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Transcatheter Aortic Valve Replacement in Forme Fruste Bicuspid Aortic Valve With the Dedicated LIRA Sizing Method

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Forme fruste, or partial-fusion, bicuspid aortic valve (BAV) is a phenotype whose true prevalence remains unknown; it has been historically underdiagnosed or identified only intraoperatively during surgical interventions for ascending aorta dilatation.

Recently, this variant has been formally included in the International Consensus classification.[1] It is characterized by partial fusion of the aortic valve cusps, resulting in a valve morphology that may closely resemble a tricuspid configuration, particularly when assessed with routine imaging techniques.

Because of this anatomical subtlety, forme fruste BAV may be challenging to recognize and may therefore be underrepresented in clinical trials and registries. Accurate identification of this phenotype requires dedicated high-resolution computed tomography imaging with multiphase reconstructions covering the full cardiac cycle (Figure 1). Although forme fruste BAV can mimic tricuspid aortic valve anatomy on standard imaging, the key feature distinguishing these entities is the presence of partial cusp fusion (less than 50% of cusp length), a mandatory diagnostic criterion according to the International Consensus classification[1] that is identifiable in systole and absent in true tricuspid valves. In addition, forme fruste BAV is defined by a commissural angle of approximately 120°, which must be assessed in a diastolic phase.

Recognizing forme fruste BAV is clinically relevant, as this phenotype may share the intrinsic risk of aortopathy observed in other bicuspid morphologies, even when overt aortic dilatation is not present. Consequently, inaccurate transcatheter aortic valve replacement (TAVR) prosthesis sizing may predispose to procedural complications, highlighting the potential benefit of a dedicated sizing approach in this setting.

The aim of our study was to evaluate the clinical outcomes following TAVR in forme fruste BAV patients with the use of the Level of Implantation at the RAphe (LIRA) method, a sizing strategy specific for BAV anatomy that has recently shown encouraging results in Sievers type 1 and type 2 BAV patients.[2]

As previously described,[3] the LIRA method is applied by comparing the perimeter measured at the level of the maximal protrusion of the raphe in the aortic root (the LIRA plane)—which represents the expected functional anchoring level in BAV anatomy—[4] with the perimeter found at the virtual basal ring, and choosing the smallest value for prosthesis sizing. This approach accounts for the functional narrowing created by partial cusp fusion, which is not captured by annular measurements alone and may have a clinically relevant impact on valve anchoring and expansion during TAVR.

Forme fruste BAV was defined according to the International Consensus (commissural angle of 120° and partial cusp fusion).

Abbreviations: BAV, bicuspid aortic valve Level of Implantation at the RAphe; TAVR, transcatheter aortic valve replacement.

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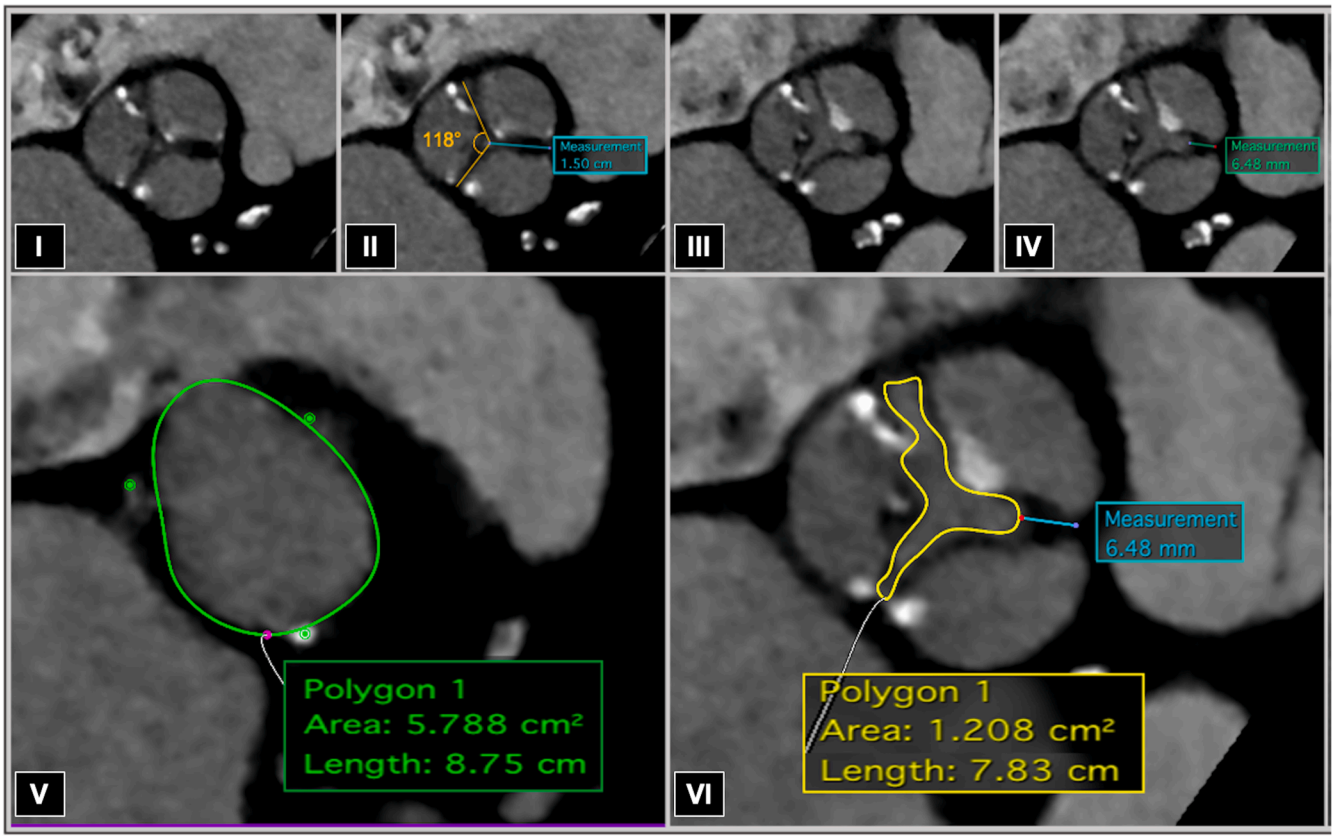

Figure 1. CT assessment of forme fruste BAV. In diastole, this BAV phenotype mimics a tricuspid configuration with three symmetric cusps (I–II). Full-cycle analysis reveals a mini-raphe in systole (III–IV). After confirmation of forme fruste BAV, the Level of Implantation at the RAphe (LIRA) method is applied by comparing the perimeter measured at the virtual basal ring (VBR, V) with that measured at the level of maximal raphe protrusion (LIRA plane, VI). When the LIRA perimeter is smaller than the VBR perimeter, prosthesis sizing is driven by the LIRA measurement. In this case, annular sizing based on a VBR perimeter of 87.5 mm would have suggested a 34-mm Medtronic prosthesis, whereas a LIRA perimeter of 78.3 mm led to the selection of a 29-mm Medtronic prosthesis
Abbreviations: BAV, bicuspid aortic valve; CT, computed tomography.

The primary endpoint was the device success: a composite endpoint including technical success; freedom from mortality; freedom from any intervention related to a) the device or b) a major vascular or cardiac structural complication; and the intended valve performance, defined as mean gradient <20 mmHg, peak velocity <3 m/s, and less-than-moderate aortic regurgitation. Secondary endpoints were in-hospital and 30-day safety outcomes. All study endpoints were adjudicated according to the Valve Academic Research Consortium 3 criteria.[5]

The study was approved by the local institutional review board and conducted in accordance with the Declaration of Helsinki. All patients were scheduled for TAVR after a Heart Team discussion and signed a written informed consent.

From January 2021 to March 2025, a total of 43 patients (mean age 80.6 ± 6.0; 39.5% women) with forme fruste BAV and severe aortic stenosis who underwent TAVR in our center with the implantation of supra-annular self-expanding prostheses sized according to the LIRA method were enrolled in our study. The median Society of Thoracic Surgeons score was 4.12% (2.6-5.5). Mean ejection fraction was 56.4% ± 9.8%, while mean transaortic gradient was 47.3 ± 13.4 mmHg. Mean virtual basal ring perimeter was 80.1 ± 14.2 mm, and mean LIRA perimeter was 71.3 ± 7.1 mm.

In most patients (86%; n = 37), the application of the LIRA method led to prosthesis downsizing.

Predilatation was performed in 93% of patients (n = 40), while postdilatation was performed in 18.6% of cases (n = 8). The primary endpoint of device success was observed in 97.6% (n = 42) of patients, while technical success was achieved in all patients (100%; n = 43). There was no embolization, conversion to surgery, or in-hospital death. The only case not achieving device success was due to moderate paravalvular leak.

At 30 days, mean aortic gradient was 8.5 ± 2.9 mmHg, and the intended valve performance was reached in 97.6% of patients (n = 42).

No all-cause death was reported; the rate of stroke was 2.3% (n = 1), and the rate of permanent pacemaker implantation was 9.3% (n = 4).

The successful downsizing observed in our population supports the concept that the perimeter at the LIRA plane is the key determinant for prosthesis sizing, independently of raphe length.

Considering that our study was a single-center experience with a small sample size and the lack of a core lab analysis for imaging assessments, our results should be considered exploratory. Larger comparative studies will be required to determine whether this anatomically guided sizing strategy provides incremental benefit over conventional annular-based approaches.

However, this preliminary experience is encouraging and, to the best of our knowledge, represents the first report exploring TAVR outcomes in this specific BAV phenotype.

In conclusion, the promising results of the LIRA method in forme fruste BAV support the adoption of a BAV-dedicated sizing approach in this setting.

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Ethics statement

The study was approved by the local institutional review board.

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Disclosure Statement

M.B. Ancona received consultant fees from Abbott and Abiomed. B. Bellini received consultant fees from Medtronic. M. Montorfano received consultant fees from Abbott, Boston Scientific, Kardia, and Medtronic. F. Russo received consultant fees from Boston Scientific. The other authors had no conflicts to declare.

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