

# Outcomes in patients with contained ruptures of the aortic annulus after transcatheter aortic valve implantation with balloon-expandable devices



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## Introduction

Contained ruptures of the aortic annulus (CR) have been diagnosed as an incidental finding on computed tomography angiography (CTA) performed after TAVI with an incidence of up to 5%<sup>1</sup>. Information on outcomes in patients with CR is limited<sup>2-6</sup>. Therefore, the aim of the present study was to evaluate long-term outcomes in patients with CR from a large European multicentre cohort with systematic post-TAVI CTA.

## Methods

We report on 12 patients (out of a total of 1,030) who underwent post-TAVI CTA between July 2009 and July 2015 at three centres in Denmark and Germany. Data collection was performed via case report forms, and a final interview (by phone or via mail) was conducted in all patients between May and November 2016.

## Results

The median interval from TAVI to diagnosis was 16±15 days. Patient characteristics are summarised in **Table 1**. All patients had received a balloon-expandable valve (SAPIEN XT or SAPIEN 3; Edwards Lifesciences, Irvine, CA, USA). Mean degree of oversizing was 26.7±10.5%. In three of the 12 patients, periprocedural transoesophageal echocardiography (TEE) revealed findings suggestive of aortic dissection, an aortic intramural haematoma, and/or a pericardial effusion. In the remaining nine patients, periprocedural echocardiographic monitoring, including TEE in seven patients, was unremarkable and the rupture was detected incidentally on post-TAVI CTA. In nine cases (75%), the contained rupture was found adjacent to the left coronary cusp, whereas the bulk of calcification was found next to the non-coronary cusp (**Table 1**). At the time of diagnosis, none of the patients was symptomatic, and no specific

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**Table 1. Patient characteristics.**

		Contained ruptures (n=12)
Age, years		80.7±5.0
Female sex, n (%)		9 (75.0)
STS score, %		4.1±1.4
log EuroSCORE, %		12.0±4.9
Previous PCI, n (%)		2 (16.7)
Atrial fibrillation, n (%)		4 (33.3)
Echocardiography		
Aortic valve area, cm <sup>2</sup>		0.7±0.1
Gradient over the aortic stenosis, mmHg		49.0±16.2
Ejection fraction, %		55.2±6.2
Computed tomography		
Aortic annulus area, mm <sup>2</sup>		424.8±50.9
Aortic annulus diameter, mm		23.2±1.2
Sinus of Valsalva diameter, mm		30.6±2.7
Ascending aorta diameter, mm		34.3±5.6
Degree of calcification of the device landing zone	Left coronary cusp, scale 1-4*	2.6±1.2
	Right coronary cusp, scale 1-4*	2.0±0.8
	Non-coronary cusp, scale 1-4*	3.1±1.1
Degree of prosthesis oversizing <sup>#</sup> , %		26.7±10.5
TAVI access route		
Transfemoral, n (%)		10 (83.3)
Transapical, n (%)		2 (16.7)
Post-dilatation, n (%)		2 (16.7)
Size of the contained rupture, mm		13±5x8±2x8±2
Location/region of the contained rupture		
Left coronary cusp, n (%)		9 (75.0)
Non-coronary cusp, n (%)		3 (25.0)
Periprocedural and in-hospital complications		
Major vascular complication, n (%)		1 (8.3)
Cerebrovascular event <sup>†</sup> , n (%)		2 (16.7)
New permanent pacemaker <sup>†</sup> , n (%)		4 (33.3)
Acute kidney injury, n (%)		1 (8.3)
Pericardial effusion, n (%)		2 (16.7)
Haemothorax, n (%)		1 (8.3)
Pneumothorax (transapical approach), n (%)		1 (8.3)
Aortic intramural haematoma, n (%)		1 (8.3)
Values are mean ± standard deviation or n (%). *4-point scale for calcification: 1 mild; 2 moderate; 3 severe calcifications; 4 massive calcifications. <sup>#</sup> Oversizing calculated as transcatheter heart valve (THV) (nominal area/MDCT annular area-1)×100 (nominal areas of 415 mm <sup>2</sup> [23 mm THV], 531 mm <sup>2</sup> [26 mm THV] and 661 mm <sup>2</sup> [29 mm THV]). <sup>†</sup> During the first 30 days post TAVI. PCI: percutaneous coronary intervention; STS: Society of Thoracic Surgeons		

treatment related to the CR was initiated. During a median follow-up of 2.5±1.5 years, none of the patients developed symptoms or died from CR-related causes. In five patients, follow-up-CTA was performed after 287±218 days, three with stable findings and two with no longer detectable ruptures (**Figure 1**).

## Discussion

To the best of our knowledge, this is the first study to investigate the long-term follow-up of patients with contained rupture of the aortic annulus after TAVI, documenting a benign course over a mean follow-up period of 2.5±1.5 years. In none of our patients was a specific treatment necessary, and all remained asymptomatic during the follow-up period. This is in line with prior short-term follow-up studies, which demonstrated unchanged follow-up CTA and favourable outcomes up to six months<sup>1-4</sup>.

## Limitations

Due to the clinical characteristics of our patient cohort, we achieved a post-TAVI CTA rate of 69%. Therefore, a number of contained ruptures may have been missed and a higher incidence of this condition cannot be excluded. Although our observations are based on a large cohort undergoing TAVI, the number of patients with contained ruptures is limited as is the duration of follow-up.

## Conclusions

The data presented suggest that previously reported favourable short-term outcomes<sup>1-4</sup> in patients with CR extend to long-term follow-up, supporting a conservative approach in these patients.

## Impact on daily practice

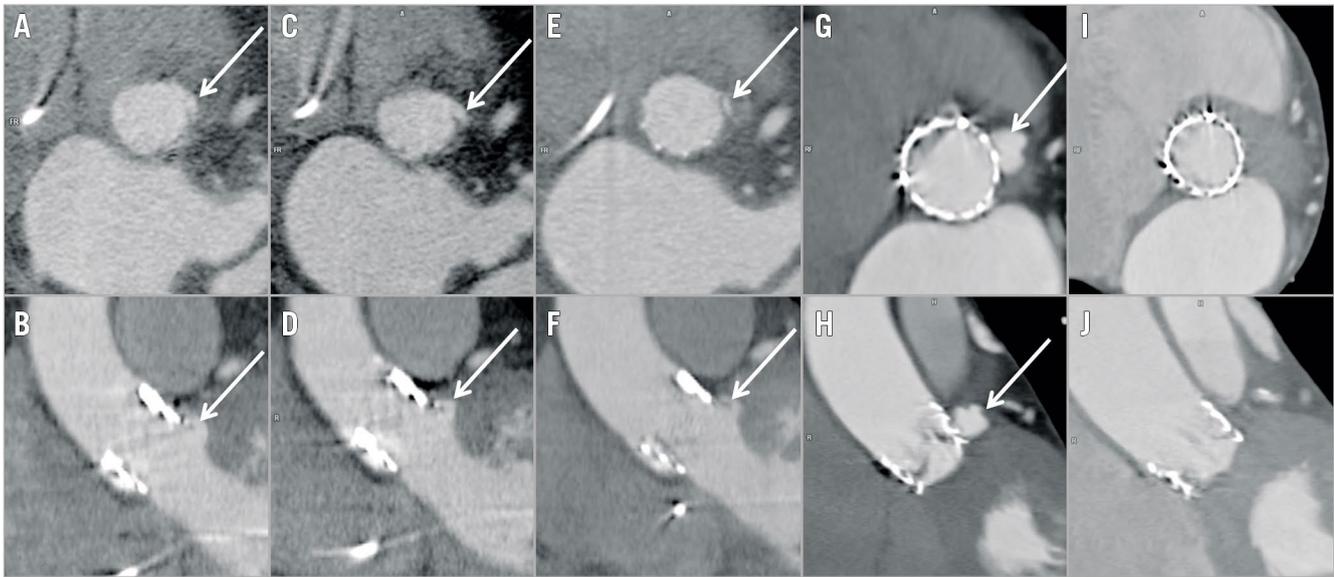
A contained rupture after TAVI represents a rare, predominantly incidental finding on post-TAVI CTA. No adverse events related to the contained rupture were reported during long-term follow-up, supporting a watch-and-wait strategy in these patients.

## Conflict of interest statement

F.-J. Neumann reports receiving grants and non-financial support from Edwards Lifesciences. G. Pache is a consultant for Edwards Lifesciences. P. Blanke provides core laboratory services for Edwards Lifesciences, Medtronic, Neovasc, Tedyne and Aegis, for which he does not receive direct financial compensation. He is a consultant to Edwards Lifesciences, Neovasc, Tedyne, Circle Cardiovascular Imaging. The other authors have no conflicts of interest to declare.

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**Figure 1.** Typical CTA findings of contained ruptures of the aortic annulus post TAVI (arrow in A-H). The first case represents an 80-year-old female with a contained rupture diagnosed eight days post TAVI (A & B). Findings on CTA are unchanged after one (C & D) and three years (E & F). The second case demonstrates a contained rupture in a 77-year-old female diagnosed 15 days post TAVI (G & H) with complete remission in a follow-up CTA performed eight months later (I & J).

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