



Update on Minimalist TAVR Care Pathways: Approaches to Care in 2022

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Abstract

Purpose of Review This review summarizes current data supporting a minimalist TAVR approach and identifies the need for additional study to optimize TAVR care. The authors discuss future directions of the TAVR landscape and how this necessitates evolution of minimalist care pathways.

Recent Findings Transcatheter aortic valve replacement (TAVR) has become a mainstay in the treatment of aortic stenosis since the initial procedure in 2002. Recently, attention has shifted to TAVR optimization and the minimalist approach with a focus on minimizing procedural sedation, protocolization of perioperative management, and prioritization on early discharge. This approach has been shown to be safe and reduce procedure time, length of stay, and overall cost for hospital systems.

Summary The minimalist care pathway avoids general anesthesia, shortens procedure time and length of stay, and reduces cost without changing mortality or readmission rates at 30 days. A variety of protocols have been proposed without a clear consensus on specific components or patient eligibility. There is a continued need for data regarding patient risk stratification, valve selection, and discharge strategy as TAVR becomes increasingly common.

Keywords Transcatheter aortic valve replacement (TAVR) · Minimalist TAVR · Minimalist care pathway · Next-day discharge · Same-day discharge

Abbreviations

AS	Aortic stenosis	Hr	Hour
BE	Balloon-expandable	IQR	<i>interquartile range</i>
CABG	Coronary artery bypass grafting	IV	Intravenous
CAD	Coronary artery disease	LA	Local anesthesia
CD	Carotid artery disease	MDCT	Multidetector computed tomography
COPD	Chronic obstructive pulmonary disease	MI	Myocardial infarction
COVID-19	<i>Coronavirus</i> Disease-19	NDD	Next day discharge
CS	Conscious sedation	PA	Pulmonary artery
ECG	Electrocardiogram	PCI	Percutaneous coronary intervention
EuroSCORE	European System for Cardiac Operative Risk Evaluation	PPM	Permanent pacemaker
GE	General anesthesia	SAVR	Surgical aortic valve replacement
		SDD	Same day discharge
		SE	Self-expandable
		STS	Society of Thoracic Surgeons
		TEE	Transesophageal echocardiogram
		TF	Transfemoral
		TTE	Transthoracic echocardiography
		TVAR	Transcatheter aortic valve replacement
		USA	United States of America

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Introduction

In April 2002, the first-in-man transcatheter aortic valve replacement (TAVR) was successfully performed by Alain Cribier, MD. Two decades later, more than 75,000 TAVRs are performed in the USA per year [1]. Now, most patients (95.3%) are treated via transfemoral (TF) access and the adoption of conscious sedation (CS) in lieu of general anesthesia (GA) has been shown to shorten procedure time, lower hospital cost, reduce length of stay, and avoid anesthesia-related complications without affecting patient safety or outcomes [1–9]. The 2020 Society of Thoracic Surgeons-American College of Cardiology Transcatheter Valve Therapy registry (STS-ACC TVT) showed median length of stay after TAVR decreased to 2 days (inpatient quality reporting (IQR), 1–3 days), from a historic median of 7 days (IQR, 4–10 days) [1]. As TAVR becomes the preferred treatment for aortic stenosis, optimization of patient care pathways has advanced the “minimalist approach,” much of which focuses on early discharge to home.

The minimalist approach, or minimalist TAVR care pathway, has been used as a more comprehensive way of describing perioperative and postoperative management of patients. The feasibility of this comprehensive minimalist approach with next-day discharge (NDD) was demonstrated in a prospective multicenter study by Wood et al. in the 3 M TAVR Study [10••]. The 3 M pathway used objective patient criteria and management guidelines; the study included all patients with severe symptomatic aortic valve stenosis who were considered at increased surgical risk by the heart team and excluded patients with unfavorable vascular access for percutaneous access, poor social support, unfavorable airway for emergent intubation, and patients who are unable to lie supine. NDD was achieved in 80.1% of patients with promising safety data regardless of hospital volume [10••]. Subsequent studies have confirmed the safety of early discharge strategies in select patient populations, further supporting minimalist approaches to TAVR management [10••, 11, 12]. Very recently, the feasibility and safety of even same-day discharge (SDD) TAVR has been described [13, 14, 15••].

This review summarizes current data supporting a minimalist TAVR approach and details the components of the minimalist TAVR care pathway, including patient selection, sedation strategies, procedural details, and post-procedure care. The future of the minimalist TAVR care pathway and the importance of optimal management for all patients undergoing TAVR are also discussed.

Pre-Procedural Planning

Eligibility

When evaluating patients with severe aortic stenosis for minimalist TAVR, comorbid conditions and past medical

history are important considerations in determining eligibility. Advance age (age > 90), immobility, severe chronic obstructive pulmonary disease (COPD), morbid obesity, and inability to lie supine for the duration of the procedure and 4–6 h post-procedure have been considered exclusion criteria in some minimalist TAVR protocols [10••, 13]. Cognitive, psychosocial and functional status must also be considered, and limited social support may make early discharge unfeasible.

Current tools developed for risk prediction after surgical aortic valve replacement (SAVR), such as the STS (Society of Thoracic Surgeons) score and EuroSCORE II (European System for Cardiac Operative Risk Evaluation II), do not code for important variables such as frailty, social support, or TAVR-specific factors such as access route or hostile anatomy. Therefore, a thorough multidisciplinary evaluation is essential to determine patients' eligibility for the minimalist pathway.

Preprocedural Imaging

In the early era of TAVR, transesophageal (TEE) was often used for procedural planning. TEE could be used to measure the aortic root, assess the amount of valvular calcification, and size the valve but at the expense of additional invasive procedural exposure to the patient. Currently, transthoracic echocardiography (TTE) is used to define the severity of aortic valve disease and cardiac gated multidetector computed tomography (MDCT) is used for preprocedural planning. MDCT provides superior anatomic characterization of the aortic valve annulus and root, precise coronary artery height and sinus of Valsalva diameters, severity and location of the aortic root calcification as well as appropriateness for transfemoral access or planning for alternative access [16, 17].

Carotid Artery Disease (CD) Screening

To reduce the risk of embolic stroke, early trials required screening for CD prior to TAVR. This was extrapolated from cardiac surgery data [18] as historically all patients undergoing open cardiac surgery were screened for the potential need for carotid artery intervention. However, in a study by Condado et al. among 467 patients who underwent screening for CD prior to TAVR, the authors found no statistical association between carotid artery disease and procedure-related stroke after TAVR [19]. In a larger study by Kochar et al. among 29,143 patients undergoing TAVR across 390 sites in the USA, 22% had CD. Observed in-hospital stroke rates were 2.0–3% but no association between the presence of CD and 30-day stroke or mortality after TAVR. Furthermore, there was no significant risk-adjusted association between

severity of CD and 30-day or 1-year stroke or mortality [20]. Therefore, universal preprocedural CD screening on asymptomatic patients before TAVR is no longer considered standard of care.

Coronary Artery Disease Screening

Given the prevalence of coronary artery disease (CAD) in patients with severe aortic stenosis (AS), left heart catheterization (LHC) was commonly performed prior to TAVR to rule out any coexisting CAD that may contribute to symptoms and require revascularization. With the use of MDCT for preoperative planning, relevant CAD can be assessed and a LHC and the need for revascularization can be reserved for those patients with proximal disease or presenting with angina. A meta-analysis published in 2019 by Lateef et al. showed revascularization in conjunction with TAVR failed to offer additional clinical advantage and did not improve important clinical outcomes (risk of myocardial infarction (MI), stroke, or death at 30 days) [21]. The ACTIVATION trial (percutaneous coronary intervention (PCI) prior to transcatheter aortic valve implantation: a randomized controlled trial), which randomized patients with significant CAD to pre-TAVR PCI and no pre-TAVR PCI, found no difference in the rates of stroke, myocardial infarction, death, or rehospitalization at 1 year [22].

Procedural Details

Sedation Strategy

The adoption of CS, in lieu of GA, has become the main sedation strategy for patients undergoing minimalist TAVR. The randomized SOLVE-TAVI trial (Comparison of Second-Generation Self-Expandable Versus Balloon-Expandable Valves and General Versus Local Anesthesia in Transcatheter Aortic Valve Implantation) showed no difference in all-cause mortality, stroke, acute kidney injury or infection between patients who underwent TAVR with CS versus those who underwent TAVR under GA. Moreover, the use of CS led to a reduction in procedure time, length of stay, and lower need for inotropes or vasopressors [23].

Careful evaluation of individualized risks and benefits of the two methods (CS versus GA) by the heart team is essential. Common exclusion criteria for CS include: morbid obesity, severe chronic obstructive disease, high risk of coronary artery obstruction, and the need for certain alternative access [24].

Device Selection

With regard to device selection, individual anatomic factors, such as aortic valvular structural dimensions, the

presence of annular and subannular calcification, coronary heights, and the need for future coronary access may factor into the prosthesis choice. In addition, the familiarity of the implanting team with a transcatheter platform may guide their decisions. SOLVE-TAVI, and the five-year results from the CHOICE trial (Randomized Comparison of Transcatheter Heart Valves in High Risk Patients with Severe Aortic Stenosis: Medtronic CoreValve Versus Edwards SAPIEN XT), showed no difference in clinical outcomes among patients treated with a self-expanding (SE) or balloon-expandable (BE) valve [23, 25]. Despite this, large studies examining the safety of NDD or SDD have mostly described the utilization of BE valves [10••, 14], as the authors express concerns for higher pacemaker rates with SE valves. However, the Optimize PRO trial is examining a next-day discharge protocol with the SE Evolut valves (Medtronic). At the 30-day interim analysis, the median length of stay was 1 day, and the rate of new permanent pacemaker (PPM) was 8.8%, demonstrating the potential safety of a minimalist protocol after implantation of a SE valve [26].

Access

TF access is typically the default access specified in minimalist TAVR protocols [2, 7, 10••, 27–29]. TF TAVR ease of use, low stroke risk, familiarity to operators, avoidance of surgical incisions, and rapid postoperative mobilization renders it the access of choice for 95.3% of patients in the USA [1].

Until recently, patients with unfavorable anatomy to permit safe TF access were typically relegated to alternative access pathways such as transaxillary, transcarotid, and transcaval. Although transcaval access does preserve many aspects of the transfemoral pathway, it typically involves general anesthesia and has not typically been included in minimalist protocols. However, in patients with calcified iliofemoral vessels and diameters of reasonable size, the use of intravascular lithotripsy (Shockwave IVL; Shockwave Medical) has shown promising results in facilitating transfemoral TAVR and frequently preserving minimalist approaches [30]. This technology may be considered prior to resorting to alternative access in an attempt to mitigate the higher procedural complication rates associated with an alternative access approach.

Intraprocedural Imaging

The use of TTE has gained momentum to replace TEE as a means for complementary intraoperative imaging with fluoroscopy. Multiple studies demonstrate that TTE provides necessary information regarding location and performance of the replacement valve, including its position

within the aortic root, presence of aortic regurgitation, and its impact on nearby cardiac structures including the anterior leaflet of the mitral valve, left ventricular outflow tract, and coronary arteries. In the French registry (FRANCE 2), the use of TEE guidance was performed in 16.9% of patients who underwent TAVR with conscious sedation ($n = 949$), compared to 76.3% of the patients who underwent TAVR with GA ($n = 1377$). After propensity-matching, no significant differences in 30-day survival nor post-procedural aortic regurgitation \geq mild were identified [31]. In a retrospective study performed by Sengupta et al. TAVR using TTE under CS showed decreased procedure time and no difference in procedural success or rate of complications when compared to TAVR using TEE and GA [32].

Invasive Monitoring

With implantation times 30 to 60 min [10••], invasive monitoring is often unnecessary, as most patients only require a peripheral intravenous line. For most patients undergoing minimalist TAVR, there is no need for a central venous catheter, pulmonary artery catheter, or a urinary catheter [40]. As part of the minimalist TF TAVR procedure, the arterial access for the pigtail catheter; preferably radial artery access to minimize adverse bleeding outcomes, can be used for hemodynamic monitoring and the sheath for the transvenous pacer can serve as a central venous line. At the completion of the procedure, all access can be removed if there is no new conduction abnormality or hemodynamic instability.

Post-Procedural Care

Patients can be transferred to the post-procedural care unit and monitored on telemetry [14]. All patients should receive a 12-lead electrocardiogram (ECG) within 1 h of arrival to the post-procedural care unit and prior to discharge to assess for new conduction abnormalities [14, 15••]. To promote hemostasis at the large bore sheath site, patients are maintained on bedrest in a supine position for 4–6 h. Early mobilization is encouraged 4–6 h post-TAVR, per the institutional protocol. A complete transthoracic echocardiogram must be obtained and reviewed prior to discharge.

Complications/Outcomes

The minimalist TAVR care pathway aims to decrease complications. By eliminating general anesthesia, patients avoid cardiovascular (hypotension, reduced vascular tone), respiratory (atelectasis, aspiration, bronchospasm) and neurologic (postoperative cognitive dysfunction) complications [33] and experience shorter total procedural times [3, 10••, 34].

Multiple studies have found similar rates of mortality and readmission in patients who undergo minimalist TAVR care pathway with a focus on early or NDD compared to traditional TAVR approach [5, 7, 8, 11, 12, 15••, 34].

Kamioka et al. reviewed 663 patients undergoing TAVR and compared those who had NDD to those with longer hospital stays. No difference in the hazard rates was found of 30-day outcomes (composite of mortality and readmission) and lower one-year composite outcomes, after cases with complications were excluded. Additionally, they found that patients with NDD had lower composite mortality and readmission at 1-year when compared to those who did not have NDD. The factors associated with NDD were male sex, the absence of atrial fibrillation, lower creatinine, and younger age [2].

In a meta-analysis comparing minimalist with standard approach in 2,880 patients, there was no difference in in-hospital mortality, 30-day mortality, or readmissions [12]. The authors report a decrease in the risk of acute kidney injury (OR 0.49; 95% CI 0.27–0.89), major bleeding (OR 0.21; 95% CI 0.12–0.38), and major vascular complications (OR 0.60; 95% CI 0.39–0.91).

In the original 3 M study, the rate of late heart block was low (0.24%) and not associated with morbidity [10••]. In a prospective, cohort study evaluating 459 TAVR patients with continuous ECG monitoring for 14 days post-TAVR, Muntané-Carol et al. found high-degree atrioventricular block or complete heart block episodes in 5%. Baseline right bundle branch block and new-onset conduction disturbances were associated with increased risk. Regardless, there was no mortality at one month [36]. Subsequent studies have found that minimalist TAVR protocols do not confer higher risk of permanent pacemaker placement [7, 11, 13] (Table 1). However, to avoid morbidity, patients with high-risk conduction features should be considered for an additional night of monitoring in-hospital at this time.

There are several recent studies demonstrating feasibility and safety of SDD after TAVR during the coronavirus disease 2019 (COVID-19) pandemic. Krishnaswamy et al. retrospectively analyzed single-center data of patients who were undergoing TAVR with SDD or NDD. The SDD patients accounted for 22.1% ($n = 114$ out of 516) and NDD for 63.8% ($n = 329$ out of 516). They reported no significant difference in 30-day readmissions or mortality [14]. In a multicenter study by Barker et al. 124 of 2,100 patients who underwent elective transfemoral TAVR were chosen for SDD. There were no vascular complications, strokes, or deaths during the index admission. One patient required PPM but was still discharged the same day. The authors examined a primary composite outcome, including cardiovascular death, stroke, MI, readmission, major vascular complications and new PPM. Out of the 124 selected by the multidisciplinary team for SDD, the composite outcome occurred in 5.7%, which was driven by readmission [15••]. In both studies, a same-day discharge protocol was applied

Table 1 Outcomes in minimalist TAVR pathways

<i>Authors</i>	<i>Year of Publication</i>	<i>Study details</i>	<i>Aspect of minimalist approach examined</i>	<i>Summary of Findings</i>
Frohlich et al.	2014	Systematic review and meta-analysis of 7 studies (1542 patients) comparing monitored anesthesia care with general anesthesia	Sedation strategy	<ul style="list-style-type: none"> Minimal sedation strategies were associated with shorter hospital stays ($p = 0.004$), shorter procedure time ($p < 0.0001$) No difference in overall 30-day mortality ($p = 0.460$) No significant difference in in-hospital mortality (2.5% vs 0.8%, $p = 0.3$) or rates of stroke/TIA (1.7% vs 0.8%, $p = 0.6$) Lower rates of major or life-threatening bleeding (3.4% vs 1.7%, $p = 0.003$) and transfusion (6.8% vs 2.9%, $p = 0.0002$) in minimalist approach group Lower ICU time and length of stay in minimalist group ($p < 0.0002$) No significant difference in in-hospital mortality, 30-day mortality, or readmissions Reduction in risk of kidney injury (OR 0.49; 95% CI 0.27–0.89), major bleeding (OR 0.21; 95% CI 0.12–0.38), and major vascular complications (OR 0.60; 95% CI 0.39–0.91) in minimalist group Combined endpoint of all-cause mortality, stroke, MI, and AKI occurred in similar rates (25.7% vs 23.8%, $p = 0.63$) No difference in 30-day composite (mortality and readmission) (HR: 0.62; 95% CI 0.20–1.91) Lower composite outcome at 1 year in NDD group (HR: 0.47; 95% CI 0.27–0.81) No significant difference in 30-day mortality (OR: 0.65; 95% CI 0.23–1.82), new PPI (OR: 1.61; 95% CI 0.19–13.71) Early discharge patients were less likely to be readmitted (OR: 0.63; 95% CI 0.41–0.98) No deaths in either group No difference in delayed pacemaker placement ($p > 0.99$) or cardiovascular readmission ($p = 0.35$) at 30 days The percentage of next-day discharge from TAVR increased from 1.5% to 12.2% from 2012 and 2016. However, the 30-day readmission rate remained the same
Hosoba et al.	2017	Retrospective review of post-operative complications in 118 matched pairs of patients undergoing minimalist sedation strategy (local or conscious sedation) versus general anesthesia	Sedation strategy	
Qureshi et al.	2021	Meta-analysis of 9 studies (2880 TAVR patients) comparing minimalist with standard approach	Sedation strategy, early mobilization	
Feistritz et al.	2021	Comparison (using 2 × 2 factorial design) of valve type and sedation strategies in patients undergoing TAVR	Sedation strategy	
Kamioka N et al.	2017	Retrospective review of baseline characteristics and composite outcome (mortality and readmission) in patients with next-day discharge (NDD) compared to non-NDD, excluding cases with complications	Next-day discharge	
Kotronias et al.	2018	Meta-analysis of 8 studies evaluating outcomes in patients with early versus standard discharge strategies following TAVR	Early discharge (less than 3-day stay)	
Perdoncin et al.	2020	Prospective analysis of outcomes in patients with same-day discharge compared with matched patient population with longer stays	Same-day discharge	
Yerasi et al.	2020	Retrospective review of readmission rates in 49,742 TAVR procedures, comparing outcomes in those with next-day discharge	Next-day discharge	

Table 1 (continued)

Authors	Year of Publication	Study details	Aspect of minimalist approach examined	Summary of Findings
Barker et al.	2022	Prospective analysis of outcomes in patients selected for same-day discharge following TAVR	Same-day discharge	<ul style="list-style-type: none"> • No major vascular complications, strokes, or death during the index admission • One patient required PPM for heart block but was discharged same day • Composite outcome of cardiovascular death, stroke, MI, readmission, vascular complication rates, and new PPM occurred in 5.7% ($n = 6$ of 106)
Krishnaswamy et al.	2022	Retrospective analysis of outcomes in TAVR patients with same versus next-day discharge	Same-day discharge	<ul style="list-style-type: none"> • No significant difference in in-hospital events and 30-day readmissions • No deaths in either group • One patient required PPM following SDD on day 25

This table summarizes the findings of major studies examining safety data in patients undergoing minimalist TAVR pathways. While the study populations and endpoints vary between studies, all of the studies suggest an incredibly favorable safety profile with respect to sedation strategy and early discharge. Early studies focused on the transition from general to local anesthesia. As these anesthesia strategies became the standard and minimalist pathways refined, the focus shifted in the literature to prioritizing early discharge

for screening of suitable patients and also almost exclusively involved BE valves. This warrants further study to assess its generalizability to patients undergoing TAVR with alternative access and to self-expanding valve platforms.

Follow-Up

The minimalist TAVR pathway's focus on early discharge (within three days) or NDD raises the question of the ideal follow-up strategy. In the 3 M study, the criteria-driven discharge included an individualized plan developed for each patient by the multidisciplinary team [37]. The protocol places specific emphasis on the importance of patient-provider communication. The average time to follow-up was not specified, but all patients had social support for a minimum of 24–48 h after returning home [10••, 37]. For patients with new intraventricular conduction delay, an outpatient ECG was obtained on postoperative days 3 and 5, and beta blockade was held for one-week [10••]. The outpatient follow-up interval and frequency are difficult to study given the wide range of patient complexity. The report by Perdoncin et al. highlighting a SDD protocol, employed a telehealth visit the day after discharge and routine follow up at 30 days [13].

Cost

From a cost perspective, minimalist TAVR has helped streamline resource use. This includes the use of CS rather than GA, utilizing the catheterization laboratory as opposed to the operating suite, and post-procedural protocols designed to facilitate early discharge, all of which have been shown to lower cost of index hospitalization without compromising procedural safety or efficacy [34, 37].

In a study of intermediate-risk patients undergoing TAVR by Baron et al. cost-effectiveness of TAVR was more favorable compared to SAVR. Among patients enrolled in the randomized PARTNER 2 trial, TAVR led to greater quality-adjusted life expectancy while reducing long-term costs by ~\$9,000 compared with SAVR. Moreover, for patients treated with TAVR in the Sapien-3 (S3i) registry, long-term cost savings were even greater (more than \$11,000 per patient) [38•].

Results from an economic analysis of data from PARTNER 3 demonstrated that index hospitalization costs were \$47,196 for TAVR and \$46,606 for SAVR. Between hospital discharge and 2 years, follow-up costs were less for TAVR compared with SAVR (\$19,638 vs. \$22,258, a difference of \$2,620) [39]. Assuming there are no long-term differences in survival or cost, TAVR is projected to be an economically dominant strategy (lower cost, better outcome) with a 95% probability of being cost-effective compared with SAVR. It is conceivable that minimalist care pathways (especially SDD) may further reduce the costs seen during the initial

hospitalization and render TAVR even further economically dominant. That said, TAVR is currently designated by the Centers for Medicare and Medicaid Services as an inpatient-only procedure. Under that regulation, hospital systems should be aware that they risk reimbursement loss if Medicare patients were to be discharged on the same day of the procedure.

Future Directions

As TAVR becomes the main treatment for aortic stenosis, our understanding of the ideal periprocedural care becomes more defined. The minimalist TAVR care pathway avoids GA, shortens procedure time and length of stay, and reduces cost without worsening 30-day mortality or readmission rates [2, 3, 5, 7, 8, 11, 12, 34, 35].

Various minimalist TAVR protocols have been proposed with no clear consensus on eligibility criteria. A comprehensive risk assessment tool specifically for patients undergoing minimalist TAVR would be helpful for broad adoption of NDD. Valve selection for minimalist TAVR is also evolving. Most of the minimalist TAVR studies, both NDD and SDD, have reported on the safety of BE valves. To date, The SOLVE-TAVI and CHOICE trials are the only randomized clinical trials that directly compared BE vs SE valve with both trials demonstrating similar outcomes in patients undergoing conventional TAVR regardless of valve type [23, 25]. The data from the Optimize PRO study in selected patients demonstrate NDD is also safe with a self-expanding TAVR valve [26], and 1-year outcomes will be available soon.

From a resource utilization and cost perspective, minimalist TAVR uses significantly less resources compared to traditional approaches. The COVID-19 pandemic served as a catalyst in the evolution of TAVR to a SDD procedure for carefully selected patients. Importantly, SDD did not carry higher risk of readmission, complications, or mortality [13, 14, 15••]. During the height of the COVID-19 pandemic, SDD TAVR facilitated the continued treatment of patients presenting with heart failure due to severe symptomatic aortic stenosis at a time when hospital systems were faced with critical bed shortages. SDD TAVR was safely done without the need for inpatient beds and decreased the risk of exposure to nosocomial infection to patients and their families. As NDD becomes the standard, it will likely prove more cost effective over time.

Conclusions

Over the last 20 years, the TAVR patient has evolved from high-risk and inoperable to now low-risk and younger patients. By necessity, the care pathway must also evolve. There is a growing need for data to clarify patient risk stratification,

preoperative evaluation, valve selection, and support SDD strategies. Minimalist TAVR is likely to become the standard for aortic valve replacement, allowing patients a less invasive approach, faster recovery, shorter hospital stay, and reduced cost for hospital systems.

Compliance with Ethical Standards

Conflict of Interest Dr. Chandan M. Devireddy receives compensation for the following roles: Medtronic: Consultant; Edwards Lifesciences: Proctor; ReCor Medical: Consultant; and Shockwave Medical: Consultant. Dr. Kendra Grub reports consulting fees from Medtronic, Abbot, W.L. Gore, and 4C Medical. She also reports payment or honoraria from Medtronic, Edwards Lifesciences (Institution), Boston Scientific, and OpSens. The other authors declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent 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.

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Papers of particular interest, published recently, have been highlighted as:

- Of importance
- Of major importance

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