

TAVR Optimization Using Best Practices

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Transcatheter 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.

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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.

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TABLE 1. BUNDLE PAYMENT FOR CARE IMPROVEMENT: PERFORMANCE SUMMARY

Average Margin Per Case	Average DRG 90-day target price – average 90-day performance spend (ie, index admission + 90-day post-discharge payment)
Postdischarge Payment	• Readmission payments • In-patient rehab payments • Subacute rehab payments • Home care agency payments

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.^{1,2} 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.² 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.³ 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 2.³

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.³ 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)
N	55	12,558	214
Sedation cases	0 (0%)	629 (5%)	194 (91%)
LOS days: average (median)	5.4 (5)	6.1 (5)	2.6 (2)
ICU LOS hours: average (median)	42.3 (25)	64.1 (33)	15.1 (8)
Procedure time: average (median)	127 min	144 min (119 min)	88 min (81 min)
Discharged to home (excludes VA patients)	74%	68%	91%
In-hospital mortality	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.

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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.⁴

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.⁵ 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.³
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.⁶ 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.^{7,8} 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 – Ensure dressing over the wires is secure and reinforced – Temporary venous pacemaker box should be close to patient – If the patient is temporary venous pacemaker dependent and has no underlying rhythm, the patient should remain in bed – If the patient has underlying stable rhythm, out of bed to chair and out of bed to chair for all meals

- 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.⁹ 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

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

Transfemoral TAVR
• Inclusion criteria – Extubated—requiring only up to 4-L nasal cannula O₂ – Cannot be temporary venous pacemaker dependent – No continuous infusions (ie, pressors, nicardipine, inotropes) – No vascular complications (no cutdowns, poorly controlled hematomas) – No significant bleeding – No change in mental status or neurologic deficits – No significant pain or uncontrolled pain • Accepting team will monitor patient for 4–6 hours (as per postprocedure order set) – Vitals – Vascular access – Change in mental status/neurologic deficits • Nurse practitioner will reevaluate patient at 4 or 6 hours and determine if patient is suitable for floor • Call step-down floor (universal bed)

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. ■

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