

Proceed with caution: addressing the evidence gap and patient bias in transcatheter aortic valve replacement for bicuspid aortic stenosis

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<https://doi.org/10.26599/1671-5411.2026.06.002>

With the comparative evidence between transcatheter aortic valve replacement (TAVR) and surgical aortic valve replacement (SAVR) now being well-established, TAVR has become an effective alternative to surgery in all risk spectra. In recent years, TAVR has been increasingly adopted, with its procedural volume surpassing that of SAVR and is being performed in progressively younger patients.^[1] As the age of patients undergoing TAVR decreases, the proportion of those with bicuspid aortic valve (BAV) anatomy is likely to rise. The applications of TAVR have also expanded to BAV patients,^[2] but the condition often involves complex anatomical challenges such as heavy leaflet calcification and aortopathy. Although the current recommendations for TAVR in BAV patients remain prudent in the major guidelines,^[3] current widespread adoption of TAVR in BAV patients is of concern.

THE CURRENT ISSUE OF TAVR

If the efficacy of TAVR matched the enthusiasm surrounding it, performance benchmarks set from SAVR in patients at lower surgical risk should also be achieved at early mortality approximately of 1%, major vascular complications of < 5%, moderate–severe paravalvular leak (PVL) of < 5% and aortic root injury of < 1%. However, the reality does not seem to align with expectations. The 1-year and 3-year follow-up outcomes in BAV patients from the NOTION-2 trial (The Nordic Aortic Valve Intervention) consistently demonstrated a significantly higher risk for the primary endpoint (composite of death, stroke, or rehospitalization related to the procedure, valve, or heart failure) with TAVR than SAVR (14.3% vs. 3.9%, 20.4% vs. 7.8%),^[4,5] among

which the risk of disabling stroke is twice as high following TAVR compared to SAVR in BAV patients.^[5] Propensity-matched data have demonstrated that TAVR was associated with worse mid-term survival compared with SAVR in patients aged > 65 years with BAV.^[6] Regarding non-fatal complications such as PVL, permanent pacemaker implantation and reintervention, a higher incidence in TAVR compared to SAVR has also been confirmed by multiple studies.^[2,5,7] The rate of PVL is higher in TAVR patients with BAV than in SAVR patients.^[7] Moreover, available bicuspid data indicated higher rates of both complete heart block and permanent pacemaker implantation post-TAVR (14.9% and 13.8%, respectively) compared with post-SAVR (6.2% and 4.6%, respectively),^[8] which have been demonstrated to be independently associated with a significantly increased risk of long-term all-cause mortality and heart failure rehospitalization.^[9] BAV anatomy presents distinct structural complexities that can affect TAVR prostheses. The odds of early reintervention are significantly higher in BAV patients undergoing TAVR than in those undergoing SAVR (5.9% vs. 0.3%).^[2] Furthermore, there is uncertainty whether TAVR long-term durability will match SAVR. As these younger patients look forward to decades of life with high expectations, the potential reintervention and rehospitalization burden cannot be neglected.

PREJUDICE TOWARDS SURGERY AND WARNINGS FROM THE PAST

Amid the growing utilization of TAVR, open-heart surgery appears to have been labeled with frightening tags such as “major postoperative trauma” and “prolonged recovery”. However, the difference in hospital length of stay

(LOS) between TAVR and SAVR is not as vast as the patients commonly perceived. Elbadawi, *et al.*^[8] found that the median LOS for SAVR is no more than 4 days longer than that for TAVR. The excessive fear and concern regarding open-heart surgery may be unwarranted, while the indiscriminate recommendation or application of TAVR should be viewed with a degree of skepticism, particularly in the absence of large-scale randomized controlled trials (RCTs) validating the efficacy of either procedure for young, low-risk BAV patients. In the 1990s, endovascular aneurysm repair of abdominal aortic aneurysm was rapidly adopted and replaced the prior gold standard of open repair, owing to its profile of dramatically reduced LOS, negligible blood loss, quicker convalescence, and lower perioperative mortality. However, large-scale RCTs comparing endovascular aneurysm repair and open repair have conclusively revealed the long-term superiority of open repair, demonstrating higher survival and lower complication rates.^[10] The debate over surgical approach for abdominal aortic aneurysm serves as a key reference. All-inclusive aggregated data from statewide cardiac registries in New York shows that the volume of TAVR among younger (< 65 years) patients increased by 463.63% from 2012 to 2018, despite SAVR being recommended by the American College of Cardiology/American Heart Association guidelines for patients aged < 65 years old.^[1,3] In light of this similar remarkable trend of expanding TAVR, a dedicated RCT to compare the long-term outcomes of TAVR versus SAVR has become a crucial step to guide appropriate therapy.

PATIENTS' PERCEPTION IN CLINICAL PRACTICE

In face of this evidence gap, we are currently conducting the PROMIS-BAV (Comparison of Transcatheter Aortic Valve Replacement with Surgical Aortic Valve Replacement: A Prospective, Multicenter, International, Randomized Controlled, Non-inferiority Study for Bicuspid Aortic Valve Stenosis) trial (<http://www.clinicaltrials.gov>, NCT number: NCT06597188). The trial is designed to enroll 452 subjects, who would be randomly assigned in a 1:1 ratio to either the TAVR or SAVR group. However, the actual implementation progressed much more slowly than anticipated because around two thirds of eligible patients at centers where TAVR is performed by cardiologists declined randomization and expressed reluctance to potentially undergo SAVR during enrollment discussions. A questionnaire was conducted among 11 declining patients and their immediate fam-

ily members at our center in order to learn their perspectives. After an in-depth discussion of their low surgical risk, how SAVR and TAVR are conducted, the complexity of bicuspid anatomy and current evidence of major adverse events in both procedures, 63.64% of interviewees acknowledged that the unique anatomy of the BAV poses greater challenges for interventional procedures than the tricuspid aortic valve. However, 36.36% of interviewees still believed minimally invasive surgery was inherently superior to open surgery. More than half of interviewees (54.55%) stated that their foremost concern was surviving the procedure itself, rather than other complications or long-term outcomes. On the other hand, in enrolling centers where TAVR is performed by the surgical team, patients' willingness to participate in the trial is stronger because they have already mentally prepared themselves for open-heart surgery, but they are now informed that participation in the trial may offer an opportunity to receive a minimally invasive procedure. These findings collectively point to an irrational patient preference for TAVR over SAVR.

To address this bias, it is worth noting that the majority of patients reported that their physician was both their primary and most trusted source of information on treatment options and the predominant factor influencing their final decision. Therefore, during the initial outpatient consultation, physicians should clearly explain the current evidence, present the advantages and disadvantages of both procedures in an unbiased manner, and actively work to dispel stereotypes about surgeries among patients. Another factor influencing patients' decisions was advice from relatives and friends. A major source of fear for surgery can stem from unsuccessful surgical experiences of people around the patient, and such biases are often deeply ingrained. This underscores the need to engage in thorough and balanced communication, using real-world data and successful case examples to help patients accurately understand surgical risks and benefits, while responding to their concerns with empathy to gradually build trust and reduce irrational fear. Thus, effective physician communication is essential to counter patients' baseline preference for less invasive procedures (Figure 1).

A distinct but related barrier to surgery is patients' fear of age. The average age of the patients we interviewed was 70 years old or below; however, regardless of whether the interviewees were the patients themselves or their adult children, they both expressed reluctance to subject the patients to the trauma of surgery, citing their "advanced age". Conversely, as physicians, we consider this age range to repre-



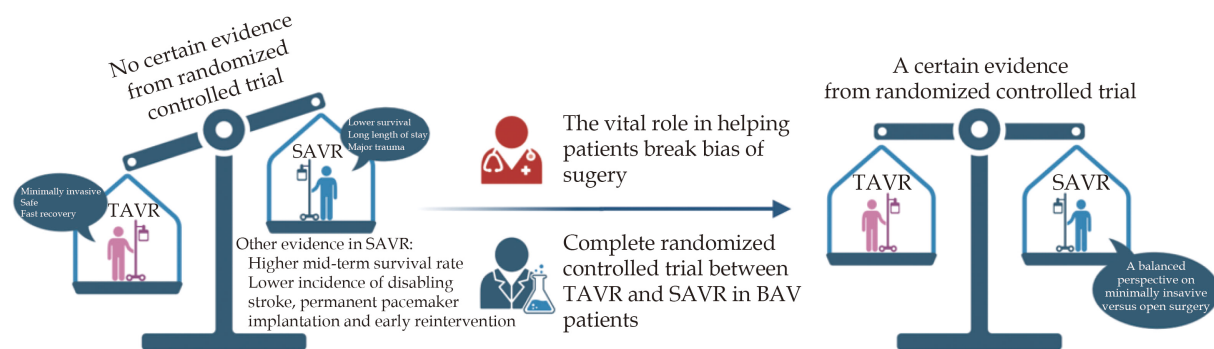


Figure 1 BAV patients' bias between TAVR and SAVR and solutions. BAV: bicuspid aortic valve; SAVR: surgical aortic valve replacement; TAVR: transcatheter aortic valve replacement.

sent a “golden window” in which SAVR offers less operative challenges in certain anatomies than TAVR while the associated risks remain relatively low. The fundamental issue lies in the discrepancy between public perceptions of elderly patient undergoing surgery and the current state of medical progress. Therefore, physicians should rectify these misperceptions, which mistakenly regard age as the “gold standard” for surgical risk assessment. Patients should be informed that, following a thorough preoperative evaluation, low-risk individuals can undergo SAVR with an acceptable safety profile (1-year all-cause mortality in the NOTION-2 trial: 1.1%).^[5] Furthermore, the availability of a comprehensive postoperative pain management protocol should be explained to alleviate any undue fear associated with the surgical procedure. Hospitals may consider establishing a communication platform that includes physicians, nurses, and prior surgical patients to help potential patients understand the postoperative course of both open surgery and minimally invasive procedures, thereby alleviating their concerns regarding prolonged postoperative recovery associated with surgical treatment.

CONCLUSIONS

In summary, based on current evidence, significant differences remain between TAVR and SAVR for BAV patients in key endpoints including mid-term mortality and reintervention, thus the rapid adoption of TAVR in BAV is unwarranted. This does not mean we are promoting surgery over transcatheter approaches, the evidence is inconclusive. Both physicians and patients should maintain cautious optimism toward TAVR. The pursuit of minimally invasive benefits must not compromise long-term survival and valve durability, especially for younger BAV patients. While awaiting higher-level evidence, physicians play a pivotal role in guiding patients and providing them with unbiased data of treatment options, as well as actively correcting their inherent fear of open heart surgery.

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ACKNOWLEDGMENTS

This study was supported by the National Natural Science Foundation of China (No.82570596) and Sichuan Province Natural Science Foundation Project (No.2025ZNSFSC-0739). All authors had no conflicts of interest to disclose.

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Please cite this article as: JIAO YY, XIONG TY. Proceed with caution: addressing the evidence gap and patient bias in transcatheter aortic valve replacement for bicuspid aortic stenosis. *J Geriatr Cardiol* 2026; 23(6): 364–367. DOI: 10.26599/1671-5411.2026.06.002

