



## Debate: Severe bicuspid aortic valve stenosis in non-high-risk surgical patients. In favor of TAVI

### *A debate: Estenosis aórtica grave bicúspide en el paciente sin riesgo elevado para cirugía. A favor del TAVI*

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**QUESTION:** What is the prevalence of bicuspid aortic valve (BAV) in your case series of transcatheter aortic valve implantation (TAVI) to this date? And what's the patients' surgical risk?

**ANSWER:** Over 1000 TAVIs have already been performed at our center, and the prevalence of BAV stands at around 4.4%. It is greater compared to the Spanish TAVI registry where nearly 2% of the patients treated with TAVI have BAV.<sup>1</sup> Thanks to the use of computed tomography scan as a systematic imaging modality to plan TAVI, its diagnosis has gone up. As a matter of fact, our group included the number of patients treated with TAVI or surgery in 2019 in 17 Spanish centers being the prevalence of BAV around 4.6%, and 16%, respectively. At times, the diagnosis of BAV is not an easy one, and when the heart valve is highly unstructured and calcified, it can go unnoticed. Therefore, it can be underdiagnosed in our series of TAVI. However, an «active» search can increase the number of diagnoses.

In our series the risk profile of these patients is intermediate-high. The mean age is 80 years old with a similar distribution by sex. The risk scores measured were the logistic EuroSCORE (14.8%), the EuroSCORE II (5.8%), and the STS (5.7%). However, these scores are influenced by the ones obtained in younger patients (< 75 years) that, although with lower scores, have proven inoperable or are very high-risk surgical patients (mainly due to a respiratory condition or hemodynamic instability).

**Q.:** What evidence do we have for TAVI to treat bicuspid aortic valve stenosis? Are the actual results equivalent to the ones reported for the non-bicuspid aortic valve?

**A.:** In short, I would say that although scarce (mainly from retrospective registries), evidence is mounting. The results coming from the oldest series were worse. However, they are currently similar with certain differences.

The evidence available on TAVI in the BAV aortic stenosis fall into 3 categories: *a/* TAVI in the BAV vs TAVI in the tricuspid valve; *b/* different types of TAVI in the BAV (TAVI vs TAVI), and *c/* TAVI vs surgery in the BAV.

The early studies showed that TAVI performed in the BAV had higher rates of paravalvular leak, embolization, need for second valve implantation, and a lower rate of successful device implantation. Thanks to the technical advances made and second and third-generation valves, these results have equalized. However, there is still a significant rate of stroke (2.5%) that is even higher compared to tricuspid valves.<sup>2</sup> A meta-analysis demonstrated that the rate of paravalvular leak is still a little higher in self-expanding valves, as well as the rate of mechanical complications in balloon-expandable valves.<sup>3</sup> No all valves are the same for the different anatomical and clinical settings. In the BAV only 1 retrospective registry has been published comparing the Edwards SAPIEN 3 valve (Edwards Lifesciences LLC, United States) to the Evolut R/Pro (Medtronic, United States). The outcomes were similar regarding mortality and stroke, but with higher rates of paravalvular leak and device embolization, and fewer overall events of successful implantation in the self-expanding valve group vs higher gradients (approximately 2 mmHg) in the balloon-expandable valve group.<sup>4</sup> In the most recent series published on the SAPIEN 3 valve in the context of the Partner-3 trial, a group of patients with BAV was compared—after propensity score-based risk adjustment—to another group of patients with tricuspid valve. It turned out that the clinical outcomes overlapped in both (mortality and stroke rates of 0% and 1.4%, respectively at 30 days). We should mention that the CoreValve Evolut device achieved an indication in patients with BAV (based on the TVT registry<sup>5</sup>) while the SAPIEN 3 valve does not have a specific contraindication in this context in its instructions for use. However, the remaining valves available today are specifically contraindicated for BAV in the instructions for use. Finally, the outcomes of TAVI vs surgery in the BAV were published in 2 studies,

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one with in-hospital outcomes and the other with the outcomes reported at the 2-year median follow-up.<sup>6,7</sup> Patients treated with TAVI had a higher rate of pacemaker implantation, and better data regarding bleeding, vascular complications, and lengths of stay with similar rates of in-hospital mortality and stroke at the 2-year follow-up. Therefore, although we still don't have robust evidence that TAVI is superior to surgery regarding the BAV, there is no single piece of evidence that says that TAVI fares worse compared to surgery.

**Q.:** What special considerations should be made with TAVI when performed on the bicuspid aortic valve? Are there any anatomical variants with specific technical implications?

**A.:** The first consideration should be to know whether we are really talking about a BAV or not. Like I said, in heavily calcified and unstructured valves it can go unnoticed. For procedural planning purposes, it is essential to make a thorough assessment of the baseline computed tomography scan. It should provide us with detailed information on the valve and the ascending aorta to obtain optimal results. In the first place, we should know both the type of BAV (type 0, I or II) and its morphology. In highly asymmetrical type 0 valves with a heavily calcified raphe, the expansion of the valve can be inadequate (very elliptical) and affect the hemodynamic outcomes (due to gradients and paravalvular regurgitation). Also, both the location of the raphe and calcification *per se* can have an impact on the position of the valve that can move towards either one of the sinuses (with greater risk of coronary obstruction in case of displacement towards the left or the right sinus). We should mention that the presence of a calcified raphe plus excessive leaflet calcification has been associated with a higher mortality rate.<sup>8</sup> The computed tomography scan can also be used to measure the right size of the valve both at annular and supra-annular level (intercommissural distance) always remembering that minimal valve oversizing is often necessary.

Once the right procedural planning is in place, the technical considerations on the day of the surgery should be:

- Avoid brain damage as much as possible and, if possible, always use cerebral protection devices.
- Use high support guidewires like Lunderquist (Cook Medical, United States) or Back-up Meier (Boston Scientific, United States) when treating tortuous aortas.
- Use the necessary time to locate the angiographic plane for implantation since it is often more complex compared to tricuspid valve cases.
- Always predilate (in most cases with the minimum diameter and without exceeding the medium) and watch the degree of balloon opening and calcium displacements from the leaflets towards the coronary arteries. The strategy of performing a simultaneous injection during predilation provides us with valuable information to analyze the risk of coronary occlusion and select the size of the valve.
- Select the right type of TAVI based on the patient's characteristics. Self-expanding valves with less radial strength can remain underexpanded so before their implantation we should always acquire several projections to confirm their correct expansion. If there is a high risk of rupture in the annulus with an aggressive expansion, the Evolut Pro+ valve can be used. However, if the risk of aortic regurgitation is high, the SAPIEN 3 Ultra valve should rather be used. We should mention that these risks happen together and the trade-off is complex. The tortuosity of the aortic arch and the horizontally

of the ascending aorta (very common in the BAV) can also help us select a flexible valve or with a deflectable catheter. Another significant aspect to select the type of valve is the operator's experience.

- If postdilation is required (needed in over 50% of the cases with self-expanding valves), the balance between the rupture of the annulus and the leak should be observed when selecting the balloon size. On many occasions, the annuli of BAVs are large meaning that large balloons will also be needed (26 mm, 28 mm or 30 mm). Still, balloons this big are not always available at the cath lab.

**Q.:** Which cases with BAV do you think are clearly eligible for TAVI and which are not?

**A.:** This is a very relevant question because, like I said, evidence is scarce and barely any randomized trials have been published on this regard (at least in the short and mid-term) comparing TAVI to surgery in the BAV setting. Therefore, decisions should be made based on the operator's experience and the local outcomes. When examining a patient with BAV for TAVI a series of clinical, and anatomical (or technical) aspects should be taken into consideration. The clinical features in favor of TAVI are the same as for tricuspid valves, that is, old, frail, and female patients (> 75 years) with comorbidities and lack of coronary artery disease or other concomitant valvular heart disease. The favorable anatomical aspects would be a suitable femoral access, type 1 bicuspid anatomy (versus type 0 and 2), small annuli, mild or moderate calcification, no dilatation of the ascending aorta, no calcification of the raphe, and no risk of coronary artery occlusion. I would use TAVI as the first-line therapy for high-risk frail or elderly patients. However, I would use surgery for young low-risk patients (< 70 years). It should be the job of the heart team to know how to deal with intermediate settings in each case like young patients with comorbidities and intermediate risk but with a favorable anatomy for TAVI or high-risk older patients with an unfavorable anatomy for TAVI. Something that should be studied based on the patients' clinical and anatomical features is whether the long-term results of surgery are predominant compared to its immediate risks or if, on the contrary, TAVI less invasive approach is preferred in this balance even after obtaining suboptimal outcomes in highly unfavorable anatomies. Thanks to the technical advances made, the new valves available, and the experience gained with TAVI with careful procedural planning good results can be achieved even in complex settings. However, since a proportion of patients with BAV are young, we interventional cardiologists need to be aware of the heterogeneity of this disease, refine the technical details of implantation, and the selection of patients and devices to optimize results.

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## CONFLICTS OF INTEREST

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