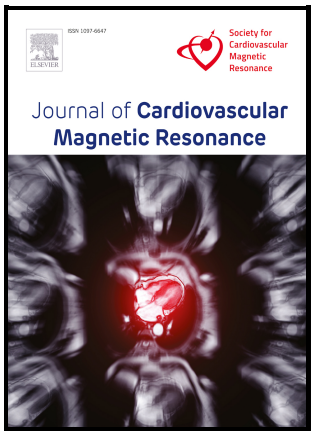

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Cardiovascular magnetic resonance reclassification of aortic regurgitation after transcatheter aortic valve implantation: A COMPARE-TAVI 1 substudy

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Abstract

Background: Aortic regurgitation (AR) after transcatheter aortic valve implantation (TAVI) is a clinical concern. Echocardiography is routinely used to assess AR but relies on semiquantitative and operator-dependent measures, while cardiovascular magnetic resonance (CMR) allows direct quantification of regurgitant flow. This study compared transthoracic echocardiography (TTE) and CMR in assessing AR after TAVI using standardized Valve Academic Research Consortium-3 (VARC-3) criteria.

Methods: In this prespecified substudy of the multicenter COMPARE-TAVI 1 trial, patients were randomized to treatment with Sapien 3/Sapien 3 Ultra or Myval/Myval Octacor transcatheter heart valves. TTE and CMR were performed in 327 participants 4-6 weeks post-TAVI, and AR severity was graded according to VARC-3 criteria. TTE was evaluated by core laboratory consensus, whereas CMR-derived regurgitant fraction was quantified by phase-contrast velocity mapping. Agreement, diagnostic accuracy, and clinical predictors of discordance were evaluated.

Results: By TTE, AR was none-trace-mild in 88.4% (n = 289), mild-moderate in 10.1% (n = 33), moderate in 0.9% (n = 3), and moderate-severe in 0.6% (n = 2) of patients. Corresponding CMR results were 92.7% (n = 303), 7.0% (n = 23), 0.3% (n = 1) and 0%, with a median [IQR] AR fraction of 5% [3-9]. Overall agreement between modalities was 86%, with TTE overestimating AR in 9% and underestimating in 5% as compared with CMR. Using CMR as the reference for detecting moderate or greater AR (AR fraction ≥30%), TTE did not identify the one patient who had moderate AR by CMR. Of five patients graded as moderate or greater by TTE, all were downgraded by CMR to less than moderate AR (sensitivity 0.00, 95% CI 0.00-0.98; specificity 0.99, 95% CI 0.97-1.00). Discordance was more frequent with extensive aortic valve calcification and those receiving Myval/Myval Octacor valves.

Conclusion: In this multicenter study, current-generation transcatheter valves exhibits low rates of moderate or greater AR. One patient with moderate AR by CMR was not detected by TTE. CMR reclassified all five patients classified with moderate or greater AR by TTE to lower severity categories, underscoring the complementary value of CMR to TTE, when moderate or severe AR is suspected.

Clinical trial identifier: Clinical.Trials.gov NCT04443023

Key words: aortic valve stenosis, transcatheter aortic valve implantation, aortic regurgitation, paravalvular leakage, cardiovascular magnetic resonance, phase-contrast imaging

Introduction

Aortic regurgitation (AR) following transcatheter aortic valve implantation (TAVI) remains a clinical concern, given the excess morbidity and mortality associated with AR [1-4]. While paravalvular leaks (PVL) were frequent and extensive in the early generations of transcatheter heart valves (THV), advancements in valve design, procedural planning, and procedural techniques have reduced the regurgitation rates and severity [5].

Transthoracic echocardiography (TTE) is routinely used to assess AR due to its wide availability. The assessment may, however, be limited by suboptimal acoustic windows, operator dependency, and the inability of ultrasound to penetrate the metallic stent frame or calcified native valve tissue [6]. In addition, regurgitant jets are often excentric, complicating their visualization by two-dimensional TTE. Alternatively, cardiovascular magnetic resonance (CMR) can be applied for quantification of AR, which has been demonstrated for native [7] as well as prosthetic valves [2, 8]. Using phase-contrast velocity mapping, CMR enables direct quantification of forward and backward aortic flow volumes to calculate aortic regurgitation fraction (ARF) with high reproducibility [8-11]. Accordingly, current guidelines recommend CMR when echocardiographic findings are inconclusive [6]. In addition, CMR enables assessment of left ventricular function and remodeling, providing a comprehensive evaluation after TAVI. Substantial inconsistencies in agreement between TTE and CMR have been reported, likely reflecting differences in echocardiographic grading systems and the previous lack of validated CMR cut-offs for AR severity [12]. To address this, we aimed to compare TTE and CMR for the assessment of AR after TAVI in a multicenter cohort, applying the Valve Academic Research Consortium (VARC-3) recommendations for classification of prosthetic aortic valve regurgitation [13].

Methods

Study design

The study was a prespecified substudy of the COMPARE-TAVI 1 trial (Clinical.Trials.gov ID NCT04443023 and Ethical Committee Central Denmark Region J. No. 1–10–72–389–17). This study was a multicenter, randomized trial conducted at three Danish tertiary centers (Aarhus, Odense and Aalborg University Hospitals) enrolling patients scheduled for transfemoral TAVI. The trial compared the Sapien 3/Sapiens 3 Ultra THV series with the Myval/Myval Octacor THV series with 1:1 randomization between heart valve systems. The design and results of the main trial are published elsewhere [14, 15]. Patients entering the COMPARE-TAVI 1 trial at all three study sites were asked to participate in the current CMR substudy before randomization. Exclusion criteria were claustrophobia or contraindications to CMR. At study initiation in June 2020, patients having a pacemaker before TAVI were excluded, but, via a protocol amendment approximately two months later, pacemaker was removed as an exclusion criterion. Implanted THVs were evaluated after four weeks by TTE and CMR. Patients who had a pacemaker implanted following TAVI were scheduled for CMR six weeks after pacemaker implantation due to safety considerations. Initially, the CMR substudy aimed to enroll 166 patients to document differences in AR between Sapien and Myval THVs. However, enrolment was paused during the study period owing to a legal ruling against the use of Myval. When the study was reinitiated in August 2022, the Myval Octacor had replaced the Myval THV, and therefore, another CMR-cohort comparing Sapien with Myval Ocatcor was recruited. When the inclusion in COMPARE-TAVI 1 trial had finalized in November 2023, 387 patients had consented to the CMR substudy.

Transthoracic echocardiography

TTE was performed according to a standardized protocol previously published [14]. Echocardiograms were analyzed by a core laboratory (Odense University Hospital) by five highly experienced TTE readers without access to CMR findings. Left ventricular ejection fraction was calculated using the Simpson biplane method. Gradings of regurgitant flow was based on a multiparametric approach with qualitative and semiquantitative measures, including number of jets, jet width, pressure half-time, diastolic flow reversal, and circumferential extent of paravalvular leakage [6, 13]. The number and extent of jets was assessed in the parasternal short-axis, long-axis, modified apical five-chamber, and apical three-chamber views. Vena contracta was measured just below the prosthetic valve cusps for central regurgitations and just below the stent frame for paravalvular regurgitant jets. Total regurgitation severity was categorized based on the following scheme conferring to VARC-3 recommendations: none, trace, mild, mild-to-moderate, moderate, moderate-to-severe or severe [13]. For direct comparison with CMR AR classifications, “none”, “trace”, and “mild” were grouped into one category, yielding a 5-category scale. An example of AR assessment by TTE is provided in Figure 1.

Cardiovascular magnetic resonance imaging

CMR image acquisition were performed with 1.5 Tesla using Siemens Magnetom Sola (Siemens Healthineers, Erlangen, Germany; Aarhus, n = 95), Philips Achieva (Philips Healthcare, Best, the Netherlands; Aarhus and Odense, n = 221) or GE Discovery (GE Healthcare, Chicago, USA; Aalborg, n = 11) systems with dedicated phased-array cardiac coils. Images were acquired during successive breath-hold with prospective electrocardiogram gating. Standard cine sequences were obtained using balanced

steady-state-free precision technique. Phase-contrast velocity-encoded images were obtained at the level of LVOT and sinotubular junction. The latter was used for comparison with TTE. Velocity encoding typically ranged from 2.0 to 3.0 m/s, depending on the peak systolic velocity, and was adjusted in case of aliasing. Additional MR parameters for phase-contrast imaging were slicing thickness 6-8 mm, field-of-view 300-370 x 280-300 mm, TE 2.5-3.1 ms, and 30 to 40 phases per cardiac cycle.

CMR analysis was performed by a core laboratory (Aarhus University Hospital) using CVI42 (Circle Cardiovascular Imaging Inc., Calgary AB, Canada) by a single operator without access to echocardiographic findings. Contouring of ventricular volumes and aortic phase-contrast images was automated, with only minimal manual corrections performed based on visual inspection when needed. Left ventricular volumes, mass, and ejection fraction were calculated from cine-short axis stacks, and values were indexed to body surface area. Papillary muscles and trabeculae were included in the left ventricular mass. Aortic regurgitant fraction (ARF) was calculated from phase-contrast images at the sinotubular junction as follows: total backward volume/total forward volume x 100. Static tissue background correction was performed to account for phase-offset errors [16]. AR severity by CMR was categorized according to the VARC-3 recommendations as follows: none, trace, or mild (ARF <15%); mild-to-moderate (ARF 15 to <30%); moderate (ARF 30 to <40%); moderate-to-severe (ARF 40 to <50%); or severe (ARF ≥50%) [13]. An example of ARF assessment by CMR is provided in Figure 1.

In cases where TTE and CMR assessments differed more than one severity grade, echocardiograms were reassessed by an independent, highly experienced TTE observer, and CMR images were reviewed by another independent, highly experienced CMR observer to establish a consensus assessment.

Cardiac computed tomography

As part of routine clinical practice, all patients underwent contrast-enhanced, electrocardiogram-gated cardiac computed tomography (CT) prior to TAVI [17]. Scans were acquired according to each center's standard practice. Scanners used were dual-source Siemens Somatom Force or Siemens Somatom Definition Flash (Siemens Healthineers, Forchheim, Germany). Aortic annular dimensions, aortic valve morphology, and semiquantitative grading of valvular and annular calcification was obtained as part of the on-site clinical read of the CT scan. For quantitative calcium volume analysis, images were analyzed at a core laboratory (Aarhus University Hospital) by a single experienced TAVI CT reader using dedicated TAVI CT planning software (3mensio Structural Heart, 3mensio Medical Imaging BV, Bilthoven, the Netherlands). Calcium volume was quantified using patient-specific detection thresholds in two predefined regions: (1) the aortic valve region (from the aortic annulus plane to the left main ostium); and (2) the LVOT (the upper 5 mm below the annular plane) [18].

Statistical analysis

Data were assessed for normality using quantile-quantile plots and histograms. Continuous variables are reported as means ± standard deviation (SD) if normally distributed and as medians with interquartile range [IQR] if non-normally distributed. Categorical variables are reported as numbers and percentages. Groups were compared using Student's *t*-test or Mann-Whitney U test for two-group comparisons, and ANOVA, chi-square test, or Fisher's exact test was used for comparisons involving more than two groups, as appropriate. ARF was stratified into quartiles to evaluate

differences in CMR-, TTE-, and CT-derived parameters across increasing degrees of regurgitation. Agreement between imaging modalities was defined as matching classification by both modalities, whereas disagreements was defined as differing classifications. Agreement was evaluated using kappa(κ)-statistics. Reclassification was evaluated using categorical net reclassification index, defined by a binary classification of AR severity (less-than-moderate versus moderate-or-greater), with CMR as the reference. The diagnostic performance of TTE for detecting moderate-or-greater AR was further assessed by calculating sensitivity, specificity, negative predictive value, and positive predictive value using CMR as the reference. Patient characteristics potentially associated with inter-modality disagreement were compared between patients with concordant and discordant gradings by CMR and TTE. Statistical analyses were performed using Stata/SE version 18.0 (StataCorp, Texas, US).

Results

In this predefined substudy, 387 patients were enrolled, of whom 327 (85%) underwent CMR. Non-completion was due to death within 30 days (n = 5), pacemaker or implantable cardioverter defibrillator (n = 12), claustrophobia (n = 2), withdrawal of consent (n = 31), high body mass index (n = 2), cerebral shunt (n = 1), or unavailable CMR phase-contrast images (n = 1). Baseline patient characteristics were balanced between patients who completed the study and those who did not, except that pacemakers and atrial fibrillation or flutter were more frequent in the latter group (Supplementary Table 1). TTE and CMR were performed within a median [IQR] of 0 [0 to 5] days. Baseline patient characteristics are shown in Table 1.

Aortic regurgitation following TAVI

TTE and CMR imaging parameters after TAVI are presented in Table 2. By TTE, 289 (88.4%) patients had no, trace or mild AR. Mild-to-moderate AR occurred in 33 (10.1%), moderate AR in 3 (0.9%), and moderate-to-severe AR in 2 patients (0.6%). No patients had severe AR. By TTE, the regurgitation was paravalvular in all patients with regurgitation, with only 7% of patients also exhibiting central regurgitation (Supplementary Table 2).

By CMR, the median [IQR] aortic regurgitant volume was 4 [2 to 7] ml, with a median regurgitation fraction of 5% [3 to 9] (Table 2). Forward flow volume decreased with increasing ARF. Aortic valve region calcium volume was associated with higher ARF, with a median calcium volume [IQR] of 1016 cm^2 [625 to 1404] in the fourth quartile compared with 626 cm^2 [395 to 1143] in the first quartile. Neither end-diastolic nor end-systolic volume indices were associated with increasing ARF. ARF did not differ between CMR scanner vendors (median [IQR]: 5% [3 to 9] for Siemens, 6% [3 to 9] for Phillips, and 3% [1 to 8] for GE; $p = 0.094$) or across study sites (6% [3 to 9] for Aarhus, 6% [3 to 7] for Odense, and 3% [1 to 8] for Aalborg University Hospitals; $p = 0.149$). When categorized according to VARC-3, 303 (92.7%) patients had none, trace or mild AR, 23 (7.0%) had mild-to-moderate AR, 1 (0.3%) had moderate AR, while no patients had moderate-to-severe or severe AR by CMR (Figure 3).

Agreement between echocardiography and cardiovascular magnetic resonance

CMR-derived absolute ARF in relation to echocardiographic AR grading is shown in Figure 2. Figure 3 presents the categorical agreement between modalities. Overall, they agreed in 281 of 327 patients, yielding an agreement rate of 86% (weighted $\kappa = 0.19$, $p < 0.001$; Figure 3A). Disagreement was observed in 46 (14%) patients. CMR downgraded AR severity in 31 (9%) patients; by one grade in 28, two grades in 1, and three grades in 2. On the other hand, CMR upgraded severity in 15 (5%); by one grade

in 14 and by two grades in 1 (Graphical Abstract). Using CMR as reference to detect moderate or greater AR, the overall net reclassification index (95% confidence interval, CI) for TTE was -0.03 (-0.06 to 0.00). TTE misclassified the one patient classified with moderate AR by CMR, yielding an event net reclassification index of -1, whereas it correctly classified most patients with less than moderate AR, with a non-event net reclassification index of 0.97 (0.94 to 1.00). The sensitivity, specificity, positive predictive value, negative predictive value (95% CI) for TTE to detect moderate or greater AR were 0.00 (0.00 to 0.98), 0.99 (0.97 to 1.00), 0.00 (0.01 to 0.52), and 1.00 (0.98 to 1.00), respectively. Examples of patients with discordant assessments are presented in Figure 4.

Characteristics of patients with disagreement between modalities

The median native aortic valve region calcium volume was greater in patients with disagreement in AR severity assessment between imaging modalities than in those with agreement (Table 3). In addition, hypertension, age, and sex were associated with disagreement. The two modalities disagreed more frequently in patients receiving treatment with the Myval THV series as compared with patients treated with the Sapien 3 THV series (Figure 3B-C). Although the proportion of patients with pacemakers was higher in the group with disagreement, particularly among patients in whom AR severity was greater by CMR than by TTE, this difference did not reach statistical significance.

Discussion

Key findings of this multicenter study are as follows: First, among patients treated with Sapien 3/Sapien 3 Ultra or Myval/Myval Octacor THVs, CMR demonstrated a low aortic regurgitation fraction of median 5%, with moderate or greater AR observed in

less than 1% of patients; second, agreement between CMR and TTE in assessing AR severity was 86%, with TTE overestimating the AR grade in 9% and underestimating it in 5% of patients as compared with CMR; and last, discrepancies between modalities were more frequent in patients with Myval THVs or extensive aortic valve region calcification.

AR after TAVI may arise if the implanted valve is undersized, fails to seal properly against heavily calcified native valve tissue or a non-circular annulus, or if the valve is implanted too deep without sealing from the external skirt. AR increase left ventricular volume load in often small, non-compliant ventricles of TAVI-patients, potentially leading to heart failure. Decisions regarding reintervention in patients with suspected significant AR after TAVI are typically based on echocardiographic evaluation. The ability of TTE for ruling out AR is well supported [12] but grading more than mild AR is often challenging, especially in the presence of multiple eccentric jets or acoustic shadowing from calcifications or prosthetic material [6, 19]. Phase-contrast CMR is a well-established method for aortic flow quantification and is recommended as an alternative imaging modality in patients with prosthetic valves when echocardiographic findings are equivocal [20]. A key advantage of CMR is the ability to quantify volumetric flow rate and thereby ARF with high reproducibility [8, 11], as opposed to the semiquantitative assessment by TTE, which relies on both optimal conditions for image acquisition and integration of multiple parameters from different echocardiographic views for the final categorical grading [6]. CMR may facilitate differentiation between even small differences in ARF and may be useful in the assessment of new THVs [21]. Furthermore, the prognostic value of CMR-derived ARF has previously been demonstrated [2], providing insights of the impact of even mild AR on morbidity and mortality [22, 23]. Considering the quantitative assessment

and high reproducibility, CMR may be preferrable as the reference modality for AR assessment, while TTE remains the clinical standard.

Reported agreement between CMR and echocardiography has varied considerably across studies [12]. This variability may partly be explained by the subjectivity of echocardiographic interpretation [6], but limitations of CMR, including metal-related artefacts in patients with pacemakers, through-plane motion, and residual phase-offset errors, must be accounted for and corrected when possible. Varying echocardiographic classification systems and the lack of standardized thresholds for defining the severity of AR with CMR may contribute further to inconsistencies [12, 13, 24]. The present study benefitted from core laboratory evaluations with application of guideline-based definitions and thresholds for AR. The observed prevalence of moderate or greater AR and the tendency of TTE to overestimate regurgitation severity were consistent with findings from a prior study of Sapien 3 recipients, which applied identical CMR classification thresholds but used the VARC-2 criteria for TTE [25]. The rate of misclassification in the prior study was approximately twice as high (32%) as that observed in the present study (14%), with most discrepancies occurring in patients with echocardiographic mild AR, who were subsequently downgraded to none/trace AR by CMR. The implementation of VARC-3 directed uniform criteria for echocardiographic- and CMR-derived AR classification is likely to enhance comparability across studies and help clarify the relationship between TTE and CMR in post-TAVI AR assessment. Notably, CMR-based ARF thresholds between 30% and 40% have been suggested to identify patients at increased risk of clinical deterioration, with a meta-analysis proposing an ARF above 33% for timing of surgical intervention [7, 26-28].

The rate of moderate or greater AR was low when assessed by TTE (1.5%) and even lower when assessed by CMR (0.3%) in the present study. These rates resemble those reported in recent five-year outcome data from the PARTNER 3 trial [29], which,

together with the findings from the COMPARE-TAVI 1 main trial, indicate excellent performance of the current-generation ballon-expandable THVs [14]. A previous meta-analysis, combining data on AR from seven studies, reported a high specificity of TTE for ruling out moderate or severe post-TAVI AR, emphasizing its ability to distinguish mild from moderate or severe AR, which aligns with the specificity and negative predictive value observed in the current study [12]. The low prevalence of moderate or severe AR in our cohort limited robust statistical analyses of the diagnostic performance of TTE compared with CMR, resulting in wide confidence intervals for sensitivity estimates and, thus, precluding firm conclusions on the ability of TTE to rule out moderate or severe AR. Importantly, transforming a continuous parameter, such as ARF, into categorical grades inherently introduces misclassification, as values close to the cut-off may be assigned to different categories despite representing very similar physiological conditions. This issue, combined with the markedly imbalanced data distribution with most patients exhibiting none to mild-moderate AR and very few with more severe regurgitation, likely contributed to the low kappa value observed, which may therefore reflect methodological limitations rather than true lack of agreement. Furthermore, the limited number of patients with moderate or greater AR may be insufficient to demonstrate a link between ARF and LV remodeling.

Forward flow volumes measured at the sinotubular junction and in the LVOT were similar, although the absence of coronary flow was anticipated to result in lower forward flow volume at the sinotubular junction. Post-TAVI flow dynamics may have mitigated this effect. From a practical perspective, flow measurement at the sinotubular junction is preferable, as automated segmentation is more accessible, whereas contouring of the LVOT require manual delineation due to its irregular geometry.

In this study, 19 of 26 patients with echocardiographic mild-to-moderate AR, who were reclassified to none-trace-mild by CMR, were treated with Myval or Myval

Octacor THVs. Thus, it may be that the AR in Myval THVs is more challenging to quantify using color-Doppler TTE. Given the nature of degenerative aortic valve stenosis, calcification in the native aortic valve is frequent, and aortic valve region calcium volume has previously been associated with greater degrees of AR following TAVI [18, 30], a finding that was supported by the present study. High volumes of pre-TAVI valvular calcification were associated with discrepancies between TTE and CMR gradings, together with hypertension, age, and sex, which are known risk factors for valvular calcification [31]. The lack of agreement between TTE and CMR in patients with heavily calcified valves warrants cautious clinical evaluation of these patients and may reflect the occurrence of greater regurgitation severity.

In a clinical context, the results of the study imply that supplementary CMR was needed in only 5 of 327 patients for whom AR was classified as moderate or greater by TTE, and CMR downgraded the severity in all these patients. CMR may therefore have a central role for confirming AR severity before considering reintervention in TAVI-patients with suspected symptomatic AR and may potentially render reintervention unnecessary. In contrast, CMR identified only one patient with moderate AR, who was classified with a lower AR severity by TTE. Such cases may be more challenging to detect; however, clinical presentation and evidence of left ventricular volume overload may prompt further testing e.g. by CMR or close clinical observation.

Limitations

Limitations of the study should be acknowledged. Since no patients were classified with severe AR by either modality, the study cannot evaluate the accuracy of detecting severe regurgitation. The results apply to balloon-expandable THVs only. Patients who underwent CMR had a lower prevalence of atrial fibrillation or flutter and pacemakers compared with those who consented to participate but did not complete the study,

potentially introducing selection bias. Although CMR was used as the reference modality method for AR assessment, it should be acknowledged that PC-CMR is subject to potential sources of measurement error. These include residual phase-offset errors, through-plane motion, inaccuracies related to high velocity-encoding, and image artifacts arising from aortic valve prostheses or pacemakers, all of which necessitates careful CMR planning, acquisition, and post-processing.

Conclusion

Current-generation THVs exhibit low levels of AR. In this multicenter study, CMR reclassified all patients with moderate or greater AR by TTE to a lower severity, while one patient with moderate AR by CMR was missed by TTE. These findings support the role of CMR as a complementary modality to TTE for confirming AR severity in patients with suspected symptomatic regurgitation.

Abbreviations

ANOVA: analysis of variance

AR: aortic regurgitation

ARF: aortic regurgitation fraction

CMR: cardiovascular magnetic resonance

CT: computed tomography

IQR: interquartile range

LVOT: left ventricular outflow tract

SD: standard deviation

TAVI: transcatheter aortic valve implantation

THV: transcatheter heart valve

TTE: transthoracic echocardiography

VARC-3: Valve Academic Research Consortium-3

Declarations

Authors contributions

The study was designed by CJT and WYK. PF, HN, TT, and EHC assisted in the study design. CJT, WYK, PF, HN, TT, EHC, LHN, TZ, and BLN was involved in the study conduct and data acquisition. JSD and NSBM were responsible for echocardiography core laboratory analyses. AUP and WYK were responsible for CMR core laboratory analyses. BLN and NH were responsible for CT core laboratory analyses. AUP and ALDP conducted the statistical analyses. AUP, WYK and CJT drafted the initial manuscript. All authors reviewed and approved of the decision to submit for publication.

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Declaration of Generative AI and AI-assisted technologies in the writing process

During the preparation of this work the authors used ChatGPT (https://chat.openai.com) in order to enhance readability and language of the manuscript. After using this tool, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

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Declaration of competing interests

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Data availability statement

Data underlying this study are subjected to data protection and ethics regulations but anonymized may be shared upon reasonable request and with appropriate approvals.

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Table 1. Baseline clinical and procedural characteristics.

	All patients
Demography	
Number of patients	327
Age, years	80 ± 7
Sex, male	203 (62%)
Body mass index, kg/m^2	28 ± 5
Ischemic heart disease, n	80 (24%)
Stroke, n	63 (19%)
Hypertension, n	235 (72%)
Hyperlipidemia, n	225 (69%)
Diabetes, n	77 (24 %)
Peripheral vascular disease, n	19 (6%)
Atrial fibrillation or flutter, n	112 (34%)
COPD, n	50 (10%)
EuroSCORE II	2.1% [1.4-3.6]
STS-PROM	1.8% [1.3-2.7]
Acute or subacute TAVI, n	29 (9%)
Pacemaker before TAVI, n	25 (8 %)
New pacemaker after TAVI in pacemaker naïve patients, n	34 (10%)
Annulus area, mm^2 (valve-in-valve excluded)	480 [428-545]
Valve morphology, n	
Tricuspid	278 (85%)
Bicuspid	37 (11%)
Valve-in-valve	12 (4%)
THV-system, n	
Sapien 3/Sapien 3 Ultra	166 (51%)
Myval/Myval Octacor	161 (49%)

Data are means ± standard deviation, medians [interquartile range], or numbers (percentages, %).
Abbreviations: COPD = chronic obstructive pulmonary disease, EuroSCORE II = European System for Cardiac Operative Risk Evaluation, STS-PROM = Society of Thoracic Surgeons Predicted Risk of Mortality, TAVI = transcatheter aortic valve implantation, THV = transcatheter heart valve.

Table 2. Imaging parameters one month after transcatheter aortic valve implantation.

	All patients	Aortic regurgitation fraction (%) by CMR				p-value
		1. quartile 0-3%	2. quartile 4-5%	3. quartile 6-9%	4. quartile 10-39%	
Number of patients	327	91	73	97	66	
Cardiovascular magnetic resonance						
LVEF, %	60 ± 13	60 ± 13	60 ± 12	59 ± 13	60 ± 14	0.98
LV mass index, g/m^2	78 ± 18	75 ± 18	77 ± 17	78 ± 17	81 ± 20	0.12
LVEDV index, ml/m^2	70 [58-83]	69 [61-81]	71 [57-82]	70 [57-84]	71 [56-83]	0.99
LVEDV index >96/108 ml/m^2, n[a]	17 (5%)	5 (5%)	3 (4%)	6 (6%)	3 (5%)	0.93
LVESV index, ml/m^2	26 [18-38]	26 [20-39]	25 [18-37]	25 [19-38]	29 [17-37]	0.98
LVESV index >40/47 ml/m^2, n[b]	46 (14%)	15 (16%)	9 (12%)	13 (13%)	9 (14%)	0.88
Cardiac index, l/min/m^2	2.9 ± 0.7	2.9 ± 0.7	3.0 ±0.7	2.9 ± 0.7	2.9 ± 0.7	0.75
Forward flow volume at STJ, ml	74 [62-90]	80 [65-93]	79 [66-91]	70 [58-88]	72 [61-86]	0.040
Regurgitation volume at STJ, ml	4 [2-7]	2 [1-2]	3 [3-4]	5 [4-6]	10 [7-12]	<0.001
Regurgitation fraction at STJ, %	5 [3-9]	2 [1-3]	5 [4-5]	7 [6-8]	13 [11-17]	<0.001
Forward flow volume in LVOT, ml	73 [59-87]	74 [59-91]	75 [65-86]	71 [56-86]	70 [59-83]	0.23
Regurgitation volume in LVOT, ml	3 [1-4]	2 [1-3]	2 [1-4]	3 [2-4]	5 [3-7]	<0.001
Regurgitation fraction in LVOT, %	4 [2-6]	2 [1-4]	3 [2-5]	4 [3-6]	8 [5-11]	<0.001
Transthoracic echocardiography						
LVEF, %	61 [53-69]	60 [51-67]	62 [54-69]	61 [53-69]	63 [52-70]	0.66
AV peak velocity, m/s	2.1 ± 0.4	2.2 ± 43	2.1 ± 36	2.1 ± 37	2.2 ± 50	0.27
AV peak gradient, mmHg	19 ± 8	20 ± 8	18 ± 6	19 ± 7	20 ± 10	0.23
Aortic regurgitation						
None, trace, or mild	289 (88%)	89 (98%)	67 (92%)	86 (89%)	47 (71%)	
Mild-moderate	33 (10%)	2 (2%)	5 (7%)	9 (9%)	17 (26%)	<0.001
Moderate	3 (1%)	-	-	1 (1%)	2 (3%)	
Moderate-severe	2 (1%)	-	1 (1%)	1 (1%)	-	
Cardiac Computed Tomography						
Aortic valve region calcium, mm^3	789 [500-1277]	626 [395-1143]	844 [533-1307]	777 [511-1268]	1016 [625-1404]	0.018
LVOT calcium, mm^3	2 [0-36]	0 [0-23]	0 [0-43]	4 [0-41]	8 [0-37]	0.69

Data are means ± standard deviation, medians [interquartile range], or counts (percentages, %).

[a] LVEDV index above upper normal reference interval (>96 ml/m^2 for women and >108 ml/m^2 for men) [32].

[b] LVESV index above normal reference interval (>40 ml/m^2 for women and >47 ml/m^2 for men).

Abbreviations: AV = aortic valve, LV = left ventricle, LVEF = left ventricular ejection fraction, LVEDV = left ventricular end-diastolic volume, LVESV = left ventricular end-systolic volume, LVOT = left ventricular outflow tract, STJ = sinotubular junction.

Table 3. Patient characteristics by agreement or disagreement in aortic regurgitation (AR) classification between transthoracic echocardiography (TTE) and cardiovascular magnetic resonance (CMR).

	Agreement	**Disagreement**		**Disagreement**		
	All patients with agreement	All patients with disagreement	*p*-value[a]	TTE AR > CMR AR	TTE AR < CMR AR	*p*-value[b]
Number of patients	281	46		31	15	
Demography						
Age, years	80 ± 7	78 ± 6	0.035	80 ± 5	77 ± 8	0.067
Sex, male	165 (58.7%)	38 (82.6%)	0.002	25 (80.6%)	13 (86.7%)	0.008
Diabetes, n	66 (23.5%)	11 (23.9%)	0.950	5 (16.1%)	6 (40.0%)	0.190
Hypertension, n	195 (69.4%)	40 (87.0%)	0.014	26 (83.9%)	14 (93.3%)	0.038
Hyperlipidemia, n	195 (69.4%)	30 (65.2%)	0.570	19 (61.3%)	11 (73.3%)	0.620
COPD, n	43 (15.3%)	7 (15.2%)	0.920	4 (12.9%)	3 (20.0%)	0.900
Atrial fibrillation or flutter, n	101 (35.9%)	12 (26.1%)	0.190	8 (25.8%)	4 (26.7%)	0.430
Pacemaker, n	46 (16.4%)	13 (28.3%)	0.052	7 (22.6%)	6 (40.0%)	0.054
THV-system, n						
Sapien 3/Sapien 3 Ultra	153 (54.4%)	13 (28.3%)	<0.001	9 (29.0%)	5 (31.2%)	0.008
Myval/Myval Octacor	128 (45.6%)	33 (71.7%)		22 (71.0%)	11 (68.8%)	
Cardiac computed tomography						
Aortic valve region calcium, mm^3	748 [486-1222]	1101 [662-1687]	<0.001	1123 [662-1761]	1058 [650-1615]	0.003
LVOT calcium, mm^3	2 [0-32]	8 [0-38]	0.460	6 [0-38]	9 [0-40]	0.740

Data are means ± standard deviation, medians [interquartile range], or counts (percentages, %).

[a] Comparison between patients with agreement and those with disagreement between modalities.

[b] Comparison between patients with agreement, higher AR severity by TTE, and lower AR severity by TTE as compared to CMR.

Abbreviations: COPD = chronic obstructive pulmonary disease, LVOT = left ventricular outflow tract, THV = transcatheter heart valve

Figure 1. Paravalvular leakage assessment by transthoracic echocardiography (TTE) and cardiovascular magnetic resonance (CMR).

Paravalvular leakage was assessed by TTE using a multiparametric approach combining qualitative and semiquantitative parameters. This

included visual assessment of the number and width of regurgitant jets using color-Doppler in the **(A)** apical and **(B)** parasternal long-axis, and **(C)** parasternal short-axis views. **(D)** Cine CMR images guided planning of through-plane phase-contrast acquisitions at the sinotubular junction, oriented perpendicular to the aortic root (red dashed line). **(E)** Velocity-encoded phase-contrast and corresponding magnitude images are shown. **(F)** The aortic flow curve displays forward and backward flow volumes. In this example, aortic regurgitation fraction by CMR was 17%, corresponding to mild-to-moderate regurgitation consistent with the echocardiography assessment.

Abbreviations: Ao = aorta, LV = left ventricle, PVL = paravalvular leakage.

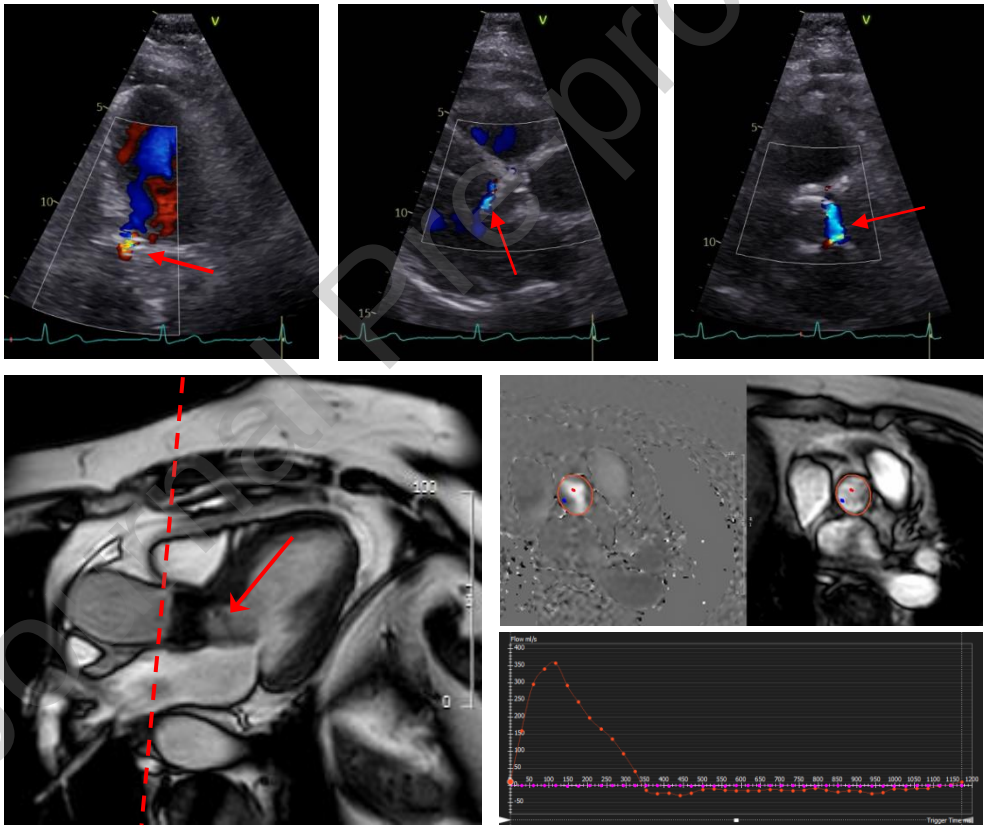


Figure 2. Absolute aortic regurgitation by cardiovascular magnetic resonance (CMR) compared with transthoracic echocardiography (TTE) gradings.

CMR-derived aortic regurgitation fraction of patients treated with transcatheter aortic valve implantation are plotted according to the third Valve Academic Research Consortium TTE classification. Within each TTE category, solid black lines represent the median [interquartile range] CMR-derived aortic regurgitant fraction, while dashed horizontal lines denotes CMR thresholds defining categorical severity.

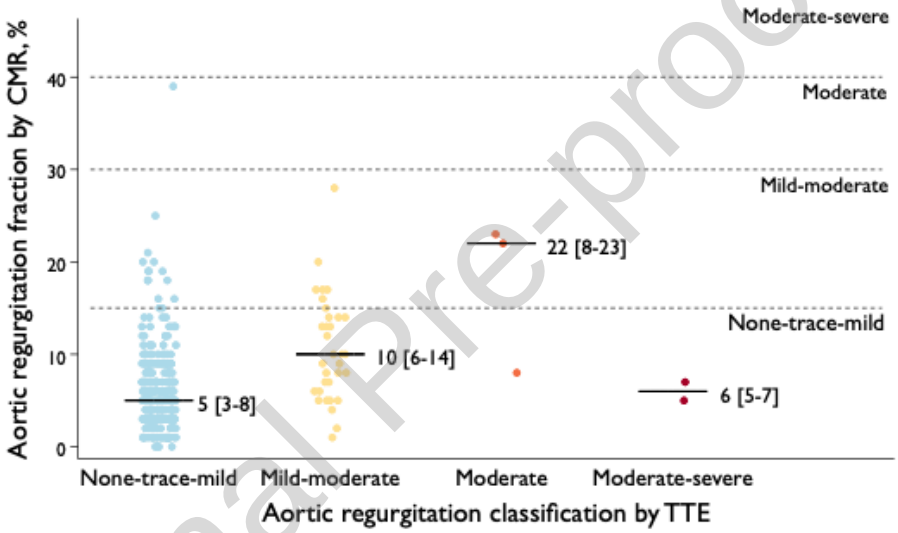


Figure 3. Agreement between transthoracic echocardiography and cardiovascular magnetic resonance (CMR) in categorical assessment of aortic regurgitation.

Panels show agreement between modalities for: **A)** all patients undergoing transcatheter aortic valve implantation, **B)** patients treated with Sapien transcatheter heart valves (THV), and **C)** patients treated with Myval THVs. Aortic regurgitation was categorized according to the third Valve Academic Research Consortium criteria.

Abbreviations: ARF = aortic regurgitation fraction.

A All patients

		Echocardiography				
		None-trace-mild	Mild-moderate	Moderate	Moderate-severe	Total
CMR	None-trace-mild ARF 0 to <15%	274 (83.8%)	26 (8.0%)	1 (0.3%)	2 (0.6%)	303 (92.7%)
	Mild-moderate ARF 15 to <30%	14 (4.3%)	7 (2.1%)	2 (0.6%)	-	23 (7.0%)
	Moderate ARF 30 to <40%	1 (0.3%)	-	-	-	1 (0.3%)
	Moderate-severe ARF 40 to <50%	-	-	-	-	-
	Total	289 (88.4%)	33 (10.1%)	3 (0.9%)	2 (0.6%)	327 (100%)
Agreement rate: 86% (weighted κ = 0.19, p <0.001)						

B Sapien THVs

		Echocardiography				
		None-trace-mild	Mild-moderate	Moderate	Moderate-severe	Total
CMR	None-trace-mild ARF 0 to <15%	149 (89.8%)	7 (4.2%)	1 (0.6%)	1(0.6%)	158 (95.2%)
	Mild-moderate ARF 15 to <30%	4 (2.4%)	4 (2.4%)	-	-	8 (4.8%)
	Moderate ARF 30 to <40%	-	-	-	-	-
	Moderate-severe ARF 40 to <50%	-	-	-	-	-
	Total	153 (92.2%)	11 (6.6%)	1 (0.6%)	1 (0.6%)	166 (100%)
Agreement rate: 92% (weighted κ = 0.30, p <0.001)						

C Myval THVs

		Echocardiography				
		None-trace-mild	Mild-moderate	Moderate	Moderate-severe	Total
CMR	None-trace-mild ARF 0 to <15%	125 (77.6%)	19 (11.8%)	-	1(0.6%)	145 (90.1%)
	Mild-moderate ARF 15 to <30%	10 (6.2%)	3 (1.9%)	2 (1.2%)	-	15 (8.7%)
	Moderate ARF 30 to <40%	1 (0.6%)	-	-	-	1 (0.6%)
	Moderate-severe ARF 40 to <50%	-	-	-	-	-
	Total	136 (84.5%)	22 (13.7%)	2 (1.2%)	1 (0.6%)	161 (100%)
Agreement rate: 80% (weighted κ = 0.12, p = 0.04)						

Figure 4. Representative cases of discordant assessments between cardiovascular magnetic resonance (CMR) and transthoracic echocardiography (TTE)

Case 1) CMR demonstrated holo-diastolic regurgitation equivalent to moderate-severe AR with an ARF of 39%. In contrast, TTE classified AR as mild. The secondary TTE assessment agreed with the core laboratory assessment.

Case 2) By CMR, the regurgitation was trace-to-mild with ARF of 5%. TTE graded the regurgitation as moderate-to-severe. The secondary TTE assessment evaluated AR as only mild-moderate.

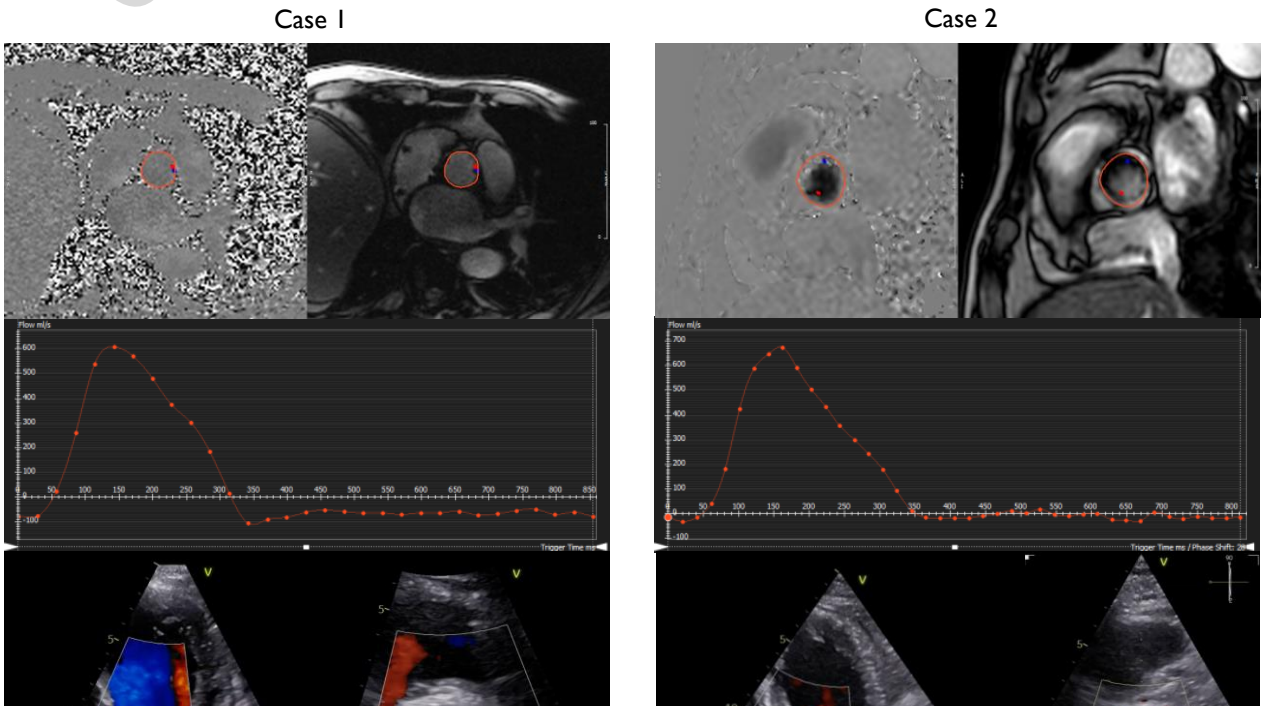
Case 3) CMR showed trace-to-mild AR with an ARF of 7%. By TTE, the AR was classified as moderate-severe. The secondary TTE assessment revised AR severity as mild-to-moderate.

Case 4) CMR images at the sinotubular junction was affected by phase-offset errors. Instead, images at the level of the left ventricular outflow tract were used, showing an AFR of 22%. By TTE, the regurgitation was moderate, and the secondary TTE assessment graded the regurgitation as mild-to-moderate.

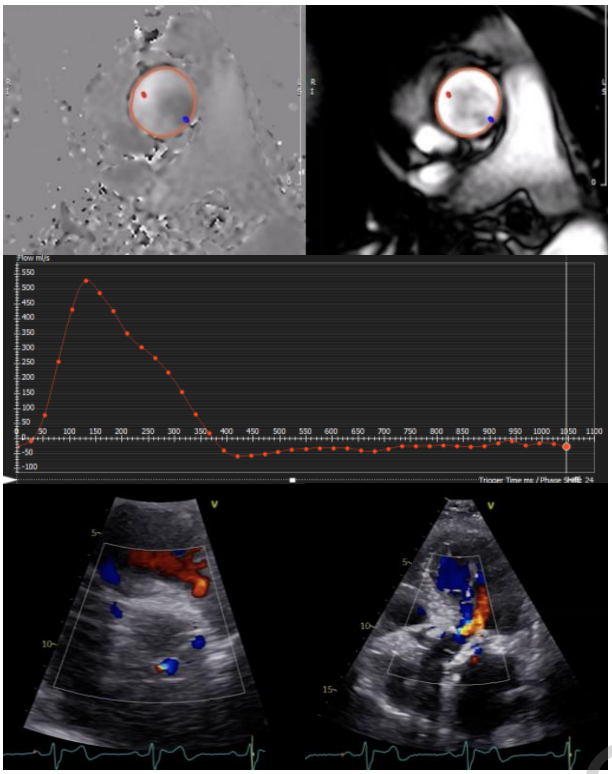
Case 5) The regurgitation was mild-moderate by CMR with an ARF of 23%, whereas it was graded moderate by TTE.

Case 6) CMR demonstrated trace-to-mild regurgitation with an ARF of 8%. TTE classified the regurgitation as moderate, while the secondary TTE assessment revised the severity to mild-moderate.

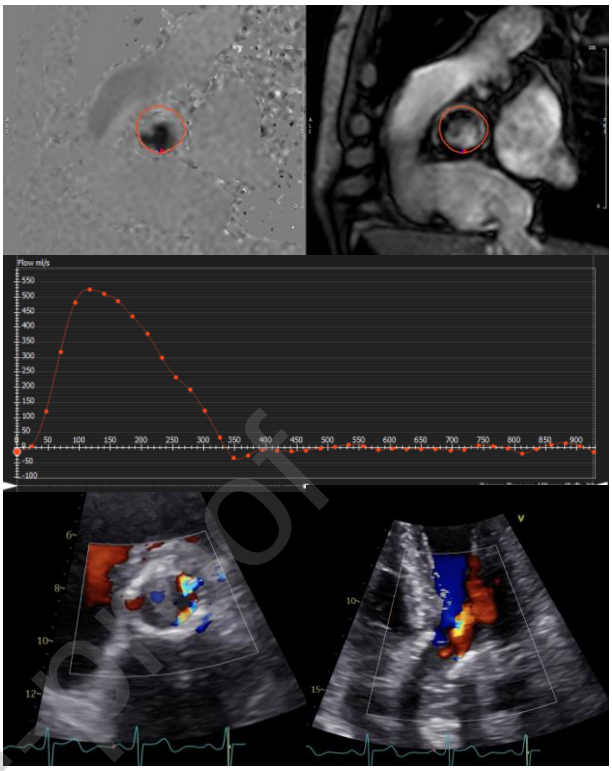
Abbreviations: AR = aortic regurgitation, ARF = aortic regurgitation fraction, CMR = phase-contrast cardiovascular magnetic resonance, LVEDVi = left ventricle end-diastolic volume index.



Case 5

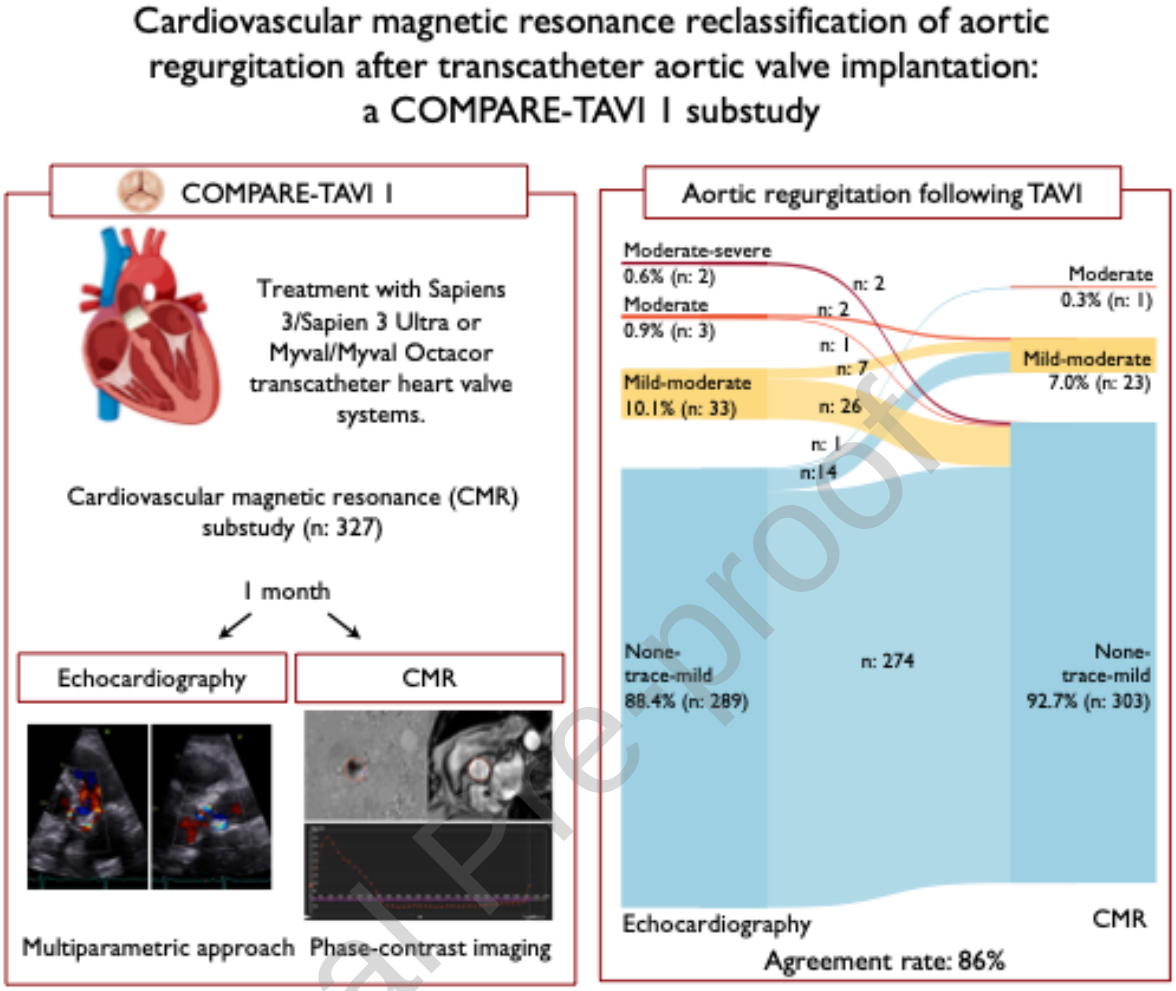


Case 6



Case number	TTE core laboratory classification	TTE secondary classification	ARF, %	CMR classification	LVEDVi, ml/m²
1	None, trace, or mild	None, trace, mild	39	Moderate	137
2	Moderate-severe	Mild-moderate	5	None, trace, mild	98
3	Moderate-severe	Mild-moderate	7	None, trace, mild	80
4	Moderate	Mild-moderate	22	Mild-moderate	81
5	Moderate	Moderate	23	Mild-moderate	50
6	Moderate	Mild-moderate	8	None, trace, mild	81

Graphical abstract:



Graphical abstract legend:

In a cardiovascular magnetic resonance (CMR) substudy of the COMPARE-TAVI 1 trial, aortic regurgitation by transthoracic echocardiography and by CMR was compared. CMR reclassified the aortic regurgitation severity in 14% of patients. Figure created with use of BioRender.com.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests. Christian Juhl Terkelsen reports financial support was provided by Meril Life Science. Christian Juhl Terkelsen reports financial support was

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