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(Case Report)

TAVR with self-expandable valves: what challenges in bicuspid aortic valve disease?

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Abstract

Background: The bicuspid aortic valve (BAV) represents a complex anatomic entity for transcatheter aortic valve replacement (TAVR) because of its unique technical challenges. All the randomized clinical trials comparing outcomes of TAVI with surgery till date, have excluded patients with bicuspid aortic valve. The only data in literature come from empirical observations, with large variability in implantation techniques across differentcenters and operators.

Objective: These case reports describe the results of transcatheter aortic valve replacement (TAVR) in bicuspid aortic valve stenosis (BAV) using self-expandable valves with their clinical, imaging, procedural, and follow-up settings.

Case reports: We report 3 cases of TAVR with BAV. The patients were at high risk of surgery. Baseline cardiac computed tomography (CT) was analyzed by interventional cardiologists. We used self-expandable valves in all the procedures. There were no cases of valve embolization or need for a second valve, no post-dilatation, no cases of moderate or severe aortic regurgitation, and none of the cases required a permanent pacemaker implantation.

Conclusion: With the available observational data, it seems that TAVI is indeed technically feasible in selected BAV patients with acceptable results. Self-expandable valves can be safe and effective devices for these procedures. Most of the current data studies highlight the importance of preprocedural imaging determining the outcome of TAVI inBAV patients. Advancements device iterations and procedural refinements will continue to improve the outcomes of these patients treated by TAVR.

Keywords: Aortic stenosis; Bicuspid aortic valve; TAVR; BAV

1. Introduction

The bicuspid aortic valve (BAV) represents a complex anatomic entity for transcatheter aortic valve replacement (TAVR) because of its unique technical challenges. All the randomized clinical trials comparing outcomes of TAVI with surgery till date, have excluded patients with bicuspid aortic valve. The only data in literature come from empirical observations, with large variability in implantation techniques across differentcenters and operators.

2. Case reports

2.1. Case 1

Seventy year-old female patient with the medical history of diabetes, hyperlipidemia on statins, and high bloodpressure on ACE inhibitors was referred to our department for severe symptomatic aortic stenosis. She endorses that her

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condition has deteriorated over past year. She started noticing lower extremity swelling, two pillow orthopnea and fatigue on exertion. Echocardiogram showed severe aortic stenosis with a peak velocity of 5.04 m/sec, mean gradient 56 mmHg, and AVA 0.8 cm^2 (Figure 1). It was not clear that the patient has bicuspid or tricuspid aortic valve from the echocardiogram. After heart team discussion, it was decided that the patient is not a candidate for open surgical valve replacement because of her age and frailty. CT scan showed done as a part of TAVI work up showed: Bicuspid aortic valve (Type 1 N-R) with massive calcifications extending to the LVOT. The annulus was elliptical with a perimeter of 64.7mm. Left and right coronary ostia height were respectively 16.8 and 11.6 mm. (Figure 2)

The details of the TAVI procedure, especially drawbacks of this technique for patients with BAV were describedfor the patient and her family, followed by written consents from them. General anesthesia, and right ventricular pacing were carried out as a routine standard protocol. Arteriotomy was performed to obtain an appropriate femoral access. Pre-implantation balloon aortic valvuloplasty was performed with a 18*30mm balloon. An 14 French 26 mm CoreValve EVOLUT (Medtronics) was selected. We used the cusp overlap view forvalve positioning and targeted the virtual basal ring level (Figure 3). No obvious aortic insufficiency was detected, nor under-expansion of the valve. The mean pressure gradients (MPG) accessed by echocardiography decreased from 56 mm Hg to 13 mm Hg. A 30 day follow-up showed significant improvement in clinical and hemodynamic findings in that the patient who had milder dyspnea (NYHA Class II), prosthetic aortic valve MPG of 6.5 mm Hg, mild tricuspid regurgitation, and systolic pulmonary artery pressure of 35 mmHg. No conduction abnormalities were noted on her ECG.

2.2. Case 2

Fourty-five-year-old male patient with the medical history of diabetes, hyperlipidemia on statins, high blood pressure, end-stage renal disease under dialysis, and respiratory insufficiency secondary to pulmonary tuberculosis was referred to our department for severe symptomatic aortic stenosis. He reported shortness of breath (NYHA IV) and typical angina. Echocardiogram showed a bicuspid aortic valve with severe stenosis with a peak velocity of 5.63 m/sec, mean gradient 80 mmHg, and AVA 0.6 cm^2. Coronary angiogram showed multiple non-significant stenoses. After heart team discussion, it was decided that the patient is not a candidate for open surgical valve replacement because of his very high surgical risk and comorbidities. CT scan showed done as a part of TAVI work up showed: tricomissural valve with total commissural fusion between theLCC and RCC and heavy calcifications (Figure 4). The annulus was elliptical and his perimeter measured 83.3mm.

The details of the TAVI procedure, especially drawbacks of this technique for patients with BAV and end stage renal disease and the inherent risk of prosthesis degeneration were described for the patient and his family, followed by written consents from them. General anesthesia, and right ventricular pacing were carried out as aroutine standard protocol. Arteriotomy was performed to obtain an appropriate femoral access. Pre- implantation balloon aortic valvuloplasty was performed with a 22*40 mm balloon (Figure 5). An 14 French 34 mm CoreValve EVOLUT (Medtronics) was selected. We used the cusp overlap view for valve positioning and aim to reach a high positioning, than the coplanar view for final valve deployment (Figure 6).

No obvious aortic insufficiency was detected, nor under-expansion of the valve, and no pericardial effusion on TTE were noted. The mean pressure gradients (MPG) by echocardiography decreased from 80 mm Hg to 19 mm Hg. A 30 day follow-up showed significant improvement in clinical and hemodynamic findings in that the patient had milder dyspnea, prosthetic aortic valve PPG of 21 mm Hg, MPG of 10 mm Hg, mild tricuspid regurgitation, and systolic pulmonary artery pressure of 38mm Hg. No conduction abnormalities were noted on his ECG.

2.3. Case 3

Seventy-three year-old male patient with the medical history of diabetes was referred to our department for severe symptomatic aortic stenosis. He reported shortness of breath (NYHA IV). Echocardiogram showed severe aortic stenosis with a peak velocity of 4,5 m/sec, mean gradient 58 mmHg, and AVA 0.7 cm^2. It was not clear that the patient has bicuspid or tricuspid aortic valve from the echocardiogram. After heart team discussion, it was decided that the patient is not a candidate for open surgical valve replacement because of hisage and frailty. CT scan showed done as a part of TAVI work up showed: tricommissural valve with total commissural fusion between the NCC and LCC. The annulus was elliptical with a perimeter of 77.1 mm. Left and right coronary ostia height were respectively 15 and 20 mm from the annulus (Figure 7).

As for the two previous patients, the details of the procedure and the consent were obtained before the intervention. We carried out the same routine protocol. A 14 French 29 mm CoreValve EVOLUT (Medtronics) was selected. No predilatation was performed. We used the cusp overlap view for valve positioning and aim toreach a high positioning, then we used to the coplanar view for final valve implantation (figure 8). No obvious aortic insufficiency was detected, nor under-expansion of the valve. The mean pressure gradients (MPG) by echocardiography decreased from 58 mm Hg to 11 mm Hg. A 30 day follow-up showed significant improvement in clinical and hemodynamic findings: prosthetic aortic valve gradient decreased significantly PPG of 12 mm Hg, MPG of 6.7 mm Hg, trivial tricuspid regurgitation, and systolic pulmonary artery pressure of 29 mm Hg. No conduction abnormalities were noted on his ECG.

3. Discussion

3.1. Anatomic settings

Outcomes of TAVR in bicuspid patients are strictly related to the BAV phenotype. The specific concernsregarding TAVR for BAV include:

- An elliptically shaped annulus that may impair valve positioning and sealing.
- Asymmetrical and heavy calcification of leaflets may impede valve expansion and valvehemodynamics
- Presence of aortic disease increases the risk of dissection or rupture during valvuloplasty,postdilatation, or implantation of balloon-expandable valves.
- Fused commissures are susceptible to disruption during balloon valvuloplasty, resulting in severe aortic regurgitation.
- Underexpansion and/or a non-circular shape of the transcatheter heart valve may affect long-term durability.

The characterization of BAV phenotypes by multislice computed tomography (CT) plays a key role in TAVRplanning. As BAV includes a variety of morphological abnormalities (1).

More recently, a TAVR-specific classification was suggested by Jilaihawi et al, depicting 3 BAV phenotypes based on the presence or absence of raphe and the number of commissures (2): bicommissural nonraphe type (like Sievers type 0); bicommissural raphe-type (equivalent to Sievers type 1); and tricommissural BAV, a morphology with some anatomic features similar to Sievers type 1 and others similar to tricuspid aortic valve (TAV), often described as acquired (indeterminate Sievers class) (3) .

There have been conflicting reports on the impact of different anatomical BAV variants on clinical outcomes. Mylotte *et al.* (4) found type 1 BAV to be associated with a higher rate of moderate–severe aortic regurgitationcompared to other BAV anatomies after TAVR, whereas Yousef *et al*. (5) showed that type 1 BAV anatomy (particularly L–R subtype), was associated with significantly lower 30-day and 1-year mortality and a higher device success, and lower rate of moderate–severe aortic regurgitation after TAVR. Studies have showed that type 0 BAV was strongly associated with a higher residual transprosthetic pressure gradient than other BAVs after TAVR. As observed, type 0 BAV had no raphe with extensive calcification on the leaflet than the aortic annulus. Therefore, THVs were less prone to expand, resulting in higher gradients secondary to valve asymmetrical expansions (6) (7). All of our patients had Type 1 or equivalent type 1 BAV, we didn't observe anyof the complications above.

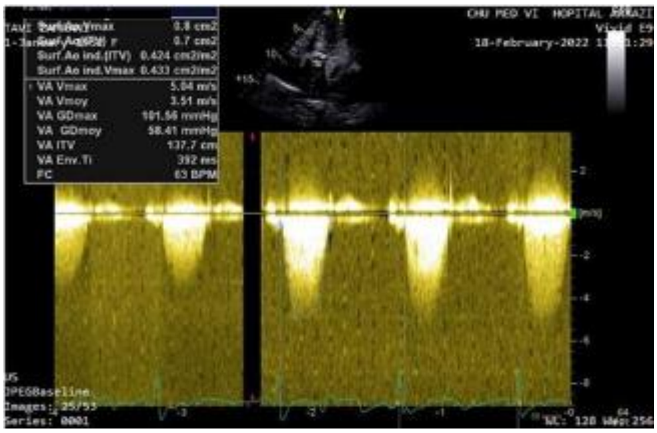

Figure 1 Doppler echocardiography before TAVR showedpeak pressure gradient: 101 mean pressure gradients: 58 mmHg

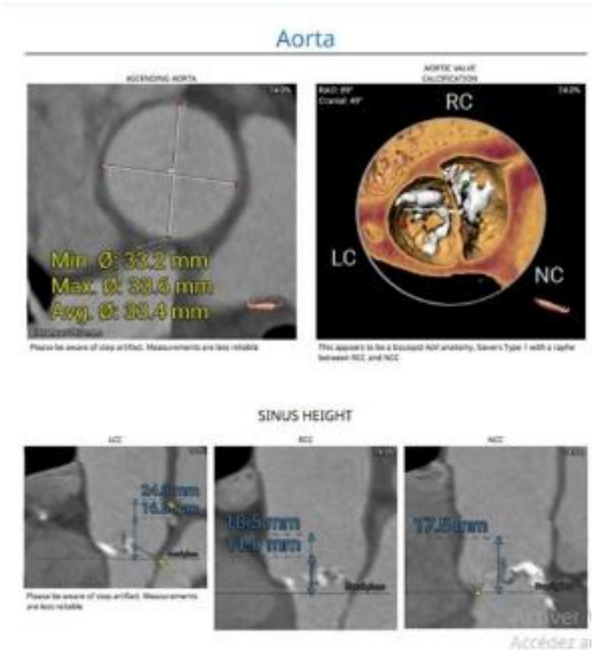

Figure 2 CT-scan showed a type 1 bicuspid aortic valve

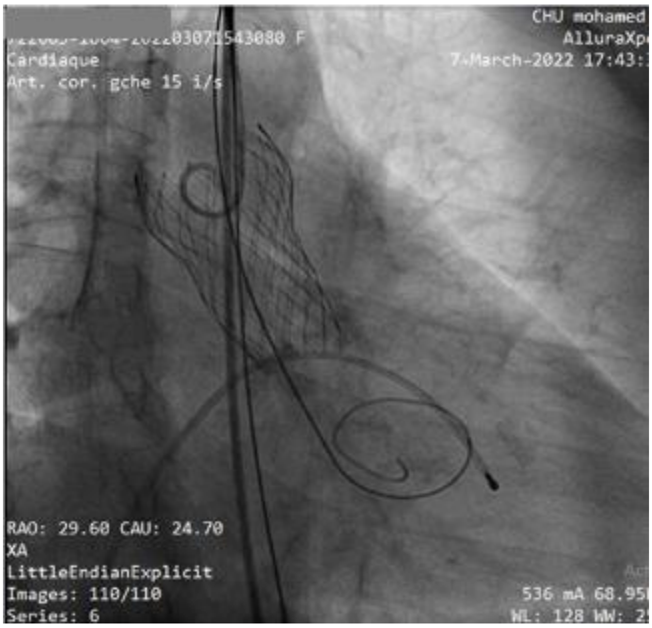

Figure 3 Implantation of CoreValve 26 mm

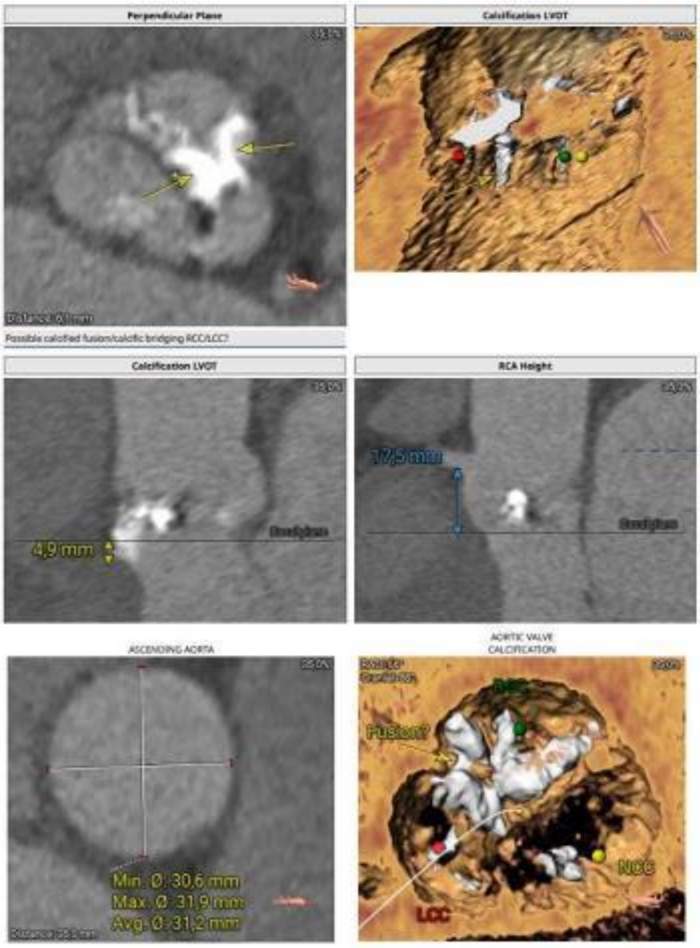

Figure 4 CT-scan showed tricomissural valve with total comissural fusionbetween the LCC and RCC

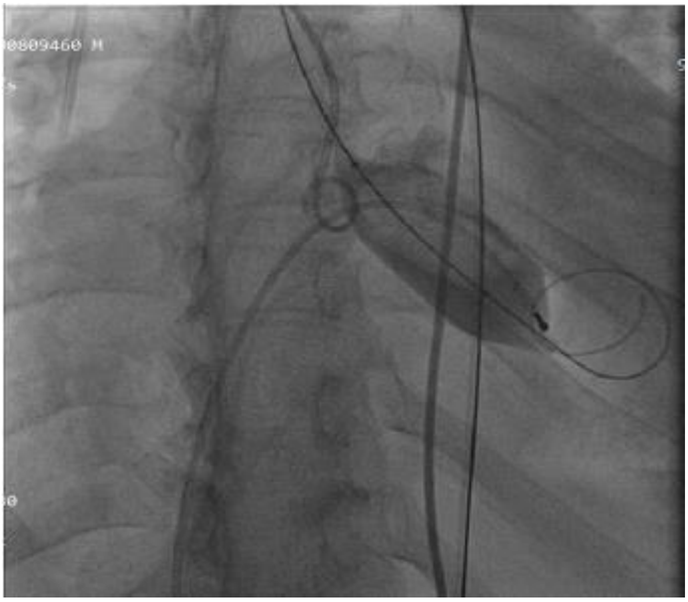

Figure 5 Ballon annuloplasty with 22*40 mm balloon

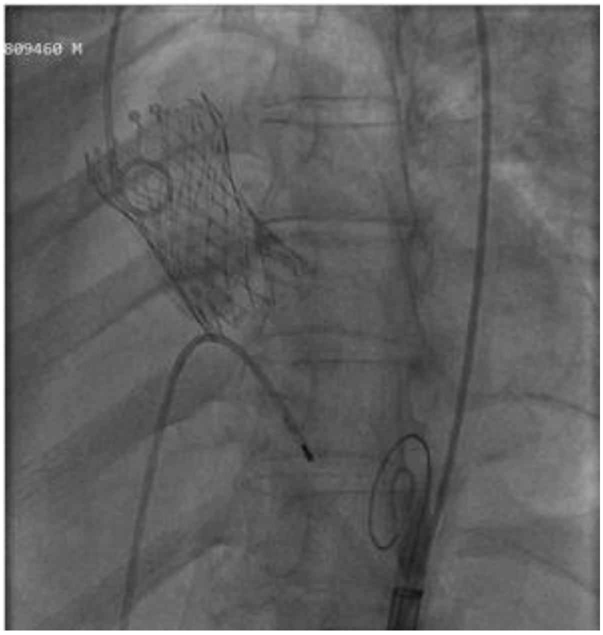

Figure 6 Implantation of CoreValve 34 mm

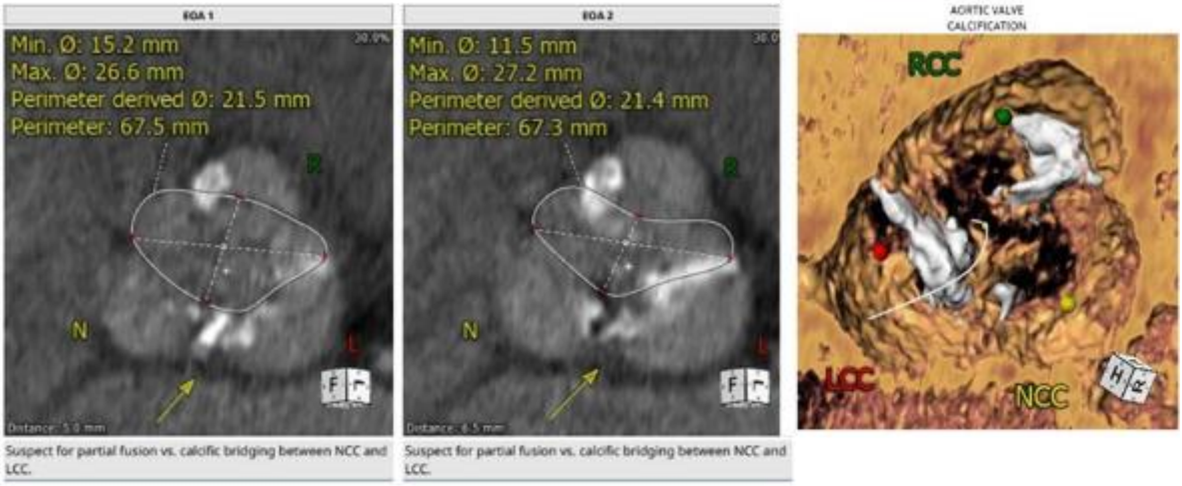

Figure 7 CT-scan showed tricomissural valve with total comissural fusion between the NCC and LCC

Figure 8 Implantation of CoreValve 29 mm

3.2. Imaging assessment

In tricuspid AS, the so-called virtual basal ring (VBR) is the tightest part of the aortic root, where the THV will anchor and seal (8). Therefore, this virtual structure, bounded by 3 anatomic hinge points at the nadir of each of the aortic cusp insertions, represents the appropriate reference plane for prosthesis sizing and implantationheight. However, in BAV, the anatomic definition of the VBR may be more difficult:

In BAV without raphe, the definition of a 3-dimensional structure (ie, the VBR) is challenging becauseof the presence of only 2 anatomic hinge points. Manual multislice CT assessment of annulus should be chosen over automatic detection since it is more accurate in alignment of the cusps

In bicommissural raphe-type and in tricommissural BAV, the VBR definition is more accurate as 3 cuspsare easily recognizable. Nevertheless, the detection of the cusps nadir might be difficult because of their typical unequal size (fused versus nonfused cusp).

Recently, some authors suggested a supraannular plane, the virtual raphe ring (VRR) in analogy with the VBR,for prosthesis sizing in BAV. They suggest that the supraannular plane should be sited at 4 to 5 mm from the annular plane (9).

However, the selection of an identical VRR height for all BAVs should be considered arbitrary, as the extension of commissural fusion is variable. Rather, it seems preferable to consider the plane where the supraannular structure has the tightest dimensions (10). In support of this, a post-TAVR CT scan study in raphe-type BAVs showed that the level of maximal THV constriction matches that of highest protrusion of raphe along the aorticroot (11).In case 2 and 3, as we observe a VBR> VRR in tricomissural valves with cusp fusions, we chose a supra-annular plane for valve implantation.

3.3. Prosthesis selection

Balloon-expandable THVs: The new-generation Sapien 3 valve is characterized by an external skirt that improves sealing in complex anatomies, such as irregularly shaped and calcific landing zone of BAV, reducing the need for oversizing. The high radial strength might theoretically prevent major valve underexpansion, aswell as minimize the gap at the intercommissural triangles. This feature should be balanced with the risk of aortic injury in high-risk BAV phenotype or preexisting aortopathy.

Self-expandable THVs: These devices might better adapt to the irregularly shaped landing zone of BAV. Moreover, the supraannular valve design may provide a better THV hemodynamic even in the presence of major under or asymmetrical expansion at the inflow portion (9) (12). Finally, the repositioning and recapturingfeatures of some of them might allow a more accurate positioning. The majority of evidence is available for theEvolut TAVR systems (12) (13). In the recently published nonrandomized Low-Risk Bicuspid study (13) TAVR with the Evolut R/PRO THVs achieved favorable 30-day results, with low rates of death and stroke and high device success rate.

With regard to THV choice in bicuspid anatomy, in the BEAT registry (Balloon Versus Self-Expandable Valve forthe Treatment of Bicuspid Aortic Valve Stenosis), the balloon-expandable Sapien 3 (Edwards Lifesciences) had higher residual gradients and a trend towards higher rates of annular rupture, while the self-expanding CoreValve Evolut R/PRO (Medtronic) valves had higher rates of moderate or severe percutaneous paravalvularleak (14).

3.4. Procedural techniques

3.4.1. Balloon valvuloplasty

Specifically, balloon aortic predilation allows to facilitate THV crossing, proper positioning, and expansion; testraphe's resistance, predicting THV expansion; and define device size for borderline/uncertain CT-based sizing. We realized balloon valvuloplasty in two of our patients

3.5. Prosthesis Implantation Technique

According to the 3 aortic root configurations for THV sizing, the operator can aim for one of 2 different landingzones:

In codominant and VBR-dominant scenarios, the VBR is the proper landing zone.

In VRR-dominant pattern, a supra-annular landing zone is advisable based on raphe characteristics. When the VRR is the selected landing zone, THV implantation height should be targeted for optimalsupraannular sealing

It is important to note that determining the optimal angiographic projection for THV deployment may be complex in BAV, as the leaflets appear irregular at fluoroscopy. Therefore, correct coaxial alignment of the THVframe should be based on the combination of CT-derived orthogonal view and orientation of the valve at fluoroscopy. We used both co-planer and cusp-overlap view for valve positioning.

3.6. Balloon post-dilatation

In the BEAT registry, the rate of postdilatation was significantly higher with the self-expandable Evolut R/PRO THVs compared with balloon-expandable Sapien 3 valve (14). Although postdilatation might mitigate BAV- related THV distortion, it should be limited to those cases with residual significant PVL or transvalvular gradientdue to the potential increase of balloon-related complications. None of our cases needed post-dilatation.

4. Conclusion

With the available observational data, it seems that TAVI is indeed technically feasible in selected BAV patients with acceptable results. Self-expandable valves can be safe and effective devices for these procedures. Most of the current data studies highlight the importance of preprocedural imaging determining the outcome of TAVI inBAV patients. Advancements device iterations and procedural refinements will continue to improve the outcomes of these patients treated by TAVR.

Compliance with ethical standards

Disclosure of conflict of interest

The authors have no conflicts of interest to declare.

Statement of informed consent

The authors confirm that written informed consent has been obtained from the involved patients.

References

[1] Siu SC, Silversides CK. Bicuspid aortic valve disease.J Am Coll Cardiol. 2010; 55:2789–2800. doi: 10.1016/j.jacc.2009.12.068

[2] Vincent, Flavien, et al. "Transcatheter aortic valve replacement in bicuspid aortic valve stenosis." Circulation 143.10 (2021): 1043-1061.

[3] Jilaihawi H, Chen M, Webb J, Himbert D, Ruiz CE, Rodés-Cabau J, Pache G, Colombo A, Nickenig G, Lee M, et al.. A bicuspid aortic valve imaging classification for the TAVR era.JACC Cardiovasc Imaging. 2016; 9:1145–1158. doi: 10.1016/j.jcmg.2015.12.022

[4] Mylotte D, Lefevre T, Søndergaard L, Watanabe Y, Modine T, Dvir D, et al. Transcatheter aortic valve replacement in bicuspid aortic valve disease. J Am Coll Cardiol 2014;64:2330–9.

[5] Yousef A, Simard T, Webb J, Rodés-Cabau J, Costopoulos C, Kochman J, et al. Transcatheter aortic valve implantation in patients with bicuspid aortic valve: a patient level multi- center analysis. Int J Cardiol 2015;189:282–8.

[6] Bugani G, Pagnesi M, Tchetchè D, Kim WK, Khokhar A, Sinning JM, et al. Predictors of high residual gradient after transcatheter aortic valve replacement in bicuspid aortic valve stenosis. Clin Res Cardiol 2021;110:667–75.

[7] Kong WKF, Delgado V, Bax JJ. Bicuspid aortic valve: what to image in patients considered for transcatheter aortic valve replacement? Circ Cardiovasc Imaging 2017;10:e005987.

[8] Piazza N, de Jaegere P, Schultz C, Becker AE, Serruys PW, Anderson RH. Anatomy of the aortic valvar complex and its implications for transcatheter implantation of the aortic valve.Circ Cardiovasc Interv. 2008; 1:74–81. doi: 10.1161/CIRCINTERVENTIONS.108.78

[9] Tchetche D, de Biase C, van Gils L, Parma R, Ochala A, Lefevre T, Hovasse T, De Backer O, Sondergaard L, Bleiziffer S, et al.. Bicuspid aortic valve anatomy and relationship with devices: the BAVARD Multicenter Registry.Circ Cardiovasc Interv. 2019; 12:e007107. doi: 10.1161/CIRCINTERVENTIONS.118.007107

[10] Xiong TY, Li YJ, Feng Y, Liao YB, Zhao ZG, Mylotte D, Wei X, Xu YN, Peng Y, Wei JF, et al. Understanding the interaction between transcatheter aortic valve prostheses and supra-annular structures from stent geometry.JACC Cardiovasc Interv. 2019; 12:1164–1171. doi: 10.1016/j.jcin.2019.02.051

[11] Iannopollo G, Romano V, Buzzatti N, De Backer O, Søndergaard L, Merkely B, Prendergast BD, Giannini F, Colombo A, Latib A, et al.. A novel supra-annular plane to predict TAVI prosthesis anchoring in raphe-type bicuspid aortic valve disease: the LIRA plane.EuroIntervention. 2020; 16:259–261. doi: 10.4244/EIJ-D-19-00951

[12] Forrest JK, Kaple RK, Ramlawi B, Gleason TG, Meduri CU, Yakubov SJ, Jilaihawi H, Liu F, Reardon MJ. Transcatheter aortic valve replacement in bicuspid versus tricuspid aortic valves from the STS/ACC TVT Registry.JACC Cardiovasc Interv. 2020; 13:1749–1759. doi: 10.1016/j.jcin.2020.03.022

[13] Forrest JK, Ramlawi B, Deeb GM, Zahr F, Song HK, Kleiman NS, Chetcuti SJ, Michelena HI, Mangi AA, Skiles JA, et al.. Transcatheter aortic valve replacement in low-risk patients with bicuspid aortic valve stenosis.JAMA Cardiol. 2021; 6:50–57. doi: 10.1001/jamacardio.2020.4738

[14] Mangieri A, Tchetchè D, Kim WK, Pagnesi M, Sinning JM, Landes U, Kornowski R, De Backer O, Nickenig G, Ielasi A, et al.. Balloon versus self-expandable valve for the treatment of bicuspid aortic valve stenosis: insights from the BEAT International Collaborative Registrys.Circ Cardiovasc Interv. 2020; 13:e008714. doi:10.1161/CIRCINTERVENTIONS.119.008714