

# EuroPCR highlights

## Part 1: Evolving eligible patient population for TAVI

18-20 May 2021

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This year, the annual meeting of EuroPCR was held as a 3-day digital event, supplemented with on-demand content. EuroPCR historically covers a diverse range of topics in interventional cardiovascular medicine.

There were many sessions dedicated to the evolving changes of transcatheter aortic valve implantation (TAVI). This first part of the report details conference highlights on the evolving eligible aortic stenosis patient populations for TAVI such as young, low-risk patients and bicuspid aortic stenosis, along with contemporary challenges.

### EuroPCR: relevant sessions attended

Session type	Session title	Speakers
Livestream	TAVI in bicuspid aortic valve	Bernard Prendergast Simon Redwood Darren Mylotte Raj Makkar
Livestream	TAVI in bicuspid aortic valve patients, SAPIEN 3™ platform, a safe and efficient option	Radoslaw Parma Didier Tchetché Jörg Kempfert Christoph Klein
Livestream	TAVI: contemporary indications and techniques	Didier Tchetché Hendrik Treede Lars Sondergaard Helene Eltchaninoff
On-demand	TAVI for bicuspid aortic valve stenosis in low surgical risk population	Raj Makkar
Poster: POS295	Five-year results of balloon-expandable transcatheter aortic valve implantation	Olaf Wendler, et al.

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### Patient selection

Discussions on appropriate patient selection for TAVI took place with Dr Hendrik Treede, Dr Didier Tchetché, and Prof. Lars Sondergaard. As TAVI is now approved for all-age patients, regardless of the surgical risk profile, categorising patients by surgical risk category may be an outdated process, according to Dr Didier Tchetché. It is far more important to categorise patients based on age, comorbidities, life expectancy, valve anatomy and extent of calcification. Dr Hendrik Treede agreed, adding that, after good results in low-risk trials, even age for TAVI may not be a factor. There is no defined age cut-off for TAVI vs surgical aortic valve replacement (SAVR), but a ‘cut-off’ around 65 years of age might be considered based on life expectancy and valve durability.

“The definition of acceptable outcomes has changed based on increased life expectancy”

Nicolas Dumonteil

### Valve durability

Dr Didier Tchetché explained that most experts agree on a cut-off age of 65 years because of valve durability concerns. With TAVI indications expanding into the low-risk surgical patient population, valve durability becomes one of the biggest contemporary challenges. The younger patient cohort along with increased life expectancy means that patients are expected to outlive their device, and some structural valve deterioration is expected. However, there is a paucity of long-term data on outcomes.

5-year outcomes from the SOURCE 3 registry were reported by Prof. Olaf Wendler, et al. The SOURCE 3 registry included 1947 patients from 80 centres in 10 countries, enrolled between July 2014 and October 2015, who underwent TAVI with the SAPIEN 3™ valve.<sup>1</sup> The results showed that over time, non-cardiovascular causes of deaths increased in the elderly cohort of patients with an infrequent need for re-intervention: only 22 re-interventions were needed. Looking at the 5-year outcomes, it was concluded that the SAPIEN 3™ device provides a safe and effective treatment for patients with severe, symptomatic aortic stenosis.

### TAVI for bicuspid aortic valve

TAVI for bicuspid valve aortic stenosis was a hot topic at this year’s EuroPCR – with the evolution of TAVI into these patients who have previously been excluded from clinical trials based on their anatomy. Bicuspid aortic valve discussions were held with Prof. Bernard Prendergast, Prof. Simon Redwood, Dr Darren Mylotte, Dr Raj Makkar, Dr Didier Tchetché, and Dr Jörg Kempfert.

Bicuspid aortic valve disease is the most common congenital heart disorder in adults, affecting 1-2% of the population, and can be complicated by aortic stenosis. Traditionally, SAVR has been the treatment of choice for symptomatic bicuspid aortic stenosis because of their challenging anatomy: up to 50% of patients undergoing SAVR for AS have bicuspid valves.<sup>2</sup> Patients with bicuspid aortic valves are frequently observed in younger patients who undergo SAVR; it has been reported that as many as 41.7% of those who are 70 years of age who undergo SAVR have a bicuspid aortic valve.<sup>1</sup> As TAVI expands into the intermediate- and low-risk patient cohorts, this has critical implications for TAVI and valve anatomy.<sup>2</sup>

In such patients, the heart team conduct a thorough assessment, and the patient’s age, severity and distribution of calcification and surgical risk are key factors in the decision-making process

“It is now believed that TAVI is a reasonable alternative to surgery in carefully selected low-risk bicuspid aortic stenosis patients”

Raj Makkar

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Dr Raj Makkar presented registry results that examined outcomes of TAVI in bicuspid valvular aortic stenosis.<sup>3</sup> 160,000 low-risk patients underwent TAVI with SAPIEN 3™ and SAPIEN 3 Ultra™ valves: of these, 3,243 had bicuspid valves with a mean age of 69 years. Procedural and in-hospital outcomes were reported to be excellent with all-cause mortality reported as 0.6% vs 0.4% in bicuspid and tricuspid valves, respectively. The primary endpoint of stroke was 1.1% vs 0.9% in bicuspid and tricuspid valves, respectively. Despite concerns that surround the use of TAVI in bicuspid anatomy, procedural success rate was high and intraprocedural complications were low. The rates of death and/or stroke at 30 days and 1 year were found to be favourable in low surgical risk patients undergoing TAVI for bicuspid aortic stenosis and similar to tricuspid aortic stenosis. These results suggest that TAVI may be a reasonable treatment option in carefully selected patients with bicuspid aortic stenosis who are of low surgical risk.

### Looking ahead

It is very apparent that TAVI has come a long way since the first successful attempt in 2002. As EuroPCR 2021 draws to a close for another year, it is evident where we might expect the research and evolution of TAVI to continue in 2021: honing the patient selection criteria for TAVI to, as Dr Sandra Lauck described, get it right for every patient, first time. Long-awaited long-term data on valve durability is highly anticipated and will guide TAVI treatment decisions and finally, following such promising early results, there is an expectation of more research with promising outcomes in performing TAVI in a before-now excluded patient group for TAVI: the bicuspid aortic stenosis patient.

### References

1. Wendler O, et al. SOURCE 3 Registry: Design and 30-Day Results of the European Postapproval Registry of the Latest Generation of the SAPIEN 3 Transcatheter Heart Valve. *Circulation* 2017, 135(12), 1123–1132.
2. Makkar R, et al. Transcatheter aortic valve replacement for bicuspid aortic stenosis: are we ready for the challenge? *JACC* 2016;68:1206-8.
3. Edwards Lifesciences (2021, May 18). Real-World Data Confirm Excellent Results For Bicuspid Patients Treated With Edwards SAPIEN 3 TAVR [Press release]. <https://www.edwards.com/ch-en/news-releases/real-world-data-confirm-excellent-results-for-bicuspid-patients-treated-with-edwards-sapien-3-tavr/>

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