgery centers (ASCs) have filled a critical void in cardiovascular care created by COVID-19. Performing cardiac procedures in an outpatient setting is nothing new. In fact, many of these procedures have been taking place in freestanding ASCs for decades. However, in 2019 and 2020, after sustained and hard-fought, years-long advocacy efforts by myself and numerous others, the Center for Medicare & Medicaid Services finally approved the addition of several coronary diagnostic and treatment procedures in an outpatient setting.

This game-changing decision not only allowed for all patients to have access to high-quality, cost-effective, and convenient care, it had the added benefit of relieving some of the massive burden felt by our frontline hospital workers during this tumultuous time and ensured a safer environment for our patients.

Safely handling the influx of patients was no easy task. There was much work to be done, and time was of the essence. Like hospital systems, ASCs were feeling the effects of a nationwide shortage of PPE. This equipment is not only essential to protect our team members from contracting the virus, but to ensure our patients, who by definition had preexisting conditions, were protected as well. Our procurement team worked day and night to find and secure the proper PPE, and we quickly developed and implemented very stringent policies and processes to ensure our facility was clean and safe.

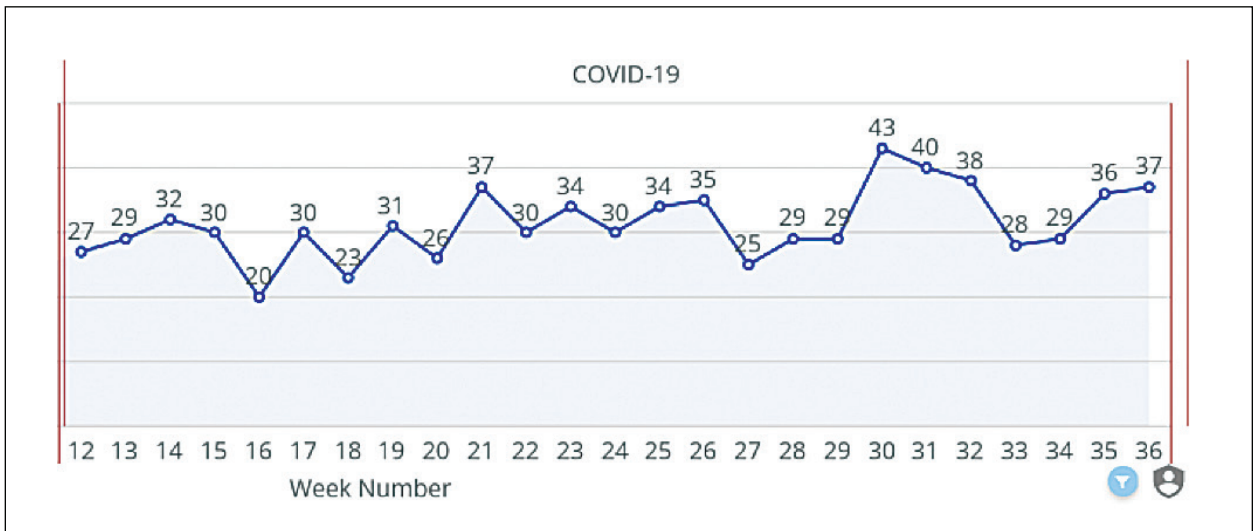


Figure 1. Number of cardiovascular cases performed per week at Waco Cardiology ASC.

We leaned more heavily on telemedicine services when possible, instituted social distancing when feasible, and carefully screened our patients to ensure they were well-suited for the procedures.

As a result of these efforts, Waco Cardiology ASC realized a > 20% increase in the number of cases in the second quarter of 2020, and the uptick in volume is holding steady in the third quarter as well (Figure 1). We have been able to provide timely and much needed high-quality cardiac and vascular care to our patients while protecting them from possible COVID-19 exposure in the hospital setting, while at the same time freeing up precious resources for those requiring in-hospital treatment.

SUMMARY

Even with the increase in case volume, I am proud to report that our staff and physicians have remained healthy and COVID-19-free throughout the pandemic. This is truly a testament to the hard work and professionalism of our team, but we are hardly alone. I have never been prouder to be a part of the medical community, nor more impressed by the quality and caliber of care we provide to all of our patients.

As we continue to navigate these “interesting” times, there is still a lot of uncertainty. When, if ever, we return to business as usual is unclear. But if this pandemic has taught us anything, it is that as an industry, we are at our best when we are agile and adaptive. We believe that the sure and steady outmigration of safe and effective surgical care will continue. And we know it will save lives. ■

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