JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
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AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION

VOL. 82, NO. 20, 2023

EDITORIAL COMMENT

Adoption of TAVR in Europe vs the United States

Is it Deja-Vù?*

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Transcatheter aortic valve replacement (TAVR) was born in Rouen, France, on April 16, 2002, and the earliest solid scientific evidence accrued in the United States with the PARTNER (Placement of Aortic Transcatheter Valves) trials.[1] Since its introduction, TAVR has achieved excellent clinical results in a wide range of patients with aortic stenosis. Originally reserved for inoperable patients and progressively implemented in patients at lower risk of mortality after surgical aortic valve replacement (SAVR), such surgical risk-driven decision making for treatment selection has been surpassed in the 2020 American College of Cardiology/American Heart Association guidelines,[2] which introduced age rather than surgical risk as a decision-making factor. On the other hand, most recent European guidelines maintain surgical risk within the equation: SAVR is recommended in patients <75 years of age at low predicted risk of mortality.[3,4]

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In this issue of the *Journal of the American College of Cardiology*, Prosperi-Porta et al[5] report data on large-scale adoption and outcomes of TAVR in France between 2015 and 2020. This study can be considered a window onto the European panorama across the years before dissemination of the latest guidelines. The data presented are quite different from the recent U.S. picture reported by Sharma et al.[6] We believe there are 4 main take-aways from this study:

1. Although TAVR adoption increased across all age intervals, only 1 in 10 young (<65 years of age) patients with aortic stenosis undergoing intervention were treated with TAVR;
2. Charlson comorbidity index (CCI) declined across the years in all except young patients, in whom in-hospital mortality after TAVR remained unchanged over time and was twice of that reported among patients undergoing SAVR;
3. Despite the fact that TAVR was the dominant procedure in patients ≥80 years of age across the years with a reported mortality of 2.4%, about 10% of these patients underwent SAVR with a mortality of 3.5%; and
4. Females were more commonly referred for TAVR and, despite lower reported CCI, were found to experience higher in-hospital mortality rates when treated with either TAVR or SAVR.

The first 2 observations stem from the fact that the observed increased proportion of young French patients undergoing TAVR was likely mostly represented by candidates at high risk of mortality after surgery with lower life expectancy than their peers and who would have had lower access to intervention if SAVR had been the only available procedure. This fact would explain why young patients were treated with SAVR in most cases in 2020, maintained a consistently high CCI, and experienced a superimposable in-hospital mortality after TAVR across the years. The consideration that in-hospital mortality in

*Editorials published in the *Journal of the American College of Cardiology* reflect the views of the authors and do not necessarily represent the views of the *Journal of the American College of Cardiology* or the American College of Cardiology.

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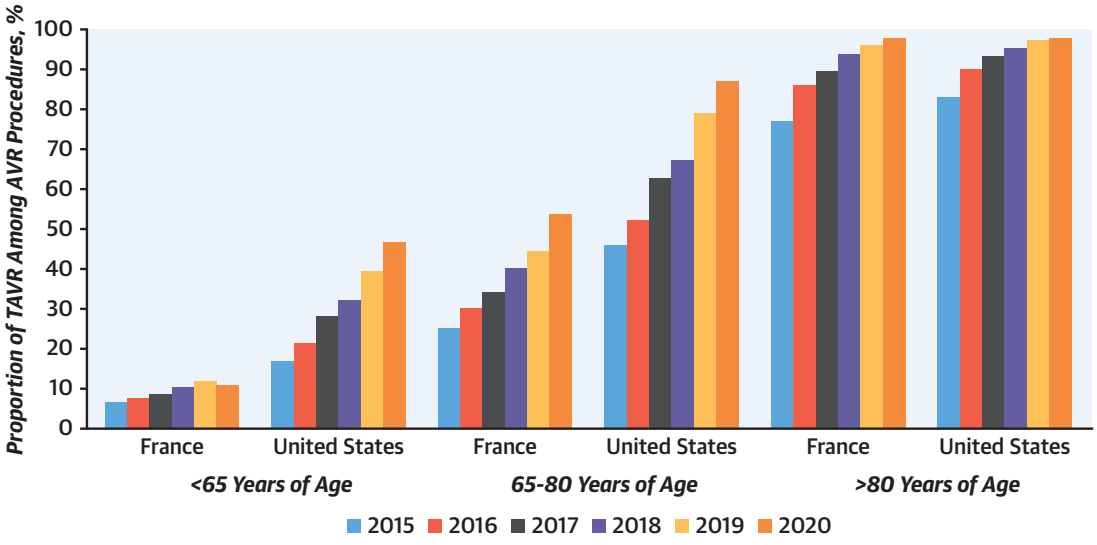
The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

ISSN 0735-1097/$36.00
https://doi.org/10.1016/j.jacc.2023.09.002

JACC VOL. 82, NO. 20, 2023
NOVEMBER 14, 2023:1903–1905

FIGURE 1 Proportion of TAVR Among AVR Procedures According to Year, Age Group, and Country



Note the progressive increase in utilization of transcatheter aortic valve replacement (TAVR) in patients <65 years of age in the United States vs the stable and low utilization in France. Of note, the proportion of patients treated with TAVR is similar when comparing French patients between 65 and 80 years of age to U.S. patients <65 years of age. Surgical aortic valve replacement (AVR) was almost universally abandoned for patients ≥80 years of age as of 2020 in United States. The proportion of TAVR was visually estimated from Figure 1 in Sharma et al.[6]

this subpopulation was twice of that reported among patients undergoing SAVR, as expected, should be critically acknowledged, and further corroborates what was stated previously. We cannot be firm in these considerations because no specific data on Society of Thoracic Surgeons predicted risk of mortality (STS-PROM) was reported.

In general, the fact that TAVR was not the most performed intervention in patients <80 years of age (TAVR utilization in patients between 65 and 80 years of age was only slightly >50%) may reflect a persistent concern regarding durability of transcatheter valves, although this issue is not supported by recent data.[7] Excluding scenarios where SAVR with a mechanical valve might be selected, preference for SAVR with bioprosthetic valves vs TAVR in young and relatively young patients might be explained from the conservative belief that current transcatheter heart valves do not have comparable durability to surgical bioprosthetic valves. The decision to use SAVR in young patients, possibly with annular enlargement procedure when indicated, considers TAVR as a secondary option at time of surgical valve deterioration. On the other hand, a TAVR-first approach might be justified should transcatheter heart valves be proven to have longer durability than surgical bioprosthetic valves.[8]

In contradistinction to the French panorama, the dramatic growth of TAVR described across all age groups of patients treated in the United States suggests otherwise (**Figure 1**).[6] Indeed, a near-equal utilization of TAVR and SAVR was observed in 2021 in patients <65 years of age, notwithstanding the just published guidelines recommending SAVR for patients belonging to this age group. Although predictors of TAVR performance included comorbidities such as congestive heart failure, prior coronary artery bypass grafting, prior vascular disease, prior percutaneous coronary intervention/stroke/myocardial infarction, chronic obstructive pulmonary disease, and kidney disease, such a large adoption of TAVR almost necessarily required inclusion of patients who were not at high risk of mortality after SAVR. The current conservative European approach may then represent "a deja-vù" of what happened in the United States before the PARTNER 3 trial, with a successive shift from a restrictive approach to a more general adoption.

The observation of higher risk of in-hospital mortality with SAVR than TAVR among patients ≥80 years of age across the years is paralleled by a significant decline in the same endpoint after TAVR (3.2% in 2015 and 2.0% in 2020; P for year trend < 0.001), but not after SAVR (4.4% in 2015 and

3.2% in 2020; *P* for year trend = 0.207). Hypothesizing that patients undergoing SAVR would have likely had lower STS-PROM (should any differences between groups be expected), these considerations support the hypothesis that SAVR should be abandoned in older patients.

The observed intersex differences reflect on large-scale evidence available from previous studies. First, increased morbidity and mortality after SAVR is reported for females vs males.[9] Second, females with aortic stenosis are more likely to be treated with TAVR than males.[10] Third, notwithstanding the superimposable incidence of device success across sexes, females do have an increased risk of major vascular complications and major bleeding events that could lead to the observed higher in-hospital mortality rates.[11] Unfortunately, we are not able to capture specific factors contributing to such observations. Considering that TAVR is currently being performed more commonly than SAVR,[6] it is key to recognize whether clinical outcomes in particular scenarios might be subject to effect modification according to sex. Besides currently existing gaps in evidence regarding indication to intervention across the spectrum of patients with aortic stenosis, we acknowledge that definite recommendations on types of bioprosthetic surgical and transcatheter valves to be implanted are not available yet. We look forward to suggestions for TAVR devices for specific anatomies and subsets of patients to reduce risk of in-hospital and long-term complications such as prosthesis-patient mismatch[12] and to optimize potential valve-in-valve procedures and lifetime management of the disease.

FUNDING SUPPORT AND AUTHOR DISCLOSURES

The authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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KEY WORDS age, aortic stenosis, surgical risk, TAVR