Transcatheter aortic valve implantation (TAVI) has given a great impulse to less-invasive percutaneous interventions for structural heart disease. Since the first case was performed in humans by Alain Cribier in 2002, transcatheter therapy for severe aortic stenosis (AS) has undergone rapid development, becoming a reasonable alternative to conventional surgical aortic valve replacement (SAVR) in elderly patients at increased surgical risk. Over the past few years, TAVI technology has had impressive uptake, with > 500,000 procedures performed in > 70 countries, evolving from a challenging intervention to a standardized and streamlined procedure.

In real-world practice, lower-risk patients with more complex anatomic features (bicuspid valves) are treated with TAVI. In addition, the minimalist approach is gaining attention from the clinical community with the aim of saving resources and increasing patient comfort before, during, and after the procedure. This article provides an overview of the current practice of TAVI in Europe.

ADOPTION OF TAVI

Ever since feasibility and early safety of TAVI were assessed and major technical issues resolved, the rate of TAVI adoption has increased throughout Europe and is currently the most frequently used strategy for treating AS in elderly patients. In Germany, all TAVI and SAVR procedures are registered within an obligatory quality assurance program led by the independent Institute for Applied Quality Improvement and Research in Health Care (AQUA). The AQUA reports showed that the annual number of isolated SAVR procedures decreased from 11,205 in 2008 (mean age, 69.8 years; 56.3% men) to 9,953 in 2014 (mean age, 68.5 years; 60.5% men). In contrast, the number of TAVI procedures has increased 20-fold, from 637 in 2008 (mean age, 81.6 years; 39.5% men) to 13,264 in 2014 (mean age, 80.9 years; 47.6% men) and has surpassed the annual numbers of isolated SAVR since 2013.

EXPANDING INDICATIONS

From the first compassionate use cases, indications for TAVI have rapidly changed in the last 15 years, moving through inoperable and high-risk to intermediate-risk patients (Figure 1). PARTNER B (2010) and PARTNER A (2011) were the trailblazing trials that facilitated adoption in inoperable and high-risk patients, respectively. In the last 2 years, the PARTNER II and SURTAVI trials demonstrated noninferiority of TAVI compared with SAVR in intermediate-risk patients, whereas the NOTION trial and some national observational registries laid the foundation for treatment of low-risk patients. The European Society of Cardiology updated its guidelines for valve disease in 2017, for the first time assigning a class I, level of evidence B indication for TAVI treatment, even in patients at intermediate risk, if the heart team recognizes a contraindication to surgery.

Confirming this, Auffret et al analyzed temporal trends of TAVI in France from 2010 to 2015 and underlined the tendency to treat lower-risk patients, with a reduction in median logistic EuroSCORE from 20.3% (interquartile range, 12.1%–30.8%) to 13.6% (interquartile range, 9%–21%) over the study period.

Currently, evaluation of individual patient risk goes beyond the already established surgery risk scores (Society for Thoracic Surgeons score and EuroSCORE II), as they do not include many significant comorbidities that favor one treatment over another. The European guidelines...
suggest different factors to take into account in treatment choice, as evidenced in major observational studies and randomized trials. In particular, previous surgery and frailty, age > 75 years, and the feasibility of a transfemoral approach are considered to favor TAVI. On the other hand, geographic dissemination accompanied by simplification and standardization of the procedure will allow patient preference to become a central role in real-world practice. Moreover, as transcatheter aortic valve durability is extending toward and beyond the 5-year time frame, the indications for TAVI are already expanding to younger and lower-risk patients (Figure 1).

To date, the only published randomized trial of TAVI versus SAVR in low-risk patients is the NOTION study. In this Nordic study, 280 patients (82% of whom were low-risk) were randomized 1:1 to TAVI or SAVR. There was no significant difference in the primary endpoint of all-cause death, stroke, or myocardial infarction at 2 years (15.8% vs 18.8%; P = .43). Results of the ongoing PARTNER 3 (Edwards Lifesciences) and Low-Risk Evolut R (Medtronic) trials will provide more information.

TAVI for Degenerating Surgical Bioprostheses
Transcatheter valve-in-valve implantation has emerged as a novel, less-invasive treatment for failed bioprosthetic surgical valves. As experience with valve-in-valve TAVI increases and technical issues are resolved, transcatheter treatment has become a valid and safe alternative to redo surgery. Nevertheless, patients with small surgical bioprostheses represent an important challenge because they seem to have higher residual gradients and late mortality than other patients. High implantation of either annular or supra-annular transcatheter heart valves has been shown to partially mitigate this phenomenon. Recently, the results of the PARTNER II Valve-in-Valve registry and the CoreValve US Expanded Use study (Medtronic) showed overall mortality rates of 2.7% and 2.2% at 30 days and 12.4% and 14.6% at 1 year, respectively.

Bicuspid Valves
A significant proportion of elderly patients with a stenotic bicuspid aortic valve present high surgical risk and undergo TAVI, despite the fact that bicuspid valve anatomy is considered an unfavorable factor for TAVI.

Early experience demonstrated that bicuspid aortic valves have several features that may make the outcomes of TAVI suboptimal and less predictable—an oval annular shape, unequal leaflet size, heavy and uneven calcification of the leaflets, and the presence of calcified raphes. Nevertheless, Yoon et al recently demonstrated that clinical outcomes of TAVI are favorable in patients with bicuspid AS and that improving and new-generation devices are associated with less paravalvular leak and higher overall device success rates than earlier-generation devices.

MINIMALIST APPROACH
Considering the aging population in European countries and the expanding indications for transcatheter treatment, cardiology wards and clinics are increasingly going to be overloaded with patients waiting for TAVI. This is already a reality for high-volume centers. Many groups have developed local programs that incorporate specific pre-, peri-, and postprocedural algorithms aimed at simplifying the TAVI pathway. The objectives of these pathways are to create more efficient systems for patient assessment and screening, optimize the TAVI procedure without compromising its safety, accelerate patient recovery and mobilization, and minimize unnecessary use of medical resources.

Preprocedural Evaluation
All patients with severe AS at increased surgical risk should be evaluated for TAVI treatment before hospitalization. After confirming the severity of AS by clinical examination and transthoracic echocardiography, CTA should be performed, if feasible, to improve the accuracy of device sizing, anticipate and predict potential complications, and confirm suitability for transfemoral access.

The final treatment strategy is best selected by a multidisciplinary, collaborative heart valve team. The heart valve team should not only consider the indication for treatment, but also whether a patient is eligible for a minimalist approach by assessing clinical and anatomic criteria as well as clinical, nonclinical, and psychosocial factors that could affect postprocedural recovery. The heart team approach and the opinion of other key specialists, such as a cardiothoracic surgeon, geriatrician, or imaging specialist allow complete, integrative evaluation in uncertain cases.

TAVI Procedure
Once the decision is made to proceed with TAVI, the patient is admitted a day before the date of the intervention to allow the TAVI center to optimize resources and shorten the waiting list. Currently, TAVI can be safely performed in a regular cardiac catheterization laboratory. The components of a minimalist TAVI procedure include fully percutaneous transfemoral access under local anesthesia, elimination of peri procedural transesophageal echocardiographic (TEE) guidance, and reduction or elimination of balloon predilatation before valve implantation.

If a transfemoral approach is used, the presence of a cardiac surgeon in the room is not mandatory. Recent studies demonstrate that transfemoral TAVI can be performed via the percutaneous route with similar risk of vascular complications and a shorter postprocedural length of
stay than after surgical isolation of the common femoral artery.17,18 Nevertheless, carefull management of the access site is required to avoid late bleeding and other vascular complications.

With increasing operator experience and preprocedural CTA, TAVI can be safely performed under fluoroscopuc guidance, with TEE only required for challenging cases or when postdeployment device malfunction is suspected.21-23 TAVI without balloon predilation is safe and feasible, shortens procedural duration, and lowers contrast volume.22

Postprocedural Management

A consistent postoperative management strategy is essential. Early discharge (within 24–72 hours) after TAVI is not associated with an increased risk of rehospitalization or sudden cardiac death,22,24 suggesting that 24 hours of electrolycardiogram monitoring (instead of 72 hours as recommended in European Society of Cardiology guidelines) may be sufficient in patients with no conduction abnormalities immediately following the procedure.25 Nevertheless, early pacemaker implantation on the same day as TAVI is safe in cases of complete atrioventricular block and slow escape rhythm and enables rapid patient mobilization.26

Finally, early mobilization after the procedure promotes rapid return to baseline status, minimizes nosocomial complications, and decreases length of stay in the frail elderly. Early discharge after TAVI, therefore, seems to be a reasonable option in patients who do not experience procedure-related complications.

Currently, there are limited data on the feasibility, safety, and cost-effectiveness of the minimalist approach and early discharge, but there is growing interest in literature. The ongoing multicenter 3M TAVR trial (NCT02287662) and FAST-TAVI study (NCT02404467) will provide invaluable insights, with initial results expected this year.

CONCLUSION

TAVI is a safe and proven treatment for patients at increased surgical risk. As the durability of transcatheter heart valves continues to be assessed in comparison with surgical bioprostheses, TAVI is being evaluated for use in lower-risk patients and trial results will be available in the near future.1