



## Recent highlights from the *International Journal of Cardiology Heart & Vasculature*: Transcatheter aortic valve implantation

Aortic stenosis (AS) is the most common valvular heart disease in developed countries, and its prevalence is increasing with the aging of the population [1]. Interestingly, the burden of non-rheumatic valvular heart diseases is on the rise not only in Western countries, but also in Africa and Asia. In order to reduce the incidence of severe aortic stenosis, it has been suggested that the development of appropriate plans to meet the health needs of patients, the better control of modifiable risk factors, the allocation of adequate resources for early diagnosis and management of the diseases, and an improvement in access to treatment technologies are urgently warranted [2].

Recently, there has been a significant improvement in the surgical treatment of aortic stenosis (AS). Gerosa et al. analyzed data of 2,589 patients from two national multicenter registries and one Institutional database in order to investigate the safety of three different bio-prostheses: Magna Ease, Intuity/Intuity Elite and Inspiris Resilia (Edwards Lifesciences, Irvine, CA, USA) [3]. The investigators found that all study devices provided excellent early clinical and hemodynamic outcomes. Also, Inspiris showed low rates of permanent pacemaker implantation and its transaortic gradients were similar to rapid-deployment valves and lower than Magna Ease.

In the last two decades, along with the progress in cardiovascular pharmacotherapy and surgery [4,5], transcatheter aortic valve implantation (TAVI) has emerged as an effective alternative strategy for the treatment of AS [6–8]. This topic has been addressed by several authors who have published their experience on TAVI in the *International Journal of Cardiology: Heart & Vasculature* in the last years. Overall, the Journal published articles dealing with the short and long outcomes of TAVI, complications of the procedure, the role of comorbidities, and the outcome predictors.

### 1. The short and long-term outcome of TAVI

With the development of newer generation transcatheter bio-prostheses, improved delivery systems, better pre-procedural planning with imaging guidance, increased operator experience, shorter hospital length of stay, and low short- and mid-term complication rates, TAVI is increasingly expanded to younger-age patients with low or intermediate surgical risk. However, TAVI in these subsets of patients with otherwise longer life expectancies has raised concerns about transcatheter valve longevity.

To address this issue, Hammad et al. investigated the durability and extended outcome of TAVI as compared to surgical aortic valve replacement in a total of 5,122 patients enrolled in 6 randomized controlled trials [9]. The authors found that in patients with severe AS

having low-surgical risk, patients undergoing TAVI had improved short-term survival as compared to surgical aortic valve replacement. Of note, this survival advantage was absent at intermediate-term follow-up.

The therapeutic value of TAVI versus surgery in bicuspid valve is not established, largely because such patients have been excluded from major trials evaluating outcomes of the procedure. Consequently, our knowledge concerning the efficacy and safety of treating bicuspid AS with TAVI is still incomplete. Hua-Jie Zheng et al. assessed the differences between bicuspid aortic valve and tricuspid aortic valve in 667 patients with chronic moderate to severe or severe AS regarding presentation, survival, ascending aorta diameter and dilatation rate before and after TAVI [10]. The authors showed that compared with AS in patients with tricuspid aortic valve, those patients with bicuspid aortic valve were younger and underwent TAVI more frequently, resulting in a considerable survival advantage. After TAVI, ascending aorta dilatation rates were similar in patients with bicuspid aortic valve and tricuspid aortic valve, suggesting an important role of hemodynamics in ascending aorta dilatation in patients with bicuspid morphology.

Although the relationship between AS and myocardial blood flow has been addressed in multiple trials, the impact of TAVI on coronary circulation remains a matter of debate. Accordingly, Teruaki Wada et al. investigated if changes in coronary flow reserve occur over one year after TAVI in patients with severe AS [11]. To this end, they studied a total of 59 patients and found that coronary flow reserve was impaired in a considerable proportion of patients with severe AS, but improvement was seen immediately after TAVI, and persisted up to one year after the procedure. Patients with significant improvement of coronary flow reserve had larger aortic valve area and greater increase in left ventricular ejection fraction after TAVI.

TAVI is usually characterized by a shorter length of in-hospital stay as compared with surgery. However, there is a paucity of data on the feasibility and safety of same/next-day discharge following TAVI. Jiaqi Fan et al. evaluated the safety of next-day discharge in bicuspid aortic valve patients as compared with tricuspid valve patients following TAVI [12]. The authors showed that next-day discharge after TAVI was feasible and safe in both bicuspid aortic valve and tricuspid aortic valve patients with no deaths at 30-day follow-up. The authors concluded that the younger bicuspid aortic valve patients, who usually experience a fast recovery, deserve the next-day discharge after TAVI.

TAVI has become the preferred therapy for most patients with AS and concomitant heart failure. With its instant afterload reduction, TAVI offers significant hemodynamic benefits, as it is associated with changes in left ventricular structure as well as improved mortality and quality of life. It remains unclear, however, if these favorable effects occur

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irrespective of baseline left ventricular ejection fraction. Yasar Sattar et al. investigated the in-hospital outcomes of TAVI, as compared to surgical aortic valve replacement, in an octogenarian population with heart failure [13]. They studied a total of 74,995 octogenarians included in a nationwide observational analysis. Results showed that TAVI is associated with an improved safety profile for octogenarians with heart failure with both preserved and reduced ejection fraction compared to conventional cardiac surgery.

In summary, the recently published studies in the Journal provide novel information that improves our understanding of the outcome of patients with special conditions, such as bicuspid aortic valve, abnormal coronary circulation or heart failure.

## 2. Complications by TAVI

TAVI outcome has improved through the rapidly increasing clinical experience, the use of smaller catheters and different valve sizes tailored to anatomical needs, and the improvement of delivery systems. An unresolved issue lies on the impact of race on the outcome in AS patients undergoing TAVI. Vikash Jaiswal et al. performed a *meta-analysis* of 10,009 patient from three studies [14]. Statistical analysis disclosed that the likelihood of in-hospital all-cause mortality, stroke, major bleeding, and vascular complications was comparable between white and black patients. However, black patients had a greater risk of myocardial infarction and acute kidney injury as compared with white patients.

Another controversial issue is the impact of first-time detected atrial fibrillation after TAVI on all-cause mortality and heart failure. Jeppe Kofoed Petersen et al. examined a Danish nationwide database including a series of 6,807 patients undergoing TAVI [15]. The authors found that first-time detected atrial fibrillation appeared to be at least as strongly associated with two-year rates of all-cause mortality and heart failure admissions, as compared with patients with history of atrial fibrillation.

A well-recognised worrisome complication of TAVI is bleeding, particularly when the procedure is performed through a transapical approach. To address this issue, Francesco Radico et al. tested the implication of red blood cell transfusion and the optimal transfusion strategy in patients undergoing TAVI [16]. Among 11,265 participants in the multicenter TRITAVI (Transfusion Requirements in Transcatheter Aortic Valve Implantation) registry, a total of 548 patients (4.9 %) who received transapical TAVI in 19 European centers were included. At multivariable Cox regression analysis, red blood cell transfusion was an independent predictor of 30-day mortality as well as baseline ejection fraction and acute kidney injury. The authors concluded that red blood cell transfusion is an independent predictor of short-term mortality in patients undergoing transapical TAVI, regardless of major bleeding.

In summary, these studies provide novel information on TAVI-related complications specifically in black patients, in those with atrial fibrillation or in patients receiving blood transfusion.

## 3. Role of comorbidities by TAVI

TAVI has rapidly become a reasonable alternative to conventional surgery for older and inoperable patients with AS, as it improves outcomes in elderly patients with severe AS. However, the therapeutic value of TAVI in patients with multiple comorbidities remains controversial.

A controversial issue is the effect of TAVI on preprocedural mitral regurgitation. This topic has been specifically addressed by Rafael Henrique Rangel et al. who investigated the impact of severe mitral regurgitation after TAVI and its effect on 5-year mortality [17]. In a total of 820 patients, the investigators found that 64 % of patients with grade  $\geq 2$  mitral regurgitation at baseline showed an improvement in mitral regurgitation after TAVI, which was paralleled by a decrease in systolic pulmonary artery pressure and N-terminal pro-B-type natriuretic peptide levels, but was not associated with any significant difference in mortality.

An important prognostic comorbidity often observed in patients undergoing TAVI is malignancy. Although history of active cancer is conventionally associated with worse prognosis, recent progress in oncology has turned several malignant tumors into partially or fully remitted disease. Thus, whether history of malignancy or active cancer affect the prognosis of patients with AS undergoing TAVI remains still controversial. This important issue has been addressed by Takumi Osawa et al. performed a systematic review and *meta-analysis* to investigate the clinical outcomes in patients with and without cancer who underwent TAVI [18]. They analyzed 15 studies (195,658 patients) published in PubMed and Cochrane Library databases between January 2022 and January 2023. They found that patients with cancer undergoing TAVI have a good short-term prognosis and acceptable perioperative complications compared with patients without cancer. Similar findings have been reported by Yoshimasa Kojima et al. who examined whether active cancer affects all-cause mortality rates among patients undergoing TAVI [19]. Review of data from 1,114 consecutive patients treated between April 2010 and June 2019 showed that female sex, high body mass index, New York Heart Association class III or IV, atrial fibrillation, albumin levels, and cancer metastasis were factors associated with mortality. However, active cancer without metastasis was not associated with increased mortality rates.

An unfavorable anatomy of the femoral arteries is a factor that might significantly hamper the outcome of TAVI. When transfemoral access is contraindicated, an alternative access like transsubclavian, transaxillary, transcarotid or transaortic can be considered, though the feasibility and safety of these alternative approaches is less well established. Wael Abusnina et al. performed a systematic review and *meta-analysis* of studies comparing transfemoral access versus *trans*-subclavian or *trans*-axillary accesses in patients undergoing TAVI [20]. In a total of 21 studies including 75,995 patients who underwent TAVI, *trans*-femoral access was associated with significantly lower 1-year mortality compared to *trans*-subclavian or *trans*-axillary accesses without differences in major bleeding, major vascular complications and stroke. The authors concluded that *trans*-femoral access should be the preferred approach for TAVI, though *trans*-subclavian or *trans*-axillary accesses are safe alternative approaches.

Renal dysfunction is a common comorbidity in patients undergoing TAVI, which potentially associate with a worse outcome particularly in case of complex procedures. Matthew S. Katz et al. studied the effects of valve-in-valve TAVI on renal function in patients with bioprosthetic aortic regurgitation and stenosis [21]. In a total of 141 patients, the authors found that patients who underwent valve-in-valve TAVI for aortic regurgitation experienced significant improvement of renal function at post-discharge follow-up. Noteworthy, more advanced renal dysfunction at baseline were associated with greater improvement in renal function at post discharge in patients with aortic regurgitation.

Cardiac amyloidosis frequently associates with AS, particularly in the geriatric population. It is well-recognised that these two conditions have common characteristics and worsen the prognosis when they coexist. However, the outcome of patients with cardiac amyloidosis undergoing TAVI is poorly defined. Tasveer Khawaja et al. reviewed the National Readmission Dataset to identify patients with cardiac amyloidosis and AS undergoing TAVI [22]. Of 1,127 patients with cardiac amyloidosis, 92 (8.2 %) had TAVI. Statistical analysis revealed that cardiac amyloidosis patients who received TAVI were younger, and the procedure was more commonly performed at large, teaching hospitals. TAVI was associated with a lower primary composite outcome of heart failure readmissions and all-cause mortality.

In summary, these findings provide evidence in favor of using TAVI in patients with severe mitral regurgitation, active malignancy, unfavorable transfemoral access, renal dysfunction, and cardiac amyloidosis.

## 4. Outcome predictors of TAVI

Although several studies have attempted to identify clinical

predictors of postoperative adverse outcomes in patients undergoing TAVI, preprocedural risk factor assessment remains matter of debate. A major controversial issue is the prognostic role of atrial fibrillation. Accordingly, Nso Nso Kelechi Emmanuel et al. performed a systematic review and meta-analysis in order to update current evidence concerning the incidence of 30-day mortality, stroke, acute kidney injury, length of stay, and bleeding in patients with atrial fibrillation who undergo TAVI [23]. Results showed that atrial fibrillation was associated with a higher risk of all primary and secondary outcomes. Specifically, new-onset atrial fibrillation, but not pre-existing atrial fibrillation, was associated with a higher risk of 30-day mortality, stroke, and extended length of stay after TAVI.

Similar to atrial fibrillation, the clinical impact of arm circumference on the outcome of patients after TAVI remains unclear [24]. Kenichi Shibata et al. divided a series of TAVI patients into low arm circumference (n = 220) and high arm circumference (n = 127) groups. The Cox regression analysis demonstrated the independent association of mortality with low arm circumference. When arm circumference was compared to conventional prediction models of survival, there were improvements in predicting outcomes after including the arm circumference with other frailty markers.

Several studies have explored the prognostic value of different biomarkers on TAVI outcomes. However, the predictive role of hematologic biomarkers is not yet established, because published studies on their association with TAVI outcomes have shown inconsistent results. To test whether adding blood test exams to the existing risk scores used in the preoperative evaluation of TAVI patients improves outcome, Taira Fukuda et al. examined the relationship between the serum growth differentiation factor (GDF)-15 concentration and muscle function in patients receiving aortic valve replacement [25]. The authors compared patients undergoing percutaneous or surgical aortic valve replacement with healthy elderly female subjects. Results showed that the preoperative serum GDF-15 concentration was higher in female patients receiving aortic valve replacement than in healthy elderly subjects, thus suggesting that GDF-15 might constitute a predictive serum marker. Kota Nishida et al. assessed the short- to mid-term outcomes and prognostic predictors in 519 men with symptomatic severe AS who underwent TAVI at six hospitals between April 2010 and July 2020 [26]. Results showed that serum albumin levels, along with atrial fibrillation and Society of Thoracic Surgeons score, was independently associated with all-cause mortality following TAVI in men. Georg Stachel et al. evaluated the impact of preprocedural red blood cell distribution width (RDW) levels on functional outcomes after TAVI in 176 consecutive patients treated between 2017 and 2021 [27]. They found that elevated preprocedural red blood cell distribution width identifies patients at risk for impaired functional outcome after TAVI and may represent a useful low-cost parameter to guide intensity of outpatient surveillance strategies. Louise Marqvard Sørensen et al. examined how levels of N-terminal pro-B-type natriuretic peptide levels (NT-pro-BNP) pre-TAVI is associated with one-year rates of heart failure admission and mortality following TAVI [28]. The study was carried out in patients undergoing TAVI from 2014 to 2021 who had at least one recorded NT-pro-BNP measurement within one year before TAVI. Results showed that a baseline NT-proBNP  $\geq 420$  pmol/L was associated with increased one-year rates of admission due to heart failure and mortality post-TAVI and may be used to identify a high-risk population.

Preprocedural echocardiography is often used to predict the outcome of TAVI. While global longitudinal strain is a established outcome predictor of TAVE, the prognostic role of myocardial work is poorly understood. Ana Moya et al. analyzed the supplementary benefits of myocardial work assessment for baseline risk stratification in patients with severe AS referred for TAVI [29]. A total of 110 patients with severe AS referred for TAVI were included in the study. The investigators found that a baseline global work index  $< 2,323$  mmHg% is an independent predictor of increased incidence of all-cause mortality and heart failure hospitalization following TAVI, thus providing evidence for the

enhanced usefulness of myocardial work analysis in the initial risk stratification of patients with severe AS referred for TAVI.

The clinical impact of baseline mitral regurgitation on outcomes after TAVI is still controversial. Accordingly Hua-Jie Zheng Xin Liu et al. reviewed data from 120 consecutive patients with severe AS undergoing TAVI from June 2018 and July 2020 [30]. Statistical analysis showed that significant baseline mitral regurgitation was not associated with an increased risk of all-cause mortality two years after TAVI. However, an increased all-cause mortality was observed in the subset of patients who had evidence of unchanged or worsened mitral regurgitation.

In summary, the published work suggests that preprocedural risk factors such as new-onset atrial fibrillation and arm circumference, and assessment of GDF-15 blood levels and myocardial work all have a prognostic impact for patients undergoing TAVI.

## 5. Conclusions

Overall, the *International Journal of Cardiology: Heart & Vasculature* published in the last years several articles dealing with the short and long outcomes of TAVI, complications of the procedure, the role of comorbidities, and the outcome predictors. Clearly many more studies are required to further assess and validate the feasibility and safety of the procedure in the different patients subpopulations. In addition, future randomized clinical trials with long-term follow-up specifically in younger-age lower-risk AS patients are clearly warranted.

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## Disclosures

None.

## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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