TAVIs

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The first TAVI was performed by Alain Cribier in an inoperable patient in 2002, and since that moment, transcatheter valve intervention has become an optimal alternative therapy to SAVR for patients with AS. TAVI was introduced in 2004 to treat comorbid patients at high surgical risk, avoiding cardiac arrest and cardiopulmonary bypass while reducing surgical trauma. During the subsequent years, modern transcatheter heart valves (THVs) have become more efficient, and the outcomes of TAVI have constantly improved.

Keywords: aortic stenosis ; TAVI ; SAVR ; low-risk patients ; young patients ; life-time management ; bioprosthesis durability

1. Introduction

Thanks to improved socioeconomic and health conditions leading to prolonged life expectancy in Western countries, aortic stenosis (AS) prevalence has remarkably increased [1]. According to a large meta-analysis and modelling study, the pooled prevalence of aortic stenosis in older (>75 years) populations of Europe, USA and Taiwan is 12.4%, and the prevalence of severe stenosis is 3.4% [2]. Though aging is exponentially linked with aortic stenosis prevalence [3], age-related degeneration is not the only pathogenic mechanism. In younger patients, aortic stenosis can be mostly due to the bicuspid aortic valve (BAV) or rheumatic disease. Replacement of the native valve is the treatment of choice, whereas a valve plasty is performed less frequently.

Over the past decade, more than 15,000 patients worldwide have been randomized in clinical trials concerning transcatheter aortic valve implantation (TAVI) procedure [4]. The volume of interventions is growing rapidly and, according to the Society of Thoracic Surgeons (STS) in the U.S., more than 300,000 TAVIs have been performed since the Food and Drug Administration's first TAVI device approval in 2011 [5]. The STS-ACC TVT Registry (Society of Thoracic Surgeons–American College of Cardiology Transcatheter Valve Therapy Registry) reported in 2019 that the TAVI volume (n = 72,991) overcame all forms of surgical aortic valve replacement (n = 57,626), and today it is performed in all U.S. states [6]. In 2007, the first TAVI devices got a CE mark and entered into the European market, after which several first-in-men trails demonstrated their safety [7]. Presently, TAVI is the most frequent choice for treating aortic stenosis in older patients even in Europe. The German independent Institute for Applied Quality Improvement and Research in Health Care (AQUA) reported that the annual number of isolated surgical aortic valve replacement (SAVR) procedures decreased from 11,205 in 2008 (mean age, 69.8 years) to 9953 in 2014 (mean age, 68.5 years). Meanwhile, the volume of TAVI procedures has increased 20-fold from 2008 to 2014, and since 2013 has surpassed the annual numbers of isolated SAVR [8][9].

2. The Durability Issue

Valve durability becomes a critical issue as a consequence of a better survival rate in low-risk compared to intermediate- and high-risk patients and of a prolonged life expectancy in younger individuals undergoing TAVI. No extensive data are yet available about TAVI bioprosthetic valves long-term durability, which also has been assessed with different methods and criteria. Gurvitch et al. [10] evaluated structural valve deterioration (SVD) and hemodynamic changes in 70 patients after TAVI with a balloon-expandable valve (median of 3.7 years), confirming a good medium- to long-term durability. The PARTNER 1 trial produced other long-term data on balloon-expandable valves and showed unchanged transvalvular gradient and aortic valve area over a 5-year follow-up [11]. Toggweiler et al. [12] showed a favourable outcome after TAVI in 88 patients, with signs of moderate prosthetic valve failure in 3.4% of patients and no cases of severe prosthetic regurgitation or stenosis at 5-year follow-up. Additionally, a good long-term performance at 5 years of transprosthetic gradient of self-expandable valves was observed in the Italian Clinical Service project [13], showing 1.4% of late significant prosthetic valve failure and asymptomatic degeneration with only mild stenosis in 2.8% of patients [13]. Recently, a longer follow-up for SVD and bioprosthesis valve failure (BVF) beyond 5-year follow-up has been conducted in eight studies (

Table 1). Overall, at a follow-up of 5–8 years, moderate SVD was reported in 3.6–10.8%, severe SVD in 0–2.5%, and BVF in 0.6–7.5% of cases [14]. Following the recent European consensus about SVD and BVF [15], a satisfactory long-term performance of a self-expandable CoreValve was confirmed [16] by our group, showing a cumulative incidence function (CIF) of 2.7% of significant prosthetic valve failures and a CIF of 9.3% for moderate SVD, with none needing re-intervention. A lot of factors contribute to reducing the rate of SVD after the TAVI procedure, such as careful planning with precise measurement of the aortic annulus by a CT scan, the choice of the right prosthesis type and size for that specific patient, accurate deployment techniques, an adequate temporary pacing, and the perfect synchronization and communication among operators, assistants, and technicians of the team. Due to the interaction of the bioprosthesis with the native valve apparatus and the lack of suture-based anchoring, the risk of embolization and migration will remain part of the TAVI procedure, and it should be carefully monitored during the follow-up echocardiography [17]. Even for the occurrence of PVL after the TAVI procedure we could recommend the same behavior, though it should be strictly monitored [18][19]. Notably, more recent evidence obtained for the newer generations of CoreValve, Evolut R and Evolut Pro, showed a moderate–severe PVL rate of 3.4% and 0%, respectively [20][21]. Finally, the performance of percutaneous bioprosthetic valves appears to be reassuring and favorable even when compared with the outcome of surgical bioprostheses, showing > 95% freedom from structural failure at 5 years [22], and from 60% to 90% freedom from valvular failure at 10 years [23][24]. However, larger dedicated studies are needed for determining the rate of structural deterioration of transcatheter valves over longer follow-up periods. With all this in mind, the implantation of TAVI in patients aged <75 years should currently be performed only under certain circumstances, such as in patients with comorbidities which severely increase their risk for SAVR, or in those included in controlled trials where outcomes are monitored.

3. Personalized Medicine and TAVI: The 3D Print Model

Individualized patient-center care is a central tenet of modern medicine. The variety of the transcatheter heart valves currently available affords the opportunity to select the most appropriate device for each individual patient. Prosthesis selection should be based on operator experience and, in the near future, on pre-procedural multimodal three-dimensional imaging.

Recently, 3-dimensional (3D) printing has emerged as a technique able to convert digital models into 3D objects [25], and cardiovascular models are particularly useful in interventional cardiology, where a deep knowledge of patient-specific anatomy is fundamental to guide catheter-based procedures. The valve annuls sizing is a cornerstone for the TAVI procedure. 3D printing allows to create patient-specific models of the aortic valve and aortic root anatomy, which is a revolutionary tool for planning TAVI. Moreover, 3D modeling may be useful for predicting the development of prosthetic regurgitation [26]. In particular, this method may help to simulate the implant and evaluate the best individual approach to TAVI. In addition, the tactile feedback provided by the 3D model may help in the Heart Team's decision making process. Ensuring the reproducibility of a 3D model remains an open issue before employing the technique in clinical practice. The automatization of 3D model is desirable and great care when setting the threshold values and adjusting segmentation contours is necessary in order to avoid some errors that otherwise can be generated [27]. Even if the promises of this 3D printing model of the aortic root are great, only a limited experience has been done in the research area, and more data are needed for its validation [28][29].

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