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Patient-prosthesis mismatch in new generation trans-catheter heart valves: a propensity score analysis

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Aims

When compared with the former Sapien XT (XT-THV), the Sapien 3 trans-catheter heart valve (S3-THV) embeds an outer annular sealing cuff to prevent para-valvular regurgitation (PVR). The consequences of this new feature on valve haemodynamics have never been evaluated. We aimed to compare both types of prostheses regarding patient-prosthesis mismatch (PPM).

Methods and results

Patients who underwent a TAVR for aortic stenosis were retrospectively included. Regression adjustment for the propensity score was used to compare 50 XT-THV patients with 71 S3-THV. At the 1-month follow-up, the mean indexed effective orifice area (iEOA) was $1.12 \pm 0.34 \text{ cm}^2/\text{m}^2$ with XT-THV and $0.96 \pm 0.27 \text{ cm}^2/\text{m}^2$ with S3-THV. The mean gradient was $11 \pm 5 \text{ mmHg}$ and $13 \pm 5 \text{ mmHg}$, respectively. Nine patients had moderate PPM, and two exhibited severe PPM with XT-THV. Nineteen patients had moderate PPM, and seven demonstrated severe PPM with S3-THV. There was a five-fold increased risk of PPM with S3-THV (OR = 4.98; [1.38–20.94], $P = 0.019$). S3-THV decreased the iEOA by $0.21 \text{ cm}^2/\text{m}^2$ [−0.21; (−0.38 to −0.05); $P = 0.012$] and increased the mean gradient by 4.95 mmHg [4.95; (2.27–7.64); $P < 0.001$]. The risk of PPM was increased 15.24-fold with 23 mm S3-THV [15.24; (2.92–101.52); $P = 0.002$] in comparison with the 23 mm XT-THV. PVR were reduced by 98% with S3-THV.

Conclusion

There is an increased risk of PPM with 23mm S3-THV in comparison with 23 mm XT-THV. This may be attributable to the additional sub-annular cuff that avoids the risk of PVR. Regarding the increased vulnerability of younger patients to PPM, we provide essential information on the extension of TAVR indication to the younger population.

Introduction

Trans-catheter aortic valve replacement (TAVR) has become a reliable treatment alternative to surgery for aortic stenosis in patients who are inoperable or at a high surgical risk.¹ Recently, the randomized PARTNER II trial showed similar all-cause death and disabling stroke outcomes of both techniques in intermediate-risk patients,

thus widening the TAVR indication to lower-risk patients.² However, the extension of the indications requires a reduction of several prevalent complications, such as para-valvular regurgitation (PVR), which is associated with a poorer prognosis.³

Recently, the new expandable Sapien 3 trans-catheter heart valve (S3-THV) has replaced the previous generation of Sapien XT trans-catheter heart valve (XT-THV), which was associated with a high

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prevalence of PVR. S3-THV provides new features, such as an outer annular sealing polyethylene terephthalate skirt that functions as a blood-soaked sponge and limits the risk of PVR.⁴ However, by bulging into the annular space, this material could lead to turbulence during ventricular ejection and can potentially increase the trans-prosthetic gradient (see Supplementary data online, *Appendix S1*). This could expose patients to an underlying risk of patient-prosthesis mismatch (PPM) that occurs when the effective orifice area (EOA) of a normally functioning prosthetic valve is too small in relation to patient body size.⁵ The results from several clinical studies have demonstrated the negative effect of PPM on both functional recovery and life expectancy, emphasizing the need for PPM prevention.⁶

Recently, some authors have suggested the preference of TAVR to surgical valves in patients with a high risk of PPM due to improved haemodynamic performance.⁷

Even though preliminary prospective studies have shown a dramatic reduction of PVR with S3-THV compared with XT-THV, none of these studies have evaluated the haemodynamic effects of the new skirt on post-operative gradients.⁸

In this context, the aim of our study was to retrospectively compare the occurrence of moderate and severe PPM among patients with severe aortic stenosis implanted with S3-THV and XT-THV.

Methods

Study population

This retrospective single-centre study was performed from November 2013–15 at La Timone Hospital, Marseille, France. We included 71 consecutive patients with severe aortic stenosis who underwent TAVR with S3-THV (Edwards Lifesciences LLC, Irvine, CA, USA) and 50 consecutive patients who underwent a SAPIEN XT trans-catheter heart valve implantation (XT-THV) (Edwards Lifesciences LLC, Irvine, CA, USA) after heart team endorsement. International review board approval was obtained. Patients who denied authorization for anonymous publication of their clinical data for research purposes were excluded.

Procedure

Depending on the presence of suitable access sites assessed by the CT-scan, TAVR was performed using the transfemoral, transapical, trans-subclavian or transaortic approach. The size of the prosthesis was endorsed by the heart team, mainly according to the CT scanned aortic annulus size.⁹ General anaesthesia was performed in all patients. Fluoroscopic guidance guided prosthesis positioning and deployment. Valve implantation was performed under rapid ventricular pacing. Prosthesis position and function were evaluated with angiography, aortic index measurement, and trans-oesophageal echocardiography. More than moderate aortic regurgitation was treated by post-dilatation or second valve implantation.

Data collection and follow-up assessments

Assessments, including physical examination, NYHA classification, 12 leads electrocardiography and TTE were performed at baseline and at the one-month follow-up. The main exploratory outcome was the occurrence of PPM at 1-month post-TAVR implantation. Secondary exploratory outcomes include the occurrence of PVR, clinical improvement according to NYHA class, in hospital mortality, cardiac tamponade, myocardial infarction, stroke, major bleeding, vascular complication and pace-maker implantation. All outcomes were defined according to the Valve

Aortic Research Consortium-2 definitions.¹⁰ The rate of oversizing (%) was calculated using the following formula: %oversizing = [THV nominal area/Multi-slice computed tomography (MSCT) annular - 1] × 100.

TTE was performed in a Core laboratory by experienced cardiologists. The EOA was calculated according to the continuity equation. The indexed EOA (iEOA) was calculated as the EOA divided by the Body Surface Area. After TAVR implantation, the iEOA was estimated using the Left Ventricular Outflow Tract (LVOT) diameter and velocity measured immediately proximal to the stent, as previously recommended.¹¹ Moderate PPM was defined by an iEOA ≤ 0.85 cm²/m², and severe PPM was defined by an iEOA < 0.65 cm²/m².⁶ An integrative semi-quantitative approach was used to assess the severity of central and PVR. The left ventricular mass regression ratio was calculated as (1-month follow-up LV mass – Baseline LV mass/Baseline LV mass), similar to functional amelioration (1-month follow-up NYHA—Baseline NYHA/Baseline NYHA).

Statistical analysis

The continuous variables were described by mean, SD, minimum and maximum values. The categorical variables were described by size and percentage. For the baseline analysis, categorical variables were compared with the type of prosthesis using χ^2 or Fisher's exact test, according to the conditions of application. The non-parametric Wilcoxon signed-rank test was used for continuous variables (paired if comparing baseline to follow-up characteristics).

A large number of preoperative baseline characteristics varied between the two groups. In order to adjust for these between group differences, propensity scores, which estimate the probability of treatment (prosthesis) assignment was calculated with the use of logistic regression. The following baseline and preoperative (unless otherwise stated) covariates were used in a logistic regression model. Regression adjustment for the propensity score was then used (see Supplementary data online, *Appendix S2*). The comparison of XT-THV to S3-THV was performed in the overall population and in subgroup analysis by prosthesis size, only the 23- and 26-mm groups were included (both the smallest and largest size groups had small sample sizes).

Sensitivity analyses included an alternative method for propensity score modelling, using inverse probability treatment weighting (IPTW). The final propensity score models were evaluated by comparing the covariate distribution and propensity score between groups before and after IPTW. These weights were used in the subsequent logistic regression analysis. The average treatment effect was calculated to answer the question if the valve XT THV results in better outcomes for patients drawn from the population as a whole. The results were considered statistically significant with a *P* value of *P* ≤ 0.05. Statistical analysis was performed using the software programme R (version 3.1.0).

Results

Baseline and echo characteristics

In total, 121 patients (mean age = 82.4 ± 6.5 years; 60% females) were enrolled: 50 patients to the XT-THV subgroup, and 71 patients to the S3-THV subgroup. Eighty-five patients (70%) had hypertension. The mean BSA was 1.70 ± 0.22 m². Seventy patients (58%) were in NYHA III and IV, and 49 patients (40.5%) had recently presented with congestive heart failure. The mean LVEF was 56 ± 13%. The mean aortic annulus diameter was 20.9 ± 1.95 mm. All patients had severe AS, with a mean iEOA of 0.41 ± 0.13 cm²/m² and a mean trans-aortic gradient of 51 ± 16 mmHg. Female gender was significantly more frequent in the XT-THV subgroup (78 and 48%, *P* <

Table 2 Echocardiography data at baseline

	All n = 121	XT-THV n = 50	S3-THV n = 71	P
LVEF (%)	56 ± 13	55 ± 13	56 ± 13	0.61
LVEF < 50% (%)	31 (25%)	12 (24%)	19 (26.7%)	0.4
LV septum diameter (mm)	14.8 ± 2.4	14.5 ± 2.4	15 ± 2.4	0.46
LV diastolic diameter (mm)	46.8 ± 6.7	48.3 ± 7.2	45.5 ± 6	0.16
LV systolic diameter (mm)	32 ± 6.9	33.6 ± 7	31 ± 6.7	0.32
LV mass (g/m ²)	178 ± 52	190 ± 51	168 ± 51	0.08
Aortic annulus diameter (mm)	20.9 ± 1.95	20.2 ± 1.7	21.5 ± 1.95	<0.001
EOA (cm ²)	0.69 ± 0.22	0.65 ± 0.19	0.71 ± 0.23	0.057
iEOA (cm ² /m ²)	0.41 ± 0.13	0.4 ± 0.12	0.42 ± 0.14	0.44
Mean trans-aortic gradient (mmHg)	51 ± 16	52 ± 16	51 ± 16	0.66
Aortic regurgitation	63 (52%)	35 (70%)	28 (39%)	<0.001
Aortic regurgitation grade				0.001
Trivial	40 (63%)	23(66%)	17 (61%)	
Mild	13 (21%)	5(14%)	8 (29%)	
Moderate	4 (6%)	4(11%)	0	
Severe	6 (4.9%)	3(9%)	3 (10%)	
Mitral regurgitation	57 (47%)	33(66%)	24 (34%)	<0.001
Mitral regurgitation 3–4	4 (3.3%)	1(2%)	3 (4.2%)	0.46
Systolic pressure of pulmonary artery	42 ± 14	44 ± 14	39 ± 15	0.08

LVEF, left ventricular ejection fraction; LV, left ventricle; EOA, effective orifice area; iEOA, indexed effective orifice area.

However, the 26 mm S3-THV increased the mean trans-prosthetic gradient by 4.54 mmHg [coefficient = 4.54, (1.64–7.44), *P* = 0.002] compared with the 26 mm XT-THV.

Sixty-one patients (53%) had a PVR at the 1-month follow-up, including 37 patients (82%) in the XT-THV group and 24 patients (34%) in the S3-THV. Among these patients, 47 (77%) had trivial PVR, twelve (20%) had mild/moderate PVR and 2 (3%) had severe PVR. Among the XT-THV group, 26 patients (70%) had trivial PVR, 9 (24%) had mild/moderate PVR and 2 (6%) had severe PVR. Neither moderate nor severe PVR were observed in the S3-THV group, whereas 21 (88%) had trivial PVR and 3 (12%) had mild PVR.

Using a logistic regression adjustment of the propensity score, the odds of a para-prosthetic leak were 98% reduced with S3-THV compared with XT-THV [OR = 0.02, (0.002–0.095), *P* < 0.001]. Figure 4 Sensitivity analysis results for PVR were consistent [OR = 0.03 (0.01–0.06), *P* < 0.00001] with much narrower confidence intervals.

Discussion

The aim of this study was to compare the occurrence of moderate and severe PPM with the new balloon-expandable S3-THV vs. the preceding XT-THV generation in TAVI for severe AS. The main findings were (i) a higher risk of PPM for S3-THV, (ii) a 15-fold increased risk of PPM with the smallest size of S3-THV prosthesis in comparison with the same size XT-THV prosthesis, and (iii) a similar degree of left ventricular mass regression and NYHA functional improvement with both valves.

The clinical effect of PPM after surgical aortic valve replacement (SAVR) has been a matter of controversy since the first description

by Rahimtoola in 1978.⁵ PPM occurs if the EOA of the implanted bio-prosthesis is small relative to the patient body size.

PPM is considered severe when the iEOA is < 0.65 cm²/m² and moderate if the iEOA is between 0.65 and 0.85 cm²/m². The occurrence of PPM post-SAVR is well recognized and ranges from 20 to 70% for moderate PPM and from 2 to 10% for severe PPM.¹² The adverse effects of PPM include functional impairment, reduced LV mass regression and a significant reduction of early and intermediate survival, particularly in severe PPM.¹³ A recent meta-analysis of 34 studies with 27 186 patients confirmed a significantly negative effect of PPM on long-term survival, particularly in cases of vulnerability, such as impaired LVEF, severe LV hypertrophy, concomitant mitral regurgitation, and/or paradoxical low flow/low gradient aortic stenosis.¹⁴

When compared with SAVR, the previous prostheses used for TAVR, such as Edwards Sapien and Sapien-XT, tend to have better haemodynamic performance, thus contributing to a reduction in PPM.¹⁵ In a randomized comparison of 699 patients from the PARTNER trial A cohort, TAVR was significantly associated with less PPM (46.4 vs. 60.0%, *P* < 0.001) and severe PPM (19.7 vs. 28.1%, *P* < 0.001) compared with SAVR.⁷ This study was also the first to identify an important relationship between PPM after TAVR implantation and 2-year mortality, but this relationship was found only in the TAVR nonrandomized continued access arm. The difference in severe PPM was particularly important in patients with small aortic annuli (<20 mm), assuming that the thinner stent frame and absence of a sewing ring in the annular space provide less blood flow obstruction. However, this study was based on the former generation of SAPIEN/ SAPIEN XT-THV, and none of these haemodynamic results could be extended to the new S3-THV generation, which embedded supplementary annular space material.

Table 3 Echocardiographic data at 1-month follow-up

	All n = 121	XT-THV n = 50	S3-THV n = 71	p
LVEF (%)	60.2±12.3	58.2±11.5	61.5±12.7	0.14
LV septum diameter (mm)	13.8±1.95	13.3±1.9	14.1±1.9	0.08
LV Diastolic diameter (mm)	44.5±6.9	44.8±6.9	44.3±6.9	0.77
LV Systolic diameter (mm)	32.3±6.7	32.5±6.3	32.2±7	0.88
LV mass (g/m2)	140.2±39.5	139.2±42	141±38.1	0.83
Relative LV mass regression	18%	20%	17%	0.63
Aortic annulus diameter (mm)	21.1±1.7	20.7±1.4	21.4±1.8	0.03
Systolic Pulmonary artery pressure	40.4±13.4	40.3±11.9	40.5±14.5	0.67
EOA (cm ²)	1.71±0.52	1.78±0.61	1.66±0.45	0.19
iEOA (cm ² /m ²)	1.02±0.31	1.12±0.34	0.96±0.27	0.009
Mean trans-aortic gradient (mmHg)	12.5±5.1	11±5.5	13.5±4.7	0.002
SVI (mL/m ²)	46.9±9.7	49.5±7.7	45.2±10.5	0.01
Mismatch	37(32%)	11(24%)	26(36%)	0.17
Mismatch grade				0.35
Moderate	28(76%)	9(82%)	19(73%)	
Severe	9(24%)	2(18%)	7(27%)	
Paravalvular aortic regurgitation	61(53%)	37(82%)	24(34%)	<0.001
PVR grade				<0.001
Trivial	47(77%)	26(70%)	21(88%)	
Mild	12(20%)	9(24%)	3(12%)	
Moderate	1(1.5%)	1(3%)	0	
Severe	1(1.5%)	1(3%)	0	

LVEF, left ventricular ejection fraction; LV, left ventricle; EOA, effective orifice area; iEOA, indexed effective orifice area.

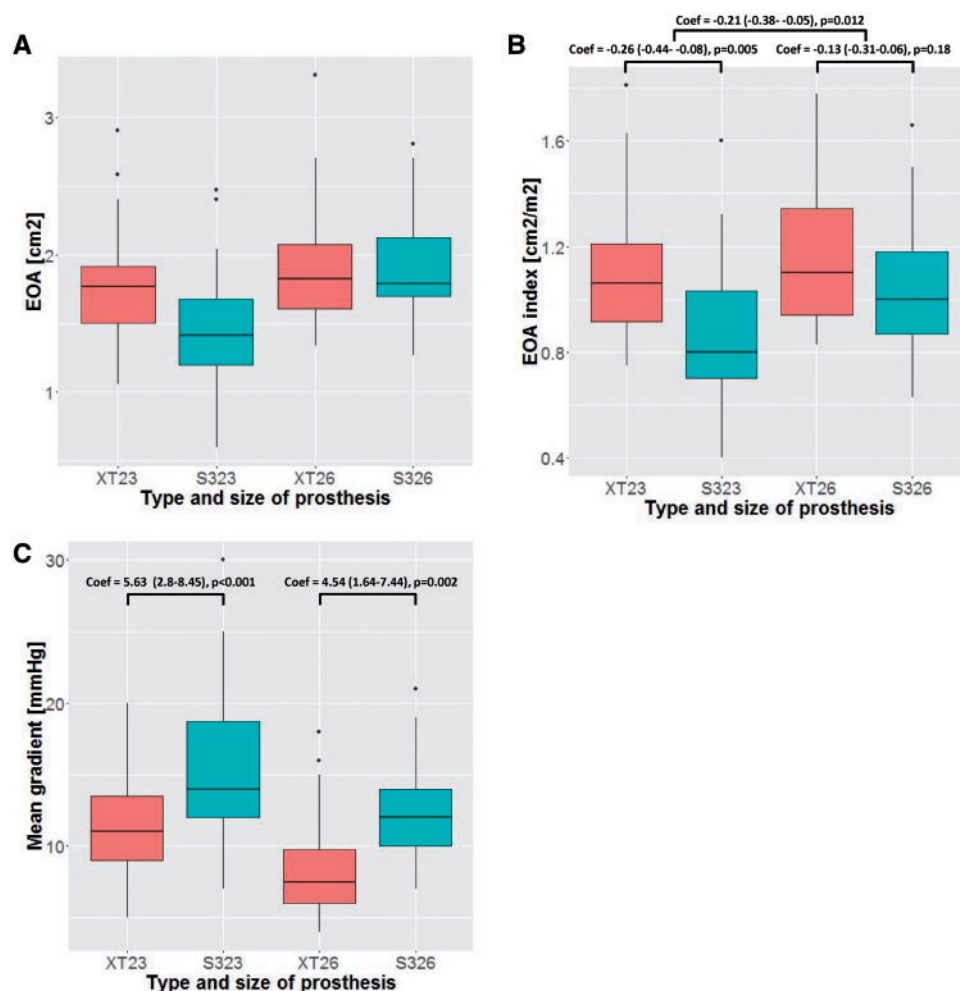
Table 4 Haemodynamic comparison of XT-THV vs. S3-THV at 1-month follow-up according to valve size

	XT THV SIZE			S3 THV SIZE		
	XT 23 mm	XT 26 mm	XT 29 mm	S3 23 mm	S3 26 mm	S3 29 mm
EOA	1.76 ± 0.47	1.93±0.49	3.4	1.45 ± 0.4	1.87 ± 0.14	1.77 ± 0.46
iEOA	1.12 ± 0.3	1.16±0.3	1.9	0.87 ± 0.25	1.04 ± 0.25	1.06 ± 0.32
Stroke volume index	51.5 ± 8	48±6	43	46 ± 12	46 ± 9.6	39 ± 6.4
Mean gradient	11 ± 4	9 ± 4	12	15 ± 5	12 ± 3	10 ± 5
Mismatch	4 (17%)	4 (19%)	0	18 (53%)	6 (20%)	2 (29%)
Moderate	4	4	0	12	5	2
Severe	0	0	0	6	1	0

EOA, effective orifice area; iEOA, indexed effective orifice area, three mismatches occurred with XT THV 20 mm: two (66%) severe and one (33%) moderate.

due to confounding variables.¹⁴ We used two transparent methods: regression adjustment and inverse weighting by the propensity score (IPTW). Two other well-described propensity score approaches were not appropriate (matching and stratification) due to differing population distributions of covariates in the two baseline groups and small sample sizes—including empty propensity score strata and lack of good matches. As there can be disadvantages of regression adjustment, we validated our results using IPTW, which reduces bias and is less vulnerable to extrapolation. This method has been previously used in cardiovascular research and is appropriate for not well-balanced matches and to retain all study data.²¹

The calculation of the ‘projected’ *in vivo* indexed EOA is particularly interesting in the clinical decision-making process to avoid the risk of post-operative PPM. The ‘projected’ *in vivo* EOA is obtained by dividing the *in vivo* EOA provided by the manufacturer by the body surface area.⁶ For surgical bioprosthesis, manufacturers provide reliable *in vivo* EOA data for each prosthesis size based on several echocardiographic studies. For a given size, it is assumed that *in vivo* EOA could not varied from one patient to another because the diameter of a stented bioprosthesis do not varied from one patient to another and the EOA is independent of flow.



Concerning THV, many pre- or peri-procedural factors varying from one patient to another, such as the degree of stent deployment, the presence and/or the localization of native valve calcification, the height of valve implantation and the ring anatomy could influence directly the estimation of post-operative iEOA.¹¹ Consequently, no *in vivo* iEOA per size are provided by manufacturer for THV. For all these reasons, we didn't use the 'projected' iEOA to diagnose PPM after THV implantation even if the presently reported values for EOA might present a unique frame of reference with regards to the haemodynamic performance to be expected from these prostheses.

Several errors can occur in this estimation of iEOA, particularly for TAVR prosthesis where LVOT diameter and LVOT VTI assessment were particularly challenging. In this study, all echocardiography was performed in a core laboratory by two experienced cardiologists to limit the risk of intra/inter-observer variability. Another cause of the discrepancies in the iEOA measurement may be the occurrence of a low-flow state [i.e. stroke volume index (SVI) < 35 mL/m²]. In our

study, only nine patients demonstrated a post-implantation low-flow state (mean LVEF = $43.6 \pm 8.5\%$, mean LVOT diameter = 21.5 ± 2.5 mm, mean SVI = 28.1 ± 4.25 mL/m², mean iEOA = 0.82 cm²/m²). These patients belonged exclusively to the S3-THV group, which could suggest some technical difficulties in SVI calculation in this subgroup. However, the LVOT measurements method was the same for both type of prosthesis and LVOT VTI measurement was also standardized by positioning the pulsed-wave Doppler sample volume at 1.0 cm below the THV insertion.¹³ The main reasons to explain the absence of low-flow state with XT-THV were the higher occurrence of PVR and the lower BSA due to a female predominance. Similarly, the higher occurrence of PVR in the XT-THV group could have increased the mean trans-prosthetic gradient.

Finally, iEOA may also be underestimated if the ascending aorta diameter is < 30 mm because of the risk of pressure recovery phenomenon.²² Unfortunately, too many data were missing to provide reliable data concerning the estimation of the energy loss index.

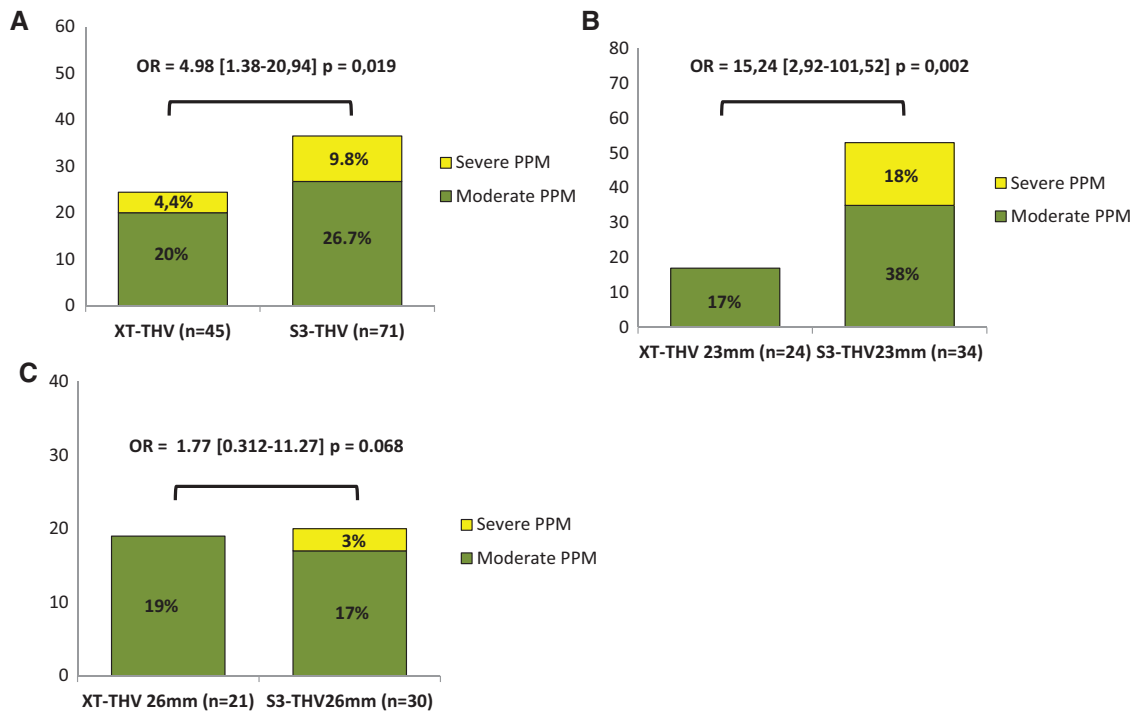


Figure 3 Incidence of moderate and severe PPM with both prosthesis in overall population (A) and according to prosthesis size: 23 mm (B), 26 mm (C).

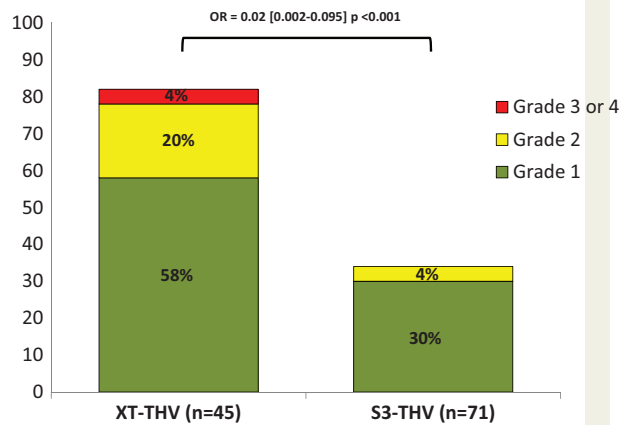


Figure 4 Incidence and severity of PVR according to prosthesis type.

Conclusion

In this single-centre, retrospective propensity score analysis, we observed an increased risk of PPM only in the smaller size (=23 mm) S3-THV compared with the former generation of XT-THV but not in

the larger sizes where the incidence of PPM remains low. In return, the additional sub-annular cuff of the S3-THV prosthesis significantly reduced the occurrence and severity of PVR. Given the enhanced vulnerability of younger patients to the consequences of PPM, these observations should be useful when considering the extension of the TAVR indication to a younger population.

Supplementary data

Supplementary data are available at *European Heart Journal - Cardiovascular Imaging* online.

Conflict of interest: None declared.

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