# STATE-OF-THE-ART REVIEW

# Same-Day Discharge After Elective Percutaneous Transcatheter Cardiovascular Interventions



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# ABSTRACT

Percutaneous transcatheter interventions have evolved as standard therapies for a variety of cardiovascular diseases, from revascularization for atherosclerotic vascular lesions to the treatment of structural cardiac diseases. Concomitant technological innovations, procedural advancements, and operator experience have contributed to effective therapies with low complication rates, making early hospital discharge safe and common. Same-day discharge presents numerous potential benefits for patients, providers, and health care systems. There are several key elements that are shared across the spectrum of interventional cardiology procedures to create a successful same-day discharge pathway. These include appropriate patient and procedure selection, close postprocedural observation, predischarge assessments specific for each type of procedure, and the existence of a patient support system beyond hospital discharge. This review provides the rationale, available data, and a framework for same-day discharge across the spectrum of coronary, peripheral, and structural cardiovascular interventions. (J Am Coll Cardiol Intv 2023;16:1561-1578) © 2023 by the American College of Cardiology Foundation.

he treatment of patients with cardiovascular disease using percutaneous methods has been nothing short of revolutionary, and many patients are eligible for same-day discharge (SDD) even after a significant intervention.<sup>1-5</sup> Both patients and facilities can benefit from SDD pathways to reduce length of stay.<sup>6,7</sup> The early ambulation that is an important part of these SDD pathways is useful for minimizing physical deconditioning. A rapid return to familiar surroundings can reduce the risk for hospitalbased stresses and iatrogenic complications, including delirium and infection. Shorter length of hospital stay can effect cost reduction by decreasing "routine" testing and optimizing the use of limited health care resources, including space and personnel. In this review, we provide the rationale, available data, and a framework for SDD pathways across the spectrum of percutaneous cardiovascular procedures.

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

#### ABBREVIATIONS AND ACRONYMS

ASD = atrial septal defect

LAAO = left atrial appendage occlusion

NCDR = National Cardiovascular Data Registry

NDD = next-day discharge

**PCI** = percutaneous coronary intervention

**PFO** = patent foramen ovale

**PPM** = permanent pacemaker

**PVI** = peripheral vascular intervention

SDD = same-day discharge

TAVR = transcatheter aortic valve replacement

TC = transcatheter closure TEER = transcatheter edge-to-

edge repair

# BASIC TENETS OF AN SDD PATHWAY

Data and details specific to each treatment arena are described in the following discussion, but there are several shared SDD characteristics (Figure 1). The first step is to set the expectations of patients and families by informing them of the possibility of SDD to prepare mentally and facilitate logistical planning. The second step is the creation of guidelines for patient selection. This advance planning also helps caregivers to schedule eligible patients' procedures at a time that ensures adequate postprocedural observation.<sup>3,8</sup> The final step is to make sure that the postprocedural assessment adequately allows the identification of potential complications or need for extended observation. We propose a general SDD pathway in Figure 2.

**PROCEDURAL FACTORS.** SDD patients should undergo their procedures without experiencing complications that would require or benefit from extended monitoring. It is important to clearly define an "uncomplicated procedure" for specific procedures with SDD in mind. For most catheter-based procedures, these generally include vascular access-related issues (including significant bleeding, hematoma, and pseudoaneurysm), stroke or other embolic sequelae, or specific procedure-related issues, which are detailed in the following sections.

Patients should have adequate time for recovery and to assess for any postprocedural complications that may develop or were not initially readily apparent (ie, slow access-site oozing or conduction deficits) (Figure 2). Generally, this implies completion of the procedure at a time early enough to allow at least 6 hours of observation with discharge possible at a reasonable hour.<sup>3,8-10</sup> Given longer recovery time and potential complications of general anesthesia compared with moderate sedation, it is ideal to perform the procedure with moderate sedation, as suggested by recent experiences with SDD following transcatheter aortic valve replacement (TAVR).<sup>3,4</sup> However, patients who undergo procedures under general anesthesia but are extubated in the procedural suite and recover quickly may still be appropriate for SDD, as suggested by contemporary literature on SDD following percutaneous left atrial appendage occlusion (LAAO) under general anesthesia.<sup>5,11</sup> Furthermore, as elderly patients are more likely to experience urinary retention from anesthetics or bladder spasm from urinary catheters, it is preferable to avoid the insertion of a urinary catheter

## **HIGHLIGHTS**

- SDD after percutaneous transcatheter interventions is increasing.
- Key elements needed for safe SDD are shared across various transcatheter procedures.
- SDD candidacy requires adequate postprocedural observation and support.
- SDD can benefit patient management and hospital-based resource use.

before or after the procedure (if not already present) when clinically feasible.

Minimizing the number of locations to which a patient must move within the hospital is beneficial for many reasons, including reducing the number of handoffs and bed spaces used. Therefore, it is preferable if patients are able to move to the same postprocedural recovery area whether they are planned for SDD or next-day discharge (NDD). This also allows the care team to pivot from SDD if there is a need for longer observation. More significant postprocedural complications that require a higher level of care (ie, intensive care unit) are less common but would necessitate patient movement.

**POSTPROCEDURAL CARE AND ASSESSMENT.** A successful SDD pathway requires caregiver alignment, and the postprocedural care team should be fully briefed on the procedure and possible complications. Postprocedural respiratory, hemodynamic, and cardiac rhythm monitoring is necessary to detect any change in a patient's condition. The caregivers on the floor should be comfortable in postprocedural physical assessment and be able to ensure that the patient will be able to mobilize safely upon discharge. Patients and their families (or other support systems) should have any necessary medications already in hand to avoid missed doses of either antiplatelet or other medications that could be detrimental after a percutaneous procedure.

Outpatient follow-up is an important step to confirm clinical stability and for the early detection of "delayed" complications after SDD. The timing and nature of an outpatient visit (whether in person or virtual), as well as necessary testing, depend on procedure type and are further outlined in the following discussion and in Figures 2 and 3. Programs that are unable to create systems that integrate appropriate postdischarge care may not wish to pursue routine SDD pathways.

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**PATIENT-SPECIFIC CONSIDERATIONS.** First and foremost, the patient and their support system should be comfortable with SDD (**Figure 2**). Some patients prefer an overnight stay, and providers should ensure that the care plans are consistent with expectations. Given the use of sedatives, it is important that patients be discharged in the care of family or friends who are able to provide uninterrupted care for at least 24 hours after discharge.

All patients should receive comprehensive instructions on the potential complications for which to be watchful and have access to a 24/7 emergency care hotline in case they have any concerns. This is relevant to both SDD and longer hospital stays given the inherent risk for readmission for patients undergoing invasive cardiac procedures, who often have multiple comorbidities. A postdischarge follow-up personal call to a patient within 24 to 48 hours by a patient care team member may be appropriate to check on the patient's status. For patients who are discharged on the same day and live significant distances from their treatment facilities, consideration can be given to postdischarge "virtual" follow-up depending on the procedure and required assessments (as outlined in Figure 3).

**ROUTINE GUALITY ASSESSMENT.** As with all aspects of patient care, maintenance of quality is of utmost importance. In the setting of SDD, caregivers and health systems should make it a priority to assess appropriate quality metrics on a regular basis and confirm that those patients who leave the hospital early do not face increased risks. In addition to routine procedural outcomes (mortality, stroke, etc), consideration should be given to rates of hospital readmission (especially in the near term), adherence to guideline-directed medical therapy, and any other procedure-specific metrics that may suffer because of early discharge (such as a higher rate of postdischarge permanent pacemaker [PPM] implantation after TAVR).

FINANCIAL IMPLICATIONS. In the United States, the Centers for Medicare and Medicaid Services adopted the 2-midnight rule in October 2013. Under this rule, inpatient admissions are reasonable only if caregivers expect that patients need inpatient care for at least 2 midnights, otherwise observation status is appropriate.<sup>12</sup> This rule is intended to reduce unnecessary inpatient admissions and related costs13 and is applicable to most successful percutaneous coronary interventions (PCIs). As a result, whether a patient is discharged on the same day or the next day after an outpatient interventional procedure does not affect hospital reimbursement. Α recent National

FIGURE 1 Basic Tenets of an SDD Pathway
Patient and family buy-in for SDD possibility prior to the procedure
Well-defined criteria for an uncomplicated procedure
Engagement of extended care team in post-procedure complication     assessment and management with the focus on SDD
Early ambulation protocols
Procurement of new medications prior to discharge
Clear and specific discharge instructions for SDD
Adequate social support for patients after discharge
Process to allow for urgent questions and readmission triage
Post-discharge follow-up for clinical assessment and testing
Routine quality assessment of the SDD pathway
SDD = same-day discharge.

Cardiovascular Data Registry (NCDR) CathPCI Registry study reported that there was an immediate increase in the use of SDD after PCI in October 2013.<sup>14</sup>

Meanwhile, structural interventions and carotid artery stenting do not qualify for the 2-midnight rule, meaning that these procedures are currently reimbursed under an inpatient diagnosis-related group in the United States regardless of length of stay. The benefit of early discharge in either of these circumstances is the reduction in hospital-based resource use (personnel, bed use, etc) and related costs. Although this provides the important provider and hospital system benefits as described earlier, the Centers for Medicare and Medicaid Services should not see this as a motivation to reduce overall payment for these procedures (as outpatient ambulatory patient classification codes generally reimburse at a lower rate than inpatient codes). That could be detrimental to the financial solvency of many interventional treatments, especially those for which the cost of the device represents a disproportionately high percentage of the overall procedure cost. For instance, some of the difficulty patients face in accessing TAVR is driven by an inability of smaller hospitals to provide the treatment because of minimal (or negative) margins; further reducing reimbursement could prove detrimental to patient care.

### **CORONARY INTERVENTIONS**

**RATIONALE FOR SDD AND SUPPORTING DATA.** Periprocedural safety of PCI has improved, allowing earlier hospital discharge. In 2006 and 2007,

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randomized trials demonstrated the safety of SDD following elective PCI in selected patients.<sup>15,16</sup> In 2009, the Society for Cardiovascular Angiography and Interventions published the first expert consensus statement regarding the feasibility of SDD following PCI.<sup>17,18</sup> Nevertheless, SDD was infrequent (1.25%), with significant hospital-level variation in adoption.<sup>19</sup> In the following decade, additional randomized trials<sup>7,20</sup> and meta-analyses<sup>1,21</sup> added to the evidence

base supporting the safety of SDD, mirroring the increasing use of the radial approach.<sup>22,23</sup> Consequently, the use of SDD increased more than 5-fold from 4.5% in 2009 to 28.6% in 2017, with a more substantial increase seen among those undergoing transradial intervention (from 9.9% to 39.7%) than those with transfemoral intervention (from 4.3% to 19.5%).<sup>14</sup> The 2018 updated Society for Cardiovascular Angiography and Interventions expert consensus document<sup>24</sup> and the 2021 American College of Cardiology expert consensus decision pathway<sup>8</sup> have incorporated SDD into the PCI standard of care. Given considerable hospital-level variance,<sup>14</sup> there remains significant room for improvement.

There have been 3 meta-analyses on SDD following PCI<sup>1,21,25</sup> compared with overnight observation (ie, NDD) (Table 1). Taken together, these demonstrate that SDD, compared with NDD, was not associated with increased risk for 30-day overall complications.<sup>1,21,25</sup> Although substantial heterogeneity exists in the definition of outcomes across the included studies, these meta-analyses consistently support the safety of SDD following elective PCI in selected patients. In 2021, an NCDR CathPCI Registry study demonstrated no significant association of SDD (vs NDD) with 30-day mortality (adjusted OR: 1.03; 95% CI: 0.73-1.46) or 30-day rehospitalization.<sup>14</sup> As the SDD pathway was more widely adopted, the risk for 30-day rehospitalization after SDD declined over time, with a low rate of 3.0% for SDD in 2014. Realworld data from the United States<sup>6</sup> and other countries<sup>26,27</sup> have demonstrated consistent results.

A post-PCI SDD pathway has also been applied in smaller analyses to more complex situations such as chronic total occlusion treatment. Generally, operator discretion for SDD was based on a lack of complications, procedure time, and contrast use, and multivariable analyses demonstrated the presence of diabetes and procedure time to be important predictors of non-SDD.<sup>28</sup> There was no difference in inhospital or 30-day complications among this group, all of whom had forearm access. A larger analysis from the British national database demonstrated the safety of SDD among 21,330 patients who underwent PCI for chronic total occlusion between 2007 and 2014.<sup>29</sup> Over the period, SDD increased from 21.7% to 44.7%, and SDD was more common among men and at higher volume centers. Although 50% of patients with SDD had transfemoral access, multivariable analysis demonstrated that radial access was most strongly associated with SDD.

The benefit of SDD can be appreciated from the patient and provider perspectives. Prior studies have demonstrated that patients with early discharge

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following PCI had better quality of life with SDD than NDD, and preference for SDD for future PCIs.<sup>7,30</sup> For younger patients, this likely reflects the ability to return to "normalcy" sooner; for older patients, a return to familiar surroundings may also reduce the risk for delirium.

For health systems, SDD can lead to cost savings. In the 2000s, the Canadian EASY (Early Discharge After Transradial Stenting of Coronary Arteries) trial demonstrated a reduction of 30-day medical costs with SDD compared with NDD (difference, Canadian \$1,141; 95% CI: \$962-\$1,320), due primarily to the lack of an extra fee for an overnight hospital stay.<sup>31</sup> In the 2010s, larger cost savings were observed with SDD in the NCDR CathPCI Registry (\$3,502; 95% CI: \$3,347-\$3,648)<sup>32</sup> and in the U.S. Premier Healthcare Database (\$5,128; 95% CI: \$5,006-\$5,248).<sup>6</sup> At the present time, the financial savings are realized primarily by providers as an improvement in the efficiency of care provided. This is especially relevant because the overnight stay is not actually reimbursed (as an addition to the PCI reimbursement). Furthermore, SDD following elective PCI provides hospitals with the benefits of increased bed availability and lower risk for nosocomial infection. For patients, an overnight "inpatient" stay can also incur a higher copay, so SDD may provide financial benefit to the patient as well.

First Author (Year)	Number of Included Studies	Number of SDD Patients	Number and Characteristics of the Control Population	Main Results
Abdelaal et al (2013) <sup>21</sup>	13 (5 RCTs, 8 non-RCTs)	RCTs, n = 1,023 Non-RCTs, n = 3,156	RCTs, n = 1,016 Non-RCTs, n = 106,629	30-d total complications <sup>a</sup> • RCTs: OR: 1.20 (95% Cl: 0.82-1.74) • Non-RCTs: OR: 0.67 (95% Cl: 0.27-1.66) • Overall: OR: 1.00 (95% Cl: 0.66-1.54) 30-d MACE <sup>b</sup> • RCTs: OR: 0.99 (95% Cl: 0.45-2.18) • Non-RCTs: OR: 0.59 (95% Cl: 0.06-5.57) • Overall: OR: 0.77 (95% Cl: 0.26-2.25) 30-d rehospitalization • RCTs: OR: 1.10 (95% Cl: 0.70-1.74) • Non-RCTs: OR: 0.62 (95% Cl: 0.10-3.98) • Overall: OR: 1.01 (95% Cl: 0.79-1.29)
Brayton et al (2013) <sup>1</sup>	37 (7 RCTs, 30 non-RCTs)	RCTs: n = 1,256 Non-RCTs: n = 10,065	RCTs: n = 1,482 Non-RCTs: n = 967	Death/myocardial infarction/TLR • RCTs: OR: 0.90 (95% CI: 0.43-1.87) • Non-RCTs: OR: 1.00 (95% CI: 0.58-1.68) Major bleeding/vascular complications • RCTs: OR: 1.69 (95% CI: 0.84-3.40) • Non-RCTs: OR: 0.68 (95% CI: 0.35-1.32)
Bundhun et al (2017) <sup>25</sup>	8 RCTs	RCTs: n = 1,598	RCTs: n = 1,483	30-d mortality: OR: 0.22 (95% CI: 0.04-1.35) 30-d myocardial infarction: OR: 0.68 (95% CI: 0.33-1.41) 30-d MACE <sup>b</sup> : OR: 0.45 (95% CI: 0.20-1.02) 30-d rehospitalization: OR: 1.53 (95% CI: 0.88-2.65)

MACE = major adverse cardiovascular event(s); RCT = randomized controlled trial; SDD = same-day discharge; TLR = target lesion revascularization.

SELECTION CRITERIA AND CLINICAL PATHWAY FOR SDD. The key aspects of the SDD pathway are summarized in Figures 2 and 3 and the Central Illustration. Patient demographic and pre-existing conditions should not preclude SDD eligibility, as long as the PCI procedure is elective and successful without significant periprocedural complications. Although femoral access has become safer over the years, and SDD is still feasible,<sup>14</sup> transradial intervention is preferable and can be an important factor given the lower bleeding risk and earlier ambulation thereafter.<sup>22,23</sup> The use of vascular closure devices should be considered in transfemoral intervention recipients to reduce the time to hemostasis and ambulation, though vigilance regarding access-site assessment and examination is still required given the potential for closure device failure.<sup>33,34</sup>

Although some investigators have reported safe SDD of patients treated with PCI for non-ST-segment elevation myocardial infarction,35-37 the 2021 American College of Cardiology expert consensus pathway excludes patients with acute myocardial infarction from SDD eligibility.<sup>8</sup> As the safety data in these patients are limited, routine observation post-PCI for acute myocardial infarction is reasonable.

**POSTPROCEDURAL MANAGEMENT.** The types and timing of procedural complications following PCI have important implications for SDD. Major procedural complications include coronary perforation, noreflow, acute side-branch occlusion, arrhythmias, and access-site complications, which are typically detected with abrupt hemodynamic and electrocardiographic changes.<sup>38,39</sup> Access-site bleeding, congestive heart failure, contrast reactions, and stent thrombosis may be delayed (ie, several hours) after PCI. Overall, most periprocedural complications of PCI occur within 6 hours after the procedure,<sup>40,41</sup> so this duration of observation is reasonable. For operators at sites routinely discharging patients on the same day of PCI, a shorter observation period (ie, 4 hours) may be reasonable per the expert opinion of the European authors of this paper, who have greater longitudinal experience with the same.

Specific recommendations regarding postprocedural follow-up are provided in Figures 2 and 3. It is imperative that providers confirm that patients understand the importance of their medications and have sufficient prescriptions at the time of discharge (especially for antithrombotic agents after PCI).<sup>42</sup> A planned outpatient visit is important not only for assessing any postprocedural delayed complications but also to reiterate the importance of secondary coronary artery disease risk factor prevention and treatment. A related goal is to provide referral for appropriate ancillary care services (nutrition consultation referral, cardiac rehabilitation prescription, etc). Consideration may be given to a "virtual" visit when preferred (and when appropriate), as many health care providers and patients have become more facile with these in the contemporary era.

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# LOWER EXTREMITY PERIPHERAL VASCULAR INTERVENTIONS

**RATIONALE FOR SDD AND SUPPORTING DATA.** Performance of peripheral vascular intervention (PVI) procedures has rapidly increased, along with improvements in device technologies and operator experience.<sup>43-45</sup> Because of modifications in reimbursement by the Centers for Medicare and Medicaid Services in 2008, PVI began to shift from the inpatient to the outpatient setting.<sup>46</sup> As a result, office-based laboratories for PVI proliferated, and outpatient PVIs rapidly increased.<sup>47</sup> Currently, outpatient "day-case" PVI (ie, SDD) has been incorporated into the standard system of PVI.

The first studies reporting the feasibility and safety of day-case PVI were published in the 2000s,<sup>9</sup> with several observational studies published in the decade thereafter, adding to the evidence base supporting the safety of SDD following PVI<sup>2,48-50</sup> (Table 2).

TABLE 2 Summar	TABLE 2 Summary of 4 Observational Studies (Enrollment in 2010 or Later) on Outpatient Day-Case Peripheral Vascular Intervention for Peripheral Artery Disease											
First Author (Year)	Study Setting	Facility	Enrollment Period	N	Age, y	Male	Complication Rate	Need for Overnight Observation	30-d Readmission Rate			
Gouicem et al (2014) <sup>48</sup>	Single center	Operating room or interventional radiology suite	August to December 2011	99	72 (mean)	73%	7.1%	27.3% <sup>a</sup>	3.0%			
Spiliopoulos et al (2016) <sup>49</sup>	3-center study	NA	January 2013 to June 2015	652	68.1 (mean)	75%	Major complications, 1.4% Minor complications, 2.6%	4.1%	0.4%			
Ansari et al (2020) <sup>50</sup>	Single center	Catheterization laboratory	December 2012 to August 2015	608	73 (median)	64%	Major complications, 0.7% Minor complications, 9.5%	0.7%	NA <sup>b</sup>			
Ahn et al (2020) <sup>2</sup>	Multicenter registry (64 centers in 18 U.S. states)	Office-based laboratory, 85.1% Ambulatory surgery center, 10.4%	January 2017 to January 2020	12,403 <sup>c</sup>	72.3 (mean)	60.1%	Overall complications, 1.87% MACE, <sup>d</sup> 0.51%	0.62% (hospital transfer rate)	NA (30-d mortality 0.03%)			
		-										

<sup>a</sup>Proportion of cases considered necessary to stay overnight in each setting. <sup>b</sup>No death at 28 days or none of the following at 1 month: worsening Doppler ultrasound findings, reduction in peripheral pulses, or acute kidney injury. <sup>c</sup>Diagnostic procedures accounted for 12.2% of procedures, while the remaining were interventions. <sup>d</sup>Defined as death, stroke, myocardial infarction, acute onset of limb ischemia, index bypass graft or treated segment thrombosis, and/or need for urgent or emergent vascular surgery.

 $\mathsf{MACE} = \mathsf{major} \ \mathsf{adverse} \ \mathsf{cardiovascular} \ \mathsf{event}(\mathsf{s}); \ \mathsf{NA} = \mathsf{not} \ \mathsf{available}.$ 

Although the data are limited by the lack of a comparator control group in these observational series, they did demonstrate that outpatient PVI procedures were feasible with low rates of periprocedural complications and need for conversion to overnight observation. The most recent and so far largest study on outpatient PVIs was reported from the Outpatient Endovascular and Interventional Society national registry in the United States, which included data on 12,403 patients with peripheral artery disease treated at 64 centers in 18 states.<sup>2</sup> Most procedures were performed in office-based laboratories (85.1%) or ambulatory surgery centers (10.4%), with excellent periprocedural outcomes (overall complications, 1.87%; major adverse events, 0.51%; hospital transfer for overnight observation, 0.62%; 30-day mortality, 0.03%). As a thought-provoking study to increase the safety of SDD, Kwan et al<sup>51</sup> demonstrated the use of transpedal access among 80 patients. All had successful angiography, and 43 of 51 patients had successful intervention without additional femoral access. There were no access-site complications.

Two observational studies reported that patients who underwent day-case PVIs had high satisfaction with the procedures and management thereafter.<sup>52,53</sup> In contrast, a small (n = 19), single-center, randomized controlled study reported that patient satisfaction and perceived safety were significantly lower after SDD.<sup>54</sup> These contrasting studies underscore the importance of assessing patient comfort regarding SDD prior to the procedure.

**SELECTION CRITERIA AND CLINICAL PATHWAY FOR SDD**. The key conditions for a safe SDD pathway are previously summarized (Figures 2 and 3, Central Illustration). Some groups that are likely to benefit from extended observation include those patients at higher risk for adverse events such as acute limb ischemia, chronic limb-threatening ischemia, and deep or invasive infection. Similarly, several prior studies excluded patients with American Society of Anesthesiologists scores  $\geq$ 4 (indicating severe systemic diseases such as recent [<3 months] myocardial infarction, stroke, or coronary artery disease with ongoing cardiac ischemia, or severely reduced ejection fraction) from candidacy for SDD.<sup>49,52</sup>

Previous studies have shown that access-site or other bleeding events occur primarily during PVI procedures or within 6 hours thereafter, <sup>53,55,56</sup> similar to PCI. Therefore, it is important to schedule PVI procedures at a time that allows 6-hour postprocedural observation. The use of a vascular closure device should be considered to facilitate early accesssite hemostasis and subsequent mobilization, though manual compression alone is not exclusionary.<sup>9</sup> Radial-access PVI, if clinically possible, may also facilitate SDD because of the lower risk for access-site complications.<sup>57</sup>

**POSTPROCEDURAL MANAGEMENT.** Significant accesssite complications must be excluded (**Figure 2**). The Society for Vascular Surgery Vascular Quality Initiative (n = 27,048) reported an access-site complication rate of 3.5%, of which three-quarters were minor complications.<sup>58</sup> An NCDR PVI Registry analysis of 18,289 lower extremity procedures showed that major bleeding (overt bleeding with a  $\geq$ 3 g/dL hemoglobin decrease, any  $\geq$ 4 g/dL hemoglobin decrease, or blood transfusion in patients with preprocedural

First Author (Location) (Year)	Enrollment Period for SDD	SDD Patients	Control Group	Valve Type in SDD Patients	30-d Outcomes (SDD vs Control)
Perdoncin et al (Emory University Hospital Midtown, United States) (2021) <sup>10</sup>	March to July 2020	29	NDD (patients who met SDD criteria July 2018 to July 2020), n = 128	BEV, 82.8% SEV, 17.2%	No death in either group CV readmission, 0% vs 5.5% ( $P = 0.35$ ) PPM implantation, 0% vs 0.8% ( $P > 0.99$ ) Stroke, 0% vs 0.8% ( $P > 0.99$ )
Pop et al (AMITA Alexian Brothers Medical Center, USA) (2021) <sup>63</sup>	June to December 2020	29	NDD or later (patients ineligible for SDD), n = 84	BEV, 96.6% SEV, 3.4%	Death, 0% vs 2.4% ( $P > 0.99$ ) CV readmission, 3.4% vs 7.2% ( $P = 0.67$ ) PPM implantation, 0% vs 3.6% ( $P = 0.57$ ) Stroke, 3.4% vs 0% ( $P = 0.26$ )
Krishnaswamy et al (Cleveland Clinic, United States) (2022) <sup>3</sup>	March to November 2020	114	Control group I: NDD in 2019, n = 481 Control group II: NDD in 2020, n = 329	BEV, 91.2% SEV, 8.9%	SDD vs NDD in 2019 vs NDD in 2020 Death, 0% vs 0% vs 0.9% CV readmission, 3.5% vs 6.2% vs 5.2% Non-CV readmission, 2.6% vs 4.0% vs 2.4% PPM implantation, 0.9% vs 0.6% vs 1.2% Ischemic stroke, 0% vs 0.6% vs 0.6% Hemorrhagic stroke, 0% vs 0% vs 0.6% (P = NS for SDD vs NDD in 2019 or 2020)
Barker et al (PROTECT TAVR study) (2022) <sup>4</sup>	March to August 2020	124	None	BEV, 96.8% SEV, 3.2%	SDD patients' data only All-cause death, 0.9% CV death, 0% All-cause readmission, 5.7% CV readmission, 2.8% PPM implantation, 0% (in-hospital new PPM, 0.8%) Stroke/TIA, 0.9%

hemoglobin >8 g/dL) occurred in 4.1%, with the majority being access-site bleeding (58%), followed by retroperitoneal bleeding (23%).<sup>59</sup> Another common complication is acute kidney injury, which occurred in 7.4% in the registry.<sup>60</sup> It is often common practice to continue observation of patients at high risk for acute kidney injury and/or with large-volume contrast exposure.<sup>28</sup> In typical clinical practice, patients with routine claudication receive follow-up at some point within 30 days, and patients treated for chronic limb-threatening ischemia are generally seen within 2 weeks.

### **OTHER PVIs**

Unlike the robust data available for SDD after the other interventions provided in this review and given the general time course of postprocedural complications noted earlier, we believe that more data are needed for patients undergoing transcatheter carotid artery stenting prior to reaching any firm recommendations regarding SDD (see "Transcatheter Carotid Artery Stenting" in the Supplemental Appendix and Supplemental Table S1). Meanwhile, given the low risk for periprocedural complications of renal artery stenting, most of which are readily apparent during the procedure, SDD appears safely achievable in uncomplicated patients undergoing renal artery stenting using the same criteria as other PVIs (see "Renal Artery Stenting" in the Supplemental Appendix).

#### TAVR

**RATIONALE FOR SDD AND SUPPORTING DATA.** TAVR is established as a minimally invasive treatment in patients with severe symptomatic aortic stenosis. As evidenced by the Society of Thoracic Surgeons/American College of Cardiology TVT (Transcatheter Valve Therapy) Registry, there has been a consistent decline in median length of stay after TAVR, from 7 days in 2013 to 2 days in 2019.<sup>61</sup> In 2019, the 3M (Multidisciplinary, Multimodality, but Minimalist) TAVR study group reported that a standardized postprocedural protocol for NDD after TAVR was feasible and safe.<sup>62</sup> In the contemporary era, NDD occurs after >25% of TAVR procedures in the United States<sup>61</sup> and is associated with reduction in health care costs.<sup>62</sup>

The literature on SDD following TAVR prior to 2020 had been limited, and clinical application was sparse, mainly because of concerns about arterial access-site complications related to the large-bore sheath and the possibility of delayed high-degree atrioventricular block. In the contemporary era, there have been 4 studies<sup>3,4,10,63</sup> of SDD, which

First Author (Location) (Year)	Enrollment Period for SDD	Number of SDD Patients, Average Age (y), and Sex	Anesthesia Approach	Etiology of Severe Mitral Regurgitation	STS-PROM and LVEF	Procedure Time, min	Management	Short-Term Outcomes
Chowdhury et al (Rochester General Hospital, United States) (2021) <sup>80</sup>	February 19, 2020, to December 2020	n = 6, 80.0 ± 10.9 y, all men	All GA	Primary MR, n = 3 Secondary MR, n = 3	STS-PROM 3.4% ± 2.2% LVEF 52.5% ± 14.4%	115.8 ± 32.0	No procedural complications Extubation in the catheterization room Ambulation within 2 h following procedure Postprocedural TTE to confirm appropriate position of the clip(s) without significant regurgitation or pericardial effusion; discharged within 3-4 h after procedure Televisit on day 1	Readmission on day 6 for acute gastrointestinal bleeding, n = 1
Marmagkiolis et al (MD Anderson Cancer Center, United States) (2021) <sup>81</sup>	February 2019 to April 2020	n = 82, 80.2 $\pm$ 2.5 y, 52% women	All MS with fluoroscopy and TEE	$\begin{array}{l} \mbox{Primary MR,} \\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ $	STS-PROM 10.6% ± 2.6% LVEF 45.2% ± 10.3%	$60.0\pm10.2$	No procedural complications Ambulation without access-site bleeding In-person visit on day 1	Mortality, 0 (0.0% Stroke/TIA, 0 (0.0%) Minor bleeding, 1 (1.2%)

are briefly summarized in Table 3. The Emory University Hospital Midtown group reported data on 29 patients discharged safely on the same day after TAVR who were selected carefully on the basis of their own baseline and periprocedural criteria, without significant difference in 30-day outcomes compared with 128 NDD patients.<sup>10</sup> Similarly, the AMITA Alexian Brothers Medical Center group demonstrated no significant difference in 30-day outcomes between 29 SDD patients and 84 patients ineligible for SDD.<sup>63</sup>

In a Cleveland Clinic study, SDD accounted for 22.1% (114 of 516 cases) of outpatient TAVR in 2020.<sup>3</sup> The 30-day event rates after SDD were compared with those after NDD in 2019 (historic control prior to the initiation of the SDD pathway) as well as those after NDD in 2020 (parallel treatment group during the same period). Among the SDD group, 13% had preexisting PPMs, and 1 SDD patient (0.9%) required late PPM implantation on postoperative day 25 for intermittent complete heart block (without any early electrocardiographic changes). Three other patients had cardiovascular readmissions within 30 days, 1 with rapid atrial fibrillation that spontaneously resolved, 1 who required diuresis and blood pressure control for hypertensive emergency with pulmonary edema, and 1 with gastrointestinal bleeding related to dual antiplatelet therapy, which was then amended to a single antiplatelet agent.

Last, the multicenter PROTECT TAVR study reported the single-arm (ie, no control group) outcomes of post-TAVR SDD patients at 7 centers (including the previously mentioned Emory University Hospital Midtown and AMITA Alexian Brothers Medical Center).<sup>4</sup> The patient selection criteria for SDD were not uniformly predefined across centers and were left at the discretion of each site. Among 2,100 elective transfemoral TAVR recipients, 124 patients (5.9%) underwent SDD. Notably, 32.3% of patients had preexisting PPMs. All procedures were performed under local anesthesia and/or moderate sedation and ended before noon. Three patients (2.8%) were readmitted within 30 days for cardiovascular causes, with no PPM implantation after SDD. On the basis of the experience of the centers across these studies, unified "selection criteria" for SDD are proposed and discussed later.

Patient and procedural characteristics and 30-day outcomes were similar between the Cleveland Clinic study and the PROTECT TAVR study.<sup>64</sup> It deserves mention that the overwhelming majority of patients (>90%) in both of these large SDD studies underwent TAVR with balloon-expandable valves; more data are needed to confirm safety of SDD across other valve platforms.

We believe that many hospitals currently applying an NDD protocol will be able to apply this SDD protocol to carefully selected patients. It is important to recognize, however, that several nationwide studies demonstrate substantial variations in the quality of TAVR care and outcomes in the United States and an inverse volume-outcome relationship between

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TABLE 5         Summary of 6 Available Studies on SDD Following Percutaneous LAAO									
First Author (Location) (Year)	Enrollment Period for SDD	Imaging and Anesthesia Approach	Number of SDD Patients and Average Age	Control Group and Average Age	LAAO Device in SDD Patients	Major Outcomes			
Gilhofer et al (Vancouver General Hospital, Canada) (2020) <sup>11</sup>	February 2018 to June 2019	TEE and GA, 87.5% ICE and MS, 12.5%	$n = 24$ , 76.6 $\pm$ 7.5 y	None	Watchman, n = 12; Amulet, n = 12	No clinical complications at 30 d			
Marmagkiolis et al (MD Anderson Cancer Center, United States) (2021) <sup>93</sup>	August 2019 to May 2020	TEE and MS, 100%	$\begin{array}{l} n = 112\text{,} \\ 83.5 \pm 8.5 \text{ y} \end{array}$	None	Watchman, n = 112	No complication during LAAO or on POD 1			
Tan et al (Brigham and Women's Hospital, United States) (2021) <sup>5</sup>	June 2016 to June 2019	TEE and GA, 100%	n = 72, 75.7 $\pm$ 7.8 y	Non-SDD, $n = 118; 75.9 \pm 8.6 y$	Watchman, n = 72	Composite outcome <sup>3</sup> : SDD vs non-SDD 7 d: 1.4% vs 5.9% ( $P = 0.26$ ) 45 d: 2.8% vs 9.3% ( $P = 0.14$ ) 45-d DRT, systemic embolism, or death, 0% vs 0% 45-d readmission, 8.3% vs 13.6% ( $P = 0.27$ )			
Piayda et al (Amulet observational postmarket study) (2021) <sup>95</sup>	June 2015 to September 2016	TEE, 98% ICE, 2% (No anesthesia details)	n = 60, 77 ± 7 y	NDD, n = 526; 75 $\pm$ 8 y	Amulet, n = 60	<ul> <li>SDD vs NDD (no <i>P</i> values for this 2-group comparison)</li> <li>7-d procedure- or device-related SAE,<sup>b</sup> 1.7% vs 2.1%</li> <li>60-d follow-up</li> <li>Death, 0% vs 1.0%; major bleeding, 0% vs 5.2%; ischemic stroke, 0% vs 0.4%</li> </ul>			
Dallan et al (Cleveland Medical Center, United States) (2022) <sup>94</sup>	June to December 2020	ICE and MS, 100%	n = 23, 74.4 $\pm$ 8.6 y	TEE and GS and overnight stay, $n = 119$ ; 76.5 $\pm$ 8.4 y	Watchman 2.5, n = 8; Watchman FLX, n = 15	SDD vs control Procedural outcomes Device success, 100% vs 99.1% ( $P = 0.66$ ) Duration, 62.1 $\pm$ 5.9 min vs 51.1 $\pm$ 21 min ( $P = 0.01$ ) Complications, 0% vs. 2.5% 45-d follow-up outcomes Death, 0% vs 0% Cardiac readmission, 0% vs 10.1% ( $P = 0.11$ ) Peridevice leak ( $\geq$ 5 mm), 0% vs 0.8% ( $P = 0.66$ )			
Gibson et al (SURPASS of the NCDR LAAO Registry) <sup>98</sup>	August 2020 to March 2021	NA	n = 3,167, 75.6 $\pm$ 7.8	Later discharge, n = 13,266; 76.2 $\pm$ 8.0 y	Watchman FLX, n = 3,167	SDD vs later discharge Major adverse events, 2.78% vs 5.22% ( <i>P</i> < 0.01) Death, 0.57% vs. 0.92% ( <i>P</i> = 0.08) Ischemic stroke, 0.22% vs 0.29% ( <i>P</i> = 0.48) Major vascular complications, 0.03% vs 0.19% ( <i>P</i> = 0.06) Pericardial effusion requiring intervention, 0.04% vs 0.64% ( <i>P</i> < 0.01) Major bleeding, 2.00% vs 3.90% ( <i>P</i> < 0.01) Peridevice leak at 45 d: ≥5 mm, 0.5% vs 0.8%; >3-5 mm, 3.8% vs 4.2%; >0-3 mm, 12.4% vs 13.7% ( <i>P</i> = 0.09)			

<sup>a</sup>Composite of stroke, systemic embolism, major bleeding requiring transfusion, vascular complications requiring endovascular intervention, or death. <sup>b</sup>SAEs include cardiac (pericardial effusion, pericardial tamponade, device embolization, device thrombus, heart failure), bleeding (access-site hematoma, gastrointestinal bleeding, anemia, and subdural hematoma), neurologic (ischemic stroke, seizure), respiratory (pneumonia, exacerbated chronic obstructive lung disease, respiratory failure, pulmonary embolism), and other events (delirium, urinary retention, transesophageal echocardiography-related event, air embolism, arteriovenous fistula, and pseudoaneurysm).

DRT = device-related thrombus; ICE = intracardiac echocardiography; LAAO = left atrial appendage occlusion; NCDR = National Cardiovascular Data Registry; POD = postoperative day; SAE = serious adverse event(s); SURPASS = Surveillance Post Approval Analysis Plan; other abbreviations as in Tables 1 to 4.

hospital and operator procedural volume and shortterm outcomes.<sup>61,65</sup> Hospitals should be cognizant of site-specific results, especially with regard to shortterm outcomes, and we do not recommend that an SDD protocol be applied to TAVR recipients at less experienced hospitals or those with historically high rates of new PPM implantation.

**SELECTION CRITERIA FOR SDD.** Although the selection criteria for SDD were somewhat different across the studies<sup>3,10,63</sup> (Supplemental Table S2), there are some essential considerations, as demonstrated in **Figures 2 and 3** and the **Central Illustration**. In developing the Cleveland Clinic SDD protocol (as provided

in Supplemental Table S2), the investigators did not set any specific criteria regarding baseline characteristics.<sup>3</sup> In this regard, these criteria differ from the Emory University criteria and can be viewed as more "liberal" for SDD selection.<sup>10</sup> Importantly, prior investigations did not demonstrate age or Society of Thoracic Surgeons risk score to be independent predictors of 30-day readmission.<sup>66,67</sup> As age is associated with a higher risk for delirium after TAVR,<sup>68</sup> conjecturally, SDD may be beneficial for elderly patients in this regard.

The procedure itself should preferably be performed under moderate sedation and without any

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TABLE 6       Summary of 4 Available Single-Center Studies on SDD Following TC of PFO or ASD										
First Author (Location) (Year)	Enrollment Period for SDD	Study Population and Procedure	Indication for Procedure	Closure Device	Age, y	Male	Complications	Need for Overnight Observation	30-d Readmission Rate	
Bijl et al (Auckland City Hospital, New Zealand) (2005) <sup>105</sup>	August 2002 to August 2004	MS TC of PFO using fluoroscopy alone, n = 40	Stroke or TIA, n = 26 TIA, $n = 8$ Stroke and TIA, n = 2 Refractory hypoxia, n = 2 Platypnea- orthodeoxia, $n = 1$ Migraine and seizures, $n = 1$	Amplatzer, n = 40	45 ± 10	60%	No death or periprocedural complications	0%	NA	
Ponnuthurai et al (John Radcliffe Hospital, United Kingdom) (2007) <sup>106</sup>	July 2004 to February 2007	MS TC of PFO using fluoroscopy and ICE, $n = 53$	Stroke or TIA, n = 39 Peripheral embolism, $n = 6$ Decompression illness, $n = 7$ Severe migraine, n = 1	Gore HELEX, n = 47 Amplatzer, n = 1 Aborted, n = 5	44.2 ± 11.0	45%	No death Access-site hematoma, 2.1% (1/48)	2.1% (access-site hematoma)	NA	
Barker et al (Toronto General Hospital, Canada) (2020) <sup>107</sup>	2006-2017	MS TC of PFO using fluoroscopy alone (n = 381) or adjunctive ICE (n = 86), n = 467	Cryptogenic stroke, $n=467$	Amplatzer, n = 467	$47.0\pm12.3$	55%	No death Arrhythmia, 1.3% Major vascular complications, 0.9% New neurologic symptoms, 0.2% Device embolization, 0.2%	2.4% Fluoroscopy alone (1.5%) vs fluoroscopy and ICE (4.7%) (P = 0.246)	0.7%	
Prashar et al (St. George Hospital, Australia) (2021) <sup>108</sup>	September 2011 to December 2020	MS TC of PFO using fluoroscopy, n = 14 GA or MS TC of ASD using TEE, n = 10	TC of PFO Cryptogenic CVA, n = 11 Recurrent CVA, n = 3 PFO with atrial septal aneurysm, n = 8 Migraine, $n = 3$ TC of ASD Secundum ASD with RV dilation, n = 10	Amplatzer PFO, n = 10 Occlutech PFO, n = 3 Amplatzer septal, n = 10 Occlutech ASD, n = 1	43.9 ± 14.3	29%	No death or periprocedural complications	4.2% (n = 1)	25% (n = 6) TIA, n = 1	

major procedural complication (Figure 2). A completion angiogram of the delivery sheath access site is highly recommended, if not mandatory, to reassure that there are no vascular concerns and confirm appropriate hemostasis. In contrast, minor complications not affecting hemodynamic status or ambulation (eg, minor vascular complications treatable with transcatheter intervention or conservative therapy) do not preclude the applicability of SDD in our experience. After the procedure, the patient should complete bed rest and telemetry for at least 6 hours postprocedure, and recommended evaluations are provided in Figures 2 and 3.

**POSTPROCEDURAL MONITORING.** Caregivers and patients often have concerns regarding SDD because of the limited postprocedural telemetry monitoring

and the potential risk for delayed high-degree atrioventricular block after discharge.<sup>69,70</sup> In this regard, the development of significant conduction deficits after TAVR is an important part of the screening process for SDD feasibility. Patients with new-onset persistent left bundle branch block would merit longer inpatient observation,<sup>71,72</sup> along with those patients with certain significant preexisting conduction disturbances.<sup>73</sup> Conversely, patients with pre-existing PPMs should be universally safe for discharge from а conduction perspective.4

Current literature suggests that high-degree atrioventricular block and sudden death are uncommon after discharge in patients carefully selected for NDD or SDD,<sup>3,4,62</sup> including those undergoing ambulatory electrocardiographic monitoring.<sup>62,74,75</sup> Postdischarge

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ambulatory electrocardiographic monitoring may be useful in detecting delayed high-degree atrioventricular block after TAVR among high-risk groups (ie, baseline right bundle branch block or new-onset persistent left bundle branch block).<sup>76</sup> In a recent study<sup>75</sup>, patients without new electrocardiographic changes post-TAVR had lower delayed high-degree atrioventricular block risk (2.2%) than those with pre-existing right bundle branch block (13.2%) or new electrocardiographic changes (8.5%), highlighting the importance of confirming stable electrocardiographic findings in the SDD selection criteria.

A rapid atrial pacing test immediately after TAVR may provide further risk stratification with regard to the stability of the conduction system. Withdrawing the temporary pacemaker to the right atrium and pacing up to 120 beats/min is an important "stress test" of the nodal conduction system.<sup>77</sup> The study cited found that among the 130 patients (of 284) who did not demonstrate Wenckebach atrioventricular block with right atrial pacing, only 2 required pacemakers within 30 days (negative predictive value 98.7%). Notably, of these 2 patients, 1 had a PPM because of new left bundle branch block, and the other simply underwent planned cardiac resynchronization therapy defibrillator implantation given severe left ventricular dysfunction and no expectation of its recovery after TAVR. Although the development of Wenckebach atrioventricular block does not necessarily imply the need for PPM implantation (13.1% of all patients with Wenckebach atrioventricular block), it is important in risk stratification for early discharge.

The previously cited consensus document by Rodés-Cabau et al<sup>73</sup> is expectedly conservative and provides an important framework for observation of these patients. Over time, centers may find that the use of information gathered from a right atrial pacing study, postprocedural electrocardiography, and/or outpatient electrocardiographic monitoring may further broaden the application of SDD, as demonstrated in the Cleveland Clinic experience.<sup>3</sup>

**POSTDISCHARGE OUTPATIENT EVALUATION.** We recommend outpatient visits for SDD patients on postoperative day 1 or 2 (**Figure 2**). In addition to the physical examination and appropriate laboratory testing (especially for patients with chronic kidney disease or anemia), 12-lead electrocardiogram should be obtained to rule out any delayed conduction deficits. Subsequently, typical outpatient follow-up is recommended.

# MITRAL TRANSCATHETER EDGE-TO-EDGE REPAIR

Mitral transcatheter edge-to-edge repair (TEER) is an important therapy for severe symptomatic mitral regurgitation among patients at prohibitive or high surgical risk.<sup>78</sup> Over time, advances in device technology and increasing annual procedural volume have resulted in a high safety profile in contemporary experience.<sup>79</sup> Relatedly, the latest TVT Registry data demonstrated that the median length of hospital stay for mitral TEER recipients was 1 day (IQR: 1-4 days) in 2019, demonstrating that more than one-half of mitral TEER recipients were discharged on the next day or possibly earlier.<sup>79</sup> Thus, there seems to be a sufficient potential for SDD after mitral TEER.

The current literature on SDD following mitral TEER is limited to 1 case series (n = 6)<sup>80</sup> and 1 retrospective study (n = 82)<sup>81</sup> (**Table 4**). The latter study, from the University of Texas MD Anderson Cancer Center, reported the feasibility of SDD in 82 patients (mean age 80.2  $\pm$  2.5 years, 52% women, mean Society of Thoracic Surgeons risk score 10.6%  $\pm$  2.6%) who underwent successful MitraClip (Abbott Vascular) procedures with moderate sedation without major complications (1 patient had minor bleeding) between February 2019 and April 2020. All patients were seen at the cardiology clinic on the next day. These provocative data should provide the impetus for larger, multicenter studies given the increasing frequency of these cases.

Although several studies have reported the feasibility and safety of conscious or deep sedation for mitral TEER,<sup>81,82</sup> most institutions still use general anesthesia for mitral TEER because of the need for transesophageal echocardiography and the stability provided by low-tidal volume respiration or breathhold during leaflet grasping. Nevertheless, it is quite feasible to extubate these patients immediately after the procedure, while still in the hybrid suite,<sup>80</sup> which allows an appropriate duration of postanesthetic observation and assessment prior to SDD. The necessary postprocedural assessments for SDD are elaborated in Figure 2. As operators will know the patient's volume status on the basis of the left atrial access, they can also consider when a longer inpatient stay for diuresis and/or optimization of heart failure guideline-directed medical therapy is appropriate.

# OTHER TRANSCATHETER VALVE INTERVENTIONS

Given the same venous access sites (without need for a large-bore arterial access) as mitral TEER, SDD appears theoretically feasible in selected uncomplicated

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patients following transfemoral transcatheter mitral valve-in-valve replacement or transcatheter tricuspid valve intervention. As with TEER,<sup>83,84</sup> general recommendations for assurance of venous-site hemostasis prior to SDD are relevant and may point to a benefit in the use of suture-based vascular access closure, which has been shown to facilitate early ambulation. However, as the experience of these procedures is currently limited (see "Transcatheter Mitral Valve-in-Valve Replacement" and "Transcatheter Tricuspid Valve Interventions" in the Supplemental Appendix), further data are needed to examine the safety and feasibility of SDD following these procedures.

### PERCUTANEOUS LAAO

RATIONALE FOR SDD AND SUPPORTING DATA. Percutaneous LAAO is an alternative to oral anticoagulation for stroke prevention in patients with nonvalvular atrial fibrillation.<sup>85</sup> The pivotal PROTECT AF (Watchman Left Atrial Appendage System for Embolic Protection in Patients With Atrial Fibrillation) and PREVAIL (Evaluation of the Watchman LAA Closure Device in Patients With Atrial Fibrillation Versus Long Term Warfarin Therapy) randomized trials established the safety and efficacy of Watchman 2.5 device (Boston Scientific) LAAO, although the incidence of major periprocedural complications (eg, pericardial tamponade, ischemic stroke, device embolization) was not insignificant (8.7% in PRO-TECT AF and 4.2% in PREVAIL).86,87 As these complications typically occur during the procedure or within a few hours thereafter, in typical clinical practice in the United States, most (>80%) patients are hospitalized overnight postprocedure and discharged on the next day.88

More recent experience in the PRAGUE-17 (Left Atrial Appendage Closure vs. Novel Anticoagulation Agents in Atrial Fibrillation) and EWOLUTION (Registry on Watchman Outcomes in Real-Life Utilization) trials reported periprocedural complication rates of 4.5% and 2.8%, respectively,<sup>89,90</sup> and confirming the trends seen in contemporary trials, the NCDR LAAO Registry demonstrated that the complication rate has decreased to 2.16%.<sup>91</sup> In the Amulet IDE (Amplatzer™ Amulet<sup>™</sup> Left Atrial Appendage Occluder Randomized Controlled Trial), investigators also demonstrated a low but slightly higher risk for periprocedural complications for the Amulet (Abbott St. Jude) compared with the Watchman 2.5 (4.5% vs 2.5%), which was driven primarily by pericardial effusion beyond 2 days (1.1% vs 0.1%) and device embolization (0.6% vs 0.2%).92

More recently, several centers have implemented SDD protocols following LAAO. There are currently 6 observational studies, which are summarized in 
 Table 5 and Supplemental Table S3. Gilhofer et al<sup>11</sup>
 and Marmagkiolis et al<sup>93</sup> reported their early experience of SDD after LAAO without significant periprocedural complications, although data are limited because of the lack of a control group. Tan et al<sup>5</sup> compared short-term outcomes between SDD and non-SDD following LAAO and found no significant difference in complications and readmission rates within 45 days post-LAAO (composite outcome 2.8% vs 9.3% [P = 0.14], all-cause readmission 8.3% vs 13.6% [P = 0.27]). Dallan et al<sup>94</sup> also demonstrated the safety of the SDD protocol using intracardiac echocardiography under moderate sedation compared with the conventional protocol using transesophageal echocardiography under general anesthesia, showing no significant difference in procedural and short-term outcomes. The multicenter postmarket study of the Amplatzer Amulet demonstrated similar outcomes between SDD and NDD.95 On the basis of the totality of these data, SDD after LAAO appears to be a safe option in appropriately selected patients.

Most of the available data for SDD after LAAO using the Watchman are based upon implantation of the prior generation Watchman 2.5 device, while the PINNACLE FLX (Protection Against Embolism for Nonvalvular AF Patients: Investigational Device Evaluation of the Watchman FLX LAA Closure Technology) trial using the current Watchman FLX device demonstrated a better safety profile with an incidence of the combined safety endpoint of 0.5%.96 Furthermore, the most recent SURPASS (Surveillance Post Approval Analysis Plan) analysis of the NCDR LAAO Registry, including >16,000 Watchman FLX recipients, demonstrated a similarly low incidence of the safety endpoint (0.37%).<sup>97</sup> Gibson et al<sup>98</sup> recently reported their analysis of 3,167 patients in this registry who underwent SDD compared with 13,266 with a later discharge. Patients selected for SDD were younger, were at lower risk, and had few procedural complications compared with non-SDD patients. Overall, the investigators concluded that SDD following LAAO using the newer device was safe in this real-world registry experience.

**SELECTION CRITERIA FOR SDD AND PERIPROCEDURAL MANAGEMENT.** Criteria for SDD after LAAO are outlined in Figures 2 and 3 and the Central Illustration. Transesophageal echocardiography under general anesthesia has been used mainly to guide the LAAO procedure, and the SDD data provided earlier generally reflect this clinical practice.<sup>5,11,95</sup> Recently,

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several investigators have demonstrated the feasibility and safety of intracardiac echocardiography under moderate sedation as an alternative procedural guidance to transesophageal echocardiography under general anesthesia,<sup>99,100</sup> though the impact on SDD is not yet clear. As access-site bleeding and pericardial effusion are the most common complications of LAAO,<sup>91</sup> it is essential to confirm the access-site hemostasis (suture-based closure may be encouraged) and the lack of pericardial effusion on TTE prior to discharge (**Figure 2**).

A nationwide administrative data study showed that the rate of 30-day readmission after LAAO was 8.3%, and the most common reason for readmission was gastrointestinal bleeding (16.2%), followed by systemic bleeding or anemia (9%).<sup>88</sup> In addition, it has been reported that delayed pericardial effusion after discharge is rare but possible.<sup>101</sup> Therefore, early outpatient follow-up to document both adherence to and tolerance of post-LAAO anticoagulation is important. The contemporary generation Watchman FLX may have a lower complication risk and further facilitate SDD, and recent approval of dual antiplatelet therapy after Watchman implantation may also reduce bleeding risk. Further multicenter studies are warranted to confirm the safety and feasibility of SDD following LAAO along with the evaluation of its costeffectiveness.

## TRANSCATHETER CLOSURE OF PATENT FORAMEN OVALE AND ATRIAL SEPTAL DEFECT

Patent foramen ovale (PFO) and atrial septal defect (ASD) are common congenital heart anomalies, and transcatheter closure (TC)<sup>102</sup> procedures have seen increasing volumes in recent years given supportive data.<sup>103,104</sup>

TC of PFO or ASD is generally guided by fluoroscopy and intracardiac echocardiography with moderate sedation, which facilitates SDD.<sup>105-108</sup> The periprocedural complication rate of TC of PFO or ASD is low (device embolization, 0.1%; cardiac erosion, 0.2%; hemodynamic compromise, 0.65%; new-onset atrial fibrillation, 1.5%)<sup>103,109</sup> and noted primarily during the procedure or early thereafter. A metaanalysis revealed that major periprocedural complications of TC of PFO or ASD occurred in 1.4% of patients (TC of PFO, 1.1%; TC of ASD, 1.6%), with low follow-up complication rates (cerebrovascular events, 1.3%; device thrombosis, 1.2%).<sup>110</sup>

There have been 4 studies investigating SDD following TC of PFO or ASD<sup>105-108</sup> (Table 6). The

largest study, conducted by Barker et al,<sup>107</sup> showed that SDD was achieved in 97.6% of 467 patients undergoing day-case TC of PFO with only selective use of intracardiac echocardiography (18% [n = 86]), with no death and a low 30-day readmission rate of 0.7%. The other 3 smaller studies similarly demonstrated the feasibility and safety of TC of PFO or ASD.

There has been no guideline or consensus document on an SDD pathway following TC of PFO or ASD. However, given the venous access, we propose an SDD pathway similar to that proposed for percutaneous LAAO in this review (**Figures 2 and 3**). Patients should be instructed (regardless of discharge time) regarding the risks for atrial arrhythmia (including atrial fibrillation) after device implantation.

#### **CONCLUSIONS AND FUTURE PERSPECTIVES**

The current health care climate is difficult for patients and providers, with almost all care systems facing unprecedented shortages in workforce resources. Furthermore, longer stay has been shown to adversely affect patient outcomes. In both of these regards, safe reductions in length of hospital stay after interventional procedures can be beneficial to patients and health care systems. There is mounting evidence for SDD after various coronary, peripheral, and structural procedures, and creating care pathways that reflect the safety of earlier discharge with appropriate patient selection can be safe and successful. Further study of SDD safety using observational study designs and registry data analyses, such as those provided, will be beneficial to provide a more robust evidence base.

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KEY WORDS hospital-based resource utilization, patient selection criteria, percutaneous transcatheter cardiovascular intervention, postprocedure management, same-day discharge

**APPENDIX** For supplemental information and tables, please see the online version of this paper.



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