DOI: 10.1002/ccd.30372

COMMENTARY

WILEY

SAPIEN 3 transcatheter heart valve in patients with borderline annulus: "stretched better than bigger?"

Giuseppe Tarantini MD, PhD | **Francesco Cardaioli MD**

Department of Cardiac, Thoracic, Vascular Sciences and Public Health, University of Padua Medical School, Padua, Italy

Correspondence: Giuseppe Tarantini MD, PhD, FESC, Department of Cardiac, Thoracic, Vascular Sciences and Public Health, University of Padova Via Giustiniani 2, 35128 Padova, Italy.
Email: giuseppe.tarantini.1@unipd.it

Transcatheter aortic valve replacement (TAVR) has become the treatment of choice in older and high-surgical risk patients with aortic stenosis. At present, different valve types with different sizes are available, allowing optimal TAVR performance and clinical outcome in a wide range of patients. Selection of valve size (and type) that best fits the individual patient is mandatory as a patient-specific or -tailored approach ensures higher procedural safety and efficacy. Currently, computed tomography scan of the heart is the standard and recommended imaging technique for valve's size selection. However, patients with borderline annular dimensions remains a particularly challenging setting. Different approaches have been proposed in this setting, such as the implantation of an undersized overexpanded (OE) device or the implantation of a nominally sized valve. Nevertheless, currently there is no consensus on what is be the most advisable implantation strategy in these patients.

In this issue of catheterization and cardiovascular interventions, Basman et al. performed an observational study, comparing postprocedural outcomes of 336 patients with borderline annuli treated with balloon expandable (BE) Sapien 3 Ultra transcatheter heart valves (THVs), using either OE undersized devices or nominally sized valves (OE: 20 vs. 23 mm, $N = 10$ vs. 47; OE: 23 vs. 26 mm, $N = 74$ vs. 81; OE: 26 vs. 29 mm, $N = 62$ vs. 62).[1] About 40% of patients overall underwent annular predilation before valve implantation. The authors found a significant reduction of the primary composite outcome (in-hospital mortality, aortic injury, moderate/severe paravalvular leak [PVL], permanent pacemaker implant [PPM], stroke, or conversion to surgery) when an OE undersized device was used. This reduction in adverse outcomes was mainly driven by results observed in the OE 26 mm group compared with the 29 mm THVs ($p = 0.02$), while no significant differences were found in the other two groups. Among the individual components of the primary endpoint, PPM rate was numerically the main driver of the combined outcome difference observed.

Though some previous studies have already reported the efficacy and feasibility of OE undersized BE device implantation, this is the very first paper comparing this strategy with a standard nominal-device technique, showing some possible advantages of using smaller devices in borderline situations. Furthermore, previous studies were mostly represented by bench tests analyses and small case series involving patients with very large annuli treated with 29 mm BE-OE devices.[2,3]

Granted that, we should acknowledge that several anatomical characteristics, which may have been important to the final THV size (such as the presence, severity, and distribution of aortic valve calcifications, the sino-tubular junction width and the annulus eccentricity) and relevant to patient's outcome, are not reported. Similarly, nothing is known about the implantation height and the balloon size for predilation or postdilation, which are well-known determinants for PPM rate.[4] Additionally, the present analysis was focused on BE valve type with the use of Sapien 3 Ultra device for 20–23 and 26 mm sizes but Sapien 3 for the 29 mm one. Thus, we cannot exclude that the use of two different platforms (with different frame height and different skirts) in the larger annuli subgroup (OE: 26 vs. 29 mm), may also have played a role in the observed results.[5] The last consideration is that the present study had a follow-up of 1 year. Despite the observed good and comparable 1-year echocardiographic results of the two groups, longer observations are needed to evaluate the impact of OE THVs choice on both prosthesis performance and clinical outcome of the patients.

In conclusion, the results of the current study remain to be proven by appropriately designed randomized studies. Given the rapid development of valve technologies, in the future, it will be

important to have reliable bench test on how much bigger each valve type can be stretched.

Moreover, a well-designed study comparing physician versus simulation-driven valve size and type selection (which must imply that the software keeps track of the novel valve technologies and sizes) may be also an interesting test. To this regards, patient-specific computer simulation may add an important clinical value in cases of uncertainty in valve size selection (for instance due to the strict sizing criteria proposed by the manufacturer in combination with observer variability in CT scan analysis), allowing to refine the choice for a specific THV that best fits the individual patient.

ACKNOWLEDGEMENT

Open Access Funding provided by Universita degli Studi di Padova within the CRUI-CARE Agreement.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

REFERENCES

1. Basman C, Kodra A, Pirelli L, et al. Comparison of clinical outcomes between use of over-expanding an under-sized versus nominal-sized SAPIEN 3 ultra transcatheter heart valve in patients with borderline annulus area brief title: over-expanding under-sized transcatheter valve. *Catheter Cardiovasc Interv*. 2022:1-7. doi:10.1002/ccd.30349
2. Sathananthan J, Sellers S, Barlow A, et al. Overexpansion of the SAPIEN 3 transcatheter heart valve: an ex vivo bench study. *JACC Cardiovasc Interv*. 2018;11(17):1696-1705. doi:10.1016/j.jcin.2018.06.027
3. Mathur M, McCabe JM, Aldea G, Pal J, Don CW. Overexpansion of the 29 mm SAPIEN 3 transcatheter heart valve in patients with large aortic annuli (area >683 mm^2): a case series. *Catheter Cardiovasc Interv*. 2018;91(6):1149-1156. doi:10.1002/ccd.27190
4. Nai Fovino L, Cipriani A, Fabris T, et al. Anatomical predictors of pacemaker dependency after transcatheter aortic valve replacement. *Circ Arrhythm Electrophysiol*. 2021;14(1):009028. doi:10.1161/CIRCEP.120.009028
5. Saia F, Gandolfo C, Palmerini T, et al. In-hospital and thirty-day outcomes of the SAPIEN 3 ultra balloon-expandable transcatheter aortic valve: the S3U registry. *EuroIntervention*. 2020;15(14):1240-1247. doi:10.4244/EIJ-D-19-00541