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Operator preference and determinants of size s… intermediate-size aortic transcatheter heart val…

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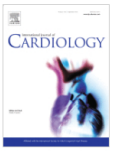

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Abstract Outline

Highlights

- Myval THV provides three intermediate-size THVs and two extra-large sizes in addition to the conventional sizing matrix.
- Intermediate-size Myval THVs were implanted in 42.0% of patients worldwide.
- Availability of the intermediate-size THVs could mitigate the hazardous selection of grossly undersized or oversized valve.

Abstract

Background

Appropriate size selection of transcatheter heart valves (THVs) is fundamental to reduce transcatheter aortic valve implantation (TAVI) related complications, particularly paravalvular aortic regurgitation, new permanent pacemaker implantation, and annular rupture. We sought to investigate the frequency of operator selection of intermediate-size balloon-expandable Myval THVs (Meril Life Sciences Pvt. Ltd., India) for TAVI in a real-world dataset.

Methods

In this retrospective survey of patients treated with TAVI using the Myval THV, 20, 23, 26, and 29 mm are conventional-size THVs, 21.5, 24.5 and 27.5 mm are intermediate-size THVs, and 30.5 and 32 mm are extra-large THVs. Operator size selection for implantation was based on multislice computed tomography (MSCT) derived aortic-root dimensions.

Results

A total of 1115 patients underwent Myval THV implantation in 27 countries worldwide. The Myval intermediate-size THVs were used in 468 (42.0%) patients. MSCT data were available in 562 patients. There was no statistical difference between the Intermediate/Upsized and Appropriately sized groups or Intermediate/Downsized and Appropriately sized groups in terms of different variables measured with MSCT except for annular dimensions and degree of calcification.

Conclusions

Intermediate-size Myval balloon-expandable THVs are used in nearly half of all cases in contemporary real-world TAVI practice, addressing the unmet need of TAVI operators for a more calibrated THV choice. Our hypothesis should be tested in randomized prospective studies currently initiated in Europe, including clinical outcomes of patients treated with both conventional- and intermediate-size THVs.

Keywords

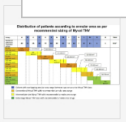
Aortic stenosis · Balloon-expandable valve · Transcatheter aortic valve implantation · Transcatheter heart valve · Intermediate-size

Appropriate size selection of the transcatheter heart valves (THVs) is critical to reduce the incidence of paravalvular aortic regurgitation (PVR), conduction disturbance requiring new permanent pacemaker implantation (PPI), and the risk of life-threatening complications, such as valve embolization or annular rupture [1]. Rupture of the aortic root during transcatheter aortic valve implantation (TAVI) using balloon-expandable valve (BEV) has been documented in the past with severe prosthesis oversizing [2]. BEVs are sized on the basis of aortic annular area on multislice computed tomography (MSCT) with the percentage of oversizing calculated using the formula: % oversizing = (THV nominal area/aortic annular area - 1) X 100 [3] [4]. The optimal threshold for oversizing is device specific. The sizes of most of the commercially available BEVs such as SAPIEN 3 and SAPIEN 3 Ultra THVs (Edwards Lifesciences, Irvine, CA, US) differ by 3 mm (20, 23, 26, and 29 mm), which is more than the typical 2-mm increment for most surgical bioprostheses [5]. The balloon-expandable Myval THV (Meril Life Sciences Pvt. Ltd., India) is available in a unique dimensional matrix which comprises three extra intermediate-size THVs (21.5, 24.5, and 27.5 mm) and two extra-large sizes (30.5 and 32 mm) [6]. This expanded size-matrix of the Myval THV has the potential to optimize THV sizing.

In this retrospective survey of patients treated with TAVI, the use of the Myval THV, 20, 23, 26 and 29 mm is defined as the conventional-size THV, whereas 21.5, 24.5 and 27.5 mm are defined as the intermediate-size THV. The use of the Myval THV 30.5 and 32 mm is defined as the extra-large-size THV. All available MSCT data were collected to investigate the determinants of intermediate-size THV versus conventional-size THV selection based on anatomical and morphological MSCT scan assessments. MSCT scans were analyzed in an independent core laboratory using the 3-Mensio software (Pie Medical, Maastricht, The Netherlands) in a close collaboration with the CORRIB Core Lab (National University of Ireland, Galway, Galway, Ireland). The aim of the present survey is to investigate the frequency of operator selection of the intermediate-size THVs during Myval THV implantation in the real-world. This report is not intended to examine the outcomes of intermediate-size THVs, but to document the preferential size selection of THVs by TAVI operators based on anatomical and morphological MSCT scan assessments.

In order to investigate the determinants of operator preference for upsizing or downsizing THV instead of appropriately sized THV based on MSCT measurements, we classified the operators' selection of Myval THV size as follows: 1) "Appropriately sized" group, in

Fig



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which operators selected the commercially available THV sizes corresponding to the manufacturer's recommendations; 2) "Intermediate/Upsized" group, in which operators selected THV above the recommended BEV sizes such as 24.5 mm instead of 23 mm. In rare instances, operators selected a larger conventional THV size such as 26 mm instead of 23 mm; 3) "Intermediate/Downsized" group, in which operators selected THV below the recommended BEV sizes such as 21.5 mm instead of 23 mm. In rare instances, operators selected a smaller conventional THV size such as 20 mm instead of 23 mm.

The size-matrix of Myval is designed such that the aortic annular areas are overlapping between the two adjacent THV sizes. For example, the recommended size for annular area between 270 and 330 mm^2 is 20 mm Myval THV and that for annular area between 314 and 380 mm^2 is 21.5 mm Myval THV. The annular area of 314 to 330 mm^2 is overlapping and the operator can choose either of the two sizes. This overlap provides operator the opportunity to choose a THV size based on anatomical factors, other than aortic measurements, with optimum sizing that does not require excessive over–/under-sizing (Fig. 1). Furthermore, based on the annular area measured on MSCT and following the manufacturer's sizing recommendations, we categorized patients treated with Myval THV into two cohorts: *Cohort A:* the aortic annular area lying within the overlapping range of two consecutive Myval THV sizes; *Cohort B:* the aortic annular area lying specifically within the range of one Myval THV size (Table 1). The patients from groups B, D, F, H, J, L, M and N (Fig. 1) are categorized as Cohort A and those from groups A, C, E, G, I, K, and O (Fig. 1) are categorized as Cohort B.

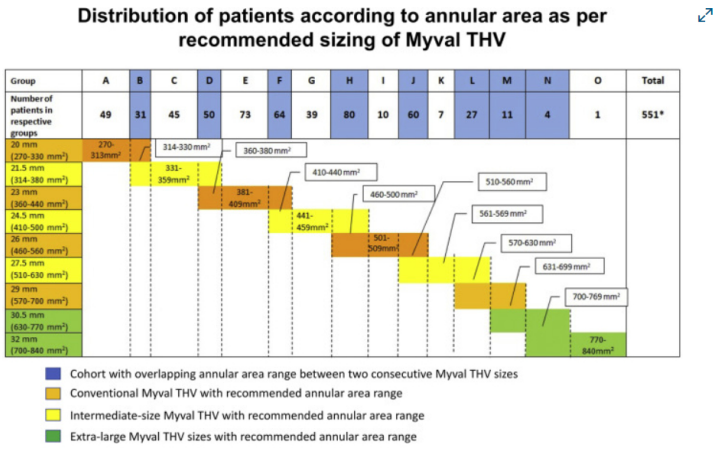

Fig. 1 Sizing Matrix of Myval THV with number of patients with different annular area range.

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Group corresponding to Fig. 1[a]	Appropriately sized (N = 138)	Intermediate/Upsized (N = 80)	Intermediate/Downsized (N = 6)	Total no. of Patients
A (270–313 mm^2)	26	23	–	49
C (331–359 mm^2)	25	18	2	45
E (381–409 mm^2)	48	24	1	73
G (441–459 mm^2)	26	11	2	39
I (501–509 mm^2)	7	2	1	10
K (561–569 mm^2)	5	2	–	7
O (770–840 mm^2)	1	–	–	1

Table 1
Actual operator sizing of Myval THV based on MSCT measurements according to recommended sizing.

THV: transcatheter heart valve.

a Eleven (1.9%) patients had annular area less than 270 mm^2 and were not included in either of the two cohorts.

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The variables derived from MSCT measurements are reported in Table 2A, B, and C. Comparison of quantitative variables was performed using the unpaired Student's *t*-test. The chi-square test was used to compare categorical variables. The Intermediate/Upsized group and the Intermediate/Downsized group are respectively compared to the Appropriately sized group as a reference.

Variable	Appropriately sized group N = 419	Intermediate/Upsized group N = 112	*P* value*	Intermediate/Downsized group N = 20	*P* value**
Age, year	74.5 ± 9.2	73.6 ± 10.8	0.392	76.0 ± 8.3	0.454
Male	268(64.0)	68 (60.7)	0.526	14 (70.0)	0.582
Maximum aortic annular diameter, mm	26.8 ± 2.7	25.5 ± 2.5	≤0.001	28.5 ± 2.8	0.016

Minimum aortic annular diameter, mm	20.9 ± 2.4	19.6 ± 2.3	≤0.001	22.3 ± 3.4	0.078
Aortic annular perimeter, mm	75.5 ± 7.8	71.0 ± 8.2	≤0.001	79.5 ± 8.8	0.059

Table 2A
Determinants of upsizing in total population.

Data are presented as mean ± standard deviation or number (percentage).

*P value (Appropriately sized group vs Intermediate/Upsized group).

**P value (Appropriately sized group vs Intermediate/Downsized group).

MSCT: multislice computed tomography; THV: transcatheter heart valve: RCC: right coronary cusp; NCC: non-coronary cusp; LCC: left coronary cusp.

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The total population comprised 1115 patients, who underwent Myval THV implantation in 27 countries worldwide according to each participating institution's heart team recommendation (Fig. 2). The Myval intermediate-size THVs were used in 468 (42.0%) patients (Fig. 2). Out of 1115 patients, MSCT data were available in 562 patients. Fig. 3 shows, –as a function of the aortic annular area measured on MSCT-, the box-whisker plots of actually implanted Myval THV sizes according to the Myval THV expanded sizing chart. The size choice of Myval THV by operators is presented in Table 1. Based on operator's selection of Myval THV sizes, out of 562 patients, 419 (74.6%) were appropriately sized, 20 (3.6%) intermediate/downsized and 112 (19.9%) intermediate/upsized. In total population of 562 patients whose MSCT data was available, 11 (1.9%) patients had annular area less than 270 mm² and were not included in either of the two cohorts. In Cohort A, 114 patients out of 281 (40.6%) were appropriately sized and implanted with intermediate-size Myval THV. Similarly, in Cohort B, 56 patients out of (138) (40.6%) were appropriately sized and implanted with intermediate-size Myval THV. Therefore, nearly 41% of appropriately sized patients were implanted with the intermediate-size Myval THV, indicating the operator's preference of using an intermediate-size THV that is appropriately sized than an over-/under-sized conventional THV size. The determinants of downsizing and upsizing are shown in Table 2A, 2B, and 2C. Other than aortic annular dimensions and degree of calcification, there was no statistical difference between the Intermediate/Upsized and Appropriately sized groups or Intermediate/Downsized and Appropriately sized groups, most probably due to expanded size matrix of Myval THV.

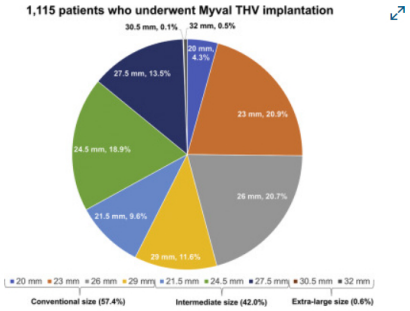

Fig. 2 Worldwide use of Myval THV.

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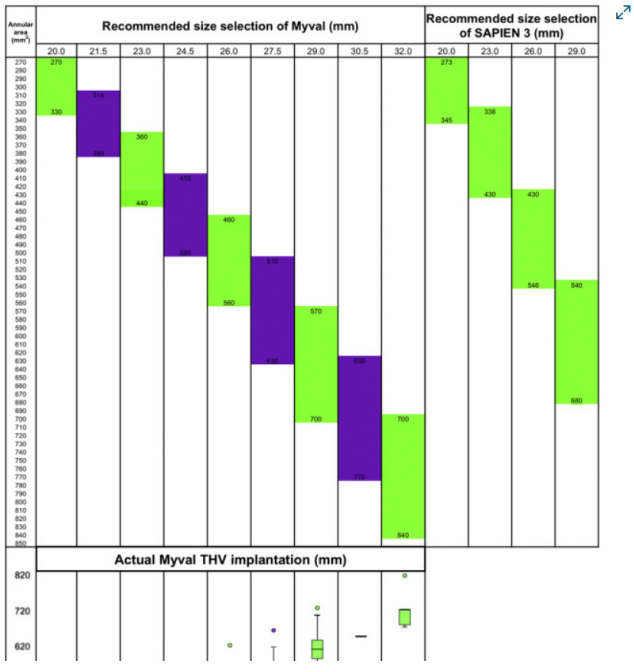

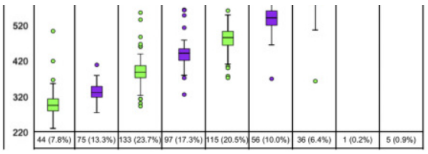

Fig. 3 **Manufacturer recommended sizing charts of Myval THV and SAPIEN 3 THV series and box-whisker plot constructed of actually implanted Myval THV size and aortic annular area.**

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Variable	Appropriately sized group N = 281	Intermediate/Upsized group N = 32	P value*	Intermediate/Downsized group N = 14	P value**
Age, year	74.3 ± 8.6	73.1 ± 9.2	0.243	76.9 ± 9.4	0.372
Male	197 (71.6)	19 (59.4)	0.157	10 (71.4)	1.0
Maximum aortic annular diameter, mm	27.5 ± 2.7	26.6 ± 2.6	0.078	29.3 ± 2.8	0.016
Minimum aortic annular diameter, mm	21.5 ± 2.3	21 ± 2.6	0.339	23.4 ± 3.4	0.004
Aortic annular perimeter, mm	77.5 ± 7.4	75.1 ± 7.1	0.079	82 ± 8.8	0.004

Table 2B
Determinants of upsizing and undersizing in cohort A.

Data are presented as mean ± standard deviation or number (percentage).

*P value (Appropriately sized group vs Intermediate/Upsized group).

**P value (Appropriately sized group vs Intermediate/Downsized group).

MSCT: multislice computed tomography; THV: transcatheter heart valve: RCC: right coronary cusp; NCC: non-coronary cusp; LCC: left coronary cusp.

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Variables	Appropriately sized group N = 138	Intermediate/Upsized group N = 80	P value*	Intermediate/Undersized group *N* = 6	P value**
Age, year	74.1 ± 10.5	73.8 ± 11.8	0.821	74.0 ± 5.3	0.803
Male	71(51.4)	49(61.3)	0.161	4(66.7)	0.465
Maximum aortic annular diameter, mm	25.4 ± 2.6	25.1 ± 2.4	0.397	26.5 ± 1.4	0.302
Minimum aortic annulus diameter, mm	19.7 ± 2.1	19.4 ± 2	0.326	19.8 ± 2	0.875
Aortic annular perimeter, mm	71.3 ± 6.7	69.4 ± 8.1	0.066	73.4 ± 5.3	0.439

Table 2C
Determinants of upsizing and undersizing in cohort B.

Data are presented as mean ± standard deviation or number (percentage).

*P value (Appropriately sized group vs Intermediate/Upsized group).

**P value (Appropriately sized group vs Intermediate/Downsized group).

MSCT: multislice computed tomography; THV: transcatheter heart valve: RCC: right coronary cusp; NCC: non-coronary cusp; LCC: left coronary cusp.

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To the best of our knowledge, this is the first report documenting the usage pattern of intermediate-size THVs in contemporary TAVI practice in a real-world multicenter registry. In approximately half of TAVI cases, the intermediate-size THVs were selected following MSCT based sizing, reflecting a heretofore unmet need of TAVI operators for a more calibrated THV choice. Considering the spectrum of aortic annular areas based on MSCT measurements, there was a lack of intermediate-size THV that could fulfill the stepwise gaps between the conventional-size THVs (Fig. 1). In that context, the size selection is traditionally left to the operator's discretion. Operators use some minor adjustments in balloon volume in order to prevent any procedural trauma to the aortic root complex. The consequence of this empirical adjustment to fit the "Patient to Prosthesis" might be hazardous and lead to procedural trauma. Furthermore, it could cause changes in the prosthetic valve geometry, which may lead to compromised long-term performance. This might, in turn, trigger a cascade of events such as significant conduction disturbances or PVR and might lead to poor clinical outcomes. The choice of THV size and depth of implantation traditionally involve a trade-off between the

potential development of PVR and the requirement for a new PPI [7] [8] [9]. In addition, there is a sizable proportion of patients with small sinus of Valsalva where downsizing is required to prevent coronary occlusion. In the THV size selection, the operators' own judgment also takes into considerations the individual patients' anatomical characteristics of the pre-procedural MSCT, such as bicuspid versus tricuspid, and the amount of aortic annulus/left ventricular outflow tract calcification. The present study suggests that total aortic annular calcification volume is presumably the main determinant of operator's decision for undersizing. The multiple stepwise choice (1.5 mm instead of 3 mm) in valve diameter based on the aortic root anatomy analyzed by the pre-procedural MSCT could safely allow for improved hemodynamic performance (excessive upsizing) and to avoid the catastrophic risk of aortic annulus rupture (excessive undersizing). Thus, the availability of expanded size-matrix of Myval THV focuses to fit "Prosthesis to Patient" thereby preserving prosthetic valve geometry and respecting patient's anatomy.

In conclusion, the intermediate-size THVs have been implanted worldwide in significant numbers, at the operator's discretion based on anatomical features derived from the pre-procedural MSCT measurements. The availability of the intermediate-size THVs could mitigate the hazardous selection of grossly undersized or oversized valve, thereby reducing PVR, conduction disturbances as well as life-threatening aortic annular rupture. Our hypothesis should be tested in randomized prospective studies currently initiated in Europe including clinical outcomes of patients treated with both conventional- and intermediate-size THVs [10].

Disclosures

Prof. Serruys reports personal fees from Biosensors, Medtronic, Micel Technologies, Sinomedical Sciences Technology, St. Jude Medical, Philips/Volcano, Xeltis, and HeartFlow, outside the submitted work.

Dr. Mylotte is a consultant for Medtronic, Boston Scientific, and Microport.

Dr. Amat-Santos is consultant for Boston Scientific, Medtronic, and Meril Life Sciences.

Prof. Wijns reports grants and personal fees from MicroPort, outside the submitted work, and co-founder of Argonauts, an innovation facilitator.

Prof. Abdel-Wahab reports other from Boston Scientific, other from Medtronic, outside the submitted work.

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