

# Cardiac Interventions TODAY

November/December 2016

## Transcatheter Aortic Valve Replacement (TAVR): Economies, Efficiencies, and Effectiveness



Four leading institutions provide insights on the many approaches to improving outcomes, efficiencies, and economics in TAVR centers.

*Funding for this supplement provided by Medtronic*

# Collaboration Allows TAVR to Reach its Potential

BY CHRISTOPHER U. MEDURI, MD, MPH; MEREDITH BRAZELL, PA-C; BRYAN GRIFFITH; MORRIS BROWN, MD; JIM KAUTEN, MD; AND VIVEK RAJAGOPAL, MD; ON BEHALF OF THE MARCUS HEART VALVE CENTER, PIEDMONT HEART INSTITUTE, ATLANTA, GA

The advent of transcatheter aortic valve replacement (TAVR) has ushered in a new era of interdisciplinary collaboration in valve therapy and transformed the fields of both cardiology and cardiac surgery. Much of the attention to date has appropriately centered on optimizing the valve and delivery system design to reduce procedural complications and rates of paravalvular leak. Certainly, we can look forward to other technologic advancements in the coming years. On the other hand, it behooves the medical community to ensure the optimization of all aspects of patient care and the seamless integration of these technologic advances in order to allow TAVR to reach its full potential. This impetus drove a transformation in TAVR care at the Piedmont Heart Institute in Atlanta, Georgia.

## THE PIEDMONT EXPERIENCE

In the spring of 2014, our center felt the effect of having a TAVR program. We had an average length of stay of more than 7 days, struggled with care efficiencies, and were at a significant financial loss. We had recently received a grant of \$20 million from the Marcus Foundation to start the Marcus Heart Valve Center to enhance the outcomes and experience of patients diagnosed with valvular heart disease and thought this would be a perfect opportunity for change.

Implementation of a broad range of strategies designed to optimize all aspects of TAVR began in August 2014. Our primary goal was to provide the best possible outcomes for our patients, with a secondary goal of measuring the effect of these interventions on the length of stay and the average per-patient cost of TAVR. Although these measures seem logical, intuitive,

and had been proven in other areas of medicine, they remained to be fully validated for TAVR.

Our center used a three-tiered approach involving an explicit transition away from general anesthesia, staff education initiatives, and the implementation of post-procedure clinical pathways. Over a period of 3 months, our goal was to transition to optimized care for our patients. During this time, the most significant changes were the transition from 100% general anesthesia to 100% conscious sedation for transfemoral cases and the implementation of postprocedure pathways.

## Transition to Conscious Sedation

To accomplish our goal, we held numerous sessions to explain both the rationale and the implementation of the proposed care changes to cardiologists, anesthesiologists, and cath lab and operating room staff. We worked at length with our supportive anesthesia team to help form a system using light sedation that focused on patient safety while keeping the patients comfortable and giving them the ability to recover quickly. There were also multiple meetings made with our imaging team to ensure that our transition away from transesophageal echocardiograms would not compromise our ability to detect paravalvular leak. These included having excellent transthoracic echocardiograms, optimizing our hemodynamic assessments, and using more aortography. Such efforts paid off by fostering broad stakeholder buy-in for the transition.

Our first cases involved a few select patients that had tolerated their pre-TAVR cardiac catheterization with minimal sedation. After the first patients did well, we then met as a valve team to determine additional ways to optimize the experience. Several small changes

were made after several cases, staff became more comfortable, and we then expanded treatment to the majority of our patients. Within 3 months, we transitioned from 100% general anesthesia to close to 100% conscious sedation for our transfemoral patients.

### Postprocedure Pathways

We worked closely with a dedicated team of clinical efficiency experts to develop concrete postprocedure care pathways that were specifically tailored for our institution and patients (Figure 1). The goal of pathway development was standardization of postprocedure care to reduce variation in management. After the development of the pathways, we had numerous meetings with care providers to educate them on the changes as well as the goal of our changes. In order to achieve consistent implementation of the pathways, we spent numerous hours educating the staff, implementing them, and then providing accountability for those who did not. The pathways focused on clinical objectives to be met in the first 0 to 6 hours, 6 to 12 hours, and the day after the procedure, as well as criteria for discharge and follow-up. A detailed list of objectives are shown in Figure 1. Highlights included the avoidance of narcotics and sedatives, early extubation and line removal, and early mobilization and ambulation.

### Results

Although there were challenges along the way, the results have been remarkable. After a run-in period where we field tested and refined the pathways, we set an ambitious goal of a 1- to 2-day length of stay for all transfemoral patients. Since implementation, our median length of stay has been 2 days in all TAVR patients in the past 24 months compared to a median length of stay of 6.5 days in the year before implementation (Figure 2). This remarkable reduction in length of stay has been accomplished with mortality and stroke rates well below the national average. At discharge, 88% of our patients go directly home without assistance,

compared to a national average of 68%, according to Medicare data from 2015. Of the 12% requiring any level of assistance after discharge, 72% were requiring the same level of assistance before admission. Most importantly, we have seen no adverse events from an early discharge and the patients and families are grateful for the quick recovery.

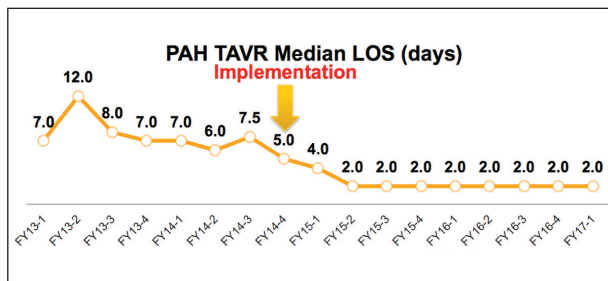
To prevent readmissions and ensure optimal care for patients, we have them check their heart rate, blood pressure, and weight on a daily basis, and we make follow-up phone calls on postdischarge days 1, 5, 14, and 21. This has allowed us to identify any potential issues, which can frequently be addressed by phone. As a result, our 30-day readmission rate is < 6%.

Not only have the clinical outcomes been outstanding, with extremely high levels of patient satisfaction,

| Piedmont Heart Clinical Pathway                                                                                                                   |                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------|------------------|
| Transcatheter Aortic Valve Replacement (TAVR)                                                                                                     |                  |
| Transfemoral and Subclavian                                                                                                                       |                  |
| Time Zero:                                                                                                                                        | Goals: 0-4 hours |
| Extubate within 1 hour, if not extubated in OR.                                                                                                   |                  |
| Wean off all drips within 1 hour of arrival. Saline lock all IVs except renal protection intravenous fluids. Continue 6 hours post op if ordered. |                  |
| Remove pulmonary artery catheter within 1 hour, if present. Continue central line.                                                                |                  |
| Remove arterial line within 1 hour, if blood pressure is stabilizing.                                                                             |                  |
| Out of bed to chair after 4 hours of bed rest.                                                                                                    |                  |
| Discontinue foley catheter once patient has been out of bed.                                                                                      |                  |
| Discontinue oxygen within 4 hours if oxygen saturation $\geq$ 90%.                                                                                |                  |
| Avoid all sedatives and narcotics.                                                                                                                |                  |
| Goals: 4-12 hours                                                                                                                                 |                  |
| Restart oral antihypertensive medications in 4 hours, if able to swallow. Hold if SBP <100.                                                       |                  |
| Restart BPH medications in 4-6 hours. Double dose for first dose.                                                                                 |                  |
| Begin incentive spirometry, cough and deep breathe every 2 hours.                                                                                 |                  |
| RN bedside evaluation for dysphagia. Consult speech therapy on POD #1 if patient unable to swallow.                                               |                  |
| Begin ice chips, advance to clear liquids, and then advance to regular diet.                                                                      |                  |
| Walk within 6 hours.                                                                                                                              |                  |
| Reinforce early ambulation with family. Educate family how to mobilize patient.                                                                   |                  |
| Goals: Post Op Day 1                                                                                                                              |                  |
| Transfer to 3 North.                                                                                                                              |                  |
| Aggressive blood sugar control.                                                                                                                   |                  |
| Antiplatelets: Begin aspirin 81 mg/day. Begin Plavix 75 mg/day, unless contraindicated.                                                           |                  |
| Anticoagulation: Begin Coumadin at 1700 if patient was taking preoperatively.                                                                     |                  |
| Insert peripheral IV and removed central line POD #1.                                                                                             |                  |
| Ambulate 6 times a day. Encourage all meals out of bed.                                                                                           |                  |
| Patient Care Coordination consult, if indicated.                                                                                                  |                  |
| Discharge if discharge criteria met on POD #1-3.                                                                                                  |                  |
| Discharge Criteria and Follow-up                                                                                                                  |                  |
| 1. Baseline neurological function.                                                                                                                |                  |
| 2. Stable heart rhythm and has not required pacing within 24 hours.                                                                               |                  |
| 3. Vital signs stable: HR 60-90, SBP 90-140 (or at baseline).                                                                                     |                  |
| 4. Voiding without difficulty, emptying bladder.                                                                                                  |                  |
| 5. Blood sugar <150.                                                                                                                              |                  |
| 6. Creatinine at or below baseline.                                                                                                               |                  |
| 7. Oxygen weaned off with oxygen saturation $\geq$ 90% with effective cough and airway clearance.                                                 |                  |
| 8. Effective pain control on oral medications.                                                                                                    |                  |
| 9. Independent in ADLs and ambulation, or has appropriate assistance and equipment.                                                               |                  |
| 10. Able to ambulate 200 feet, or baseline.                                                                                                       |                  |
| 11. Groins without bleeding or hematoma.                                                                                                          |                  |
| 12. Patient and family voice appropriate understanding of post TAVR discharge instructions.                                                       |                  |
| 13. Discharge studies completed: TTE, CXR, EKG, BMP, PT, PTT.                                                                                     |                  |
| 14. Return to Marcus Heart Valve Clinic for appointment at 30 days.                                                                               |                  |

Figure 1. Piedmont's transfemoral TAVR pathway.

Funding for this supplement provided by Medtronic



**Figure 2. Trends in median length of stay for Piedmont's TAVR program.**

but there has been a significant financial effect as well. On a per-patient level, there has been a reduction in cost of \$9,913 per hospital stay. We have had success utilizing the Post-TAVR Optimization app\* to stay advised on any early patient discharges, which are subject to Medicare's postacute care transfer (PACT) policy.

## SUMMARY

Although TAVR appears destined to be a lasting technology, the field continues to evolve, and there are still significant opportunities for improving patient care. Many opportunities exist for optimization and each center must determine how they can customize the program to enhance the outcomes and experience for their patients. At Piedmont, we have accomplished this by transitioning to conscious sedation and by implementing postprocedure clinical pathways. This transition has fostered greater engagement on the part of the medical team and administrators, improved patient outcomes and patient satisfaction, and has led to an ancillary benefit of both improving the financial viability of our TAVR program and ensuring that we can further fulfill our mission of providing excellent care to the largest number of patients. Optimizing patient care for TAVR can therefore be to the benefit of patients, programs, and society as a whole. ■

### Christopher U. Meduri, MD, MPH

Marcus Heart Valve Center  
Piedmont Heart Institute  
Atlanta, Georgia  
christopher.meduri@piedmont.org  
*Disclosures: Grant support from Medtronic, Edwards Lifesciences; consultant to Medtronic, Boston Scientific Corporation; proctor for Medtronic, Boston Scientific Corporation, Edwards Lifesciences, Mitralign.*

### Meredith Brazell, PA-C

Marcus Heart Valve Center  
Piedmont Heart Institute  
Atlanta, Georgia  
*Disclosures: None.*

### Bryan Griffith

Marcus Heart Valve Center  
Piedmont Heart Institute  
Atlanta, Georgia  
*Disclosures: None.*

### Morris Brown, MD

Marcus Heart Valve Center  
Piedmont Heart Institute  
Atlanta, Georgia  
*Disclosures: None.*

### Jim Kauten, MD

Marcus Heart Valve Center  
Piedmont Heart Institute  
Atlanta, Georgia  
*Disclosures: None.*

### Vivek Rajagopal, MD

Marcus Heart Valve Center  
Piedmont Heart Institute  
Atlanta, Georgia  
*Disclosures: Consultant to Medtronic; proctor for Edwards Lifesciences, Boston Scientific Corporation, Medtronic.*

\*Meduri CM, Potter BJ. Available at [www.post-tavr.com](http://www.post-tavr.com). Developed with educational support from Edwards Lifesciences and Medtronic.

# TAVR Optimization Using Best Practices

BY MATHEW WILLIAMS, MD; MICHAEL QUERIJERO, MSPA; AND TARA COLLINS, MSPA;  
ON BEHALF OF NEW YORK UNIVERSITY LANGONE MEDICAL CENTER, NEW YORK, NY

**T**ranscatheter aortic valve replacement (TAVR) is a transformative therapy for patients with severe aortic stenosis. As the United States population ages, it can be expected that the prevalence of valvular cardiac disease will also increase. Typically, patients of advanced age have severe comorbidities or significant frailty, making operative intervention very high risk or impossible. TAVR has proven to be an effective alternative therapy to surgery, not only in extending a patient's lifespan, but also significantly improving the quality of life.

Despite the advancement of medical technologies such as TAVR, there are financial challenges that all hospitals face. To address these challenges, an integrated partnership was formed with administration, nursing, and advanced practice providers and physicians during the development and restructuring of the TAVR program at New York University Langone Medical Center (NYULMC). The goal was to improve efficiencies in all facets of care, reduce costs, and provide the best patient outcomes.

## HEALTH CARE COST

The Affordable Care Act of 2010 (ACA) and emerging Medicare Access and CHIP Reauthorization Act (MACRA) has resulted in hospitals reexamining their programs and evaluating clinical practices and operations, which include TAVR programs. When the ACA was signed into law, the major objective of the ACA legislation was to expand access to care for all Americans, improve the quality of health care, and significantly reduce costs. Briefly, the ACA was signed into law in March 2010. A major objective of the ACA legislation was to expand access to care for all Americans but the quality of health care and a reduction in cost were also emphasized. Title III, a section of the ACA legislation, addresses the need to improve quality and efficient delivery of health care, which has resulted in a gradual shift from fee-for-service models to value-based purchasing programs. In addition, Medicare has also established payment adjustments, viewed as penalties, for hospital-acquired conditions or infections. Medicare has also

encouraged hospitals to develop readmission reduction programs. With the implementation of MACRA, this will further encourage efficiency and quality of programs and impact how physicians are compensated.

Beyond federal health care reform regulations, there are internal financial and clinical barriers that TAVR programs encounter. These internal economic barriers include a limited number of costly intensive care unit beds, modest TAVR reimbursement, high cost of the device, limited hybrid operating room/cath lab availability, staffing, the costs of readmissions, and limited resources. At NYU, there is a readmission penalty due to the participation of a bundled payment for valve surgery that includes TAVR. The management of these high-risk patients in the current financial environment requires TAVR programs to not only have resources but also strategies for favorable outcomes.

## NEW YORK UNIVERSITY LANGONE MEDICAL CENTER

In addition to the obstacles that health care reform and institutional barriers that TAVR programs all share, NYULMC is also navigating through an alternative payment method with bundled payments. This Bundled Payments for Care Improvement initiative was designed to encourage efficiencies and improve quality for all valve patients. Briefly, NYULMC electively contracted with Medicare to share in the risk for 90 days for patients who have undergone all valve procedures, which includes TAVR for 90 days. At NYULMC, the bundle system negotiated is a retrospective bundled payment arrangement in which actual expenditures are reconciled against a target price for an episode of care. Under this payment model, the total expenditures for a beneficiary's episode is later reconciled against a bundled payment amount (the target price) determined by the Centers for Medicare & Medicaid Services. A payment or recoupment amount is then made by Medicare reflecting the aggregate performance compared to the target price. Under this model, the average margin per case is determined, as depicted in Table 1.



*Funding for this supplement provided by Medtronic*

**TABLE 1. BUNDLE PAYMENT FOR CARE IMPROVEMENT: PERFORMANCE SUMMARY**

|                                |                                                                                                                                                                                       |
|--------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Average Margin Per Case</b> | Average DRG 90-day target price – average 90-day performance spend (ie, index admission + 90-day post-discharge payment)                                                              |
| <b>Postdischarge Payment</b>   | <ul style="list-style-type: none"> <li>• Readmission payments</li> <li>• In-patient rehab payments</li> <li>• Subacute rehab payments</li> <li>• Home care agency payments</li> </ul> |

Ultimately, the decision to participate in the payment method was to encourage quality and efficiency. The measurement of these improvements included: Clinical efficiencies in room turnaround, minimization of complications, intensive care unit (ICU), and overall length of stay to decrease costs; and improvement of quality by decreasing readmissions, maintaining patient functionality, improving the patient experience, streamlining the patient's transition of care and decreasing complications.

### MINIMALLY INVASIVE AND MAXIMALLY EFFECTIVE

The strategy employed at NYULMC Heart Valve Program is a minimally invasive and maximally effective (MIME) approach. The MIME approach was developed to improve outcomes to maintain a patient's functional capacity, decrease frequency of falls, decrease delirium, and decrease the risk of infections. Knowing that elderly patients have a low tolerance for complications and lengthy hospitalizations, the MIME strategy include care pathways to minimize unintended adverse consequences. The MIME approach has also allowed for a reduction in costs and has provided a better patient experience. It also has been integrated into all facets of the patient care continuum, from preprocedure to discharge.

It is known that patients with severe aortic stenosis who are symptomatic have poor survival rates unless the outflow obstruction is relieved. In patients with severe aortic stenosis, the 2-year survival from the onset of symptoms is 50%. The development of a best practice TAVR program involves several layers, which include timely access to therapy. TAVR patients in the extreme- and high-risk category typically have a mean age of 85 years, have multiple comorbidities, and are frail. The ability of these patients to have multiple visits before implantation, especially in those with heart failure, may be challenging. Given this limitation, the Heart Team at NYULMC has standardized and streamlined screening.

### PREPROCEDURE

Successful screening starts at the referral entry point. Essential patient records are collected from the referring physician, which generally include cardiology notes, recent laboratory values, and any available cardiac imaging films and reports (ie, cath, CTA, echocardiogram). Once the patient information is received, the data are reviewed and a brief summary is created for each patient. The brief summary includes pertinent medical history, Society of Thoracic Surgeons score, and diagnostic findings. Based on the summary, if a patient is thought to be a potential candidate for TAVR, a CT scan and/or echocardiogram is ordered the same day as their visit.

On the day of the patient's visit, a complete history/physical exam is performed, frailty metrics are measured, and the Kansas City Cardiomyopathy Questionnaire (KCCQ) is completed with the Heart Team. The results from the CT scan are reviewed by the Heart Team to determine access route (transfemoral, subclavian, direct aortic, transapical) and annulus sizing. The patient is then evaluated by the Heart Valve Team. If additional testing is required, such as cardiac catheterization or labs, they are obtained a week after the office visit. Each patient is reviewed during the Heart Team's weekly valve meeting, where the patient-specific procedural plan and valve type are determined. Once the plan is determined, it is communicated to the referring physician. The patient can generally expect to undergo TAVR within 1 to 3 weeks after the initial visit.

### INTRAPROCEDURAL EFFICIENCIES

The intraprocedural Heart Valve Team at NYULMC includes interventional cardiologists, structural heart fellows, cardiac surgeons, cardiac anesthesiologists, structural heart echocardiologists, scrub nurses, circulating nurses, charge operating room nurses, and valve coordinators. This core team is involved in the TAVR procedure. The role for each individual on the team is well defined to allow for consistent care of each patient. As part of the intraprocedural preparation, all members are made aware of the patient's history, anatomy as it pertains to the TAVR procedure, and any identified potential complications (eg, annular rupture, coronary occlusion).

Initially, patients undergoing TAVR would receive general anesthesia and transesophageal echocardiography (TEE). The typical anesthetic management for the TAVR procedure was similar to that for surgical aortic valve replacement. However, as TAVR technology has continued to evolve, some programs with extensive experience have moved to performing TAVR with conscious sedation, either monitored anesthesia care (MAC) or RN-administered conscious sedation.

### TAVR Device Platforms

The CoreValve™ platform (Medtronic) is a self-expanding system consisting of a nitinol frame and supra-annular porcine pericardial leaflets. The next-generation CoreValve Evolut™ R device (Medtronic) was approved in June of 2015 and remains a self-expanding device, but now has the capability to be repositioned and retrieved out of the patient's body if the valve is placed in a sub-optimal position. The system also has an in-line sheath that makes the device the equivalent of a 14-F sheath, which allows treatment down to a 5-mm vessel size. It is currently the smallest-caliber device on the market.

The Sapien™ platform (Edwards Lifesciences) is a balloon-expandable system consisting of a cobalt-chromium frame and intra-annular bovine pericardial leaflets. The latest generation is the Sapien™ 3 system, also approved in June 2015, has a modified skirt to reduce paravalvular leak after the procedure. The system has an expandable sheath, depending on the valve size, which allows treatment down to a 5.5-mm vessel.

### Anesthesia

Given the improvements in device size, physician experience, new technology features including recapturability, and a skirt to reduce paravalvular leak, TAVR with conscious sedation is becoming more widespread in Europe.<sup>1,2</sup> In the United States, there has been interest in the minimalist approach to TAVR, which is defined as the use of conscious sedation, either RN-administered or MAC, and transthoracic echocardiography (TTE) instead of TEE.

At NYULMC, a systematic MIME approach has been adopted. The protocol was developed and executed by a cardiac anesthesiologist who had a good understanding of the patient population and a great interest in outcomes

coupled with procedural efficiencies.<sup>2</sup> A key member of the Heart Team, the cardiac anesthesiologist, developed and executed a care pathway approach that was integrated into the MIME strategy. The cardiac anesthesiologist had an intuitive understanding of the patients in the extreme- and high-risk population, interest in optimizing excellent outcomes, and working collegially with his Heart Valve Team to support procedural efficiencies. A detailed review of the approach at NYULMC has been published.<sup>3</sup> Conscious sedation should be used in all transfemoral patients as long as a prolonged TEE is not needed and there are no strong relative contraindications. The contraindications and relative contraindications are listed in Table 2.<sup>3</sup>

During the first 6 months of the MIME strategy, nearly 80% of the transfemoral procedures were performed with conscious sedation; in the following 6 months, 100% were performed with conscious sedation.<sup>3</sup> The MIME transfemoral protocol also included the use of a bilateral ilioinguinal and iliohypogastric nerve block similar to what is utilized for a hernia repair. Intravenous sedation consisted of dexmedetomidine 0.4 to 0.9 µg/kg per hour, with addition of low-dose propofol (20–50 µg/kg per min) if needed.

This combination provides excellent sedation for the patient, allows the physician Heart Valve Team to safely perform TAVR without the need for general anesthesia, and provides improved procedure times and quicker room turnover.

When compared with general anesthesia, conscious sedation allows for early assessment of the patient's neurological status in the periprocedural and postprocedural period. This is particularly important if there is a suspicion of a cerebrovascular event complicating the procedure, as therapeutic intervention can be instituted earlier.

**TABLE 2. NYULMC TAVR MINIMALIST APPROACH  
CONTRAINDICATIONS AND RELATIVE CONTRAINDICATIONS**

|                                                  | NYULMC Presedation Protocol (1 y) | STS/ACC TVT Registry 2014 | NYULMC Postprocedure Protocol (1 y) |
|--------------------------------------------------|-----------------------------------|---------------------------|-------------------------------------|
| <b>N</b>                                         | 55                                | 12,558                    | 214                                 |
| <b>Sedation cases</b>                            | 0 (0%)                            | 629 (5%)                  | 194 (91%)                           |
| <b>LOS days: average (median)</b>                | 5.4 (5)                           | 6.1 (5)                   | 2.6 (2)                             |
| <b>ICU LOS hours: average (median)</b>           | 42.3 (25)                         | 64.1 (33)                 | 15.1 (8)                            |
| <b>Procedure time: average (median)</b>          | 127 min                           | 144 min (119 min)         | 88 min (81 min)                     |
| <b>Discharged to home (excludes VA patients)</b> | 74%                               | 68%                       | 91%                                 |
| <b>In-hospital mortality</b>                     | 5.5%                              | 4%                        | 1.9%                                |

Abbreviations: ACC, American College of Cardiology; ICU, intensive care unit; LOS, length of stay; NYULMC, New York University Langone Medical Center; STS, Society of Thoracic Surgeons; TVT, Transcatheter Valve Therapy; VA, Veterans Affairs.

*Funding for this supplement provided by Medtronic*

### Invasive Lines

The Heart Valve Team at NYULMC examined the number of invasive lines placed into the patient for the procedure. These invasive lines included (1) a Foley catheter, (2) a temporary venous pacemaker via right internal jugular vein, (3) a radial arterial line, and (4) a peripheral intravenous line (*see sidebar on right*). A decision was made to limit both the number of lines and length of time they remained in place.

### Echocardiography

Echocardiography plays a critical role in the assessment of the valve function during and after TAVR. As mentioned earlier, TEE has been preferred for intraprocedural image acquisition due to its higher image resolution compared with TTE. However, with the use of conscious sedation, TTE has become the preferred acquisition method. The ability of TTE to assess the location and performance of the replacement valve is similar to that of TEE. The method of inspection and technique is thoroughly discussed in a published article by our group.<sup>4</sup>

To summarize, echocardiography is performed just prior to TAVR to further evaluate if the patient's echocardiogram windows are adequate and if the echocardiogram measurements of the left ventricular outflow tract, aortic root, and aortic annulus are similar to previous images. Baseline mitral regurgitation is also quantified for comparison with postdeployment studies. Intraoperative TTE confirms that the prosthesis has been properly deployed. For self-expanding systems, such as the Evolut R device, the depth of implantation and paravalvular aortic regurgitation can be assessed after partial valve deployment. If necessary, adjustments can be made. Final gradients and velocities are measured across the new valve. The presence of worsening mitral regurgitation, postprocedure pericardial effusion with or without tamponade, and new intracardiac shunt is assessed. If necessary, TEE can be safely performed after the TAVR procedure without general anesthesia.

As a result of implementing the intraprocedural changes, including the change to conscious sedation, our median procedure time has improved by > 45%. Mortality has decreased and more patients are being sent home rather than to rehabilitation. The length of stay in the ICU and hospital length of stay has also dramatically improved (Table 2).

### POSTPROCEDURE CARE

#### Fast Track and Early Mobilization

Older adults have a higher prevalence of chronic disease leading to a greater vulnerability to acute stress and adverse events during hospitalizations.<sup>5</sup> Hospitalizations

- **Foley catheters:** In the case of transfemoral TAVR, the patient no longer has a Foley catheter placed. This has resulted in a dramatic reduction of urological issues after the procedure.
- **Temporary venous pacemaker:** A femoral temporary venous pacemaker is placed intraprocedurally, but it is removed after the case if the patient has had a permanent pacemaker placed, is undergoing a valve-in-valve procedure, or has had a balloon-expandable device placed.  
For patients with narrow QRS with no changes during the procedure, the guidelines recommend that the temporary pacer should be pulled at the end of the procedure.<sup>3</sup>  
A transvenous pacemaker wire is also placed in the right internal jugular vein for patients who may be at increased risk for potential heart block.
- **Radial arterial line:** A radial arterial line is placed and utilized for continuous blood pressure monitoring in the postprocedural unit.
- **Peripheral intravenous line:** Used for medication administration. A peripheral intravenous line is placed and a radial arterial line is placed for continuous blood pressure monitoring in the preprocedure unit or hybrid OR.

for the older adult patient can result in unintended adverse consequences, even from lifesaving interventions such as TAVR. Extended bed rest, polypharmacy, urinary catheters, intravenous lines, disruption of usual sleep patterns, and poor nutrition all contribute to possible functional, physical, and cognitive decline.<sup>6</sup> At NYULMC a postprocedure protocol was developed to improve outcomes and guard against adverse events. The protocol consists of a detailed handoff, early mobilization, and limited time in the recovery unit (*see Handoff sidebar*). The handoff is performed with members of the Heart Valve Team team that consists of the cardiac anesthesiologist, nurse practitioner/physician assistant, and recovery nurse. The on-call Heart Valve Team attending physician is also available at any time for any postprocedure issues.

Patients who stay in bed remain in bed and remain in the hospital, which leads to decline. A multidisciplinary team developed a protocol with a checklist for early ambulation and to move patients from the recovery unit to a regular telemetry bed (Table 3). The early mobilization protocol was developed so that TAVR patients ambulate with a physical therapist or nurse 3.5 hours after TAVR, if the transfemoral treatment site is stable.



**THE HANDOFF PROVIDES DETAILED INFORMATION CONSISTING OF:**

- Preprocedure history, examination, and vitals
- Preprocedure electrocardiogram
- Preprocedure medications
- Intraprocedure medications
- Valve deployed and procedural course
- Presence of any intraprocedural complications
- Postvalve deployment rhythm
- Postdeployment echocardiogram
- Postprocedural vitals
- Time arteriotomy was closed

Early and frequent mobilization helps to prevent falls and increases mobility in the hospital and is associated with less functional decline during hospitalization and shorter lengths of stay. Patients who have transvenous pacers in the intrajugular vein also ambulate, as long as the patient has a stable rhythm and is not pacer dependent.

In addition to early mobilization, after TAVR patients are under the care of the Heart Valve Team, which facilitates patients having short stays in the recovery unit or ICU (Table 4). Extended stays in the recovery unit or ICU for these vulnerable patients can lead to delirium, sleep deprivation, infections, and falls.

A number of articles confirm that patient outcomes and functional status are improved with early mobilization and decreased hospital length of stays.<sup>7,8</sup> Beyond improving patient outcomes, the cost of care in the ICU is high. Given the cost of ICU beds and their limited number, decreased length of stays in the ICU is advantageous from a financial and clinical perspective.

In summary, the implementation of the MIME strategy for the TAVR population has decreased procedure time and decreased length of stay. These intraprocedural and postprocedural changes have also not come at the expense of outcomes.

**TRANSITION OF CARE****Postprocedure Surveillance**

The goal for discharge is for the patient to continue to progress after the procedure and to ensure that the patient has adequate postdischarge services.

The elements for an ideal discharge of an elderly patient include:

- Accurate medication reconciliation
- Appropriate follow-up
- Postprocedure instructions
- Information transfer from hospital-based providers to primary care providers

**TABLE 3. EARLY MOBILIZATION: TRANSFEMORAL TAVR (TRANSVENOUS PACER [NECK ONLY])**

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| • Strict bed rest 3.5 hours after the procedure                                                                                                                                                                                                                                                                                                                                                                                                                          |
| • Ambulate out of bed to chair and ambulate if arteriotomy is stable (no hematoma, vitals are stable, peripheral pulses stable)                                                                                                                                                                                                                                                                                                                                          |
| • All meals for patients are out of bed sitting up in a chair                                                                                                                                                                                                                                                                                                                                                                                                            |
| • If groin line has been placed, no hip flexion > 30° (cannot be out of bed)                                                                                                                                                                                                                                                                                                                                                                                             |
| • Temporary venous pacemaker in neck <ul style="list-style-type: none"> <li>– Ensure dressing over the wires is secure and reinforced</li> <li>– Temporary venous pacemaker box should be close to patient</li> <li>– If the patient is temporary venous pacemaker dependent and has no underlying rhythm, the patient should remain in bed</li> <li>– If the patient has underlying stable rhythm, out of bed to chair and out of bed to chair for all meals</li> </ul> |

- Teach back—patient or caregiver can explain back concepts reviewed during discharge

Discharging patients from the hospital is a complex process with many challenges. Among Medicare patients, almost 20% discharged from a hospital are readmitted within 30 days.<sup>9</sup> Preventing avoidable readmissions has the potential to profoundly improve both the quality of life for patients and the financial well-being of health care systems.

At NYULMC the transition of care and discharge planning for TAVR patients involve a number of steps.

**1. Communication with the referring cardiologist:**

**consists of several forms.** After the procedure, the referring cardiologist is called and any intraprocedural issues are discussed. A detailed discharge summary and letter is sent to the referring cardiologist, consisting of the valve type, postprocedure echocardiogram findings, postprocedure electrocardiogram, presence of any postprocedure complications, new medication changes, and follow-ups.

**2. Patient follow-up includes several visits after the procedure, which is based on post-TAVR patients being vulnerable for readmission for the first 30 days after discharge.** Patients are seen by the Heart Valve Team at 7 to 10 days after the procedure and at 30 days after the procedure. They are seen by their cardiologist 2 weeks after the procedure.

**3. Telephone calls.** Additionally, patients receive several telephone calls at different time periods. A patient

Funding for this supplement provided by Medtronic

**TABLE 4. FAST TRACK RECOVERY UNIT TO  
TELEMETRY CRITERIA**

| Transfemoral TAVR                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>• Inclusion criteria               <ul style="list-style-type: none"> <li>– Extubated—requiring only up to 4-L nasal cannula O<sub>2</sub></li> <li>– Cannot be temporary venous pacemaker dependent</li> <li>– No continuous infusions (ie, pressors, nicardipine, inotropes)</li> <li>– No vascular complications (no cutdowns, poorly controlled hematomas)</li> <li>– No significant bleeding</li> <li>– No change in mental status or neurologic deficits</li> <li>– No significant pain or uncontrolled pain</li> </ul> </li> <li>• Accepting team will monitor patient for 4–6 hours (as per postprocedure order set)               <ul style="list-style-type: none"> <li>– Vitals</li> <li>– Vascular access</li> <li>– Change in mental status/neurologic deficits</li> </ul> </li> <li>• Nurse practitioner will reevaluate patient at 4 or 6 hours and determine if patient is suitable for floor</li> <li>• Call step-down floor (universal bed)</li> </ul> |

is called at 48 to 72 hours, 14 days, and 30 days after discharge. The call is performed by a care coordinator or someone from the Heart Valve Team.

4. **Telehealth.** When patients return home, they receive a telehealth system. The particular telehealth system used at NYULMC is Cardiocom (Medtronic). The device monitors key vitals such as blood pressure, pulse oximetry, and daily weight. The system also includes education on heart failure, medication compliance, and postdischarge recovery. The transmissions are relayed to a command center that triages patients if they fall outside the range of predetermined values. The Heart Valve Team is alerted if any follow-up intervention is necessary. The Cardiocom device allows for visual inspection of incisions and permits the Heart Valve Team or referring cardiologist to make adjustment on medications if needed.
5. **Centralized care.** In partnership with cardiology, patients are instructed to return to NYULMC for any postprocedure care. If the patient is readmitted

at an outside hospital, the patient is transferred to NYULMC for further evaluation and treatment.

These steps have reduced the frequency and costs of readmissions. Thirty-day readmissions rates have decreased to < 12% and the costs of readmission for the first quarter 2016 was cut in half compared to the third and fourth quarters of 2015. In addition to decreasing the frequency and costs of readmissions bringing patients back to the NYULMC institution avoided prolonged hospitalizations and unnecessary tests. ■

1. Binder RK, Webb JG. TAVI: from home-made prosthesis to global interventional phenomenon. *Heart*. 2012;98(suppl 4):iv30-36.
2. Dall'Ara G, Etchanchinoff H, Moat N, et al. Local and general anaesthesia do not influence outcome of transfemoral aortic valve implantation. *Int J Cardiol*. 2014;177:448-454.
3. CoreValve Evolut R TAVR pre/peri and procedure nursing considerations. Minneapolis, MN: Medtronic; 2016.
4. Neuburger PJ, Saric M, Huang C, Williams MR. A practical approach to managing transcatheter aortic valve replacement with sedation. *Semin Cardiothorac Vasc Anesth*. 2016;20:147-157.
5. Marengoni A, Winblad B, Karp A, Fratiglioni L. Prevalence of chronic diseases and multimorbidity among the elderly population in Sweden. *Am J Public Health*. 2008;98:1198-1200.
6. Creditor MC. Hazards of hospitalization of the elderly. *Ann Intern Med*. 1993;118:219-223.
7. Zisberg A, Shadmi E, Sinoff G, et al. Low mobility during hospitalization and functional decline in older adults. *J Am Geriatr Soc*. 2011;59:266-273.
8. Brown CJ, Foley KT, Lowman JD Jr, et al. Comparison of posthospitalization function and community mobility in hospital mobility program and usual care patients: a randomized clinical trial. *JAMA Intern Med*. 2016;176:921-927.
9. Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee-for-service program. *N Engl J Med*. 2009;360:1418-1428.

### Mathew Williams, MD

Associate Professor, Cardiothoracic Surgery  
Chief, Division of Adult Cardiac Surgery  
Director, Heart Valve Center  
Director, Interventional Cardiology  
New York University Langone Medical Center  
New York, New York  
mathew.williams@nyumc.org

*Disclosures: Consultant to Medtronic and Edwards Lifesciences.*

### Michael Querijero, MSPA

New York University Langone Medical Center  
New York, New York

*Disclosures: Speaker for Medtronic and Edwards Lifesciences.*

### Tara Collins, MSPA

New York University Langone Medical Center  
New York, New York

*Disclosures: None.*

# Building an Efficient TAVR Program

BY SANDEEP M. PATEL, MD; J. BRANDON ELMORE, MD; EDWIN G. AVERY, MD; MARCO A. COSTA, MD, PhD; ALAN MARKOWITZ, MD; ANGELA DAVIS, RN; AND GUILHERME F. ATTIZZANI, MD; ON BEHALF OF THE VALVE & STRUCTURAL HEART DISEASE INTERVENTION CENTER, HARRINGTON HEART AND VASCULAR INSTITUTE, CLEVELAND, OH

**T**ranscatheter aortic valve replacement (TAVR) represents one of the most important advances in the field of valvular heart disease management. From the first implantation in 2002 to the current state of the procedure, the subject of TAVR has taken some of the fastest and largest leaps ever witnessed in the field of medicine. The minimally invasive strategy (MIS) for TAVR, defined as performing the procedure in a standard cardiac catheterization laboratory using only local anesthesia and mild conscious sedation (and sometimes no sedation at all) without transesophageal echocardiography (TEE) guidance or endotracheal intubation, has begun to gain popularity as it revolutionizes the efficiency and economics of the overall process of TAVR, while maintaining patient outcomes as measured by safety and efficacy factors.<sup>1,2</sup> While European centers reveal significantly larger adoption of the MIS for TAVR compared with United States centers,<sup>3,4</sup> the latter have slowly begun to modify their procedural workflow in an effort to improve patient outcomes and the finances of the TAVR procedure.

To date, no large randomized studies have compared the conventional, more invasive approach with the MIS for TAVR. Therefore, there is still controversy about which would be best for patients' outcomes. The MIS rarely leads to hemodynamic compromise and need for vasopressors during the procedure, enables early mobilization after the procedure, and shortens length of stay at the hospital, which likely minimizes potential infection risks. Conversely, operators who favor a more invasive strategy utilizing general anesthesia and TEE guidance believe it enhances the control of the procedure should severe complications happen, while providing a better intraprocedural imaging evaluation. Importantly, our goals with the MIS are to improve patient outcomes and optimize procedural efficiency. This article focuses on the optimization of TAVR from the MIS.

## THE MIS: BASICS

### Heart Team Approach, Preprocedural Imaging, and Anesthesia Assessment

The most important aspect to the TAVR procedure is the heart team approach. This multiprofessional collaboration has led to optimal clinical and procedural related outcomes.<sup>1</sup> The multidisciplinary collaboration begins in the heart valve clinic that facilitates careful review and development of treatment recommendations based on individual patient needs. At the initial consultation, a comprehensive history and physical assessment are obtained to determine optimal pre- and post-care clinical and educational needs. These needs include understanding patient and family expectations and taking a standardized approach to assessing baseline functional status. A primary goal is to begin consideration of discharge disposition on the first visit so we can return a patient to their most familiar surroundings efficiently and safely.

After thorough heart team initial evaluation, if patients are considered potential TAVR candidates, they are typically referred for right and left heart catheterization (if they do not already have one) and low-dose contrast (~ 50 mL), retrospective, gated CT assessment of the chest, abdomen, and pelvis for procedural planning. When the patient's glomerular filtration rate is < 30 mL/min, we have a dedicated imaging protocol in place with noncontrast CT (ie, to visualize calcium distribution) and noncontrast MRI of chest and pelvis (ie, to measure the aortic valve annulus and peripheral vessel luminal sizes) are utilized for assessment.

The aortic root image is taken in a single projection with valve cusp alignment. To minimize contrast exposure, the angle at which the alignment of the cusps occur is precalculated from the CTA image. This initial picture serves only as reference for CoreValve/Evolut™ R (Medtronic) implantations; the important part is align-

*Funding for this supplement provided by Medtronic*

ing the transcatheter valve in a coplanar position for deployment.

Another tool recently incorporated to our armamentarium is the spectral CTA, which delivers exceptional images with a very low dose of contrast ( $\sim 20$  mL). Importantly, CTA interpretation is performed by TAVR operators until coherence and justification for valvular prosthesis, sizing, vascular access, and procedural specifics are clearly outlined, with back-up options and contingencies enumerated in case anticipated (but unlikely) procedural issues arise. We strongly believe that operators should “own” the CTA reading in this setting because they understand the importance of all the measurements and their interaction during the procedure, therefore, likely improving valve selection, preventing eventual complications, and planning bailout strategies.

## INTRAPROCEDURAL PROCESS

### Anesthesia

If percutaneous access is feasible (primarily via femoral approach), the procedure is performed in a regular cardiac catheterization laboratory. Barring any patient-specific factors, the entire procedure is performed with the patient awake and lightly sedated using standard analgesic and anxiolytic medications (total: fentanyl [25–50  $\mu$ g intravenous] and midazolam [1–3 mg intravenous]). Some patients receive no sedation. Of the various types of anesthesia, we elected RN-administered anesthesia under physician guidance as our default strategy for MIS TAVR. The need for monitoring anesthesia care (MAC) and general anesthesia is done on a case-by-case evaluation and the TAVR operators will ask for the anesthesia team support in case they believe it is needed. Patient and procedural specific factors, including severe respiratory disease, severe anxiety, inability to tolerate minimal sedation, patient preference, hemodynamic status, and procedural complexity (coronary intervention followed by valve implantation, complex anatomy implantation) are just some of the facets of the procedure that may drive the need for MAC or general anesthesia; typically, however, it is a combination of factors, the overall clinical picture, and patient/procedural safety that drives the need for escalation in anesthesia care.

Cardiac anesthesia is not present in the room and is only called if the patient appears to require extremely high doses of sedating medications, has a tenuous respiratory status, or requires complex airway management upfront prior to obtaining access. Approximately only 5% ( $n = \sim 30$ ) of our patients who undergo the minimalist approach required elective presence of the anesthesia team in the room after we started performing the procedure without them. In 2015, only one case of 210 TAVRs

performed in our center had to be converted to general anesthesia and no transfemoral cases were performed electively as general anesthesia. In 2016 until the end of October, of the more than 200 TAVRs performed, only one patient had to be converted to general anesthesia and one patient was electively performed under general anesthesia due to dementia/anxiety.

### Intraprocedural Patient Steps

Once on the cardiac catheterization table, the patient undergoes TAVR-specific transthoracic echocardiography (TTE) evaluating the aortic valve prior to the procedure, along with assessment of the left ventricle, mitral valve, and associated structures. Physical examination of both radials, femoral, and pedal pulses is performed. Additionally, Doppler assessment of bilateral pedal pulses is performed prior to the procedure and compared with postprocedure. Thereafter, standard femoral arterial (with no ultrasound guidance) and right internal jugular vein access (under ultrasound guidance) are performed, the latter being done for temporary venous pacemaker placement.

A straight pigtail catheter is kept in the bottom of the noncoronary cusp as a landmark and usually only two other pictures are taken until the valve is fully deployed. Hemodynamic assessment before the valve is implanted is mandatory because it will be compared with the results of postprocedural assessment. Once the valve is implanted, TTE is performed to evaluate pericardial effusion, any paravalvular leak, changes in left ventricular function, mitral valve issues, and leaflet mobility of the prosthesis. The TTE findings and the hemodynamic data are then evaluated by the heart team. If there are discordant results between the two modalities, a contrast angiogram is obtained.

### Vascular Access Management

Because femoral artery puncture is performed under fluoroscopy based on the landmarks as dictated by the vascular access assessment on computed tomography, no further contrast injections are performed to assess vascular anatomy if the patient is doing well from a hemodynamic standpoint and all findings from pulse examinations are stable as compared to the preprocedural assessment. Although we do not use contralateral wire protection on the TAVR access and also do not remove the large sheath after balloon inflation in the iliac artery, we have material available in the lab should a vascular complication happens. The main femoral access is closed as appropriate with ProGlide sutures (Abbott Vascular). Pulses are immediately checked and if there are no significant changes compared with the preprocedural findings, the contralateral access is also closed with a closure device. Pulses are regularly checked postprocedure. A postprocedure



electrocardiogram is performed and compared with the preprocedural one. The temporary pacemaker in the internal jugular vein is immediately removed if no additional conduction disturbances are revealed; otherwise it is sutured in place for the next 12 to 24 hours.

#### Postprocedure Care

The patient is then monitored in the cardiac intensive care unit (ICU) for 12 to 24 hours and is ultimately either moved to the general floor or discharged based on rehabilitation issues, development of rhythm issues, vascular issues, or chronic medical conditions.<sup>5</sup>

### THE MINIMALIST APPROACH: UNDERSTANDING AND ASSESSING CLINICAL EFFICIENCY

The TAVR program at University Hospitals/Case Medical Center places the utmost importance on patient-specific outcomes. Our initial experience with TAVR was similar to other major United States centers with the use of multiple imaging procedures, including TTE, TEE, cardiac CT, cardiac MRI, and angiography. We used mandatory Swan-Ganz catheter implantation along with transvenous pacemaker implantation. We used intraprocedural TEE with intubation and cardiac anesthesia. Finally, we performed our procedures in our hybrid operating room suite where either percutaneous femoral (45%) or femoral artery cut down (55%) access was performed. Between 2011 and 2013, approximately 90 to 100 patients underwent this conventional strategy.

#### Reasons for Moving to a Minimalist Approach

However, due to the previous large European experience of our physicians with the MIS and as comfort with the procedure evolved within the entire team, the conventional model for TAVR was recognized to be very labor intensive in that it required four to five teams of physicians, nurses, and ancillary staff, and, importantly, was extremely taxing to the patient physically, emotionally, and physiologically. The use of the hybrid operating room (OR) required preemptive scheduling and coordination with OR staff and physicians. The use of TEE and intubation resulted in longer lengths of stay after the procedure, the development of respiratory complications, or issues with neurologic status afterward associated with sedation and amnesia. The cost associated with equipment, personnel, OR space, postprocedural ICU care, and hospital stay thereafter, resulted in total procedural costs that made the economics of TAVR unacceptable as a stand-alone procedure. We understood that the overall data, in terms of a global perspective, demonstrated that there was a dramatic

reduction in health market expenditures per quality-adjusted patient life years,<sup>6,7</sup> however, per case TAVR was extremely costly and resource intensive.

#### Strategy for Moving to a Minimalist Approach

Our first evaluation of the procedure was to mimic European practice based on the experience of a number of structural heart disease centers.<sup>2-4,8-10</sup> Our team assessed the use of hybrid rooms, invasive monitoring lines, and echocardiography approaches.

We then began to phase out the need to perform this procedure in the hybrid OR, especially because the likelihood of procedural complications associated with valve implantation that required conversion to open cardiothoracic surgery was quite low (1.7%/4 years, 700 patients treated at our institution. In 2015, only one case out of our 210 TAVR procedures was converted). After confirming the safety of the procedure in the cardiac catheterization laboratory, we recognized that Swan-Ganz insertion provided no true benefit in the monitoring of hemodynamics, other than to ensure right atrial pressure evaluation. Thus, we adopted right internal jugular venous insertion of pacemakers and intra-/postprocedural left ventricular hemodynamic evaluation. We then further began to explore the need for TEE as the inherent risk of anesthesia was present.<sup>2</sup> We quickly realized the use of TEE was not an actual procedural necessity because its use was for monitoring other structures, the implantation of the valve, and ensuring wires were in their specific place.

However, again with experience, our operators became more reliant on fluoroscopy and angiography for placement and implantation of the valve. Furthermore, the comprehensive procedural planning with TAVR operators due to the preprocedural CT reading enables establishing optimized strategies of implantation and planning potential bailout strategies. We quickly changed our protocol to a preprocedural TTE and compared the pre- and post-valve implantation images, noting that our outcomes again were improved due to the lack of intubation and high doses of conscious sedation (ie, shorter length of stay: median, 3 vs 6 days. More recently, median length of stay was reduced to 2 days, and some patients are sent home the next day after the procedure). Furthermore, our clinical outcomes, paravalvular leak rates, and potential complications were similar to the more invasive strategy, ultimately demonstrating that there was absolutely no harm in adopting the MIS.

#### Intraprocedural Equipment Standardization

We streamlined our equipment choice and selection. TAVR became a routine procedure and was treated as



*Funding for this supplement provided by Medtronic*

such, with routine equipment just as in the realm of coronary intervention. Our staff was educated on the steps to successful implantation and the imperative need for the designation of roles during the procedure to avoid any confusion during implantation. Using standard sheaths and coronary catheters to obtain left ventricular access, the cost was decreased.

One important conclusion with our experience was that maintaining stable left ventricular access was imperative to the procedure to prevent the need for recrossing the aortic valve, while at the same time facilitating valve advancement and positioning. We, therefore, use a preshaped TAVR 0.035-inch guidewire (Safari wire, Boston Scientific Corporation) with a double curve for atraumatic placement in the left ventricle to avoid inadvertent left ventricular puncture and guidewire loss of access, while allowing for stable advancement of the delivery system. After we started using preshaped wires as a default strategy in all of our procedures (even in more complex anatomies such as horizontal aortas) we have not had a single ventricular perforation nor pericardial tamponade associated with the TAVR procedure.

After valvular deployment, postprocedure cardiac ICU is maintained for 12 to 24 hours; if there are no further clinical issues and postprocedural echocardiography does not demonstrate any potential concerns, the patient is either sent to the general floor and discharges the next day or directly discharged home (ie, decided upon the patient's clinical conditions) with a scheduled 48-hour follow-up phone call and with a scheduled 1-week follow-up at the outpatient clinic.

### Assessment

As with any TAVR program, our experience was assessed through formal study. In 2015, we were able to study our TAVR program by assessing our initial experience with our minimalist approach experience. In brief, approximately 200 patients, of which 50% underwent the minimalist approach to TAVR, were compared against the conventional procedure. Not surprisingly, there was no difference between 30-day outcomes; however, length of stay and savings per case were substantially improved (\$16,000/case in savings).<sup>1</sup> Furthermore, our overall contrast volume was substantially lower as compared to conventional TAVR cases and there was a trend toward reduced acute kidney injury in the minimalist approach cohort. Device success and rates of vascular complications were the same. No difference in clinical events, including stroke, new pacemaker rate, or bleeding was noted. Our study was the first of its kind in the United States comparing these different approaches to TAVR in the largest series of

United States patients utilizing self-expandable valves (and balloon-expandable valves) and led the way for a complete adoption of the minimalist approach to TAVR at University Hospitals/Case Medical Center.

### THE MINIMALIST APPROACH: LESSONS LEARNED

Our TAVR program is always evolving and we are continually searching for and evaluating ways to improve and streamline the procedure so that all parties involved can benefit. However, from our initial experience to the present, we have learned immensely about how to achieve clinical efficiency. To date, > 700 implantations have been performed, with more than 80% using the minimalist approach. It is our belief that this methodology to TAVR has been tried and true to its fullest extent in all types of patients, anatomy, and complexity, thus allowing for universal adoption as the primary mode of TAVR in experienced centers wishing to perform the minimalist approach.

That being said, we truly believe that a heart team approach to every patient is pivotal. We have dedicated nurse practitioners, structural interventional fellows and attendings, cardiac surgeons, heart failure specialists, cardiac anesthesiologists, general cardiologists, cardiac intensivists, electrophysiologists, and a dedicated catheterization lab team involved in the pre-, peri-, and post-procedure care of each and every TAVR patient. From the initial consultation to discharge, everyone involved in the procedure is well aware of the primary plan and backup plans, which inevitably improves the workflow and completion of each procedure. At our center, we have developed the "TAVR procedural planning document" that is completed and in the room during the procedure to provide information to all that are involved regarding all the complexities that may be encountered (Figure 1).

Further, there has to be an understanding between the various teams that the procedure is being performed for the good of the patient and that there should not be a competitive nature toward any one part of the procedure, whether it be requiring anesthesia, performing a TEE, requiring femoral cut downs, etc. Each team member is pivotal and the procedure should not produce the ever-so-complex "turf war," but instead should bring together the various special abilities of each person to ensure a successful procedure. All parties are invited to a regularly scheduled structural heart team meeting that discusses each patient, device, and special issues prior to the procedure.

Finally, our heart team has learned the importance of developing postprocedural clinical care paths to provide clear treatment and post-care goals to all members of

the extended heart team. Post-TAVR care pathways promote evidence-based care through standardized approaches, minimized length of stay, and optimal clinical outcomes. Our team has adopted practices to promote early mobilization, such as no Foley catheters and early removal of temporary pacing wires when clinically appropriate. Regardless of risk, all patients are managed post-TAVR in the CICU. As part of the minimalist mindset, our team continues to develop standardized criteria for early discharge, allowing some patients to be sent home the next day. As an established TAVR program, we have experienced the value of ongoing evaluation and improvement of pre- and post-care practices to build the blocks for TAVR best practices.

### THE MINIMALIST APPROACH: ASSISTIVE TECHNOLOGIES

Medtronic has two devices that may provide an improvement in a center's TAVR experience. The first piece of technology is the Confida guidewire, which is a 0.035-inch, PTFE-covered, stainless steel wire with a 20-cm flexible loop at the distal end that allows for stable position within the left ventricle and minimizes trauma and arrhythmias. The wire's stiffness is greater than an Amplatz super stiff wire but is less stiff than a Lunderquist wire, allowing for supportive advancement of the valve delivery system in tortuous and calcified vasculature. We suggest these or similar wires that provide stability for valve delivery and deployment to facilitate a successful procedure with lower observed risk of ventricular perforation. The second device that provides clinical effectiveness includes the use of an arrhythmia monitoring device that is indicated in those with asymptomatic high-grade AV block, bifascicular, or trifascicular block after valve implantation who are to be discharged after adequate observation without requiring a permanent pacemaker in the acute inpatient stay. For these special scenarios, the Medtronic SEEQ Mobile Cardiac Telemetry system provides the safety, detail, and monitoring necessary to ensure that pacemaker-requiring rhythms are promptly identified and

treated as soon as they are detected. The device is externally attached to the skin and monitors patients for up to 30 days with wireless transmission to a 24/7 monitoring center that provides continuous, live feedback from arrhythmia specialists to physicians. The slim and conveniently small device is automatically activated, sticks to the skin, water-resistant, wireless, and requires no battery changes to ensure patient compliance.

### THE MINIMALIST APPROACH: CONCLUSION

Our experience is not unique in the use of the minimalist approach, however, our continued lean methodology application to the procedure does allow for constant improvement and evolution of TAVR at our institution. Our outcomes, shorter length of stay, and dramatic reduction in cost per case may be achievable by any experienced TAVR center, in our opinion. The requirement is a full investment by all parties involved in the procedure and a complete recognition that every member of the team is important, from the physician implanting the valve to the social worker managing long-term care issues. A careful review of a TAVR program—from initial assessment to postprocedure discharge—of each step for the patient and procedure will identify unnecessary processes and equipment. This review will

| FRONT                                                                                                                                                                                                                                                                                                                                                                                                                         |                           | BACK      |  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|-----------|--|
| <b>TAVR prep checklist</b>                                                                                                                                                                                                                                                                                                                                                                                                    |                           |           |  |
| Age:                                                                                                                                                                                                                                                                                                                                                                                                                          | STS score                 |           |  |
| Comorbidities:                                                                                                                                                                                                                                                                                                                                                                                                                |                           |           |  |
| Pacemaker/ICD                                                                                                                                                                                                                                                                                                                                                                                                                 | Allergies                 |           |  |
| Prohibitive surgical risk: Yes/No                                                                                                                                                                                                                                                                                                                                                                                             | Creatinine<br>Hb/platelet |           |  |
| Coronary artery dis:                                                                                                                                                                                                                                                                                                                                                                                                          |                           |           |  |
| ECHO:                                                                                                                                                                                                                                                                                                                                                                                                                         | LV size/thickness         |           |  |
| EF                                                                                                                                                                                                                                                                                                                                                                                                                            | Other valves              |           |  |
| AV PGMG                                                                                                                                                                                                                                                                                                                                                                                                                       |                           |           |  |
| AVA                                                                                                                                                                                                                                                                                                                                                                                                                           |                           |           |  |
| ECG                                                                                                                                                                                                                                                                                                                                                                                                                           |                           |           |  |
| CT measurement                                                                                                                                                                                                                                                                                                                                                                                                                |                           |           |  |
| Annulus Area :                                                                                                                                                                                                                                                                                                                                                                                                                | Perimeter:                | %Oversize |  |
| Sinus:                                                                                                                                                                                                                                                                                                                                                                                                                        | STI:                      |           |  |
| Coronary Heights Left:                                                                                                                                                                                                                                                                                                                                                                                                        | Right:                    |           |  |
| LVOT calcium:                                                                                                                                                                                                                                                                                                                                                                                                                 | Others:                   |           |  |
| Peripherals:                                                                                                                                                                                                                                                                                                                                                                                                                  | Left:                     |           |  |
| (Narrowest diameter)                                                                                                                                                                                                                                                                                                                                                                                                          |                           |           |  |
| Right:                                                                                                                                                                                                                                                                                                                                                                                                                        |                           |           |  |
| Calcification/Tortuosity                                                                                                                                                                                                                                                                                                                                                                                                      |                           |           |  |
| TAVR Plan                                                                                                                                                                                                                                                                                                                                                                                                                     |                           |           |  |
| Valve (Type/Size):                                                                                                                                                                                                                                                                                                                                                                                                            |                           |           |  |
| Access:                                                                                                                                                                                                                                                                                                                                                                                                                       |                           |           |  |
| Antiplatelet/Anticoagulation                                                                                                                                                                                                                                                                                                                                                                                                  |                           |           |  |
| <b>Intra-procedural details</b>                                                                                                                                                                                                                                                                                                                                                                                               |                           |           |  |
| Date: _____ Time: start _____ ; end _____                                                                                                                                                                                                                                                                                                                                                                                     |                           |           |  |
| Primary access site: <u>LFA/RFA/</u>                                                                                                                                                                                                                                                                                                                                                                                          |                           |           |  |
| Closure methods for primary access site: Proglides x _____ +/- Angioseal _____ Fr x _____                                                                                                                                                                                                                                                                                                                                     |                           |           |  |
| Secondary access site: LFA/RFA, closure method: _____                                                                                                                                                                                                                                                                                                                                                                         |                           |           |  |
| ACT: _____ seconds                                                                                                                                                                                                                                                                                                                                                                                                            |                           |           |  |
| Blood pressure: _____ (pre) ; _____ (post)                                                                                                                                                                                                                                                                                                                                                                                    |                           |           |  |
| Peak to peak gradient: _____ (pre) ; _____ (post)                                                                                                                                                                                                                                                                                                                                                                             |                           |           |  |
| LVEDP: _____ (pre) ; _____ (post)                                                                                                                                                                                                                                                                                                                                                                                             |                           |           |  |
| Fluoroscopy time: _____ ; contrast volume: _____                                                                                                                                                                                                                                                                                                                                                                              |                           |           |  |
| Name and size of balloon: _____                                                                                                                                                                                                                                                                                                                                                                                               |                           |           |  |
| Name and size of valve: _____ ; position : <u>low/optimal/high</u>                                                                                                                                                                                                                                                                                                                                                            |                           |           |  |
| Sapien valve: fully filled balloon / _____ cc underfilled / _____ cc overfilled                                                                                                                                                                                                                                                                                                                                               |                           |           |  |
| Rate of rapid pacing: during BAV _____ bpm ; during valve deployment _____ bpm                                                                                                                                                                                                                                                                                                                                                |                           |           |  |
| Protamine use: <u>✓ / n</u> ; dose of protamine use: _____                                                                                                                                                                                                                                                                                                                                                                    |                           |           |  |
| Any intra-procedural complications: <u>✓ / n</u> ; if yes please check the box below                                                                                                                                                                                                                                                                                                                                          |                           |           |  |
| <ul style="list-style-type: none"> <li>- LBBB: _____ ; degree of AV block: 1 / 2a / 2b / 3</li> <li>- Acute pulmonary edema : _____</li> <li>- VT/VF : _____</li> <li>- Volume infusion : _____</li> <li>- Prolong hypotension: _____</li> <li>- Coronary obstruction: _____</li> <li>- Stroke: _____</li> <li>- Annular rupture: _____</li> <li>- Emergency surgery: _____</li> <li>- Pericardial effusion: _____</li> </ul> |                           |           |  |
| Any groin complications or special notes (please describe in words):                                                                                                                                                                                                                                                                                                                                                          |                           |           |  |

Figure 1. The TAVR procedural planning document that is completed in the room during the procedure to provide information to all involved regarding all the complexities that may be encountered.

*Funding for this supplement provided by Medtronic*

likely yield faster procedure times (our overall fluoroscopy times were shorter than conventional strategy as well) and more efficient implantation, reduce redundancy, prevent wastefulness, and allow for a more routine approach to TAVR. Hospital systems should see cost savings after implementation of the minimalist approach, as again we are not unique to the beneficial economics of this approach.<sup>8</sup> Our hope is that the minimalist approach gains popularity not for the economics, but for the improvement in overall patient-specific outcomes and the patient-TAVR experience. We foresee a future for TAVR in which the minimalist approach will someday be known as “the standard of care.” ■

1. Attizzani GF, Alkhalil A, Padaliya B, et al. Comparison of outcomes of transfemoral transcatheter aortic valve implantation using a minimally invasive versus conventional strategy. *Am J Cardiol*. 2015;116:1731-1736.

2. Attizzani GF, Ohno Y, Latib A, et al. Transcatheter aortic valve implantation under angiographic guidance with and without adjunctive transesophageal echocardiography. *Am J Cardiol*. 2015;116:604-611.
3. Frohlich GM, Lansky AJ, Webb J, et al. Local versus general anesthesia for transcatheter aortic valve implantation (tavr)—systematic review and meta-analysis. *BMC Med*. 2014;12:41.
4. Gilard M, Eltchaninoff H, Jung B, et al. Registry of transcatheter aortic-valve implantation in high-risk patients. *N Engl J Med*. 2012;366:1705-1715.
5. Barbanti M, Capranzano P, Ohno Y, et al. Early discharge after transfemoral transcatheter aortic valve implantation. *Heart*. 2015;101:1485-1490.
6. Reynolds MR, Magnuson EA, Lei Y, et al. Cost-effectiveness of transcatheter aortic valve replacement compared with surgical aortic valve replacement in high-risk patients with severe aortic stenosis: results of the partner (placement of aortic transcatheter valves) trial (cohort a). *J Am Coll Cardiol*. 2012;60:2683-2692.
7. Reynolds MR, Magnuson EA, Wang K, et al. Cost-effectiveness of transcatheter aortic valve replacement compared with standard care among inoperable patients with severe aortic stenosis: results from the placement of aortic transcatheter valves (partner) trial (cohort b). *Circulation*. 2012;125:1102-1109.
8. Babaliaros V, Devireddy C, Lerakis S, et al. Comparison of transfemoral transcatheter aortic valve replacement performed in the catheterization laboratory (minimalist approach) versus hybrid operating room (standard approach): Outcomes and cost analysis. *JACC Cardiovasc Interv*. 2014;7:898-904.
9. Behan M, Haworth P, Hutchinson N, et al. Percutaneous aortic valve implants under sedation: our initial experience. *Catheter Cardiovasc Interv*. 2008;72:1012-1015.
10. Motloch LJ, Rottlaender D, Reda S, et al. Local versus general anesthesia for transfemoral aortic valve implantation. *Clin Res Cardiol*. 2012;101:45-53.

### **Sandeep M. Patel, MD**

The Valve & Structural Heart Disease Intervention Center  
Harrington Heart and Vascular Institute  
University Hospitals, Cleveland Medical Center  
Cleveland, Ohio

*Disclosures: None.*

### **J. Brandon Elmore, MD**

The Valve & Structural Heart Disease Intervention Center  
Harrington Heart and Vascular Institute  
University Hospitals, Cleveland Medical Center  
Cleveland, Ohio

*Disclosures: None.*

### **Edwin G. Avery, MD**

Division of Cardiac Anesthesia  
Harrington Heart and Vascular Institute  
University Hospitals, Cleveland Medical Center  
Cleveland, Ohio

*Disclosures: Consultant to and speaker for Medtronic.*

### **Marco A. Costa, MD, PhD**

The Valve & Structural Heart Disease Intervention Center  
Harrington Heart and Vascular Institute  
University Hospitals, Cleveland Medical Center  
Cleveland, Ohio

*Disclosures: None.*

### **Alan Markowitz, MD**

The Valve & Structural Heart Disease Intervention Center  
Harrington Heart and Vascular Institute  
University Hospitals, Cleveland Medical Center  
Cleveland, Ohio

*Disclosures: None.*

### **Angela Davis, RN**

The Valve & Structural Heart Disease Intervention Center  
Harrington Heart and Vascular Institute  
University Hospitals, Cleveland Medical Center  
Cleveland, Ohio

*Disclosures: None.*

### **Guilherme F. Attizzani, MD**

The Valve & Structural Heart Disease Intervention Center  
Harrington Heart and Vascular Institute  
University Hospitals, Cleveland Medical Center  
Cleveland, Ohio

(216) 844-7726; [guilherme.attizzani@uhhospitals.org](mailto:guilherme.attizzani@uhhospitals.org)

*Disclosures: Physician proctor, consultant, and speaker for Medtronic.*

# TAVR Economics in a Community Program

BY HEMAL GADA, MD, MBA, AND MUBASHIR MUMTAZ, MD, FACS, FACC; ON BEHALF OF PINNACLEHEALTH CARDIOVASCULAR INSTITUTE, HARRISBURG, PA

PinnacleHealth CardioVascular Institute is the formal cardiac and cardiothoracic service line for PinnacleHealth System, a multicounty system of five hospitals surrounding Harrisburg, Pennsylvania. It was founded in 2011 and is a hospital-contracted body, formed by the merger of two large private practice groups. The Institute consists of more than 75 providers and averages more than 100,000 office and hospital visits per year. The payer mix is based on half Medicare and half private insurance. A unique facet of the program is the substantial effort placed on clinical research, much in the field of structural heart disease, involving the application of various transcatheter aortic valve replacement (TAVR) platforms in lower-risk surgical populations. The Institute's involvement in TAVR trials dates back to 2011 with initiation of the U.S. Pivotal trials for Medtronic CoreValve. The recent growth in the program has been due to robust commercial volume that has developed from expanding indications for TAVR use in populations of acceptable surgical risk.

## THE CURRENT STATE OF TAVR ECONOMICS IN A COMMUNITY PROGRAM

TAVR is a transformative, less-invasive therapy for patients with severe aortic stenosis. These procedures are now performed with percutaneous transfemoral approaches, emphasizing quick return to a heightened quality of life with outstanding clinical benefit. Despite the impressive clinical growth of TAVR with rollout to low-risk populations, the perceived cost difference of the TAVR device compared to a surgical valve bioprosthesis often takes center stage in any economics discussion, despite the fact that overall costs for the procedures are not substantially different. Because of this perception, TAVR programs often must focus on developing operational efficiencies in a way previously not usually encountered in medicine. As clinical data substantiate at least noninferiority for TAVR as compared to surgical aortic valve replacement (SAVR), a critical determinant of the success of a TAVR program in the community will be the economic barriers to entry. The financial

viability of a community TAVR program depends on a critical analysis of all aspects of resource utilization in the pre-, peri- and postprocedural settings, and adopting practices that break from the typical postoperative cardiothoracic patient while still ensuring the highest-quality clinical outcomes.

Understanding the impact of TAVR on a community program and its cost-effectiveness involves a departure from classic, payer-based methods of economic analysis, which analyze the societal perspective and costs for a therapy, including quality of life. Practical economic valuation is not based on societal parameters and thus the focus of health care administration in a community program usually does not prioritize their consideration. Instead, the administration must turn their focus to larger budget impact and cost accounting analyses.

## REIMBURSEMENT PER PROCEDURE

At its base, reimbursement determinations for Medicare and, to a significant degree, non-Medicare payers, involve an operating base payment rate that incorporates an evaluation of geographic wages. This is then adjusted for case mix based on the severity of the patient and their cost to the hospital via the assignment of a Medicare Severity-Diagnosis Related Group (MS-DRG) for inpatient procedures. MS-DRGs are primarily defined by the principal diagnosis and procedure, and secondary assignment is assigned based on the severity of the patient's illness and intensity of the services required (and resultant cost to the hospital) via any secondary diagnoses that may qualify as major complication or comorbidities (MCCs). For TAVR, the MS-DRGs are 266 and 267, which were established as specific to TAVR in fiscal year 2015. These MS-DRGs specify reimbursement for TAVR with and without MCCs. MCCs primarily include severe acute diseases, an acute exacerbation of a chronic condition, and end-stage renal disease, a rare qualifying chronic condition. Certain complications that may arise during the course of the patient's procedure or periprocedural course also qualify as MCCs. Approximately 3,200 diagnoses qualify

*Funding for this supplement provided by Medtronic*

as MCCs when reported as a secondary diagnosis. Presence of an MCC results in increased cost to the hospital for the additional care required for the secondary condition(s), which then results in an increased reimbursement. On average, in fiscal year 2015, PinnacleHealth was reimbursed \$58,588 for MS-DRG 266 versus \$44,182 for MS-DRG 267. Teaching hospitals will receive an additional payment for each MS-DRG entitled indirect medical education to assist in covering the additional cost of the teaching program. Contrasting the reimbursement for PinnacleHealth, a nonteaching institution, the Hospital of the University of Pennsylvania, an academic institution, was reimbursed \$83,627 for MS-DRG 266 versus \$63,159 for MS-DRG 267.

There are other factors that impact MS-DRGs, including cost of living for an institution's location, volume of indigent patients and uncompensated care, and credits or penalties for value-based purchasing measures. Current hospital reimbursement for TAVR envelops this fee-for-service approach and thus revenue is based on an individual episode of care. This should be contrasted from an alternate payment model, which may involve bundling of episodes, and provide reimbursement based on multiple episodes of care. This will be the future reimbursement landscape for many cardiovascular endeavors, but there are many operational efficiencies, as subsequently detailed, that will lead to economic success regardless of reimbursement model.

### POSTACUTE CARE TRANSFER POLICY

One distinguishing feature of a fee-for-service model adjudicating TAVR reimbursement is the current Medicare postacute care transfer policy (PACT). For some MS-DRGs, such as those for TAVR, special rules have been created for patients who are discharged immediately after their hospitalization to a rehabilitation hospital, skilled nursing facility, a long-term care hospital, or with home health care. This incorporates the geometric median length of stay for a particular MS-DRG. If the patient is discharged prior to this "short stay threshold" with use of the ancillary facilities or resources described previously, Medicare will appropriate a per-diem penalty. This is basically a per-day allocation of reimbursement from the hospital to the posthospital facility or resource in order to avoid double payment for the care provided. This per-diem payment is calculated from the total reimbursement for a given DRG divided by the geometric median length of stay. Current short stay thresholds for MS-DRGs 266 and 267 are 5 days and 2 days, respectively.

If home health services are present prior to the TAVR procedure, these can be resumed upon discharge with-

out incurring PACT, provided that there is adequate documentation attesting to the necessity of these preexisting services as unrelated to the TAVR episode of care.

### UNDERSTANDING AND MODIFYING COST PER PROCEDURE

The cost of a TAVR program is more complicated than simply looking at the cost of transcatheter valves. In fact, an analysis that limits itself to merely comparing implant costs and reimbursement totals will miss other major contributing factors to the total cost of valve replacement procedures.

In an analysis of PARTNER data, Arnold and colleagues described that 24% of nonimplant-related costs are related to complications, such as major cerebrovascular accident, major bleeding, renal failure, arrhythmia with need for pacemaker implantation, and need for a repeat procedure.<sup>1</sup> Avoidance of complications and maintenance of clinical excellence is key for the viability of a TAVR program in a community hospital. Outside of proficient technical skill and a methodologic approach in the procedure to avoid unnecessary complications, costs to the hospital are dependent on patient selection, peri- and postprocedural resource use, and resultant length of stay.

Ensuring the most appropriate length of stay for the best clinical outcome will allow a facility to use its resources and reimbursement for the most important areas for the patient's care. This involves a concerted effort to medically optimize patients prior to their procedure and even performing balloon aortic valvuloplasty as a bridge to TAVR when clinically indicated. By reducing length of stay prior to the procedure, there is significant cost containment.

With the safety of the transfemoral approach, operational efficiencies could be found in using the cardiac catheterization laboratory, instead of the operating room and its associated resources, and elimination of the routine setup of perfusion. Costs associated with the procedure itself, including use of expensive sheath, wire, and pacing technologies, can also slim margins significantly. A dedicated economic analysis of cost and benefit for each facet of the TAVR procedure is critical for the success of a community program. This analysis can start with listing the supplies used for a typical case and examining lower-cost alternatives, or perhaps eliminating the use of an expensive supply altogether. For example, use of one closure device (vs the conventional use of two) for the "pre-closure" technique for percutaneous transfemoral closure, in addition to protamine administration and manual pressure, would reduce cost related to the procedure by several hundred dollars. This approach has been shown not to compromise safety related to the procedure.<sup>2</sup>



A “fast track” pathway avoids the intensive care unit for lower-risk patients with straightforward procedures. As an institution, aligning providers and nursing staff on appropriate postprocedure care protocols will help develop best practices for subsets of patients. Uncomplicated percutaneous transfemoral procedures, especially those avoiding general anesthesia, may not merit the highest levels of monitoring and postprocedure care. Community institutions may benefit from development of institutional guidelines that would direct the care of appropriate patients in this manner. Such pathways would ideally focus on early ambulation and resumption of outpatient oral medications, to facilitate safe and expedient disposition. The ancillary costs incurred by laboratory and pharmacy use would also be minimized by avoidance of intensive care units.

### IMPROVING THE BOTTOM LINE: CHANGING CULTURE

In reviewing the factors related to TAVR in a community program, there is understanding of the uniqueness of all aspects of this procedure when compared to SAVR. However, most community programs maintain the same care pathway for TAVR patients as their postoperative SAVR population. This could lend to wasteful use of resources directed to specific patient care that does not merit such extravagances. Physicians, nursing, as well as ancillary services, such as physical/occupational therapy, social work, case management, and nutrition, must be aware of the differences in the care of an uncomplicated TAVR patient and should adjust their assessments accordingly. There should be strong partnership with health care administration to review the outcomes of efforts dedicated to appropriate resource consumption, as this recognition can help justify the existence and growth of a TAVR program. It is equally important for patients and their families to understand the most likely disposition for a patient who is home after TAVR, without the use of any additional postdischarge resources. This conversation should occur far in advance of the procedure, to aid the patient and their family in preparing for the procedure. In the current fee-for-service paradigm, physicians should be willing to set up immediate postdischarge outpatient visits in order to ensure patients thrive after the procedure and provide patients and their families the reassurance of continuity of care.

The Heart Team approach is absolutely necessary to aid in screening patients for TAVR and prepare patients medically and physically for the procedure. Proper documentation of acuity is essential in accurate medical records and claims submissions, and there should be consistent communication between billing/coding personnel and the providers to ensure this level of detail is achieved in charting. Knowledge of the Medicare PACT policy may also help the Heart Team appropriately plan postprocedure care.

### CONCLUSION: DON'T BE INTIMIDATED

TAVR in the United States is expensive, but it is the best therapy for many patients, and should be readily available in community hospitals with strong SAVR programs. It is up to the provider and the administration to make it work for the institution. Comprehending the constructs underpinning costs is essential for the economic viability of a community program. Transitioning from fee-for-service to alternate payment models may require some different approaches in order to achieve economic success, but the culture of a TAVR program must be separated from standard surgical practice in order to navigate pathways of care. ■

1. Arnold SV, Lei Y, Reynolds MR, et al. Costs of periprocedural complications in patients treated with transcatheter aortic valve replacement: results from the placement of aortic transcatheter valve trial. *Circulation Cardiovasc Interv.* 2014;7:829-836.

2. Kahlert P, Al-Rashid F, Plicht B, et al. Suture-mediated arterial access site closure after transfemoral aortic valve implantation. *Catheter Cardiovasc Interv.* 2013;81:E139-150.

#### Hemal Gada, MD, MBA

Medical Director, Structural Heart Program  
Staff Interventional Cardiologist  
PinnacleHealth CardioVascular Institute  
Harrisburg, Pennsylvania  
hgada@pinnaclehealth.org

*Disclosures: Receives consulting and faculty honoraria from Medtronic.*

#### Mubashir Mumtaz, MD, FACS, FACC

Surgical Director, Structural Heart Program  
Chief, Cardiovascular and Thoracic Surgery  
PinnacleHealth CardioVascular Institute  
Harrisburg, Pennsylvania

*Disclosures: Receives consulting and faculty honoraria from Medtronic.*

