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Undersizing but overfilling eliminates the gray zones of sizing for transcatheter aortic valve replacement with the balloon-expandable bioprosthesis

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ABSTRACT

Background: Current recommendations for valve size selection are based on multidimensional annular measurements, yet the overlap between two different transcatheter heart valve (THV) sizes remains. We sought to evaluate whether undersizing but overfilling eliminates the gray zones of valve sizing.
Methods: Data of 246 consecutive patients undergoing transcatheter aortic valve replacement (TAVR) with the balloon-expandable bioprosthesis with either conventional sizing and nominal filling (group 1 (NF-TAVR), n = 154) or undersizing but overfilling under a Less Is More (LIM)-Principle (group 2 (LIM-TAVR), n = 92) were compared. Paravalvular leakage (PVL) was graded angiographically and quantitatively using invasive hemodynamics.
Results: Annulus rupture (AR) occurred only in group 1 (n = 3). Due to AR adequate evaluation of PVL was possible in 152 patients of group 1. More than mild PVL was found in 13 (8.6%) patients of group 1 and 1 (1.1%) patient of group 2 (p = 0.019). Postdilatation was performed in 31 (20.1%) patients of group 1 and 6 patients (6.5%) of group 2 (p = 0.003). For patients with borderline annulus size in group 1 (n = 35, 22.7%) valve size selection was left to the physicians choice resulting in selection of the larger prosthesis in 10 (28.6%). In group 2 all patients with borderline annulus (n = 36, 39.1%) received the smaller prosthesis (LIM-TAVR). The postprocedural mean transvalvular pressure gradient was significantly higher in the NF-TAVR-group (11.7 ± 4 vs. 10.1 ± 3.6 mmHg, p = 0.005).
Conclusion: LIM-TAVR eliminates the gray zones of sizing and associated PVL, can improve THV-performance, reduce incidence of annular rupture and simplify the procedure especially in borderline cases.

1. Introduction

Current recommendations for valve size selection are based on multidimensional annular measurements by transesophageal echocardiography and CT but the overlap between two different prosthesis sizes remains [1]. For patients with borderline annulus size valve size selection is left to the physicians choice. The choice of correct bioprosthesis size based on preinterventional imaging remains challenging especially in borderline cases [1,2,3]. Selection of the smaller bioprosthesis can increase the rate of relevant paravalvular leakage (PVL) [2] associated with unfavorable outcome

Abbreviations: AR index, aortic regurgitation index; BAV, balloon aortic valvuloplasty; DAP, diastolic aortic pressure; $\Delta P_{DAP-LVEDP}$, pressure gradient between DAP and LVEDP; LIM principle, Less Is More principle; LVEDP, left ventricular end-diastolic pressure; NF, nominal filling; PVL, paravalvular leakage; THV, transcatheter heart valve.

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[3,4]. Further reduction of PVL is key especially in the target group of younger patients, in which TAVR gradually begins to win ground from other treatment strategies. On the other hand, selection of the larger bioprosthesis increases the risk of annular rupture due to annular area oversizing [5]. Current data prove feasibility of transcatheter aortic valve replacement (TAVR) without preparatory balloon aortic valvuloplasty (BAV) with good procedural results [6]. Avoidance of BAV is associated with procedural simplification and thus lower complication rates [6]. Therefore, standardized leveraging balloon sizing for transcatheter heart halve (THV) size selection loses in value considering the progressive decline in the use of BAV over time [4,6,7]. The purpose of the present study was therefore to evaluate whether undersizing but overfilling eliminates the gray zones of sizing and reduces associated PVL especially in cases with borderline annulus size.

2. Material and methods

2.1. Patient population

Data from 246 consecutive high-risk patients with symptomatic aortic valve stenosis who underwent transfemoral (TF) TAVR using the Edwards SAPIEN 3 (ES3), (Edwards Lifesciences Inc., Irvine, CA, USA) bioprosthesis were analyzed retrospectively. Patients of group 1 underwent conventional sizing and nominal filling (NF-TAVR, n = 154) even in cases of borderline annulus. For patients of group 2 undersizing but overfilling according to a standardized protocol under a Less Is More (LIM)-Principle (LIM-TAVR, n = 92) was additionally used for valve size selection and implantation. Preinterventional imaging based on manufacturer recommendations (Fig. 1) was used to define borderline annulus cases. The decision for TAVR was made by an interdisciplinary heart team according to current recommendations [8,9]. TAVR was performed according to standard techniques [6,10,11].

2.2. Management in cases of borderline annuli

There is an overlap between two different prosthesis sizes for the ES3 bioprosthesis where valve size selection is usually left to the implanters choice. For conventional implantation (NF-TAVI) with nominal filling (group 1), the THV size selection was based on multidimensional annular measurements by transesophageal echocardiography and CT performed by an experienced investigator according to current recommendations [1,12,13,14]. As recommended by the manufacturer the smaller valve was chosen in cases of severe annulus or LVOT calcification, narrow root or bulky leaflet and low coronary ostia, narrow sinotubular junction and porcelain aorta. For borderline cases valve size selection was left to the implanter's choice based on individual decision making.

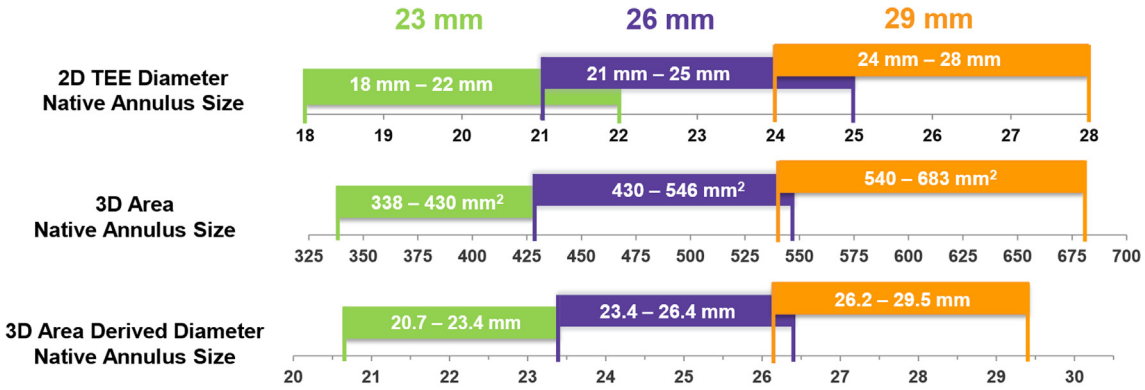
For LIM-TAVR (group 2) in cases of borderline annuli the smaller THV was implanted. The smaller ES3 bioprosthesis was always overexpanded by overfilling based on a standardized sizing chart (Table 1). For LIM-TAVR the 23-, 26-, and 29-mm ES 3 bioprosthesis were overexpanded by overfilling of the deployment balloon with 2, 3, and 4 ml additional volume, respectively.

2.3. Paravalvular leakage

In order to assist "on-table" decision making residual PVL was graded qualitatively according to the Sellers criteria [15]. The amount of regurgitating contrast medium during supraaortic angiography after final device deployment and catheter removal defined PVL severity [2,15]: absent 0/4, mild 1/4, moderate 2/4, moderate-to-severe 3/4, and severe 4/4. In addition, simultaneous left ventricular (LV) and aortic pressures were recorded at 50+ mm/s and averaged over 3 representative cardiac cycles after the procedure [2]. For quantitative evaluation of PVL severity, the aortic regurgitation index (AR index) as the ratio of the gradient between diastolic aortic pressure and left ventricular end-diastolic pressure (LVEDP) to systolic blood pressure × 100 [16] and the pressure gradient between diastolic aortic and left ventricular end-diastolic pressure ($\Delta P_{DAP-LVEDP}$) [2] were assessed. An AR index < 25 and a $\Delta P_{DAP-LVEDP} \leq 18$ mmHg have been previously associated with increased mortality especially in cases of relevant PVL after TAVR [2,16].

2.4. Endpoint

The primary endpoints were incidence of more than mild PVL, annular rupture and mortality over the duration of the study according to Valve Academic Research Consortium (VARC II) definitions. The follow up period was one year. Informed consent was obtained from each patient and the study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki. This study received ethical approval from the "Ethical Commission of the Ruhr University, Bochum".



SAPIEN 3 Valve	23 mm	26 mm	29 mm
Sheath ID (unexpanded)	14F	14F	16F
Minimum Access Vessel Diameter *	5.5 mm	5.5 mm	6.0 mm

Fig. 1. Sizing Chart According to the Manufacturer Recommendations: Current recommendations for valve size selection are based on multidimensional annular measurements by transesophageal echocardiography and CT but the overlap between two different prosthesis sizes remains. For Patients with borderline annulus size valve size selection is left to the physicians choice. Picture used with permission from Edwards Lifesciences.

Table 1
Sizing chart for the gray zones of sizing according to the LIM-principle.

Edwards Sapien (3)	Overfilling	2D TEE Diameter (mm) Native Annulus Size	3D Area (mm^2) Native Annulus Size	3D Area Derived Diameter (mm) Native Annulus Size
23 mm	2 ml	21–22	420–440	23–24
26 mm	3 ml	24–25	530–550	26–27
29 mm	4 ml	28–29	680–710	29–30

2.5. Postinterventional protocol

After TAVR, patients were transferred for 24 h to an intensive care unit for postinterventional monitoring. Besides the clinical examination, electrocardiogram, body temperature and chest x-ray, all blood parameters which had already been determined at the initial examination were determined again. Circular expansion of the overfilled THVs was evaluated by echocardiography. When available, multislice computed tomography (MSCT) performed for various reasons was additionally used for evaluation of the THVs. Follow-up examinations were performed 3 months and 1 year after discharge.

2.6. Statistics

Categorical data are presented as frequencies and percentages; continuous variables are presented as means and standard deviation. The normal distribution of the variables was tested by the Shapiro-Wilk test (p-value $\geq$ 0.1). Comparisons were made with 2-sided χ2-tests or 2-sided Fisher's exact-tests for categorical variables and one-way ANOVA for continuous variables, using Bonferroni correction for multiple testing. ANOVA and *t*-test were used to compare normally distributed variables and Mann-Whitney-test to compare the other non-normally distributed variables between the two groups. A p-value < 0.05 was considered significant. All statistical analyses were performed using SPSS (version 17.0, SPSS, Chicago, IL, USA). The authors had full access to the data and take full responsibility for their integrity. All authors have read and agreed to the manuscript as written.

3. Results

3.1. Baseline and postprocedural characteristics

Our study cohort represents a typical TAVR patient population at high risk for open heart surgery (logistic EuroSCORE of 16 ± 11%) with symptomatic aortic stenosis (aortic valve area 0.7 ± 0.2 cm^2, transvalvular gradient 46.7 ± 18 mmHg). Patients in the NF-TAVR-group underwent significantly less prior percutaneous coronary interventions than in the LIM-TAVR-group (29.9% vs 43.5%, p = 0.03). There were no other significant differences in baseline characteristics between the two groups (Table 2**A**). Regarding postprocedural evaluation the mean transvalvular pressure gradient was significantly higher in the NF-TAVR-group (11.7 ± 4 vs 10.1 ± 3.6 mmHg, p = 0.005) (Table 2**B**).

3.2. LIM-TAVR for borderline annulus size

According to preinterventional imaging 71 (28.8%) patients had a borderline annulus size. For patients with borderline annulus size in group 1 (n = 35, 22.7%) valve size selection was left to the physiciańs choice resulting in selection of the larger prosthesis in 10 (28.6%).

For 36 (39.1%) patients of group 2 who had a distinct annulus size, TAVR was performed according to the LIM-principle. All 36 patients received the smaller prosthesis (Fig. 2).

Annulus rupture (AR) occurred in 3 patients of group 1 and 0 patients of group 2.

3.3. PVL after TAVR

Due to AR, adequate evaluation of PVL was possible in 152 patients of group 1. The angiographic assessment of postprocedural PVL revealed a lower frequency of PVL in the LIM-TAVR-group than in the NF-TAVR-group.

Direct after implantation more than mild PVL was found in 39 (25.7%) patients of group 1 and 2 (2.2%) patients of group 2 (p=<0.001) **(**Table 3**A).** After postdilatation more than mild PVL was found in 13 (8.6%) patients of group 1 and 1 (1.1%) patient of group 2 (p = 0.019) **(**Table 3**B).** Severe PVL did not occur in any of our study patients. Angiographic assessment was confirmed by postinterventional echocardiography revealing significantly more moderate (relevant) PVL in patients of group 1 than group 2 (8.6% vs. 1.1%, p = 0.01) and absence of severe PVL. Postdilatation was performed in 31 (20.1%) patients of group 1 and 6 (6.5%) patients of group 2 (p = 0.003).

Echocardiographicaly severe PVL did not occur in any of our study patients.

An AR index < 25 and a $\Delta p_{DAP-LVEDP} \leq 18$ mmHg were observed more frequently in the NF-TAVR- than in the LIM-TAVR group (22.9 vs. 10.8%, p = 0.08 and 18.3 vs. 9.3%, p = 0.089). Of note, there were no complications associated with LIM-TAVR. Central aortic regurgitation associated with overfilling was not observed. Non-circular expansion of the overfilled THVs was not observed by echocardiography and MSCT (Fig. 3).

3.4. Mortality and periinterventional complications

Mortality at 30 days and 1 year was not significantly different in patients who underwent conventional NF-TAVR in comparison to those who underwent LIM-TAVR (2 vs. 5.5%, p = 0.1 and 15.4 vs. 14%, p = 0.84). There were no other significant differences regarding vascular complications or stroke incidence between the two groups (Table 2**B**). In addition, baseline data and outcomes of all patients with borderline annulus are presented separately (Table 4**,** Table 5**).**

4. Discussion

The present study is the first to demonstrate that undersizing but overfilling improves THV performance by decreasing the postprocedural transvalvular pressure gradient, eliminates the gray zones of sizing and thus may improve outcome after TAVR by reducing associated PVL and annular rupture.

Transcatheter aortic valve replacement (TAVR) is the standard of care for patients with severe, symptomatic aortic stenosis who are deemed inoperable or at high surgical risk and current data show promising results in the intermediate-risk population [9,17]. Due to the very promising results current debates focus on the expansion of TAVR as the standard of care for the treatment of all patients with aortic valve stenosis. Nevertheless, incidence of relevant PVL frequently associated with borderline annuli remains

Table 2
Baseline and postprocedural characteristics.

A	Overall (n = 246)	NF-TAVR (n = 154)	LIM-TAVR (n = 92)	p-value
Age, years	82.7 ± 5.1	82.1 ± 4.9	83.6 ± 5.3	0.09
Male gender	110 (44.7)	65 (42.2)	45 (48.9)	0.3
Weight, kg	75 ± 15.5	74.6 ± 15.1	75.7 ± 16.2	0.5
Height, cm	166.7 ± 10.8	166.0 ± 11.7	167.9 ± 9.0	0.4
Logistic Euroscore, %	16 ± 11.0	15.8 ± 10.9	16.3 ± 11.1	0.9
Aortic valve area, cm^2	0.7 ± 0.2	0.7 ± 0.2	0.7 ± 0.2	0.6
Mean transvalvular PG before TAVR, mmHg	46.7 ± 18	47.1 ± 18	46.2 ± 18	0.8
LVEF, %	53.4 ± 10.9	52.8 ± 11.1	54.4 ± 10.7	0.3
Aortic annulus diameter, mm	22.9 ± 2.4	23.0 ± 2.4	22.8 ± 2.4	0.3
CAD	141(57.3)	84 (54.5)	57 (62.0)	0.2
Prior MI	23(9.3)	17 (11)	11 (12)	0.8
Prior PCI	86 (35)	46 (29.9)	40 (43.5)	0.03
Prior heart surgery	23 (9.3)	17 (11.0)	6 (6.5)	0.2
PVD	31 (12.6)	19 (12.3)	12 (13)	1.0
B				
Mean transvalvular PG after TAVR, mmHg	11.0 ± 4.0	11.7 ± 4.0	10.1 ± 3.6	0.005
Vascular complications (major)	10 (4.1)	5 (3.3)	5 (5.5)	0.5
Vascular complications (minor)	17 (7.1)	7 (4.7)	10 (11.0)	0.07
Stroke (disabling)	1 (0.4)	0 (0)	1 (1.1)	0.37
Stroke (non-disabling)	4 (1.6)	3 (1.9)	1 (1.1)	1.0

Values are mean ± SD, n (%). CAD = coronary artery disease, LVEF = left ventricular ejection fraction, MI = myocardial infarction, PCI = percutaneous coronary intervention, PVD = peripheral vascular disease, PG = pressure gradient.

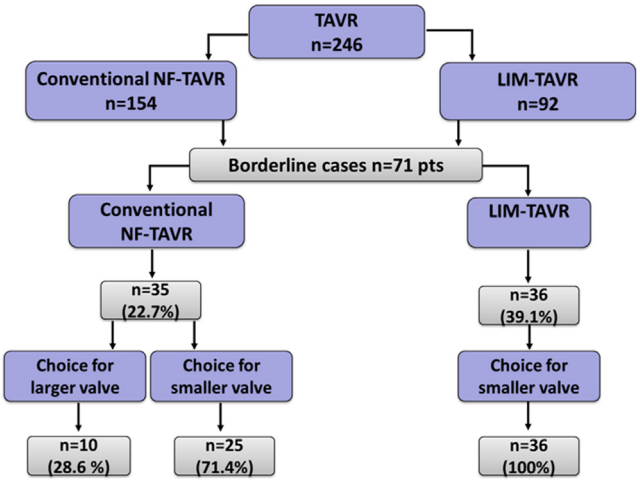


Fig. 2. LIM-TAVR for Borderline Cases: For patients with borderline annulus size in group 1 (n = 35, 22.7%) valve size selection was left to the physicians choice resulting in selection of the bigger prosthesis in 10 (28.6%). In group 2 all patients with borderline annulus (n = 36, 39.1%) received the smaller prosthesis (LIM-TAVR).

a major drawback of all transcatheter heart valves [2]. Such disadvantages need to be resolved in order establish TAVR as the main treatment option for younger patients. This study proves that performing TAVR with the balloon-expandable bioprosthesis can eliminate the overlap between two different prosthesis sizes and associated complications (PVL, annular rupture) by use of standardized overfilling of the deployment balloon.

4.1. Sizing in TAVR

Nowadays measurements of the aortic annulus based on multimodality imaging are more accurate than ever providing various of sizing tools (2D TEE diameter, 3D area, 3D area derived diameter, perimeter) for both the balloon- and self-expandable type of transcatheter heart valves. Nevertheless, current recommendations for valve size selection still contain the gray zones between two different THV sizes. For such cases valve size selection is usually left to the implanter's choice [2]. The "safe" solution of always choosing the larger THV has been associated with increased incidence of annular rupture [5]. Annular rupture occurs in about 1% of all TAVR procedures [5]. Nevertheless, the real incidence is suspected to be even higher than usually reported [5]. Moreover, frequently remains this complication undetected. Choosing the smaller THV can lead to valve migration or severe PVL [2]. Data have shown an underestimation of the annulus size by echocardiography [12] whereas in recent studies CT sizing recommendations resulted in mean annular oversizing of 13.9% [18].

Table 3
Assessment of PVL severity.

A: Direct after TAVR				B: After postdilatation		
PVL	NF-TAVR (n = 152)	LIM-TAVR (n = 92)	p-value	NF-TAVR (n = 152)	LIM-TAVR (n = 92)	p-value
absent (0/4)	94 (61.8%)	66 (71.7%)		113 (74.3%)	68 (73.9%)	
trace or mild (1/4)	19 (12.5%)	24 (26.1%)		26 (17.1%)	23 (25.0%)	
moderate (2/4)	15 (9.9%)	1 (1.1%)	<0.001	13 (8.6%)	1 (1.1%)	0.019
moderate-to-severe (3/4)	24 (15.8%)	1 (1.1%)		0 (0%)	0 (0%)	
severe (4/4)	0 (0%)	0 (0%)		0 (0%)	0 (0%)	

The distribution of postprocedural PVL before (A) and after (B) postdilatation was associated with the implantation method. Values are n (%).

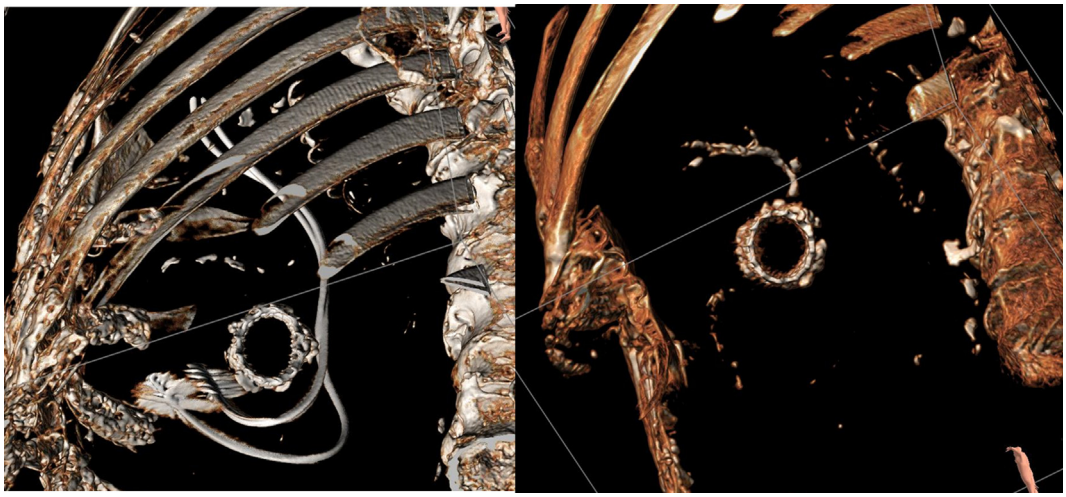


Fig. 3. Computed Tomography after LIM-TAVR: Non-circular expansion of the overfilled THVs was not observed by echocardiography. Moreover, multislice computed tomography confirmed circularity the overexpanded bioprosthesis.

Table 4
Baseline and postprocedural characteristics (borderline annulus cases).

A	Overall (n = 71)	NF-TAVR (n = 35)	LIM-TAVR (n = 36)	p-value
Age, years	82.9 ± 5.1	81.9 ± 4.9	83.9 ± 5.2	0.18
Male gender	35 (49.3)	18 (51.4)	17 (47.92)	0.8
Weight, kg	75.2 ± 14.7	74.3 ± 12.9	76.0 ± 16.5	0.6
Height, cm	167.9 ± 8.2	168.7 ± 8.1	167.1 ± 8.4	0.3
Logistic Euroscore, %	14.4 ± 8.9	13.5 ± 8.3	15.4 ± 9.4	0.4
Aortic valve area, cm^2	0.7 ± 0.2	0.6 ± 0.2	0.7 ± 0.2	0.6
Mean transvalvular PG before TAVR, mmHg	47.3 ± 19.1	48.0 ± 20.1	46.5 ± 18.1	0.8
LVEF, %	53.6 ± 10.1	54.0 ± 10.0	53.2 ± 10.3	0.45
CAD	39 (54.9)	20 (57.1)	19 (52.8)	0.8
Prior MI	10 (14.1)	6 (17.1)	4 (11.1)	0.5
Prior PCI	27 (38.0)	13 (37.1)	14 (38.9)	1.0
Prior heart surgery	8 (11.3)	5 (14.1)	3 (8.3)	0.4
PVD	6 (8.5)	4 (11.4)	2 (5.6)	0.4
B				
Mean transvalvular PG after TAVR, mmHg	10.8 ± 3.3	12.0 ± 3.4	9.9 ± 2.9	0.02
Vascular complications (major)	1 (1.4)	0 (0)	1 (2.8)	1.0
Vascular complications (minor)	4 (5.6)	0 (0)	4 (11.1)	0.1
Stroke (disabling)	0 (0)	0 (0)	0 (0)	–

Values are mean ± SD, n (%). CAD = coronary artery disease, LVEF = left ventricular ejection fraction, MI = myocardial infarction, PCI = percutaneous coronary intervention, PG = pressure gradient, PVD = peripheral vascular disease.

Table 5
Assessment of PVL severity (borderline annulus cases).

A: Direct after TAVR				B: After postdilatation		
PVL	NF-TAVR (n = 35)	LIM-TAVR (n = 36)	p-value	NF-TAVR (n = 35)	LIM-TAVR (n = 36)	p-value
absent (0/4)	18 (51.4%)	24 (66.7%)		27 (77.1%)	25 (69.4%)	
trace or mild (1/4)	2 (5.7%)	12 (33.3%)		5 (14.3%)	11 (30.6%)	
moderate (2/4)	5 (14.1%)	0 (0%)	<0.001	3 (8.6%)	0 (0%)	0.07
moderate-to-severe (3/4)	10 (28.6%)	0 (0%)		0 (0%)	0 (0%)	
severe (4/4)	0 (0%)	0 (0%)		0 (0%)	0 (0%)	

The distribution of postprocedural PVL before (A) and after (B) postdilatation was associated with the implantation method. Values are n (%).

4.2. LIM-TAVR for the gray zones of sizing

Persistence of the gray zones of sizing due to conflicting measurements obtained with multimodal imaging, asymmetric calcifications, or eccentric leaflets, still raises uncertainties regarding the THV selection in patients with borderline annulus size [2,12,19]. In such cases valve size selection remains critical and supraaortic angiography during BAV can serve in decision-making on valve

size selection [2,7]. Nevertheless, recent data show procedural simplification and thus lower complication rates due to avoidance of BAV [6]. As a consequence of this experienced operators increasingly perform direct TAVR without preparatory BAV [4,6,7]. For the balloon-expandable bioprosthesis recent data demonstrate the safety and potential advantages of overexpanding the THV by overfilling of the balloon [1]. In this study, we did not notice any balloon rupture due to the overfilling. According to the manufacturer recommendations impairment of proper leaflet function can be associated with overfilling of the THV-balloon [1]. However, similar to other data we did not observe any central aortic regurgitation associated with LIM-TAVR. Non-circular expansion of the overfilled THVs was not observed by echocardiography. Moreover, multislice computed tomography performed in some patients for various reasons confirmed circularity of the overexpanded bioprosthesis. In addition, a significantly lower mean transvalvular pressure gradient after TAVR was observed in the LIM-TAVR-group, which can play a role regarding durability of the THVs. A possible explanation could be an overfilling-associated better expansion of the stent-frame when deployed in the severe calcified native annulus. This could be of great importance considering a possible expansion of TAVR in younger patients in the future, nevertheless this mechanism remains hypothetical.

According to this study the LIM-principle provides a promising tool, available for TAVR with the balloon expandable THV, in order to resolve the problem of borderline annulus cases without leveraging preparatory BAV for balloon-sizing [2,7]. Performing conventional TAVR in cases with borderline annulus, usually accompanied with preparatory BAV with a balloon-size bigger than the minimal annulus diameter in order to perform balloon-sizing, may lead to annulus-prosthesis mismatch if choosing the smaller valve without overfilling. The calcified native valve can better facilitate undersizing if not predilatated. This can be a major contributor of clinically significant PVL, which can explain the higher incidence of postdilatation in the NF-TAVR-group. Therefore, in our hands, LIM-TAVR additionally offers an instrument in order to avoid withholding the advantages of the simplified and modern direct TF-TAVR from patients with borderline annuli.

In this study, direct TAVR was safely performed for an annulus area up to 720 mm^2. Nevertheless, we omitted annuli with an area bigger than 710 mm^2 from the LIM sizing chart in order to avoid a standardized overfilling recommendation for such annuli based only on quantitative multimodality measurements. Feasibility of TAVR for such annulus areas (710–720 mm^2) also depends on the stiffness and degree of calcification of the native valve [1]. Therefore, individual decision making is necessary for such extreme cases and TAVR with the balloon-expandable bioprosthesis should be performed by very experienced operators.

The incidence of relevant postprocedural PVL was lower in patients who underwent LIM-TAVR than in those who underwent conventional TAVR. Hemodynamic assessment of PVL severity by use of the aortic regurgitation (AR) index and the pressure gradient $\Delta P_{DAP-LVEDP}$ revealed that the incidence of exceeding the cut-off values which have previously been associated with worse outcome was decreased in the LIM-TAVR group [2,16].

5. Limitations

Our data are derived from a retrospective analysis of consecutive patients and not from a prospective, randomized trial. In addition, valve size selection for borderline cases in the NF-TAVR group was left to the operator's choice. We therefore cannot exclude bias due to non-randomization and that part of the observed benefit in group 2 vs. group 1 is due to a learning curve and not specifically to the technique of LIM-TAVR. Direct TAVR according to the standardized LIM-protocol of this analysis can be the best solution for borderline annulus cases in terms of procedural simplification. However, this remains hypothetical needing further clinical investigation focusing on a comparison between direct vs. not direct implantation for patients with borderline annuli.

Availability of intermediate bioprosthesis sizes by use of the alternative balloon-expandable THV Myval (Meril Life Sciences Pvt. Ltd) could facilitate minimizing the annulus-prosthesis mismatch in cases of borderline annuli [20]. Nevertheless, despite promising initial results, further mid- and long-term data in a larger population are necessary before considering broad usage in high- intermediate- and low-risc patients.

The main purpose of our study was to facilitate the on-table decision making-process providing a useful tool for the borderline annulus cases. We routinely perform TAVR under conscious sedation and therefore use angiographic and hemodynamic assessment for on table evaluation of PVL. Postinterventional echocardiographic assessment played therefore a secondary role and did not influence the interventional management in any case.

6. Conclusion

LIM-TAVR eliminates the gray zones of sizing and associated PVL, can improve THV performance by decreasing the mean postprocedural transvalvular pressure gradient, reduce incidence of annular rupture and simplify the procedure by avoiding valvuloplasty-related complications especially in borderline cases.

Author statement

The authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

CRediT authorship contribution statement

Polykarpos C. Patsalis: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Supervision, Validation, Visualisation, Writing-original draft. **Axel Kloppe:** Data curation, Formal analysis, Validation, Visualisation, Writing-review & editing. **Björn Plicht:** Data curation, Formal analysis, Validation, Visualisation, Writing-review & editing. **Dominik Schöne:** Data curation, Formal analysis, Validation, Visualisation, Writing-review & editing. **Fabian Schiedat:** Data curation, Formal analysis, Validation, Visualisation, Writing-review & editing. **Assem Aweimer:** Data curation, Formal analysis, Validation, Visualisation, Writing-review & editing. **Kaffer Kara:** Data curation, Formal analysis, Validation, Visualisation, Writing-review & editing. **Peter Lukas Haldenwang:** Data curation, Formal analysis, Validation, Visualisation, Writing-review & editing. **Justus Thomas Strauch:** Supervision, Validation, Writing-review & editing. **Thomas Buck:** Supervision, Validation, Writing-review & editing. **Andreas Mügge:** Supervision, Validation, Writing-review & editing.

Declaration of Competing Interest

P. C. Patsalis is proctor for Edwards Lifesciences. The other authors report no conflict of interest.

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