FROM INFORMATION CREEP TO INDICATION CREEP
To the Editor:
We read with interest the paper by Chen and colleagues in which they reported a propensity-matched study addressing the differential outcomes of transcatheter aortic valve replacement (TAVR) and surgical aortic valve replacement (SAVR) for bicuspid aortic stenosis (BAV) among 6450 Medicare beneficiaries. The findings are significant: after matching, recipients who underwent TAVR had similar risk of mortality and heart failure readmission at 6 months compared with SAVR; nonetheless, from 6 months to 3 years of follow-up, recipients of SAVR displayed a significantly lower risk of both (overall) mortality and readmission of heart failure. The authors performed a landmark analysis that confirmed these findings. This paper is timely in the current debate, as an increasing number of observational/retrospective studies over the use of TAVR in BAV have been recently published, anticipating the lack of dedicated randomized study. The conclusion and Central Message reported by Chen and colleague insist on the possible “safety” of TAVR in patients with BAV and on the results obtained during the initial follow-up. Nonetheless, it should be underlined that such clinical safety, on the basis of current data, can be reasonably applied only to the first 6 postoperative months. In fact, the overall survival curves steadily diverge in favor of SAVR after the sixth month (when the effect of early postoperative morbidity associated with SAVR is mitigated), and freedom from heart failure readmission curves diverge in favor of SAVR after 18 months (when the delayed effects of TAVR shortcomings in this population, such as greater risk of perivalvular leak and permanent pacemaker, become apparent). Overall, the current data indicate that, after 6 months, SAVR is the most effective treatment for patient survival in this BAV cohort; confirm that safety of treatment should be adjudicated under a lifetime patient’s perspective; and ultimately suggest that TAVR in BAV should be proposed with extreme caution for candidates whose life expectancy does exceeds 6 months, in order to avoid any discrepancy between data and desire of physicians (“indication creep”). This seems to be even more radical than the 3-year life expectancy cutoff evoked in meta-analyses of randomized controlled trials to discriminate the clinical effectiveness of TAVR versus SAVR with respect to overall survival in tricuspid aortic stenosis. In addition, the current investigation is coherent with a large number of registries and retrospective studies, reporting a mid-to long-term survival advantage after SAVR for tricuspid aortic stenosis compared with TAVR. The survival advantage with TAVR, namely in the low- and intermediate-risk cohorts, seems to appear essentially in a highly selected population of participants to randomized controlled trials.

We underline the critical need of considering the demonstrated therapeutic efficacy of TAVR beyond 6 months when discussing its indication in patients with BAV and emphasize the importance of tailoring the main study messages on the entirety of the core study findings in order to avoid any indication creep. The findings of this study clearly highlight the similar operative safety of TAVR and SAVR for BAV and the significant superiority of SAVR on the long-term results. Therefore, it questions the legitimacy of performing TAVR in all-comers’ patients with BAV. We definitely need further research into qualifying candidates with BAV who may benefit from TAVR in the longer term beyond operative safety.

Amedeo Anselmi, MD, PhD
Sylvain Beutheret, MD
Fabio Barili, MD, PhD
Ovidio A. García-Villarreal, MD
On behalf of International Evidence Grading Research Initiative Targeting Transparency and Quality (INTEGRITTY)

Division of Thoracic and Cardiovascular Surgery
Pontchaillou University Hospital
Rennes, France
Université de Rennes 1
LTSI
Rennes, France
Cardiac Surgery Department
Saint Joseph Hospital
Marseille, France
Department of Biomedical and Clinical Sciences
Università degli Studi di Milano
Milan, Italy
University Cardiac Surgery Unit
IRCCS Ospedale Galeazzi Sant’Ambrogio
Milan, Italy
Harvard T. H. Chan School of Public Health
Boston, Mass
Mexican College of Cardiovascular & Thoracic Surgery
Mexico City, Mexico

Conflict of Interest Statement
The authors reported no conflicts of interest.

The Journal policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.
References


