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OPTIMIZING YOUR TAVR PROGRAM

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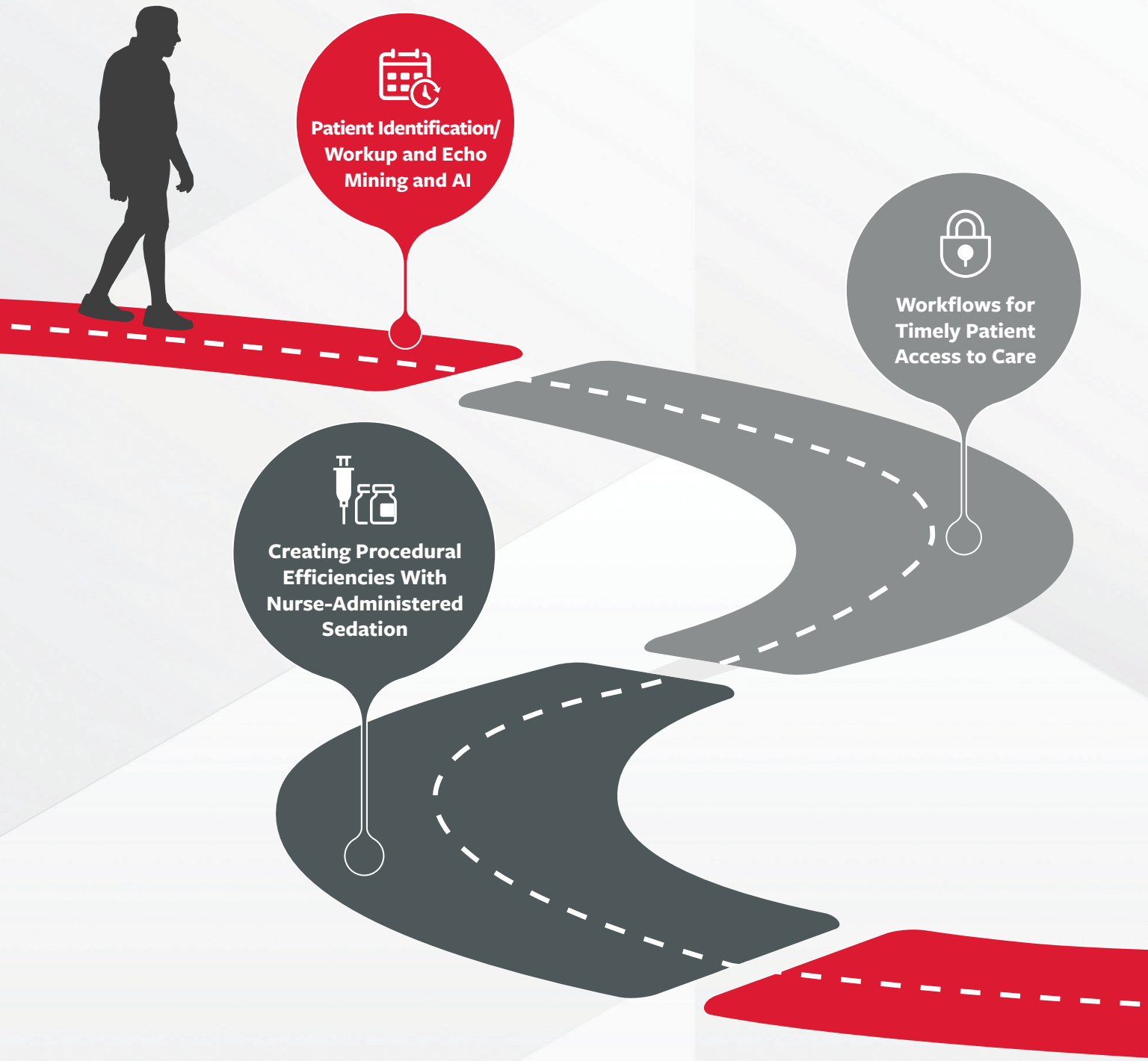

OPTIMIZING YOUR **TAVR PROGRAM**

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How Optimized Is Your TAVR Program?

A look at patient access to care, using AI/echo mining, nurse-assisted sedation, capacity, and economics.

By Rose Hansen, DNP, and Vijay Iyer, MD, PhD, MS, MBA

Transcatheter aortic valve replacement (TAVR) has revolutionized the management of severe aortic stenosis (AS), offering a minimally invasive alternative to surgical valve replacement. Since its FDA approval in 2011 for inoperable patients, indications have rapidly broadened. As of May 2025, the FDA has approved TAVR for asymptomatic severe AS based on data from the EARLY TAVR trial. Asymptomatic AS is only approved for the SAPIEN platform by Edwards Lifesciences. While this progress reflects the safety and efficacy of the procedure, it also introduces a host of challenges for health systems and clinicians tasked with identifying, evaluating, and treating an expanding pool of candidates.

CURRENT FDA-APPROVED INDICATIONS FOR THE SAPIEN PLATFORM

The SAPIEN platform currently has the following FDA-approved indications for TAVR:

- Symptomatic, severe AS in high-risk, intermediate-risk, and low-risk patients
- Asymptomatic severe AS (based on EARLY TAVR trial)
- Valve-in-valve procedures for failed bioprostheses
- Severe native AS with prior balloon valvuloplasty
- Paradoxical low-flow–low-gradient AS

KEY CHALLENGES IN TAVR PROGRAMS AND REFERRALS

Underdiagnosis and Delayed Referral

Many patients with severe AS, especially those who are elderly or have multiple comorbidities, remain undiagnosed until they present with heart failure or syncope. Studies suggest that a significant proportion of patients with echocardiographically confirmed severe AS are never referred to a cardiologist. Inconsistent access to echocardiography and limited awareness among primary care physicians contribute to this delay. Underrecognition is particularly common in asymptomatic patients, despite the new FDA approval encouraging earlier intervention.

Referral Inefficiencies and Fragmented Care

TAVR evaluation requires coordinated input from cardiologists, cardiac surgeons, imaging specialists, anesthesiologists, and valve programs. In many systems, referrals are hindered by fragmented care pathways, lack of structured referral networks, and poor communication across specialties. Regardless of symptoms, patients diagnosed with severe AS should be considered for a heart team evaluation. A growing metric of concern is the time from referral to implantation, which in high-performing systems should ideally be within 30 days to prevent clinical deterioration.

Institutional Workload and Capacity Strain

The expansion of TAVR indications has significantly increased procedural volumes. Many institutions report cath lab congestion, overburdened structural heart teams, and scheduling bottlenecks. Imaging departments, particularly echocardiography and CT, experience increased demand, straining both equipment and personnel. Without adequate investment in staffing and infrastructure, institutions risk compromising quality metrics and patient outcomes.

Staffing and Burnout

Structural heart programs rely heavily on highly specialized personnel. The growing TAVR volume exacerbates burnout among interventional cardiologists, cardiac surgeons, nurse navigators, and echo technologists. Turnover, particularly in nursing and technologist roles, disrupts continuity and delays patient throughput. Institutions must contend with the need to train new staff while maintaining procedural safety and efficiency.

Regulatory and Accreditation Hurdles

The Centers for Medicare & Medicaid Services (CMS) mandates specific institutional and team-based criteria for TAVR programs, including minimum procedural volumes, multidisciplinary heart teams, and outcomes reporting. While intended to ensure quality, these requirements can exclude smaller hospitals or those in rural areas, exacerbating geographic disparities in access. Hospitals may also be reluctant to take on high-risk patients whose outcomes could affect publicly reported performance metrics.

Risk Aversion and Case Selection Bias

To maintain strong outcomes and meet accreditation standards, some programs avoid high-risk or complex patients. This creates a feedback loop in which sicker patients are systematically excluded from referral or denied intervention, undermining the equitable promise of TAVR. Case selection pressures are intensified by the volume-outcome relationship inherent in CMS criteria.

Echo Mining and Screening Solutions

To address underdiagnosis, institutions are turning

TABLE 1. SYSTEMIC CHALLENGES IN TAVR PROGRAMS AND PRACTICAL SOLUTIONS

Challenge	Description	Proposed Solutions	Implementation Considerations
Underdiagnosis	Severe AS often goes undetected, especially in asymptomatic or frail elderly patients	▪ Echo mining ▪ Provider education campaigns	Requires access to structured echo data and IT infrastructure
Delayed or missed referrals	Patients with severe AS are not referred timely to structural heart teams	▪ Centralized referral pathways ▪ EHR-based alerts ▪ Referral-to-implant time target: < 30 d	Depends on institutional coordination and cross-specialty buy-in
Institutional capacity overload	Increased TAVR volume and other structural case volumes strains cath labs, imaging, and staff resources	▪ Workforce expansion ▪ Procedure scheduling optimization	Requires administrative investment and long-term planning
Staffing shortages and burnout	Nurse navigators, sonographers, and interventionalists face rising workload and fatigue	▪ Retention initiatives ▪ Role delegation (eg, advanced practice nurses)	Training time, reimbursement structures, and staff satisfaction metrics
Fragmented multidisciplinary evaluation	Lack of integration between cardiology, surgery, imaging, and anesthesia	▪ Multidisciplinary TAVR conferences ▪ Heart team dashboards	Requires regular coordination and leadership oversight
CMS volume requirements and regulations	Some hospitals struggle to meet procedural volumes or maintain metrics	▪ Policy advocacy for regional models ▪ Partner networks	May involve collaboration with tertiary centers or health systems
Risk-averse case selection	Avoidance of high-risk patients to protect outcome metrics	▪ Risk-adjusted benchmarking ▪ Institutional case review processes	Depends on transparent quality monitoring systems
Disparities in access	Rural, minority, and low-income patients face systemic barriers to TAVR	▪ Mobile heart teams ▪ Tele-evaluation platforms ▪ Echo screening	Requires state/federal funding or institutional mission alignment
Echo data utilization gaps	Echo data often stored in unstructured formats, limiting automation	▪ Natural language processing tools ▪ Structured reporting templates	Integration with electronic health record and radiology/imaging systems
IT and workflow integration	Automation tools and alerts are not always actionable or well integrated	▪ Care coordinator tasking systems ▪ Workflow-specific EHR customization	Depends on institutional IT bandwidth and clinician adoption

Abbreviations: AS, aortic stenosis; CMS, Centers for Medicare & Medicaid Services; EHR, electronic health record; IT, information technology; TAVR, transcatheter aortic valve replacement.

to echocardiographic data mining ("echo mining"). This involves using structured queries or AI tools, including large language model (LLM)–based technology, to scan echo databases for patients with criteria for severe AS (eg, aortic valve area < 1.0 cm^2, mean gradient > 40 mm Hg) who have not been referred. For example, the CardioCare platform (egnite) uses LLM-based algorithms to analyze echo reports and flag potential candidates for structural heart evaluation. Several studies have shown that echo mining can identify large cohorts of patients with missed or delayed referrals.

In parallel, centralized echo screening programs are emerging to proactively flag moderate-to-severe AS in outpatient echo labs. These models, often managed by nurse navigators or care coordinators, help close the loop between diagnosis and referral. They are particularly effective in large, integrated health systems with high echo volumes.

Disparities in Access and Outcomes

Socioeconomic, racial, and geographic disparities persist in TAVR access. Rural hospitals may lack the infrastructure to host a TAVR program or the volume to meet CMS requirements. Minority populations may face systemic barriers to referral or diagnostic testing. Echo mining and centralized referral systems may help address these disparities by applying objective, guideline-based criteria to identify candidates.

Technology Integration and Workflow Limitations

Even with strong echo-mining programs, integration into clinical workflow can be challenging. Automated alerts and flagged reports require follow-up coordination. Electronic health record integration, natural language processing, and interoperability between imaging and clinical systems are still evolving. Many programs lack the information technology support or care coordinators to operationalize these tools effectively.

Future Directions and Policy Implications

Efforts are underway to modernize TAVR accreditation criteria to reflect newer indications and care delivery models. Regional hub-and-spoke systems, mobile heart teams, and telemedicine consults offer ways to extend TAVR access to underserved areas. Policy reforms should prioritize resource flexibility, care equity, and support for innovation in screening and referral (Table 1).

CONCLUSION

As TAVR expands to include asymptomatic and lower-risk populations, institutions must adapt quickly to meet the rising demand. Challenges such as delayed diagnosis, fragmented referral pathways, institutional overload, and regulatory rigidity threaten to limit the reach of this life-saving procedure. Innovations like echo mining and structured screening programs offer promise but require institutional support and policy alignment to be effective. Addressing these barriers is essential to ensuring that all eligible patients can benefit from timely, equitable access to TAVR. ■

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Creating an Efficient TAVR Case Day With Nurse-Administered Sedation

Increasing the efficiency of your TAVR program via minimalist procedural strategies, including a nurse-administered/physician-supervised (NAPS) sedation pathway.

By Brian Stegman, MD, FACC, FSCAI; Sara Dezell, APRN-CNS; Scott Scepaniak, RN; Stephen Kidd, MD, FACC; and Thom Dahle, MD, FACC, FSCAI

Transcatheter aortic valve replacement (TAVR) has dramatically changed patient access to aortic valve replacement and continues to change the way we think about aortic valve disease. In the years since its inception, TAVR has undergone significant changes both in procedural workflow and device iterations. In order to expand structural program bandwidth to handle increasing TAVR indications and emerging structural heart procedures, focus now needs to turn to optimizing programmatic efficiency in an effort to manage costs, maximize patient throughput, and optimize patient outcomes. There are several strategies that can improve efficiency, including minimalist procedural techniques, transition to catheterization lab or hybrid room, utilization of swing rooms, and various sedation strategies.

As the volume of structural heart procedures requiring sedation continue to increase, it can outpace the availability of dedicated anesthesia resources at some institutions. This has led to the adoption of nurse-administered sedation pathways similar to what is used for coronary procedures. While often referred to as "nurse-led sedation," we believe this is a bit of a misnomer as it implies the nurse is operating independently, which is not the case. We believe this sedation strategy would be more appropriately named nurse-administered/physician-supervised (NAPS) sedation, suggesting that the supervising physician (TAVR operator) and nurse work as a team. In this article, we discuss how to develop a safe and efficient NAPS sedation pathway.

PROCEDURAL EFFICIENCY STRATEGIES

In 2016, Lauck et al originally described a focused program to decrease sedation and minimize resource use in TAVR.[1] In this original publication, they endeavored to minimize procedural sedation using local or minimal conscious sedation, avoid central line placement and urinary catheter placement, remove temporary pacemaker at completion of the case when feasible, and provide early mobilization. In this study, they demonstrated a decrease in length of stay (2 days vs 3 days) with no difference in mortality, readmission, or major complication.

This concept of optimizing procedural resource utilization and simplifying the procedural process was further tested in two studies published in 2019. In the 3M study by Wood et al, investigators used a minimalist approach to the TAVR procedure: local anesthesia or minimal conscious sedation, minimal invasive lines and urinary catheters, no perfusionist in the room, and use of transthoracic echocardiography (TTE) rather than transesophageal echocardiography for postprocedure evaluation in high-, intermediate-, and low-procedural-volume medical centers.[2] They were able to achieve an 80.1% next-day discharge rate without any change in procedural or postprocedural outcomes, including a 2.9% 30-day composite of all-cause mortality or stroke rate, a 2.4% vascular complication rate, and a 5.7% pacemaker rate. Furthermore, they had only a 1.5% rate of conversion to general anesthesia and saw no difference in outcomes between high-, intermediate-, and low-volume TAVR centers, suggesting the generalizability of this concept.[2]

The minimalist approach for TAVR was further supported in a publication in 2019 by Burns et al.[3] In this study, they described transitioning from a model of general anesthesia with full surgical staffing to a more

TABLE 1. KEYS TO PROCEDURAL EFFICIENCIES

Procedure	Staffing	Supplies
▪ NAPS sedation ▪ Cath lab skin prep and draping ▪ Stop unnecessary radial artery and central lines ▪ No Foley	▪ Reduce staffing; people cost money ▪ Anesthesia resources are in demand; use them where most needed ▪ Perfusionists are needed elsewhere ▪ Swing-room strategy is more expensive; it requires twice the resources and sometimes is not an option	▪ There is a cost for opening surgical supplies that are not needed ▪ Consolidation of TAVR supplies (TAVR cart) ▪ Price compare procedural supplies ▪ Standardization of procedure regardless of provider ▪ Medications are expensive, some more than others

Abbreviations: NAPS, nurse-administered/physician-supervised; TAVR, transcatheter aortic valve replacement.

minimalist approach involving conscious sedation, omission of urinary catheters and central/invasive lines not required for the procedure, TTE for postimplantation evaluation, and a staffing model that no longer included perfusion or surgical support staff. The minimalist model demonstrated a shorter length of stay (2 vs 3 days; $P < .001$); lower requirements for postanesthesia care unit or intensive care unit; a greater rate of discharge directly to home (97% vs 85%; $P < .001$); no difference in mortality, cerebrovascular events, vascular complications, or bleeding; and no conversions to general anesthesia. Furthermore, variable costs per patient were decreased by 17.9% in this minimalist arm.[3]

Additional focus on improving procedural and periprocedural efficiency was described by Pop et al, involving many of these outlined approaches while taking additional steps in optimizing room turnover and procedure day efficiency. This reportedly led to improvement in procedural times (goal < 45 min), as well as dramatically improving room turnover times to an average of approximately 15 minutes (national average, approximately 59 min).[4] These parameters are in line with our experience when employing similar programs to improve procedure day efficiency using standard ultrasound-guided access, techniques minimizing invasive lines, catheterization lab prep and staffing model with NAPS sedation, and routine removal of all lines at the end of the procedure unless high-degree atrioventricular block is noted (Table 1).

NAPS SEDATION PATHWAY

Nurse-administered/physician-supervised (NAPS) sedation differs from traditional anesthesia in that an interventionalist or cardiovascular surgeon performing TAVR monitors the hemodynamics and sedation needs of the patient, and the catheterization lab nurse administers the sedation, similar to the standard practice of other invasive cardiac procedures. While TAVR is a less invasive option than surgery, it still requires a high level of expertise to ensure the safety and comfort of patients undergoing the procedure. NAPS sedation

TABLE 2. BENEFITS OF MINIMIZING ANESTHESIA DURING PERCUTANEOUS PROCEDURES

Benefits for Patients and Families	Benefits for Hospital
▪ Faster recovery and ambulation ▪ Patient starts and returns to same unit room (telemetry/telemetry equivocal) ▪ Reduces risk of delirium/confusion ▪ Families can interact with the patient sooner ▪ More reliable and accurate periprocedural neurologic assessment, leading to less concern/formal neurologic assessments ▪ More vitally stable to reinitiate medications taken prior to administration and adjust appropriately prior to next-day discharge	▪ Light sedation can be administered by cath lab nurse, allowing limited anesthesia resources to be reserved for procedures requiring general anesthesia due to patient instability, pain, recovery, etc. ▪ Eliminates the need for PACU or ICU for recovery ▪ Reduces patient hemodynamic instability associated with general or deep anesthetics leading to vasodilation and decreased preload ▪ Less need for pressors and/or intravenous volume administration interprocedurally

Abbreviations: ICU, intensive care unit; PACU, postanesthesia care unit.

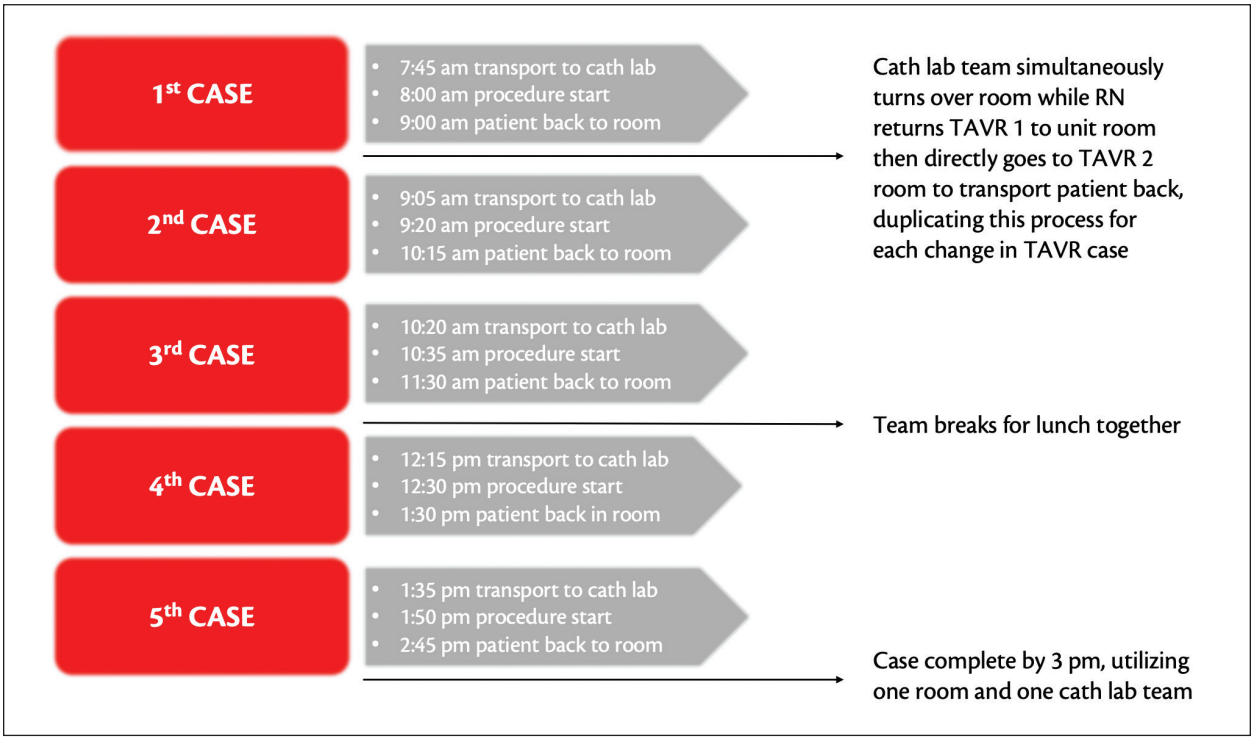

Figure 1. A typical TAVR day.

in TAVR is guided by protocols that ensure patient safety while allowing nurses to administer sedative medications, monitor the patient's response, and adjust doses as necessary. This approach is performed under the direct supervision of a physician and is supported by a multidisciplinary team, ensuring safety and compliance with institutional and regulatory guidelines. Demonstrated benefits of NAPS sedation to patients and the hospital system are shown in Table 2.

When deciding how to transition to a NAPS sedation pathway as standard practice for percutaneous TAVR, there are a few important steps to consider. First, it is important to bring together all stakeholders in every department to ensure clear communication throughout the entire process. Prior to setting a start date to transition to NAPS sedation, the procedural team should evaluate current best practices to ensure a fully optimized minimalist approach for efficient and safe procedures to improve patient comfort and decrease time on the table. All access should routinely be performed under ultrasound guidance with visualization of generous lidocaine administration all the way to the anterior wall of the vessel (approximately 10-20 mL in femoral access sites), with adequate time given for full local anesthetic effect. Care is taken to select sedation that is appropriate for the patient, allowing for minimal sedation in those who tolerate it and greater sedation in those who require it, while maintaining appropriate patient alertness. Further costs and time savings are achieved by no longer opening unnecessary surgical trays and considering patient prepping and draping consistent with that of a coronary angiogram.

An initial "structural team" of experienced staff creates a team that can be expanded and used for training to later include additional members after the process has been perfected. Finally, it is critical to involve your anesthesia team to create a stepwise plan for the transition to full NAPS sedation. This may include the presence of anesthesia during NAPS sedation for a predesignated number of cases or for higher-risk cases, until all parties are comfortable with the processes and consistent safety is demonstrated. Prior to anesthesia no longer being present during the cases, an emergency plan must be developed and agreed upon in the event the anesthesia team is needed for emergent services.

NURSING EDUCATION/TRAINING FOR NAPS SEDATION MODEL

The NAPS sedation model requires thorough training to ensure that nurses are equipped with the necessary knowledge and skills to manage the sedation process

effectively. This training focuses on patient assessment, pharmacology of sedation drugs, monitoring sedation depth, recognizing and managing potential complications, and responding to any emergencies that may arise during the procedure. Nurses are also trained in the principles of patient-centered care, emphasizing communication and ensuring that patients are informed and comfortable throughout the procedure. Conveying a consistent message from the entire team about the planned level of sedation throughout is critical.

Sedation management in TAVR procedures is a delicate balance that requires constant monitoring and swift decision-making. NAPS sedation training typically covers multiple aspects of this balance.

1. **Patient Assessment:** Nurses are trained to assess each patient's medical history, sedation history and dosages received, comorbidities, and individual risk factors that may influence sedation protocols. This is critical for determining the appropriate sedation level and ensuring that the patient is stable throughout the procedure.
2. **Sedation Pharmacology:** Nurses are educated on the various sedatives and analgesics used in TAVR procedures, including their mechanisms of action, dosing, and potential side effects. Typical dosage ranges include midazolam (1-4 mg), fentanyl (25-100 µg), ondansetron (4 mg), and phenylephrine (50-100 µg) as needed for hemodynamic support.
3. **Monitoring and Safety:** Continuous monitoring of the patient's vital signs, including heart rate, blood pressure, oxygen saturation, capnography, and level of consciousness, is a critical part of the sedation protocol and monitored by both the physician and registered nurse.
4. **Crisis Management:** In the event of an emergency, such as an adverse reaction to a sedative, nurses are trained in rapid response techniques, including the use of reversal agents (eg, Romazicon, naloxone) or other appropriate airway interventions to stabilize the patient. This training ensures that nurses are prepared to handle any unexpected developments during the procedure.

It is important to have consistent messaging to manage the expectations of patients, family, and staff members for NAPS sedation and minimalist procedural techniques. Start the conversation regarding conscious sedation early on in consultation so that when final recommendations are made after heart team discussions the patient is fully aware of their sedation type. One technique to understand how each patient will individually tolerate minimal sedation is to assess their tolerance and calmness during a pre-TAVR coronary angiogram using only local lidocaine. We often tell patients, "We will use as much or as little sedation as necessary to make sure you are comfortable and stable during the procedure." Individual nursing staff seeing the patients prior to the procedure all reiterate these optimal sedation expectations. These steps will ensure consistency among every member of the team and instill confidence in the patient and family.

CASE-DAY EFFICIENCY

Using these strategies appropriately can result in significant improvement in the efficiency of TAVR case days. By following this stepwise approach, we were able to improve the throughput of our program, manage costs, and optimize patient outcomes without the need for additional staff, catheterization labs (swing labs), or procedural days. In addition to these strategies to improve workflow efficiency, we have found it important to ensure that efficient nurse handoffs and seamless patient transfers occur while the procedural staff are tearing down and setting up the room in a coordinated efficient way. This leads to optimizing turnover times and case-day efficiency. An example of our typical TAVR day is shown in Figure 1 and has been consistently replicated for > 3 years. This has also allowed better utilization of our crucial anesthesia team for other structural procedures that require deeper sedation.

CONCLUSION

Combining these validated minimalist strategies in addition to more efficient sedation pathways can consistently lead to more efficient TAVR case days. This will allow further program growth and bandwidth of a structural heart program, without requiring additional staff and costly resources. ■

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TAVR Economics

How partnerships, a lean program, and a holistic view can grow structural heart programs.

By Andrei Pop, MD, and Michael Busky

Since its approval in 2012, transcatheter aortic valve replacement (TAVR) has evolved from a complex procedure requiring extensive personnel and hospital resources to a highly streamlined and often minimalistic procedure. As TAVR indications have expanded to include all patient surgical risk categories, the outcomes have remained excellent, reflecting improvements in technology and better understanding of all aspects of the procedure.[1]

TAVR has been widely adopted in academic and community hospitals and now represents the dominant form of aortic valve replacement (AVR) in the United States. In 2021, TAVR accounted for 47.5% of AVR performed in patients under the age of 65 years.[2] Although initially seen as a cause for alarm given the lack of randomized data in patients in this age group, later data have confirmed that the treated patients were deemed by the valve team to be at increased risk for surgical complications.[3] Indeed, the concept of the patient-centric, multidisciplinary heart team may be one of the most important contributions that TAVR has bestowed upon the field.

MINIMALISTIC TAVR

As TAVR has become increasingly streamlined, the safety of minimalistic TAVR has been demonstrated.[4,5] The COVID pandemic and subsequent staff shortages brought a further impetus to move TAVR from the operating room to the cardiac cath lab to limit the size of the team involved and reduce length of stay. Structural volumes have also increased markedly, via expanding indications as well as the advent of new technologies. This has placed additional demands on the teams performing the procedures and created additional pressure on cath labs, imaging, and anesthesia.

TABLE 1. AN OPTIMAL TAVR SCHEDULE*

	Case 1	Case 2	Case 3	Case 4	Case 5	Case 6	Case 7
Patient arrival	6:00	6:30	7:45	9:00	10:15	11:30	12:45
Anesthesia evaluation	6:45	8:15	9:30	10:45	12:00	13:15	14:30
Valve conference	7:00-7:30	–	–	–	–	–	–
Patient in room	7:00	8:30	9:45	11:00	12:15	13:30	14:45
Femoral access	7:30	8:45	10:00	11:15	12:30	13:45	15:00
Procedure completion	7:55	9:10	10:25	11:40	12:55	14:10	15:25
Transfer to holding	8:10	9:25	10:40	11:55	13:10	14:25	15:40
Ambulation	12:10	13:25	14:40	15:55	17:10	18:25	19:40
Potential discharge	14:10	15:25	16:40	17:55	19:10	20:25	–

*Longer procedure times may be needed in more complex cases, including alternative access, leaflet modification, etc. Fluctuations in staffing levels can also affect procedural turnaround.

Unique among the commonly performed structural procedures, TAVR is tied to a survival benefit, and TAVR delays carry a significant mortality risk for patients (3.7% per month in one series).[6] Aortic stenosis (AS) has been shown to be vastly underdiagnosed and undertreated, even in major academic institutions[7] and especially for underserved populations (in terms of sex, ethnicity, or socioeconomic background and also in terms of distance from TAVR centers).[8]

A range of interventions have been proposed to improve access to and the timeliness of treatment. Echo-mining software,[9] AI-assisted diagnostic algorithms,[10] automated referrals, and standardized echo reporting can facilitate getting patients to the heart team faster. Minimizing extraneous workup (eg, carotid duplex, pulmonary function test, urinalysis, coronary angiography) helps move patients from the heart team to treatment faster.[11-14] Minimalistic TAVR with limited anesthesia (nurse-administered sedation or monitored anesthesia care [MAC]) facilitates patient recovery and allows for faster room turnaround and treatment of more patients per day in one room.[15] Enhanced recovery protocols with ambulation as early as 2 to 4 hours postprocedure help expedite patient recovery and move the needle on reducing intensive care unit (ICU) usage and length of stay.[16] One-day lengths of stay are now becoming the norm in many institutions, and same-day discharge has been shown to be safe in carefully selected patients.[17,18]

THE BENCHMARK PROGRAM AT ALEXIAN BROTHERS MEDICAL CENTER

The structural program at Alexian Brothers started in 2014 with TAVR procedures performed under general anesthesia in the cardiac cath lab. The first patient was treated under MAC in 2016, and a hybrid room was built in 2019 in the cardiac cath lab. Our program was the first commercial site to adopt the Edwards Benchmark program in March 2020. The Edwards Benchmark program is designed to align the multidisciplinary heart team on the minimalist TAVR approach to improve the patient care pathway through evidence-based best practices and peer-to-peer guidance. The contemporaneous advent of the COVID epidemic spurred a need to bypass the ICU for the majority of patients and emphasize next-day discharge. To further reduce the risk of nosocomial COVID transmission, a same-day discharge program that had been started in 2011 for PCI was expanded to include a wide range of procedures, including left atrial appendage occlusion (LAAO), transcatheter edge-to-edge repair (TEER), endovascular aneurysm repair, and thoracic endovascular aortic repair. The same-day discharge program for selected TAVR patients was started in July 2020.

Our program has gradually moved our staffing for TAVR patients from a maximalist to a minimalist approach. We currently perform TAVR under MAC (generally provided by a certified registered nurse anesthetist), supported by a scrub tech, a circulating registered nurse, and a recorder; one additional staff member may be available to facilitate room turnaround. After valve deployment, an echo tech obtains limited images. We generally only evaluate for paravalvular leak and pericardial effusion; a more extensive evaluation involving ventricular ejection fraction and transaortic gradients is performed in the holding area after the patient has recovered from anesthesia and can get out of bed/turn on their side to facilitate imaging. A housekeeper is assigned to the cath lab to expedite room turnaround. Most patients are awake throughout the procedure and sedation is terminated the moment the valve is deployed, allowing for a brief neurologic examination to be performed on the table. Patient recovery can be completed in the procedure room. This allows for the anesthesia provider to evaluate the next procedure as the patient is undraped, Doppler pulses are

checked, and manual pressure is applied to the groin after administration of protamine (Table 1).

Since our program has transitioned to a limited staffing model for TAVR, we have seen no impact on outcomes and have observed an improvement in room turnaround. Our experience shows that additional staffing does not correlate with either increased safety or efficiency.

For most cases, only two ultrasound-guided access sites are obtained: femoral for the TAVR sheath and left radial for a pigtail. Most cases undergo pacing through the left ventricular wire, eliminating the need for another access site and risk of right ventricular injury from the pacing catheter. No central lines or Foley catheters are used.

In view of the known worse outcomes of patients who undergo emergent TAVR,[19] we try to avoid these procedures, performing balloon aortic valvuloplasty and offering patients a chance to rehab and recover from any acute comorbidities whenever possible before performing TAVR on a more elective basis.

Despite the surgical team and perfusion no longer being involved in the TAVR team for most patients, all patients are evaluated independently in the valve clinic by a cardiologist and a surgeon. Cases are discussed in the multidisciplinary valve conference on a weekly basis and a cardiologist and surgeon are present for every TAVR case. We consider the lifetime management of patients with AS for every valve implant—both surgical and transcatheter options.

Most patients require a single valve team visit, and the CT scan is performed the same morning. We generally maintain the ability to treat patients within 5 to 7 days of valve team evaluation. The brief procedure time and quick room turnaround allows our team to perform six to seven standard transfemoral TAVRs in one room in one day, and it facilitates ad hoc case additions on other days when needed.

Besides closely monitoring complications and STS/ACC TVT Registry database outcomes, the program conducts quarterly economic reviews. Although reimbursement and valve costs are outside most program's control, we closely monitor direct costs, including the cost and amount of equipment being used, general anesthesia use, ICU utilization, procedure time, time in room, room turnaround, length of stay, readmission rate, percentage of urgent TAVRs, and discharge destination.

THE ECONOMIC IMPACT OF A LEAN TAVR PROGRAM

As the field of structural interventions continues to expand, heart teams are required to participate in an ever-expanding range of procedures. TAVR, mitral and tricuspid TEER, LAAO, transcatheter tricuspid valve repair (TTVR), and transcatheter mitral valve repair (TMVR) procedures all compete for the same resources. At the same time, many programs are facing staffing challenges and high turnover, not only for cath lab staff but also for echo technicians, anesthesia providers, ICU, and general ward staff. Additionally, even as the population ages and cardiovascular diseases are projected to increase, the number of cardiologists retiring is outpacing the supply of new graduates.[20]

Improved diagnostics and the expansion of procedures to untreated populations—TAVR for asymptomatic AS, moderate AS, or aortic insufficiency; LAAO as first-line therapy for the prevention of cardio-embolic stroke in atrial fibrillation; percutaneous mitral valve replacement therapies—may add additional demands on already stretched providers and health systems. To accommodate the increasing demand for structural heart procedures, programs will need to increase capacity and decrease resource use, while maintaining outcomes, improving access to care, and minimizing patient wait times.

Implementing an efficient, minimalistic program that delivers good outcomes cannot be achieved overnight. This process needs to start with a strong administrator/physician leader dyad team and requires the participation of a range of stakeholders, including cardiologists, surgeons, anesthesiologists, and nursing. Transparency and data sharing on clinical and economic parameters is paramount, and savings need to return to the involved institutions and departments. Additionally, some redundancy needs to be maintained to account for inevitable surges in demand and decreases in staffing.

When confronted with the need for more streamlined procedures and economic efficiency, patient safety concerns are sometimes invoked. We now have solid clinical data demonstrating that minimalistic TAVR yields outcomes that are at least equivalent to traditional "maximalist" approaches. Enhanced recovery protocols have been widely adopted for surgical procedures and have improved patient outcomes while reducing length of stay.

Just because we have always done things this way does not mean that a better, more efficient way does not exist and should not be explored/adopted. At the same time, achieving economic efficiencies should never come at the expense of patient safety, and any deviation from prespecified safety endpoints should be closely scrutinized and addressed.

CONCLUSION

Since first becoming commercially available in the United States in 2012, TAVR has evolved considerably.

In an age of limited resources and increasing volumes for a wide variety of structural procedures, as well as new TAVR indications, programs need to be lean and efficient in order to thrive and accommodate growth. ■

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Important Safety Information
Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, and Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System

Indications: The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated to reduce the risks associated with progression from asymptomatic to symptomatic severe native calcific aortic stenosis in patients who are judged by a heart team to be appropriate for transcatheter heart valve replacement therapy.

The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a Heart Team, including a cardiac surgeon, to be appropriate for the transcatheter heart valve replacement therapy.

The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for patients with symptomatic heart disease due to a failing (stenosed, insufficient, or combined) surgical or transcatheter bioprosthetic aortic valve, or a native mitral valve with an annuloplasty ring who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for patients with symptomatic heart disease due to a failing (stenosed, insufficient, or combined) surgical bioprosthetic mitral valve who are judged by a heart team, including a cardiac surgeon, to be at intermediate or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 4% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

Contraindications: The valves and delivery systems are contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis or other active infections, or who have significant annuloplasty ring dehiscence.

Warnings: Observation of the pacing lead throughout the procedure is essential to avoid the potential risk of pacing lead perforation. There may be an increased risk of stroke in transcatheter aortic valve replacement procedures, as compared to balloon aortic valvuloplasty or other standard treatments in high or greater risk patients. The devices are designed, intended, and distributed for single use only. **Do not resterilize or reuse the devices.** There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing. Incorrect sizing of the valve may lead to paravalvular leak, migration, embolization, residual gradient (patient-prosthesis mismatch), and/or annular rupture. Accelerated deterioration of the valve due to calcific degeneration may occur in children, adolescents, or young adults and in patients with an altered calcium metabolism. Prior to delivery, the valve must remain hydrated at all times and cannot be exposed to solutions other than its shipping storage solution and sterile physiologic rinsing solution. Valve leaflets mishandled or damaged during any part of the procedure will require replacement of the valve. Caution should be exercised in implanting a valve in patients with clinically significant coronary artery disease. Patients with pre-existing prostheses should be carefully assessed prior to implantation of the valve to ensure proper valve positioning and deployment. Do not use the valve if the tamper-evident seal is broken or the storage solution does not completely cover the valve (SAPIEN 3 and SAPIEN 3 Ultra only), the temperature indicator has been activated, the valve is damaged, or the expiration date has elapsed. Do not mishandle the delivery system or use it if the packaging or any components are not sterile, have been opened or are damaged (e.g., kinked or stretched), or if the expiration date has elapsed. Use of excessive contrast media may lead to renal failure. Measure the patient's creatinine level prior to the procedure. Contrast media usage should be monitored. Patient injury could occur if the delivery system is not un-flexed prior to removal. Care should be exercised in patients with hypersensitivities to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or polymeric materials. The procedure should be conducted under fluoroscopic guidance. Some fluoroscopically guided procedures are associated with a risk of radiation injury to the skin. These injuries may be painful, disfiguring, and long-lasting. Valve recipients should be maintained on anticoagulant/antiplatelet therapy, except when contraindicated, as determined by their physician. This device has not been tested for use without anticoagulation. Do not add or apply antibiotics to the storage solution (SAPIEN 3 and SAPIEN 3 Ultra only), rinse solution, or to the valve. Balloon valvuloplasty should be avoided in the treatment of failing bioprostheses as this may result in embolization of bioprosthesis material and mechanical disruption of the valve leaflets. Do not perform stand-alone balloon aortic valvuloplasty procedures in the INSPIRIS RESILIA aortic valve for the sizes 19-25 mm. This may expand the valve causing aortic incompetence, coronary embolism or annular rupture. Transcatheter valve replacement in mitral annuloplasty rings is not recommended in cases of partial annuloplasty ring dehiscence due to high risk of PVL. Transcatheter valve replacement in mitral annuloplasty rings is not recommended in cases of partial (incomplete) annuloplasty rings in the absence of annular calcium due to increased risk of valve embolization. Transcatheter valve replacement in mitral annuloplasty rings is not recommended in cases of rigid annuloplasty rings due to increased risk of PVL or THV deformation.

Precautions: Long-term durability has not been established for the valve. Regular medical follow-up is advised to evaluate valve performance. Limited clinical data are available for transcatheter aortic valve replacement in patients with a congenital bicuspid aortic valve who are deemed to be at low surgical risk. Anatomical characteristics should be considered when using the valve in this population. In addition, patient age should be considered as long-term durability of the valve has not been established. Data on TAVR in patients with asymptomatic severe aortic stenosis are based on study of predominantly low surgical risk patients. Limited clinical data to inform benefit-risk considerations are available for TAVR in patients with asymptomatic severe aortic stenosis who are deemed to be at intermediate or greater surgical risk. Glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to, or breathing of, the solution. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water; in the event of contact with eyes, seek immediate medical attention. For more information about glutaraldehyde exposure, refer to the Safety Data Sheet available from Edwards Lifesciences. If a significant increase in resistance occurs when advancing the catheter through the vasculature, stop advancement and investigate the cause of resistance before proceeding. Do not force passage, as this could increase the risk of vascular complications. As compared to SAPIEN 3, system advancement force may be higher with the use of SAPIEN 3 Ultra/SAPIEN 3 Ultra RESILIA THV in tortuous/challenging vessel anatomies. To maintain proper valve leaflet coaptation, do not overinflate the deployment balloon. Appropriate antibiotic prophylaxis is recommended post-procedure in patients at risk for prosthetic valve infection and endocarditis. Additional precautions for transseptal replacement of a failed mitral valve bioprosthesis include, the presence of devices or thrombus or other abnormalities in the caval vein precluding safe transvenous femoral access for transseptal approach; and the presence of an Atrial Septal Occluder Device or calcium preventing safe transseptal access. Special care must be exercised in mitral valve replacement to avoid entrapment of the subvalvular apparatus. Safety and effectiveness have not been established for patients with the following characteristics/comorbidities: non-calcified aortic annulus; severe ventricular dysfunction with ejection fraction < 20%; congenital unicuspid aortic valve; pre-existing prosthetic ring in the tricuspid position; severe mitral annular calcification (MAC); severe (> 3+) mitral insufficiency, or Gorlin syndrome; blood dyscrasias defined as leukopenia (WBC < 3000 cells/mL), acute anemia (Hb < 9 g/dL), thrombocytopenia (platelet count < 50,000 cells/mL), or history of bleeding diathesis or coagulopathy; hypertrophic cardiomyopathy with or without obstruction (HOCM); echocardiographic evidence of intracardiac mass, thrombus, or vegetation; a known hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid), or clopidogrel (Plavix), or sensitivity to contrast media, which cannot be adequately premedicated; significant aortic disease, including abdominal aortic or thoracic aneurysm defined as maximal luminal diameter 5 cm or greater, marked tortuosity (hyperacute bend), aortic arch atheroma (especially if thick [> 5 mm], protruding, or ulcerated) or narrowing (especially with calcification and surface irregularities) of the abdominal or thoracic aorta, severe "unfolding" and tortuosity of the thoracic aorta; access characteristics that would preclude safe placement of the Edwards sheath, such as severe obstructive calcification or severe tortuosity; bulky calcified aortic valve leaflets in close proximity to coronary ostia; a concomitant paravalvular leak where the failing prosthesis is not securely fixed in the native annulus or is not structurally intact (e.g., wireform frame fracture, annuloplasty ring dehiscence); or a partially detached leaflet of the failing bioprosthesis that in the aortic position may obstruct a coronary ostium. For Left axillary approach, a left subclavian takeoff angle ~ ≥ 90° from the aortic arch causes sharp angles, which may be responsible for potential sheath kinking, subclavian/axillary dissection and aortic arch damage. For left/right axillary approach, ensure there is flow in Left Internal Mammary Artery (LIMA)/Right Internal Mammary Artery (RIMA) during procedure and monitor pressure in homolateral radial artery. Residual mean gradient may be higher in a "THV-in-failing prosthesis" configuration than that observed following implantation of the valve inside a native aortic annulus using the same size device. Patients with elevated mean gradient post procedure should be carefully followed. It is important that the manufacturer, model and size of the preexisting prosthesis be determined, so that the appropriate valve can be implanted and a prosthesis-patient mismatch be avoided. Additionally, pre-procedure imaging modalities must be employed to make as accurate a determination of the inner diameter as possible.

Potential Adverse Events: Potential risks associated with the overall procedure, including potential access complications associated with standard cardiac catheterization, balloon valvuloplasty, the potential risks of conscious sedation and/or general anesthesia, and the use of angiography: death; stroke/transient ischemic attack, clusters, or neurological deficit; paralysis; permanent disability; respiratory insufficiency or respiratory failure; hemorrhage requiring transfusion or intervention; cardiovascular injury including perforation or dissection of vessels, ventricle, atrium, septum, myocardium, or valvular structures that may require intervention; pericardial effusion or cardiac tamponade; thoracic bleeding; embolization including air, calcific valve material, or thrombus; infection including septicemia and endocarditis; heart failure; myocardial infarction; renal insufficiency or renal failure; conduction system defect which may require a permanent pacemaker; arrhythmia; retroperitoneal bleed; arteriovenous (AV) fistula or pseudoaneurysm; reoperation; ischemia or nerve injury or brachial plexus injury; restenosis; pulmonary edema; pleural effusion; bleeding; anemia; abnormal lab values (including electrolyte imbalance); hypertension or hypotension; allergic reaction to anesthesia, contrast media, or device materials; hematoma; syncope; pain or changes (e.g., wound infection, hematoma, and other wound care complications) at the access site; exercise intolerance or weakness; inflammation; angina; heart murmur; and fever. Additional potential risks associated with the use of the valve, delivery system, and/or accessories include: cardiac arrest; cardiogenic shock; emergency cardiac surgery; cardiac failure or low cardiac output; coronary flow obstruction/transvalvular flow disturbance; device thrombosis requiring intervention; valve thrombosis; device embolization; device migration or malposition requiring intervention; left ventricular outflow tract obstruction; valve deployment in unintended location; valve stenosis; structural valve deterioration (wear, fracture, calcification, leaflet tear/tearing from the stent posts, leaflet retraction, suture line disruption of components of a prosthetic valve, thickening, stenosis); device degeneration; paravalvular or transvalvular leak; valve regurgitation; hemolysis; device explants; nonstructural dysfunction; mechanical failure of delivery system and/or accessories; and non-emergent reoperation.

Edwards Crimper

Indications: The Edwards crimper is indicated for use in preparing the Edwards SAPIEN 3 transcatheter heart valve, Edwards SAPIEN 3 Ultra transcatheter heart valve, and the Edwards SAPIEN 3 Ultra RESILIA transcatheter heart valve for implantation.

Contraindications: There are no known contraindications.

Warnings: The device is designed, intended, and distributed for single use only. **Do not resterilize or reuse the device.** There are no data to support the sterility, nonpyrogenicity, and functionality of the device after reprocessing. Do not mishandle the device. Do not use the device if the packaging or any components are not sterile, have been opened or are damaged, or the expiration date has elapsed.

Precautions: For special considerations associated with the use of the Edwards crimper prior to THV implantation, refer to the THV Instructions for Use.

Potential Adverse Events: There are no known potential adverse events associated with the Edwards crimper.

CAUTION: Federal (United States) law restricts these devices to sale by or on the order of a physician.

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