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CASE REPORT
Other

Mind the gap: avoiding paravalvular leak using computer simulation in bicuspid transcatheter aortic valve replacement—a case report

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Background Transcatheter aortic valve replacement (TAVR) is becoming increasingly prevalent worldwide and is now more common than surgical aortic valve replacement. It is expanding into all patient subsets including younger and lower risk patients. Bicuspid aortic valve (BAV) accounts for a significant proportion of TAVR, but due to heterogenous anatomy, it is of increased complexity. One of the greatest challenges in BAV is the selection of the correct TAVR size. Transcatheter aortic valve replacement sizing is based upon computed tomography–derived annular measurements. There are a number of sizing algorithms for BAV based upon anatomical characteristics, often yielding different results. This is noted especially when a patient falls near the borderline between two valve sizes, an anatomical grey zone. Complementary to the algorithm approach is the use of pre-procedural patient-specific computer simulation using finite-element modelling.

Case summary An 86-year-old female was treated for heart failure secondary to severe and calcific BAV aortic stenosis with TAVR. Due to anatomical difficulty and grey-zone valve sizing, we demonstrate the use of pre-procedural patient-specific computer simulation with the novel Medtronic Evolut PRO+ platform to achieve a good result.

Discussion Using patient-specific computer simulation, we were able to safely select the valve and the deployment height and then accurately predict the result in a difficult, severely calcified BAV. In addition to improving outcome, this allows for patient-specific, tailored discussion to occur at heart team meetings.

Keywords Bicuspid aortic valve • TAVR sizing • Case report

ESC Curriculum 4.2 Aortic stenosis • 2.4 Cardiac computed tomography

Learning points

- Transcatheter bicuspid aortic valve (BAV) intervention is an expanding and challenging field. Determining the correct valve size is integral in ensuring a good outcome. Patient-specific simulation modelling can assist in this.
- There are several accepted methods for valve sizing in BAV: the CASPAR, Circle, LIRA, and BAVARD methods.
- We demonstrate the use of patient-specific pre-procedural modelling which may have advantages over algorithm-based methodology to achieve the best result in an individual patient.

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Introduction

Transcatheter aortic valve replacement (TAVR) is becoming increasingly prevalent worldwide. In 2019, the number of TAVRs performed in the USA exceeded surgical aortic valve replacements (SAVRs), 72 991 vs. 57 626.[1] It is estimated that 10% of those undergoing TAVR have bicuspid aortic valve (BAV); therefore, a large number of BAV TAVRs are being performed.[2]

Timeline

Index date	Admission to local hospital, new diagnosis of severe aortic stenosis, lasting 10 days, and requiring intra venous diuretics. Discharged home for outpatient assessment
5 weeks	TAVR CT
6 weeks	Diagnostic coronary angiogram—minimal atheroma only
8 weeks	Heart team meeting—initial modelling with predicted poor result with 29 mm PRO and 34 mm *R* valves
10 weeks	Repeat procedural modelling—34 mm PRO+ predicts, mild PVL. Heart team and patient decision to proceed
12 weeks	Completed transcatheter aortic valve replacement (TAVR) procedure—34 mm PRO+ valve implanted at medium depth. Resulting echocardiographic mild-to-moderate PVL
20 weeks	Uneventful recovery with resumption of usual activities and routine with no breathlessness or oedema

A recent meta-analysis found an increased risk of moderate-to-severe paravalvular leak (PVL), cerebral ischaemic events, and annular rupture in subjects with BAV compared with triscupid aortic valve stenosis.[3]

Bicuspid aortic valve cases pose increased complexity due to heterogenous valve morphology and heavy calcium burden. Valve morphology can be classified by the number of raphes, their position, and functional state using the Sievers score.[4] The annulus is often not circular, and the leaflets can form a supra-annular funnel. Therefore, one of the greatest challenges in BAV is selection of the correct TAVR size. Sizing is based upon computed tomography (CT)-derived aortic annular measurements. There are several sizing algorithms for BAV, often yielding different results depending upon anatomical characteristics. This occurs especially when a patient falls between two valve sizes, an anatomical grey zone.

An addition to the algorithm approach is using pre-procedural patient-specific computer simulation utilizing finite-element valve modelling and computational flow dynamics. In this case report, we demonstrate the use of modelling with the novel Medtronic Evolut PRO+ platform in a grey-zone patient to achieve an optimal result.

Case presentation

An 86-year-old female was admitted with a history of progressive dyspnoea, reducing exercise tolerance, one syncopal episode, and no angina.

On admission, she had both pulmonary and peripheral oedema requiring intra-venous diuretics. Baseline electrocardiogram showed sinus rhythm with normal PR interval and narrow QRS.

Transthoracic echocardiography demonstrated severe aortic stenosis (AS), peak gradient 71 mmHg and mean gradient 43 mmHg. The left ventricle was impaired with an ejection fraction of 40%.

The patient responded well to diuretics and was discharged home for outpatient TAVR assessment. On regular diuretic therapy, she was able to mobilize moderate distances with the use of a stick.

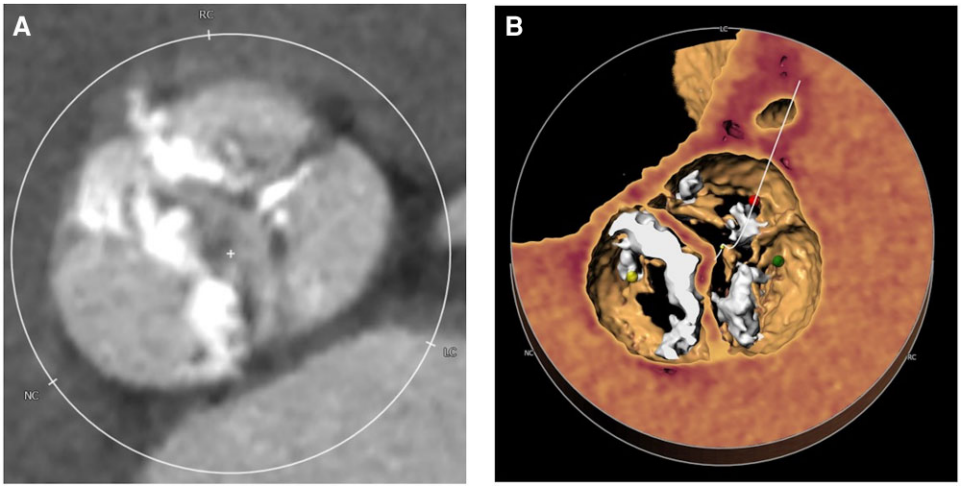

Figure 1 (*A*) Calcified Sievers Type 1 bicuspid aortic valve with R–L fusion. The annular perimeter is 82.9 mm. There was a derived annular diameter of 26.4 mm, a sinus of Valsalva diameter of 34.4 mm, and a sino-tubular junction height of 21.2 mm. (*B*) The hockey puck virtual reality reconstruction of valvular structure and calcification. Note: the valve is inverted, and therefore, the right and left coronary cusps are inverted between images.

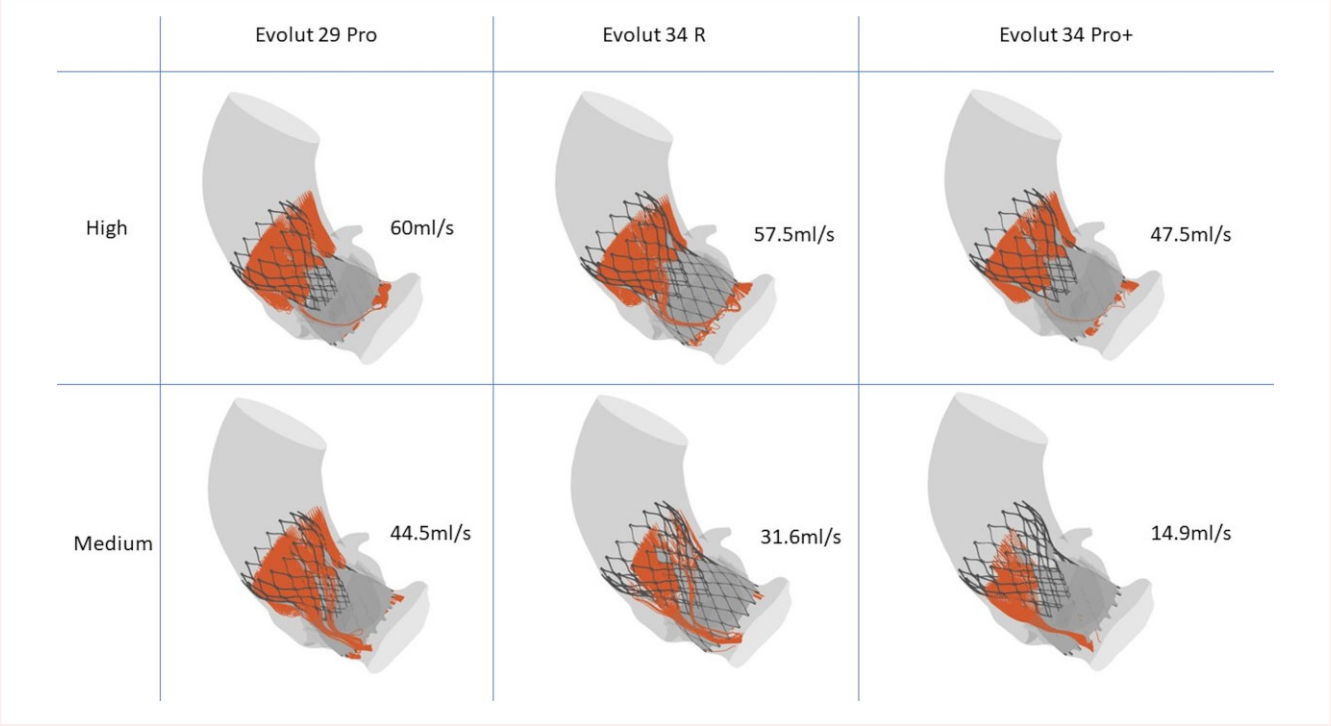

Figure 2 Demonstrating the six modelled scenarios. The three valves: Evolut 29 PRO, Evolut 34R, and Evolut 34 PRO+ in both high and medium positions with the associated predicted paravalvular leak in millilitres per second. A more than mild paravalvular leak is predicted in >16 mL/s. This demonstrates the Evolut 34 PRO+ has the lowest amount of predicted paravalvular leak.

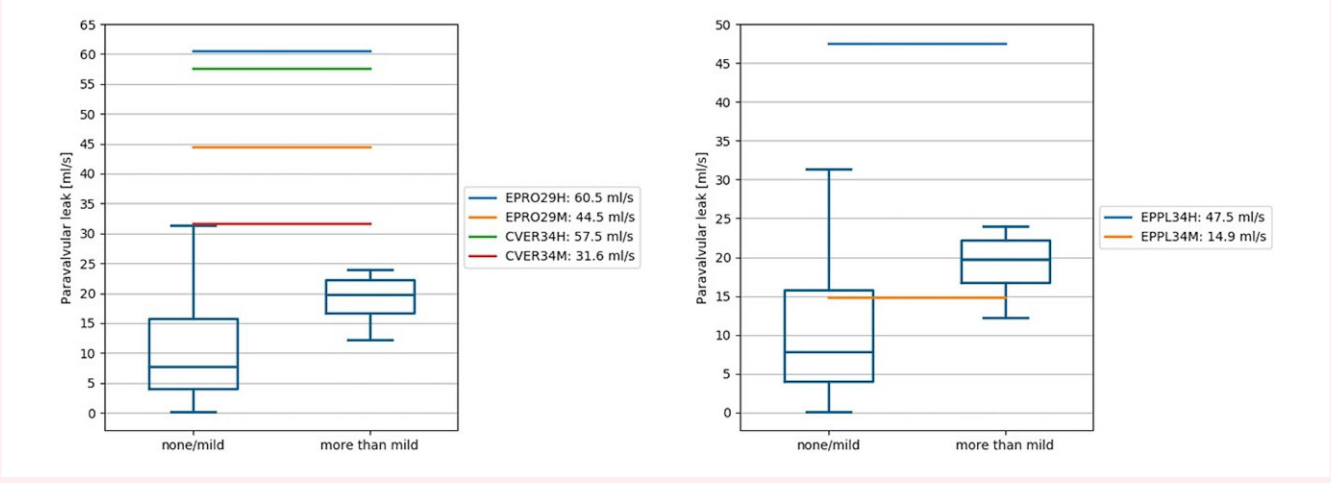

Figure 3 Demonstrating the predicted degree of paravalvular leak with each valve modelled and depth of implantation in millilitres per second. EPRO, Evolut PRO; CVER, Evolut R; EPPL, Evolut PRO+; H, high; M, medium.

Medical history is of treated breast cancer, hypothyroidism, and osteoarthritis. She is an ex-smoker. Outpatient coronary angiography showed a right dominant circulation and minimal atheroma only.

CT TAVR showed a severely calcified, Sievers Type 1, left-right fused BAV with perimeter of 82.9 mm (*Figure 1*). There was a derived annular diameter of 26.4 mm, sinus of Valsalva diameter of 36 mm, sino-tubular junction height of 21.2 mm, diameter 35.6 mm, and left-ventricular outflow tract calcium. This places the patient near the borderline between 29 and 34 mm Evolut valves, favouring a 34 mm valve. Computed tomography analysis was completed using 3mensio aortic valve (PIE Medical Imaging, Maastricht, The Netherlands).

Despite the presence of BAV, considering the patient's age and frailty, the heart team felt the best option would be TAVR rather

than surgery, should a good TAVR result be achievable. International guidelines would routinely recommend TAVR in this patient if not for the presence of BAV.[5,6]

Within our centre, we use pre-procedural patient-specific computer simulation using finite-element modelling with FEops HEARTguide (FEops nv, Gent, Belgium) platform for challenging anatomy, including heavily calcified and BAV cases.

Using HEARTguide, we simulated the Medtronic (Minneapolis, MN, USA) Evolut PRO 29 mm and Evolut R 34 mm at high and medium implantation depths. The simulation predicted severe PVL with both valve

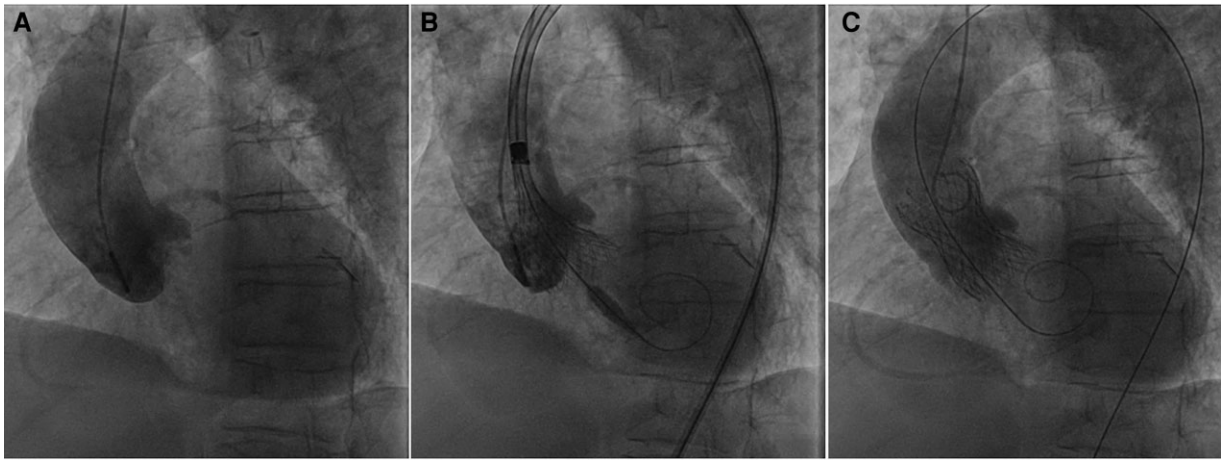

Figure 4 Transcatheter aortic valve implantation procedure: (*A*) initial aortogram, (*B*) valve deployment, and (*C*) the final deployed valve result.

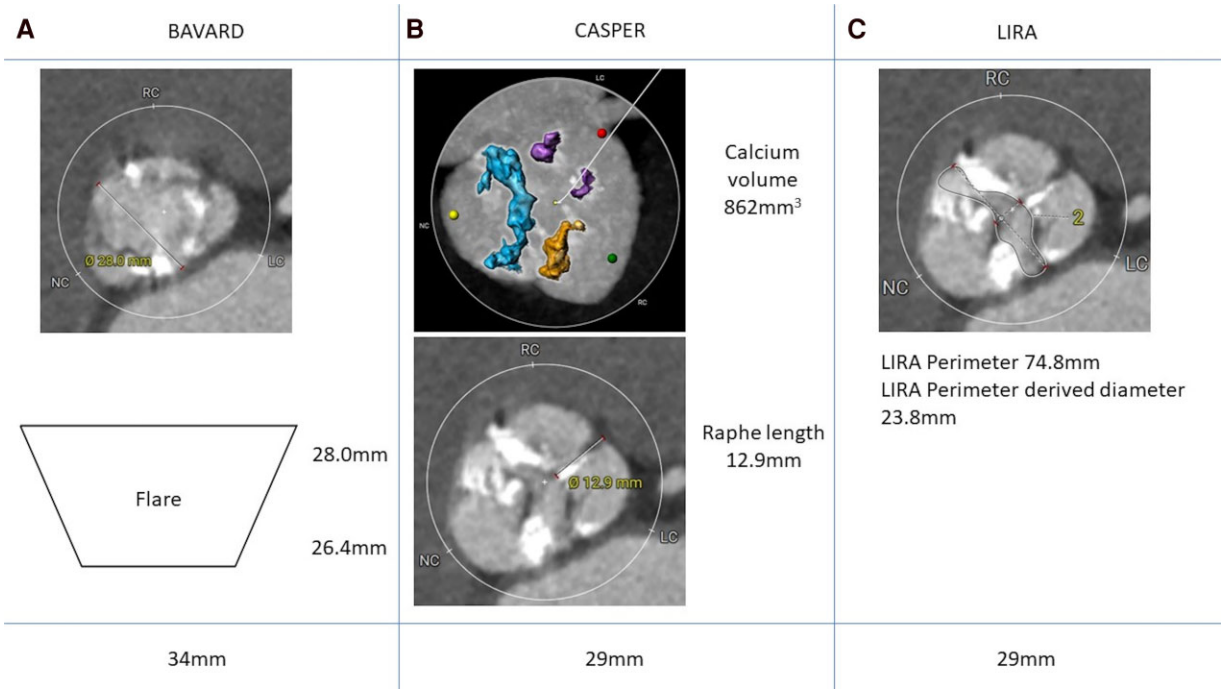

Figure 5 Panel *A* shows the BAVARD approach. The inter-commissural distance measured 28.0 mm, with an annular plane perimeter-derived diameter of 26.4 mm. This is a flare configuration and sizing should be based on the annulus, leading to a 34 mm valve. Panel *B* demonstrates Significant calcification, measured at 850 HU of 862 mm^3. The raphe length is 12.9 mm with perimeter-derived diameter of 26.4 mm, this is <50%. There is also calcium present on the raphe site leading to a detraction of 1.5 mm with a resulting derived diameter of 24.9 mm, this would recommend a 29 mm valve. Panel *C* shows the LIRA perimeter of 74.8 mm and derived diameter of 23.8 mm. This would recommend a 29 mm valve.

sizes and depths, ranging from 31.6 to 60.5 mL/s of PVL. Greater than 16 mL/s is indicative of more than mild PVL. Due to insufficient opacification of the right ventricle on TAVR CT, conduction abnormality risk could not be predicted.

Following the initial modelling, SAVR was re-discussed but felt unattractive. Given the unacceptable result described above, we simulated a Medtronic Evolut 34 mm PRO+ valve, which was just becoming available. In the high position, there was significant PVL estimated at 47.5 mL/s. In the medium depth of 4.3 mm, PVL was estimated at 14.9 mL/s, consistent with mild severity. The PVL was located posteriorly (*Figures 2* and *3*).

This result was discussed at the heart team and with the patient. Given symptom severity, it was decided to implant the 34 mm PRO+ device at medium depth.

The procedure was performed under local anaesthetic and TAVR access obtained via the right femoral artery. The mean aortic gradient was 50 mmHg. We undertook pre-dilatation with a 20 mm balloon. The valve was implanted, requiring three recapture redeployments to obtain the required target depth. Post-procedure analysis shows the valve deployed at 3 mm below the non-coronary cusp. Angiographically, there was mild PVL (*Figure 4*).

Echocardiography showed an unchanged moderate-to-severe impaired left ventricle in addition to mild-to-moderate posterior PVL. There was no post-TAVR conduction abnormality.

The patient's post-procedural recovery was uneventful. Eight weeks post procedure, she had resumed her usual activities and routine with no breathlessness or oedema.

Discussion

Multiple published and well-used algorithmic approaches exist including Calcium Algorithm Sizing for bicusPid Evaluation with Raphe (CASPER), supra-annular BAV anatomy and Relationship with Devices (BAVARD), and Level of Implantation at the RAphe (LIRA).[7–9]

Using traditional annular sizing at the time of this patient's treatment would have resulted in implantation of the 34 mm Evolut *R*-valve, with predicted severe PVL.

The BAVARD method compares annular sizing against supra-annular inter-commissural distance at 4 mm. CASPER modifies annular measurements dependent upon calcification and raphe length. LIRA takes the smallest measurement of either annulus or supra-annular plane at raphe level. These would yield 34, 29, and 29 mm Evolut valves, respectively (*Figure 5*). The 29 mm Evolut PRO valve was predicted to yield more than mild PVL.

Given the presence of LVOT calcium, our practice is to use self-expanding valves. In addition to the sizing guide provided by the BAVARD, CASPER, and LIRA methods, the HEARTguide platform enables valve modelling at different heights to achieve the optimal result.

Our group has previously published extensively the nature of this modelling. In summary, the finite-element model is based upon the cardiac and aortographic CT scan. Different structures are allocated different material properties. The finite-element analysis currently provides information on the interaction between native anatomy and valve, estimated PVL, and risk of conduction abnormality—either left bundle branch block or complete heart block. We have then used this information as a tool to guide both TAVR size and position to achieve a good clinical result.[10] A potential benefit of modelling over algorithms could be the ability to rapidly evolve as new valve models become available, whereas adapting an algorithm could be more laborious.

Without the guidance provided by modelling, it is likely that this patient would have undergone implantation of the Evolut R 34 mm valve. If the model is correct, the patient may have had significant aortic regurgitation and a suboptimal TAVI outcome.

Conclusion

In this case, using pre-procedural modelling in addition to CT-derived measurements, we were able to select a valve size and model that performed well. The valve size was different to that suggested by the CASPER and LIRA methods.

The model in this case has been shown to be safe and to accurately predict the result in a difficult, severely calcified BAV. The additional information provided with modelling could allow for a more patient-specific, tailored discussion at heart team meetings. The performance of the HEARTguide against the algorithm approach could be evaluated in further studies.

Lead author biography

Dr James Dargan is currently the St George's TAVI clinical research fellow. He was awarded BMBS and MMedSc from the University of Southampton. His post-graduate training has been in South Thames and South London. He is currently out of the cardiology specialist training programme working towards an MD with a focus on pre-procedural planning to enhance TAVI outcomes and promote TAVI for life.

Supplementary material

Supplementary material is available at *European Heart Journal – Case Reports* online.

Slide sets: A fully edited slide set detailing this case and suitable for local presentation is available online as Supplementary data.

Consent: The authors confirm that written consent for submission and publication of this case report including images and associated text has been obtained from the patient in line with COPE guidance.

Conflict of interest: St George's University Hospital has received an unrestricted research grant from Medtronic. S.B. has received grant support, consultant, and speaker fees from Medtronic.

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