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A novel supra-annular plane that predicts TAVI prosthesis anchoring in raphe-type bicuspid aortic valve disease: the LIRA plane.

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Short title: supra-annular assessment of BAV disease in TAVI.

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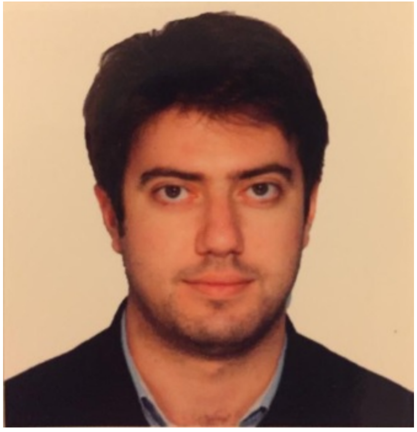

Classifications: Aortic stenosis; TAVI; MSCT

Abbreviations:

BAV: bicuspid aortic valve

CT: computed tomography

LIRA: level of implantation at the raphe

SA: supra-annular

TAVI: transcatheter aortic valve implantation

VBR: virtual basal ring

Introduction

Transcatheter aortic valve implantation (TAVI) in patients with bicuspid aortic valves (BAV) may be associated with suboptimal procedural and clinical outcomes due to inappropriate prosthesis sizing, anatomical difficulties or technical factors [1]. The narrowest part of the aortic root in BAV anatomy seems at the supra-annular level (SA), across the aortic valve leaflets, instead of the annular virtual basal ring (VBR)[2]. The main objective of our study was to identify a supra-annular plane in pre-TAVI cardiac computed tomography (CT) scan that might predict the level of valve prosthesis anchoring in raphe type-BAV patients.

Methods

All patients with available CT scans before and after TAVI performed in three high-volume centers between January 2007 and March 2018 were screened retrospectively. After exclusion of patients with trileaflet aortic valve anatomy and patient with bicuspid type 0, all patients with BAV type 1 and 2 were included in the final analysis. Post-procedural CT scans were performed due to enrolment in in-hospital clinical studies. Data collection at each participating site was performed according to the local institutional review board/ethics committee policies.

On the pre-TAVI CT scans, we identified the aortic root level where prosthesis anchoring is expect to occur, defined as LIRA (**L**evel of **I**mplantation at the **RA**phe) plane, that considers BAV type and anatomical-functional assumptions as follows;

1. In case of BAV type 1, the prosthesis should anchor at the level of the calcific/fibrotic raphe along the aortic root. Therefore, the LIRA plane was identified as the plane that cuts the raphe at its maximum protrusion along the aortic root (Figure 1 A,B,C).

2. BAV type 2 anatomy presents two raphes, therefore, the prosthesis should anchor at the level of the major raphe that was defined as the larger, in terms of mm in width and length, and with the greater amount of calcium. Therefore, the LIRA plane was identified as the level that cuts the major raphe at its maximum protrusion along the aortic root (Figure 1 D).

In post-TAVI CT scans, we identified the prosthesis anchoring level where the valvular frame becomes less expanded in the transverse direction along the aortic root (prosthesis waist) in relation to the segment of the prosthetic frame analysed and the degree of compression by the surrounding anatomy. Therefore, we evaluated if the LIRA plane predicted the anchoring level of the prosthesis valvular frame by comparing the distance of the LIRA plane from the VBR (VBR-LIRA) in pre-TAVI CT scans with the distance of the prosthesis waist from VBR (VBR-waist) in post-TAVI CT scans. To test for differences in means between groups with continuous variables, a Student t test was used.

Results

A total of 65 patients with BAV were included. CT scans identified 59 patients (91%) with type 1 and 6 patients (9%) with type 2 BAV anatomies (Table 1). VBR perimeter and area were significantly larger than LIRA plane measurements ($p<0,001$) , conferring the typical aortic root "volcano" shape of BAV disease (Table 1). Different types of TAVI valves were implanted (see Supplemental Table 1) and the prosthesis were sized according to the VBR. The VBR-LIRA distance in pre-TAVI CT scans was similar to the VBR-waist distance in post-TAVI CT scans (respectively 8.4 ± 1.7 and 7.9 ± 1.7; $p=0.10$) (Figure 2).

Discussion

The main finding of our study is the feasibility of a new method to localise the level of the aortic root at which prosthesis anchoring is expected in raphe-type BAV disease in pre TAVI-CT scans. The LIRA plane considers the most rigid anatomical structures in the aortic root (calcific/fibrotic raphes) that might facilitate valve anchoring during deployment. Pre and post TAVI-CT scans show that the LIRA plane corresponds to the prosthesis waist. Sizing according to the LIRA plane would have suggested the selection of smaller valves in most of the cases considering the significant smaller area and perimeter of the plane. Future studies will need to evaluate a prosthesis sizing method at the LIRA plane and its impact on procedural and clinical outcome in raphe-type BAV patients.

Limitations

This was a selected population based on the availability of post-procedural CT scans. Secondly, we excluded type 0 BAV because of the absence in this type of anatomy of the raphe that might indicate the anchoring prosthetic level in pre-TAVI CT scans. Finally, a low number of BAV type 2 were included.

Conclusion

The LIRA plane is a new method to localise the level where TAVI prosthesis anchoring is expected to occur in raphe-type BAV disease**.** Future prospective studies evaluating a sizing method at the LIRA plane and its impact on procedural and clinical outcomes of patients undergoing TAVI in BAV anatomies are warranted.

Impact on daily practice

Supra-annular assessment of BAV in TAVI is a concept not reproducibily demonstrated and specific methods to localise a supra-annular plane where prosthesis sizing measurements can be adequately performed are not standardised among operators. We identified a novel supra-annular plane (LIRA plane) to localise the level where TAVI prosthesis anchoring is expected to occur in BAV disease. Future studies will need to evaluate a prosthesis sizing method at the LIRA plane and its impact on procedural and clinical outcome in raphe-type BAV patients.

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Conflict of interest statement:

Ole De Backer has received consultant fees from Abbott and Boston Scientific. Lars Sondergaard has received consultant fees and institutional research grants from Abbott, Boston Scientific, Edwards Lifesciences, Medtronic and Symetis. Bernard Prendergast has received institutional research grants from Edwards Lifesciences. Azeem Latib is a consultant for Medtronic and Abbott Vascular. Matteo Montorfano serves as proctor for Edwards Lifesciences,Boston Scientific and Abbott Vascular.

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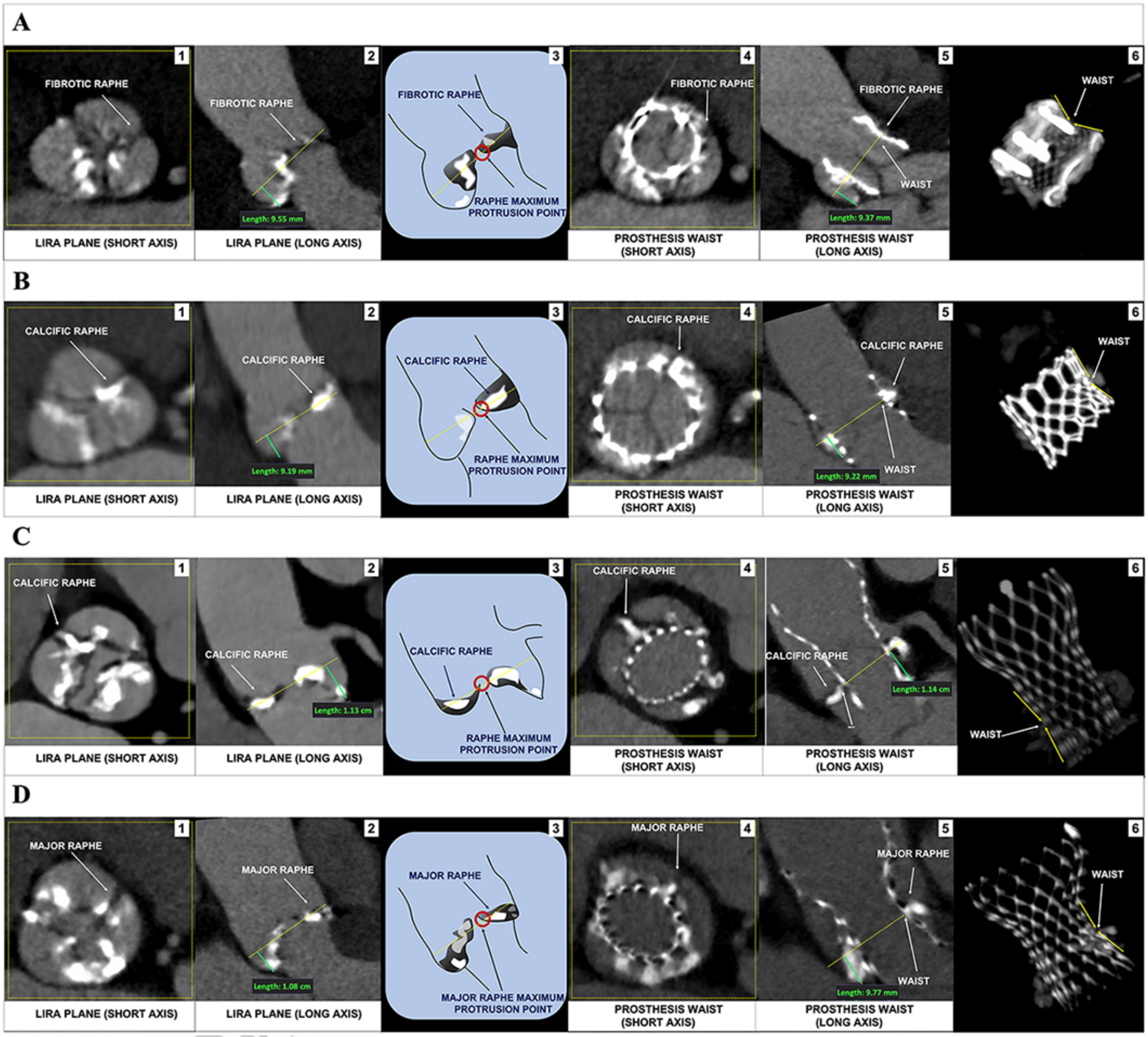
Figure legends

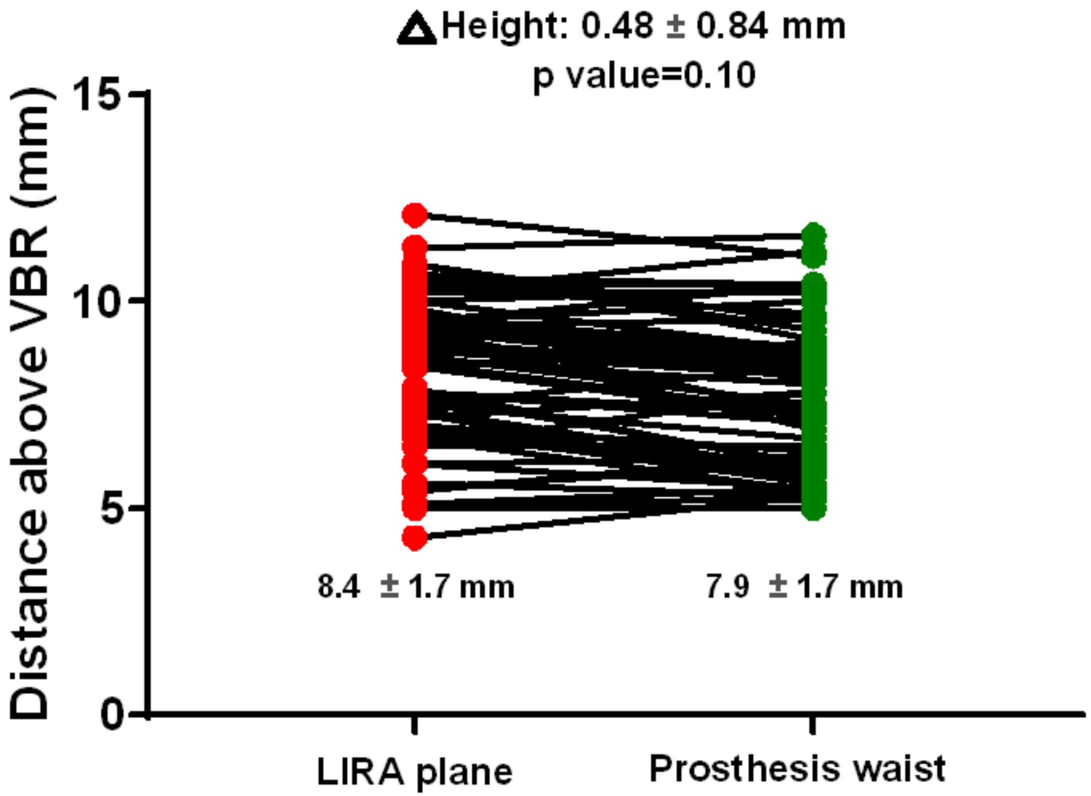
Figure 1: **A (1-6):** BAV type 1 with fibrotic raphe where a Lotus valve was implanted**; B (1-6):** BAV type 1 with calcific raphe where a Sapien 3 valve was implanted**; C (1-6):** BAV type 1 with calcific raphe where a Core Valve was implanted; **D (1-6):** BAV type 2 where a Core Valve was implanted; **1**: LIRA plane with fibrotic/calcific raphe on the short axis; **2:** LIRA plane on the long axis corresponding to the cut at the raphe maximum protrusion level (dotted yellow line); **3**: figure image that indicates the raphe maximum protrusion point and the LIRA plane (dotted yellow line) **4:** prosthesis waist on the short axis; **5**: prosthesis waist on the long axis corresponding to level where the valvular frame becomes less expanded in the transverse direction along the aortic root due to the compression by the surrounding anatomy (fibrotic/calcific raphe); **6:** 3D image that indicates the prosthesis waist.

Figure 2: Distance of the LIRA plane from VBR in pre-TAVI CT scan and distance between prosthesis waist from VBR in post-TAVI CT scan. Values in mean. Red dots represent the distance of the LIRA plane from VBR in pre-TAVI CT scan. Green dots represent the distance between prosthesis waist from VBR in post-TAVI CT scan.

Table 1: baseline CT characteristics

Type of bicuspid aortic valve	
1 – no (%)	59 (91)
2 – no (%)	6 (9)
Raphe/fusion between cusps	
Between right and left – no (%)	43(61)
Between right and non coronary – no (%)	18(25)
Between left and non coronary – no (%)	10(15)
VBR plane	
D min, mean ± SD, mm	21.9 ± 3.2
D max, mean ± SD, mm	27.7 ± 2.7
Perimeter, mean ± SD, mm	79 ± 7.2
Area, mean ± SD, mm2	492 ± 90
LIRA plane	
D min, mean ± SD, mm	7.4 ± 2.7
D max, mean ± SD, mm	26 ± 3.8
Perimeter, mean ± SD, mm	68 ± 8.9
Area, mean ± SD, mm2	159 ± 73
Height LIRA plane-VBR plane, mean ± SD,mm	8.4 ± 1.7
Raphe characteristics	
Fibrotic raphe – no (%)	20 (30)
Calcific raphe – no (%)	45 (70)
Raphe length, mm	11.1 ± 2.6
Calcium raphe length, mm	8.1 ± 2.9
Coronary artery height, mm	
LMCA, mean ± SD,mm	19 ± 3.1
RCA, mean ± SD,mm	20 ± 3.1


A
FIBROTIC RAPHE
LIRA PLANE (SHORT AXIS)
FIBROTIC RAPHE
Length: 9.55 mm
LIRA PLANE (LONG AXIS)
FIBROTIC RAPHE
RAPHE MAXIMUM PROTRUSION POINT
FIBROTIC RAPHE
PROSTHESIS WAIST (SHORT AXIS)
FIBROTIC RAPHE
WAIST
Length: 9.37 mm
PROSTHESIS WAIST (LONG AXIS)
WAIST
B
CALCIFIC RAPHE
LIRA PLANE (SHORT AXIS)
CALCIFIC RAPHE
Length: 9.19 mm
LIRA PLANE (LONG AXIS)
CALCIFIC RAPHE
RAPHE MAXIMUM PROTRUSION POINT
CALCIFIC RAPHE
PROSTHESIS WAIST (SHORT AXIS)
CALCIFIC RAPHE
WAIST
Length: 9.22 mm
PROSTHESIS WAIST (LONG AXIS)
WAIST
C
CALCIFIC RAPHE
LIRA PLANE (SHORT AXIS)
CALCIFIC RAPHE
Length: 1.13 cm
LIRA PLANE (LONG AXIS)
CALCIFIC RAPHE
RAPHE MAXIMUM PROTRUSION POINT
CALCIFIC RAPHE
PROSTHESIS WAIST (SHORT AXIS)
CALCIFIC RAPHE
Length: 1.14 cm
PROSTHESIS WAIST (LONG AXIS)
WAIST
D
MAJOR RAPHE
LIRA PLANE (SHORT AXIS)
MAJOR RAPHE
Length: 1.08 cm
LIRA PLANE (LONG AXIS)
MAJOR RAPHE
MAJOR RAPHE MAXIMUM PROTRUSION POINT
MAJOR RAPHE
PROSTHESIS WAIST (SHORT AXIS)
MAJOR RAPHE
WAIST
Length: 9.77 mm
PROSTHESIS WAIST (LONG AXIS)
WAIST



ΔHeight: 0.48 ± 0.84 mm
p value=0.10
Distance above VBR (mm)
15
10
5
0
8.4 ± 1.7 mm
7.9 ± 1.7 mm
LIRA plane
Prosthesis waist

Supplemental Table 1. : Type of TAVI valve prosthesis analized with CT scan.

CoreValve – no (%)	36 (55)
Lotus – no (%)	9 (14)
Sapien 3 – no (%)	8 (12)
Portico – no (%)	7 (11)
ACURATE *neo* – no (%)	3 (5)
Centera – no (%)	2 (3)