Transcatheter Aortic Valve Replacement (TAVR) Paradigm Shift: Minimalistic Approach with Maximal Efficiency!

Over the two decades since the first implantation of the first-in-human transcatheter aortic valve replacement (TAVR) by Cribier[1] in 2002, the technique has evolved profusely. The procedure reiterated from a multifaceted approach to a minimalistic technique owing to advances in surgical methodology, conscious sedation (CS) as an alternative to general anesthesia (GA), and miniaturization of devices used for TAVR. Although these algorithms have proven to reduce the overall intervention time, intraoperative fluoroscopy time,[2] and length of stay (LOS) in the ICU,[3] the primary end point of patient safety and efficacy cannot be compromised.

DEVICE MODIFICATIONS

Since the implantation of the prototype TAVR, a trileaflet valve made of polyurethane with a stainless steel stent, the valves and the device delivery systems have undergone significant modifications. The newer-generation valves and delivery systems facilitate deployment with accurate positioning, minimizing TAVR-related complications. Controlled deployment and miniaturized delivery systems with repositionable and retrievable features ensure precise positioning. The wide range of valves available (treating 17–30 mm annulus) with a significant reduction in their profiles enables the heart team to treat a wide gamut of patients. The 4th generation balloon-expandable Edwards Sapien 3 Ultra valve (Edwards Lifesciences LLC, Irvine, California) with the Commander delivery system provides deployment accuracy with minimum TAVR-associated complications.

Similarly, the self-expanding Medtronic Evolut Pro valve (Medtronic Inc., Minneapolis) with the Evolut PRO+ delivery system can treat a wide range of patients for up to 30 mm annulus, the broadest annulus treatable with a commercially available system. In addition, these valves, with their anti-paravalvular leakage features with an outer sealing skirt, have reduced the incidence of leakage, which has an impact on the long-term outcome of patient mortality. The low profile of the delivery systems (usually 14/16 Fr) has significantly reduced TAVR-associated vascular complications.[4-6]

SURGICAL ADVANCEMENTS

The trans-septal route used by Cribier and colleagues was later replaced by a more favorable transapical and transfemoral approach, the latter favored in comparison to the other different approaches to valve delivery. Although transfemoral access is the standard of care for TAVR, alternative access through the trans-axillary approach is gaining popularity.[7] The success of a TAVR procedure depends substantially on the preoperative assessment of the patient. The need for an extensive workup by the heart team using a multidisciplinary approach and shared decision-making algorithm has proved beneficial in assigning patients to surgical aortic valve replacement (SAVR) or TAVR. Nevertheless, irrespective of the extended indications for TAVR, there is still no proven data on the long-term durability of transcatheter heart valves. Therefore, patients under 65 years with bicuspid aortic valve and low coronary height, including peripheral anatomy not conducive for vascular access, are still recommended for SAVR. However, owing to the low invasiveness of the procedure coupled with the better patient outcome, the indications have been extended as “off-label” use for the bicuspid aortic valve, patients with aortic insufficiency, and moderate aortic stenosis with reduced ventricular function. Evidence-based medicine has not yet given a clear guideline or recommendation on whether SAVR or TAVR should be preferred in low-risk surgical groups. However, the TAVR tends to do well in patients with lung and kidney diseases, although SAVR is still the preferred method for low and prohibitive surgical risk. Two recent Randomized controlled trial (RCTs) showed that TAVR is favored over SAVR in symptomatic Aortic stenosis (AS) with low surgical risk (society of thoracic surgeonS (STS) Score <4%). The PARTNER 3 trial demonstrated the superiority of transfemoral TAVR (using balloon-expandable Sapien 3 valve) over SAVR when the primary end points were compared (death from any cause, stroke, or rehospitalization).[8]

Similarly, the Evolut low-risk study of TAVR (using self-expanding Corevalve Evolut R or PRO) showed non-inferiority as opposed to SAVR for the primary end point of all-cause death or disabling stroke.[9] Based on the
newly gathered evidence, the 2020 ACC/AHA Guidelines recommended TAVR over SAVR for patients aged between 65–80 years with prohibitive or low surgical risk as Class 1 Level of Evidence A.[10] The TAVR valve durability will define its long-term impact on patients. Presently, the NOTION trial with an eight-year follow-up comparing TAVR and SAVR showed no difference in mortality stroke or myocardial infarction rates.[11] Some studies recently performed demonstrate better durability of valves in TAVR patients compared to its SAVR counterparts, even among a younger population with low surgical risk.[12] However, recent data on leaflet thrombosis and HALT (hypo attenuated leaflet thickening) in young patients, which may predispose the patients to stroke, raised the query of long-term effects of TAVR in younger patients.[13] Longer-term data, especially in younger patients, will determine if TAVR can be routinely implanted electively in younger patients with low surgical risk.

**ANESTHESIA DEVELOPMENTS**

TAVR was usually performed under GA and with intraprocedural TEE. With time, surgeons overcame the learning curve and developed expertise, and TAVR evolved under procedural sedation without TEE. The risk–benefit ratio was weighed, and a minimalist approach without GA became popular. However, there is a significant variation in the use of GA or CS among hospitals. The SOLVE TAVI randomized trial showed no difference in outcome among patients undergoing GA or CS and when all-cause mortality, stroke, or acute kidney injury were compared.[14,15]

The study also demonstrated that the use of CS reduces LOS in the hospital, and the procedure time and also the use of vasopressors decreased. The trend toward CS is definitely on the rise, as a study of 120,000 patients from the Transcatheter Heart Valve registry showed an increase in CS from 33% in 2016 to 64% in 2019.[16] GA should be reserved for selected patients who require alternate access, patients with obstructive sleep apnea syndrome, and morbid obesity with difficulty lying flat for a longer time. The minimalist approach with same-day discharge (SDD) necessitates an intravenous peripheral line. The arterial line can be shared with the interventional cardiologist using the access for a pigtail catheter (radial or femoral), and the sheath used for pacing can be used as a central venous line. With the procedure time being drastically shortened,[17] the need for a central venous, pulmonary, or urinary catheter is not required unless specifically indicated. At the end of the procedure, the venous and arterial invasive monitoring can be removed if there are no signs of conduction disturbance. Depending on institutional/geographical infrastructure, the patients can be discharged on the same day or transferred to wards with telemetry facilities.

The minimalist approach in TAVR is a paradigm shift in TAVR management consequent to maximal efficiency. The TAVR procedure has progressed from catering to octogenarians with high-risk inoperable aortic stenosis to intermediate and low-risk and younger patients. The experience of the heart valve team and miniaturization of devices have contributed significantly to the advancement of the techniques for TAVR. Although much progress has taken place, there are many unanswered questions. An individualized, tailored approach with critical preoperative evaluation will determine the best prosthesis for the patient. Otherwise, the uncertainty of patient–prosthetic mismatch, coronary occlusion, increased usage of pacemakers, peri-procedural stroke, and eventually, the durability of the valves will hinder the progress of TAVR. The process of development in TAVR has been very rapid. The pathway from a maximalist to a minimalist approach has been hurried and is still developing. The minimalist care pathway, with its less invasive intervention, reduced LOS in hospitals, SDD, and eventual lesser treatment costs, are likely to become the standard of care for TAVR procedures.

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**Submitted:** 30-Aug-2022 **Accepted:** 31-Aug-2022 **Published:** 10-Oct-2022

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How to cite this article: Mukherjee C, Buerkle H, Loop T. Transcatheter aortic valve replacement (TAVR) paradigm shift: Minimalistic approach with maximal efficiency! Ann Card Anaesth 2022;25:381-3. This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.