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Building an Efficient TAVR Program

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Transcatheter 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.[1,2] While European centers reveal significantly larger adoption of the MIS for TAVR compared with United States centers,[3,4] 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 lead to optimal clinical and procedural related outcomes.[1] 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-

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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 (~ 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 µg 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 = ~ 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

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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.[5]

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,[6,7] 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.[2-4,8-10] 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.[2] 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

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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 re-crossing 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).[1] 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

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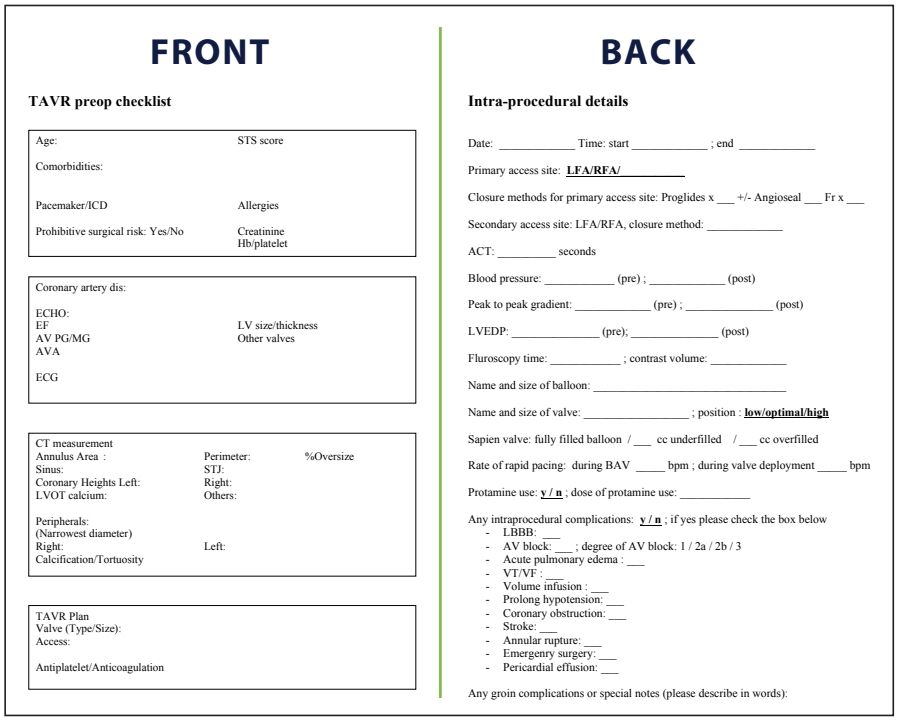
the extended heart team. Post-TAVR care pathways promote evidence-based care through standardized approaches, minimized length of stay, and optimal clinical outcomes. Our team has adopted practices to promote early mobilization, such as no Foley catheters and early removal of temporary pacing wires when 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.



FRONT

TAVR preop checklist

Age: STS score

Comorbidities:

Pacemaker/ICD Allergies

Prohibitive surgical risk: Yes/No Creatinine
Hb/platelet

Coronary artery dis:

ECHO:
EF LV size/thickness
AV PG/MG Other valves
AVA

ECG

CT measurement
Annulus Area : Perimeter: %Oversize
Sinus: STJ:
Coronary Heights Left: Right:
LVOT calcium: Others:

Peripherals:
(Narrowest diameter)
Right: Left:
Calcification/Tortuosity

TAVR Plan
Valve (Type/Size):
Access:

Antiplatelet/Anticoagulation

BACK

Intra-procedural details

Date: _____ Time: start _____ ; end _____

Primary access site: **LFA/RFA/_____**

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)

Fluroscopy time: _____ ; contrast volume: _____

Name and size of balloon: _____

Name and size of valve: _____ ; position : **low/optimal/high**

Sapien valve: fully filled balloon / ___ cc underfilled / ___ cc overfilled

Rate of rapid pacing: during BAV _____ bpm ; during valve deployment _____ bpm

Protamine use: **y / n** ; dose of protamine use: _____

Any intraprocedural complications: **y / n** ; if yes please check the box below

- LBBB: ___
- AV block: ___ ; degree of AV block: 1 / 2a / 2b / 3
- Acute pulmonary edema : ___
- VT/VF : ___
- Volume infusion : ___
- Prolong hypotension: ___
- Coronary obstruction: ___
- Stroke: ___
- Annular rupture: ___
- Emergenry surgery: ___
- Pericardial effusion: ___

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.

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

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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.[8] 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." ■

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